

ELAN CORP PLC  
Form 20-F  
March 30, 2006

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION,  
Washington, D.C. 20549**

**Form 20-F**

**(Mark One)**

- o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**OR**
- p ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the fiscal year ended: December 31, 2005**  
**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**  
**For the transition period from        to**

**Commission file number: 001-13896**

**Elan Corporation, plc**

*(Exact name of Registrant as specified in its charter)*

**Ireland**

*(Jurisdiction of incorporation or organization)*

**Treasury Building, Lower Grand Canal Street,  
Dublin 2, 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 Exchange on Which Registered**

American Depositary Shares (ADSs), representing  
Ordinary Shares,  
Par value 0.05 each (Ordinary Shares)  
Ordinary Shares

New York Stock Exchange  
  
New York Stock Exchange

**Securities registered or to be registered pursuant to Section 12(g) of the Act:**

**None**

*(Title of Class)*

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:**

**None**

*(Title of Class)*

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: 429,790,036 Ordinary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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  No

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 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes  No

Indicate by check mark whether the registrant 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  Accelerated filer  Non-accelerated filer

Indicate by check mark which financial statement item the registrant has elected to follow: Item 17  Item 18

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  No

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### **General**

As used herein, we, our, us, Elan and the Company refer to Elan Corporation, plc (public limited company) and consolidated subsidiaries, unless the context requires otherwise. All product names appearing in italics are trademarks of Elan. Non-italicized product names are trademarks of other companies.

Prior to the 2004 fiscal year, we prepared our Consolidated Financial Statements, incorporated by reference on our historical Form 20-F, in conformity with Irish generally accepted accounting principles (Irish GAAP). Beginning with our 2004 fiscal year, we adopted accounting principles generally accepted in the United States (U.S. GAAP) as the basis for the preparation of our Consolidated Financial Statements. Accordingly, our Consolidated Financial Statements contained in this Form 20-F are prepared on the basis of U.S. GAAP for all periods presented.

We also prepared separate Consolidated Financial Statements, included in our Annual Report, in accordance with International Financial Reporting Standards (IFRS), which differ in certain significant respects from U.S. GAAP. The Consolidated Financial Statements included in our Annual Report have been prepared for the first time for the year ended December 31, 2005 under IFRS. Comparative information, which was previously presented under Irish GAAP for the year ended December 31, 2004, has been restated under IFRS. The Annual Report under IFRS, which includes a reconciliation of previously reported Irish GAAP financial information to IFRS, is a separate document from this Form 20-F.

Unless otherwise indicated, our Consolidated Financial Statements and other financial data contained in this Form 20-F are presented in United States dollars (\$). We prepare our Consolidated Financial Statements on the basis of a calendar fiscal year beginning on January 1 and ending on December 31. References to a fiscal year in this Form 20-F shall be references to the fiscal year ending on December 31 of that year. In this Form 20-F, financial results and operating statistics are, unless otherwise indicated, stated on the basis of such fiscal years.

### **Forward-Looking Statements**

Statements included herein that are not historical facts are forward-looking statements. Such forward-looking statements are made pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. The forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, our results could be materially affected.

This Form 20-F contains forward-looking statements about our financial condition, results of operations and estimates, business prospects and products that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as anticipate, estimate, project, intend, plan, believe and other 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: (1) whether and when we will be able to resume marketing and developing *Tysabri*<sup>®</sup> (*natalizumab*); (2) even if we can resume marketing and developing *Tysabri*, the potential of *Tysabri* and the potential for the successful development and commercialization of additional products; (3) the potential of *Prial*<sup>™</sup> (*ziconotide intrathecal infusion*) as an intrathecal treatment for severe pain; (4) our ability to maintain sufficient cash, cash equivalents, and investments and other assets capable of being liquidated to meet our liquidity requirements; (5) whether restrictive covenants in our debt obligations will adversely affect us; (6) competitive developments affecting our products, including the introduction of generic competition following the scheduled loss of patent protection or marketing exclusivity for our products; (7) our ability to protect our patents and other intellectual property; (8) difficulties or delays in manufacturing; (9) trade buying patterns; (10) pricing pressures and uncertainties

regarding healthcare reimbursement and reform; (11) the failure to comply with anti-kickback and false claims laws in the United States; (12) extensive government regulation; (13) risks from potential environmental liabilities; (14) failure to comply with our reporting and payment obligations under Medicaid or other government programs; (15) exposure to product liability risks; (16) an adverse effect that could result from the purported class action lawsuits initiated following the voluntary suspension of the marketing and clinical dosing of *Tysabri*; (17) the volatility of our stock price; and (18) some of our agreements that may discourage or prevent someone from acquiring us. We assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

**Table of Contents****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**

The selected financial data set forth below is derived from our Consolidated Financial Statements and should be read in conjunction with, and is qualified by reference to, Item 5. Operating and Financial Review and Prospects and our Consolidated Financial Statements and related notes thereto, included elsewhere in this Form 20-F.

<b>Years Ended December 31,</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<b>(In millions, except per share data)</b>				
<b>Income Statement Data:</b>					
Total revenue	\$ 490.3	\$ 481.7	\$ 685.6	\$ 1,093.1	\$ 1,576.3
Operating income/(loss)	\$ (198.5) <sup>(1)</sup>	\$ (302.1) <sup>(2)</sup>	\$ (360.5) <sup>(3)</sup>	\$ (608.7) <sup>(4)</sup>	\$ 268.5 <sup>(5)</sup>
Net income/(loss) from continuing operations before cumulative effect of changes in accounting principles	\$ (384.2)	\$ (413.7)	\$ (474.6)	\$ (2,169.6)	\$ 285.0
Net income/(loss) from discontinued operations before cumulative effect of changes in accounting principles	0.6	19.0	(31.5)	(188.6)	(20.3)
Cumulative effect of changes in accounting principles					7.8
Net income/(loss)	\$ (383.6) <sup>(6)</sup>	\$ (394.7) <sup>(2)</sup>	\$ (506.1) <sup>(7)</sup>	\$ (2,358.2) <sup>(8)</sup>	\$ 272.5 <sup>(5)</sup>
Basic earnings/(loss) per Ordinary Share <sup>(9)</sup>					
from continuing operations	\$ (0.93)	\$ (1.06)	\$ (1.33)	\$ (6.20)	\$ 0.85
from discontinued operations		0.05	(0.09)	(0.54)	(0.06)
cumulative effect of changes in accounting principles					0.02
Total basic earnings/(loss) per Ordinary Share	\$ (0.93)	\$ (1.01)	\$ (1.42)	\$ (6.74)	\$ 0.81 <sup>(10)</sup>
Diluted earnings/(loss) per Ordinary Share <sup>(9)</sup>					
from continuing operations	\$ (0.93)	\$ (1.06)	\$ (1.33)	\$ (6.20)	\$ 0.79

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from discontinued operations		0.05	(0.09)	(0.54)	(0.06)
cumulative effect of changes in accounting principles					0.02
Total diluted earnings/(loss) per Ordinary Share	\$ (0.93)	\$ (1.01)	\$ (1.42)	\$ (6.74)	\$ 0.76 <sub>(10)</sub>

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December 31,	2005	2004	2003	2002	2001
	(In millions)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 1,080.7	\$ 1,347.6	\$ 778.2	\$ 984.5	\$ 1,478.5
Restricted cash	\$ 24.9	\$ 192.7	\$ 33.1	\$ 29.4	\$ 120.9
Current marketable investment securities	\$ 10.0	\$ 65.5	\$ 349.4	\$ 450.6	\$ 943.3
Total assets	\$ 2,340.9	\$ 2,975.9	\$ 3,029.8	\$ 4,031.7	\$ 6,840.4
Long term and convertible debt	\$ 2,017.2	\$ 2,260.0	\$ 1,500.0	\$ 1,046.3	\$ 2,227.4
Total Shareholders equity	\$ 16.9	\$ 205.0	\$ 617.9	\$ 843.1	\$ 3,211.0
Weighted-average number of shares outstanding					
Basic	413.5	390.1	356.0	349.7	336.0
Weighted-average number of shares outstanding					
Diluted	413.5	390.1	356.0	349.7	359.3

- (1) After net other charges of \$4.4 million, primarily relating to net severance, relocation, exit costs and other of \$14.4 million, offset by a credit of \$10.0 million primarily associated with a litigation settlement; and after a \$103.4 million net gain on sale of businesses.
- (2) After net other charges of \$59.8 million, primarily relating to the settlement of the Securities and Exchange Commission (SEC) investigation and the shareholder class action lawsuit of \$56.0 million; and after a \$44.2 million net gain on sale of businesses.
- (3) After net other charges of \$403.2 million, primarily relating to asset impairments of \$32.6 million, severance, relocation and exit costs of \$29.7 million, EPIL III/EPIL II waiver fee of \$16.8 million, and the purchase of royalty rights of \$297.6 million; and after a net gain of \$267.8 million on the sale of businesses and repurchase of debt.
- (4) After net other charges of \$500.7 million, primarily relating to asset impairments of \$266.1 million, severance, relocation and exit costs of \$77.8 million and the purchase of royalty rights of \$121.0 million, partially offset by a gain of \$37.7 million on the repurchase of debt.
- (5) After net other charges of \$323.3 million, primarily relating to asset impairments of \$209.0 million and severance, relocation and exit costs of \$115.0 million.
- (6) After net charges of \$4.4 million, primarily relating to net severance, relocation, exit costs and other of \$14.4 million, offset by a credit of \$10.0 million primarily associated with a litigation settlement; a \$103.4 million net gain on sale of businesses; and after a net charge of \$51.8 million on the retirement of debt.
- (7) After net other charges of \$403.2 million, primarily relating to asset impairments of \$32.6 million, severance, relocation and exit costs of \$29.7 million and the purchase of royalty rights of \$297.6 million, offset by a net gain of \$267.8 million on the sale of businesses and repurchase of debt; and after charges of \$136.5 million, primarily relating to investments and the guarantee issued to the noteholders of Elan Pharmaceutical Investments II, Ltd. (EPIL II).

- (8) *After net other charges of \$500.7 million, primarily relating to asset impairments of \$266.1 million, severance, relocation and exit costs of \$77.8 million and the purchase of royalty rights of \$121.0 million, partially offset by a gain of \$37.7 million on the repurchase of debt; and after charges of \$1,443.0 million, primarily relating to investment impairments and the guarantee issued to the noteholders of EPIL II.*
- (9) *Earnings per share is based on the weighted average number of outstanding Ordinary Shares and the effect of potential dilutive securities including options, warrants and convertible securities.*
- (10) *Basic and diluted earnings per share for 2001 would have been \$0.90 and \$0.84, respectively, if goodwill was not amortized for that year. This disclosure is provided as SFAS No. 142, Goodwill and Other Intangible Assets, (SFAS 142), which was adopted in 2002, no longer requires the amortization of goodwill.*

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

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### **D. Risk Factors**

*You should carefully consider all of the information set forth in this Form 20-F, including the following risk factors, when investing in our securities. The risks described below are not the only ones that we face. Additional risks not currently known to us or that we presently deem immaterial may also impair our business operations. We could be materially adversely affected by any of these risks. This Form 20-F also contains forward-looking statements that involve risks and uncertainties. Forward-looking statements are not guarantees of future performance and actual results may differ materially from those contemplated by such forward-looking statements.*

***The failure to reintroduce Tysabri to the market, or a substantial delay in such reintroduction, would have a material adverse effect on us.***

In February 2005, Elan and Biogen Idec, Inc. (Biogen Idec) voluntarily suspended the marketing and clinical dosing of *Tysabri*. This decision was based on reports of two serious adverse events, one of which was fatal, in patients treated with *Tysabri* in combination with Biogen Idec's product Avone® (Interferon beta-1A) in clinical trials. These events involved two cases of progressive multifocal leukoencephalopathy (PML), a rare and potentially fatal, demyelinating disease of the central nervous system. In March 2005, the companies announced that a patient who had received eight infusions of *Tysabri* in a Crohn's disease trial had died of PML in December 2003. The case had originally been reported by a clinical trial investigator as malignant astrocytoma.

Elan and Biogen Idec completed a comprehensive safety evaluation in October 2005 of more than 3,000 *Tysabri* patients in collaboration with clinical trial investigators and leading experts in PML and neurology. The results of the safety evaluation identified no new confirmed cases of PML beyond the three previously reported.

In September 2005, Elan and Biogen Idec submitted to the U.S. Food and Drug Administration (FDA) a supplemental Biologics License Application (sBLA) for *Tysabri*, which the FDA subsequently designated for Priority Review. On March 7-8, 2006, the Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee of the FDA reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of multiple sclerosis (MS). On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

If it is determined that PML is caused by *Tysabri*, if there are more such serious adverse events in patients treated with *Tysabri* or if we cannot obtain sufficient information to understand the risks associated with *Tysabri*, then we would be seriously and adversely affected. Further, if we cannot resume marketing *Tysabri*, or if we face a substantial delay in the resumption of marketing *Tysabri*, then we will be materially and adversely affected.

***Our future success depends upon the successful development and commercialization of Tysabri and the successful development of additional products. If Tysabri is not commercially successful, we will be materially and adversely affected.***

Excluding *Tysabri*, we market three products and have two potential programs in clinical development. The two programs are in the early stages of clinical development. Our future success depends upon the successful commercialization of *Tysabri* and the development and the successful commercialization of additional products.

Even if we can reintroduce *Tysabri* to the market, uncertainty created by the serious adverse events that have occurred or may occur, or restrictive labelling changes that may be mandated by regulatory agencies, may significantly impair the commercial potential for *Tysabri*.

We commit substantial resources to our research and development (R&D) activities, including collaborations with third parties such as Biogen Idec with respect to *Tysabri*. We expect to commit significant cash resources to the development and the commercialization of *Tysabri* and to the other products in our development pipeline. We cannot assure you that these investments will be successful.

In the pharmaceutical industry, the R&D process is lengthy and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage, there is a substantial risk that products in our

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R&D pipeline, including *Tysabri*, and product candidates from our Alzheimer's disease research programs, will experience difficulties, delays or failures. A number of factors could affect our ability to successfully develop and commercialize products, including our ability to:

- Establish sufficient safety and efficacy of new drugs or biologics;
- Obtain and protect necessary intellectual property for new technologies, products and processes;
- Recruit patients in clinical trials;
- Complete clinical trials on a timely basis;
- Observe applicable regulatory requirements;
- Receive and maintain required regulatory approvals;
- Obtain competitive/favorable reimbursement coverage for developed products on a timely basis;
- Manufacture sufficient commercial quantities of products at reasonable costs;
- Effectively market developed products; and
- Compete successfully against alternative products or therapies.

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Earlier stage trials are generally based on a limited number of patients and may, upon review, be revised or negated by authorities or by later stage clinical results. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates. In addition, as happened with *Tysabri*, unexpected serious adverse events can occur in patients taking a product after the product has been commercialized.

Our failure to successfully develop and commercialize *Tysabri* and other products would materially adversely affect us.

***We have substantial future cash needs and potential cash needs and we may not be successful in generating or otherwise obtaining the funds necessary to meet our other future and potential needs.***

At December 31, 2005, we had \$2,017.2 million of debt. At such date, we had cash and cash equivalents and restricted cash of \$1,105.6 million. Our substantial indebtedness could have important consequences to us. For example, it could:

- Increase our vulnerability to general adverse economic and industry conditions;
- Require us to dedicate a substantial portion of our cash flow from operations to payments on indebtedness, thereby reducing the availability of our cash flow to fund R&D, working capital, capital expenditures,

acquisitions, investments and other general corporate purposes;

Limit our flexibility in planning for, or reacting to, changes in our businesses and the markets in which we operate;

Place us at a competitive disadvantage compared to our competitors that have less debt; and

Limit our ability to borrow additional funds.

We estimate that we have sufficient cash, liquid resources and current assets and investments to meet our liquidity requirements for at least the next twelve months. Although we expect to continue to incur operating losses in 2006, in making our liquidity estimates, we have also assumed a certain level of operating performance. Our future operating performance will be affected by general economic, financial, competitive, legislative, regulatory and business conditions and other factors, many of which are beyond our control. If our future operating performance does not meet our expectations, including our failure to reintroduce and commercialize *Tysabri*

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on a timely basis, then we could be required to obtain additional funds. If our estimates are incorrect or are not consistent with actual future developments and we are required to obtain additional funds, then we may not be able to obtain those funds on commercially reasonable terms, or at all, which would have a material adverse effect on our financial condition. In addition, if we are not able to generate sufficient liquidity from operations, we may be forced to curtail programs, sell assets or otherwise take steps to reduce expenses. Any of these steps may have a material adverse effect on our prospects.

***Restrictive covenants in our debt instruments restrict or prohibit our ability to engage in or enter into a variety of transactions, which could adversely affect us.***

The agreements governing some of our outstanding indebtedness contain various restrictive covenants that limit our financial and operating flexibility. The covenants do not require us to maintain or adhere to any specific financial ratio, but do restrict within certain limits our ability to, among other things:

Incur additional debt;

Create liens;

Enter into certain transactions with related parties;

Enter into certain types of investment transactions;

Engage in certain asset sales or sale and leaseback transactions;

Pay dividends; and

Consolidate, merge with, or sell substantially all our assets to, another entity.

The breach of any of these covenants may result in a default under the applicable agreement, which could result in the indebtedness under the agreement becoming immediately due and payable. Any such acceleration would result in a default under our other indebtedness subject to cross-acceleration provisions. If this were to occur, we might not be able to pay our debts or obtain sufficient funds to refinance them on reasonable terms, or at all. In addition, complying with these covenants may make it more difficult for us to successfully execute our business strategies and compete against companies not subject to similar constraints.

***Our industry and the markets for our products are highly competitive.***

The pharmaceutical industry is highly competitive. Our principal pharmaceutical competitors consist of major international companies, many of whom are larger and have greater financial resources, technical staff, manufacturing, R&D and marketing capabilities than Elan. We also compete with smaller research companies and generic drug manufacturers.

A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and, thereafter, it may be subject to further competition from generic products. The price of pharmaceutical products typically declines as competition increases.

Our product *Azactam*<sup>tm</sup> (*aztreonam for injection, USP*) lost its basic U.S. patent protection in October 2005. We expect that *Azactam* will be subject to generic competition in 2006 and that our sales of *Azactam* will be materially and adversely affected by such generic competition. However, to date, no generic *Azactam* product has been approved.

Generic competitors may also challenge existing patent protection or regulatory exclusivity. Generic competitors do not have to bear the same level of R&D and other expenses associated with bringing a new branded product to market. As a result, they can charge much less for a competing version of our product. Managed care organizations typically favor generics over brand name drugs, and governments encourage, or under some circumstances mandate, the use of generic products, thereby reducing the sales of branded products that are no longer patent protected. Governmental and other pressures toward the dispensing of generic products may rapidly and significantly reduce, or slow the growth in, the sales and profitability of any of our products not protected by

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patents or regulatory exclusivity and may adversely affect our future results and financial condition. The launch of competitor products, including generic versions of our products, may materially adversely affect us.

Our competitive position depends, in part, upon our continuing ability to discover, acquire and develop innovative, cost-effective new products, as well as new indications and product improvements protected by patents and other intellectual property rights. We also compete on the basis of price and product differentiation and through our sales and marketing organization. If we fail to maintain our competitive position, then we may be materially adversely affected.

***If we are unable to secure or enforce patent rights, trade secrets or other intellectual property, then we could be materially adversely affected.***

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and intellectual property protection for new technologies, products and processes. Our success depends in large part on our continued ability to obtain patents for our products and technologies, maintain patent protection for both acquired and developed products, preserve our trade secrets, obtain and preserve other intellectual property such as trademarks and copyrights, and operate without infringing the proprietary rights of third parties.

The degree of patent protection that will be afforded to technologies, products and processes, including ours, in the United States and in other markets is dependent upon the scope of protection decided upon by patent offices, courts and legislatures in these countries. There is no certainty that our existing patents or, if obtained, future patents, will provide us substantial protection or commercial benefit. In addition, there is no assurance that our patent applications or patent applications licensed from third parties will ultimately be granted or that those patents that have been issued or are issued in the future will prevail in any court challenge. Our competitors may also develop products, including generic products, similar to ours using methods and technologies that are beyond the scope of our patent protection, which could adversely affect the sales of our products.

The U.S. basic patent covering our product *Maxipime*<sup>™</sup> (*cefepime hydrochloride*) for injection expires in March 2007. Two formulation U.S. patents covering *Maxipime* expire in February 2008.

Although we believe that we make reasonable efforts to protect our intellectual property rights and to ensure that our proprietary technology does not infringe the rights of other parties, we cannot ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our products or technologies. In addition, third parties may be able to obtain patents that prevent the sale of our products or require us to obtain a license and pay significant fees or royalties in order to continue selling our products.

There has been, and we expect there will continue to be, significant litigation in the industry regarding patents and other intellectual property rights. Litigation and other proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to our management. Our competitors may sue us as a means of delaying the introduction of our products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents or litigation against our licensors may be costly and time consuming and could adversely affect us. In addition, litigation may be necessary in some instances to determine the validity, scope or non-infringement of patent rights claimed by third parties to be pertinent to the manufacturing, use or sale of our products. The outcome of any such litigation could adversely affect the validity and scope of our patents or other intellectual property rights and hinder or delay the marketing and sale of our products.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property, then we could be materially adversely affected.

***If we experience significant delays in the manufacture of our products or in the supply of raw materials for our products, then sales of our products could be materially adversely affected.***

We do not manufacture *Tysabri*, *Prialt*, *Maxipime* or *Azactam*. Our dependence upon collaborators and third parties for the manufacture of our products may result in unforeseen delays or other problems beyond our control. For example, if our third-party manufacturers are not in compliance with current good manufacturing practices

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(cGMP) or other applicable regulatory requirements, then the supply of our products could be materially adversely affected. If we are unable to retain or obtain replacements for our third-party manufacturers or if we experience delays or difficulties with our third-party manufacturers in producing our products (as we did with *Maxipime* and *Azactam* in 2005 and prior years), then sales of these products could be materially adversely affected. In this event, we may be unable to enter into alternative manufacturing arrangements on commercially reasonable terms, if at all.

Our manufacturers require supplies of raw materials for the manufacture of our products. We do not have dual sourcing of our required raw materials. The inability to obtain sufficient quantities of required raw materials could materially adversely affect the supply of our products.

***Buying patterns of wholesalers and distributors may cause fluctuations in our quarterly results.***

Our product revenue may vary quarterly due, in part, to buying patterns of our wholesalers and distributors. In the event that wholesalers and distributors determine, for any reason, to limit purchases of our products, sales of those products would be adversely affected. For example, wholesalers and distributors may order products in larger than normal quantities prior to anticipated price increases for those products. This excess purchasing in any quarter could cause sales of those products to be lower than expected in subsequent quarters.

***We are subject to pricing pressures and uncertainties regarding healthcare reimbursement and reform.***

In the United States, many pharmaceutical products and biologics are subject to increasing pricing pressures, including pressures arising from recent Medicare reform. Our ability to commercialize products successfully depends, in part, upon the extent to which health care providers are reimbursed by third-party payers, such as governmental agencies, including the Centers for Medicare and Medicaid Services, private health insurers and other organizations, such as health maintenance organizations (HMOs), for the cost of such products and related treatments. In addition, if health care providers do not view current or future Medicare reimbursements for our products favorably, then they may not prescribe our products. Third-party payers are increasingly challenging the pricing of pharmaceutical products by, among other things, limiting the pharmaceutical products that are on their formulary lists. As a result, competition among pharmaceutical companies to place their products on these formulary lists has reduced product prices. If reasonable reimbursement for our products is unavailable or if significant downward pricing pressures in the industry occur, then we could be materially adversely affected.

Recent reforms in Medicare added a prescription drug reimbursement benefit beginning in 2006 for all Medicare beneficiaries. Although we cannot predict the full effects on our business of the implementation of this legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers, and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to generate revenues. In addition, Managed Care Organizations, HMOs, Preferred Provider Organizations, institutions and other government agencies continue to seek price discounts. In addition, certain states have proposed and certain other states have adopted various programs to control prices for their seniors and low-income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

We encounter similar regulatory and legislative issues in most other countries. In the European Union (EU) and some other international markets, the government provides health care at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored health care system. This price regulation may lead to inconsistent prices and some third-party trade in our products from markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices.

***The pharmaceutical industry is subject to anti-kickback and false claims laws in the United States.***

In addition to the FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict some marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

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The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Additionally, another pharmaceutical company settled charges under the federal False Claims Act relating to off-label promotion. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

In January 2006, Elan received a subpoena from the U.S. Department of Justice and the Department of Health and Human Services, Office of Inspector General asking for documents and materials primarily related to our marketing practices for Zonegran<sup>tm</sup> (zonisamide). We intend to cooperate with the government in its investigation. In April 2004, we completed the sale of our interests in Zonegran in North America and Europe to Eisai Co. Ltd. (Eisai).

***We are subject to extensive government regulation, which may adversely affect our ability to bring new products to market and may adversely affect our ability to manufacture and market our existing products.***

The pharmaceutical industry is subject to significant regulation by state, local, national and international governmental regulatory authorities. In the United States, the FDA regulates the design, development, pre-clinical and clinical testing, manufacturing, labelling, storing, distribution, import, export, record keeping, reporting, marketing and promotion of our pharmaceutical products, which include drugs, biologics and medical devices. Failure to comply with regulatory requirements at any stage during the regulatory process could result in, among other things, delays in the approval of applications or supplements to approved applications, refusal of a regulatory authority to review pending market approval applications or supplements to approved applications, warning letters, fines, import or export restrictions, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously approved marketing applications or licenses, recommendations by the FDA or other regulatory authorities against governmental contracts, and criminal prosecutions.

We must obtain and maintain approval for our products from regulatory authorities before such products may be sold in a particular jurisdiction. The submission of an application to a regulatory authority with respect to a product does not guarantee that approval to market the product will be granted. Each authority generally imposes its own requirements and may delay or refuse to grant approval, even though a product has been approved in another country.

In our principal markets, including the United States, the approval process for a new product is complex, lengthy, expensive and subject to unanticipated delays. We cannot be sure when or whether approvals from regulatory authorities will be received or that the terms of any approval will not impose significant limitations that could negatively impact the potential profitability of the approved product. Even after a product is approved, it may be subject to regulatory action based on newly discovered facts about the safety and efficacy of the product, on any

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activities that regulatory authorities consider to be improper or as a result of changes in regulatory policy. Regulatory action may have a material adverse effect on the marketing of a product, require changes in the product's labelling or even lead to the withdrawal of the regulatory marketing approval of the product.

All facilities and manufacturing techniques used for the manufacture of products and devices for clinical use or for sale in the United States must be operated in conformity with cGMPs, the FDA's regulations governing the production of pharmaceutical products. There are comparable regulations in other countries. Any finding by the FDA or other regulatory authority that we are not in substantial compliance with cGMP regulations or that we or our employees have engaged in activities in violation of these regulations could interfere with the continued manufacture and distribution of the affected products, up to the entire output of such products, and, in some cases, might also require the recall of previously distributed products. Any such finding by the FDA or other regulatory agency could also affect our ability to obtain new approvals until such issues are resolved. The FDA and other regulatory authorities conduct scheduled periodic regulatory inspections of our facilities to ensure compliance with cGMP regulations. Any determination by the FDA or other regulatory authority that we, or one of our suppliers, are not in substantial compliance with these regulations or are otherwise engaged in improper or illegal activities could have a material adverse effect on us.

In May 2001, our wholly-owned subsidiary, Elan Holdings, Inc. (Elan Holdings) and the late Donal J. Geaney, then our chairman and chief executive officer, William C. Clark, then president of operations, and two then employees of Elan Holdings, Hal Herring and Cheryl Schuster, entered into a consent decree of permanent injunction with the U.S. Attorney for the Northern District of Georgia, on behalf of the FDA, relating to alleged violations of cGMP at our Gainesville facility. The facility manufactured, and continues to manufacture, verapamil hydrochloride controlled-release tablets for the treatment of high blood pressure. The consent decree does not represent an admission by Elan Holdings or the former officers or employees named above of any of the allegations set forth in the decree. Under the terms of the consent decree, which will continue in effect until at least May 2006, Elan Holdings is permanently enjoined from violating cGMP regulations. In addition, Elan Holdings was required to engage an independent expert, subject to FDA approval, who conducted inspections of the facility through May 2004 in order to ensure the facility's compliance with cGMP. The first of these inspections was completed and reported upon by the independent expert to the FDA on September 3, 2002. A corrective action plan was prepared and sent to the FDA in response to this inspection. A second independent consultant audit occurred in May 2003 and was reported upon by the independent expert to the FDA on August 14, 2003. In response to the inspection, a corrective action plan was prepared and sent to the FDA. The independent consultant inspected the facility for the third time in May 2004 and reported his findings to the FDA in August 2004. The independent expert found our response and corrective action to that date to be satisfactory. During the term of the consent decree, we expect that the facility will be subject to increased FDA inspections and, under the terms of the consent decree, we will be required to reimburse the FDA for its costs related to these inspections.

***Our business exposes us to risks of environmental liabilities.***

We use hazardous materials, chemicals and toxic compounds that could expose people or property to accidental contamination, events of non-compliance with environmental laws, regulatory enforcement and claims related to personal injury and property damage. If an accident occurred or if we were to discover contamination caused by prior operations, then we could be liable for cleanup, damages or fines, which could have an adverse effect on us.

The environmental laws of many jurisdictions impose actual and potential obligations on us to remediate contaminated sites. These obligations may relate to sites that we currently own, sites that we formerly owned or operated or sites where waste from our operations was disposed. These environmental remediation obligations could significantly impact our operating results. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to us, and could subject our handling, manufacture, use, reuse or

disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures, as well as other costs and liabilities, which could materially adversely affect us.

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***If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, then we could be subject to additional reimbursements, penalties, sanctions and fines, which could have a material adverse effect on our business.***

As a condition of reimbursement under Medicaid, we participate in the U.S. federal Medicaid rebate program, as well as several state rebate programs. Under the federal and state Medicaid rebate programs, we pay a rebate to each state for our products that are reimbursed by those programs. The amount of the rebate for each unit of product is set by law based on reported pricing data. The rebate amount may also include a penalty if our prices increase faster than the rate of inflation.

As a manufacturer of single source, innovator and non-innovator multiple source products, rebate calculations vary among products and programs. The calculations are complex and, in some respects, subject to interpretation by governmental or regulatory agencies, the courts and us. The Medicaid rebate amount is computed each quarter based on our pricing data submission to the Centers for Medicare and Medicaid Services at the U.S. Department of Health and Human Services. The terms of our participation in the program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in an overage or shortfall in our rebate liability for past quarters (up to 12 past quarters), depending on the direction of the correction. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

U.S. Federal law requires that any company that participates in the federal Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Services pharmaceutical pricing program. This pricing program extends discounts comparable to the Medicaid net price to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as outpatient utilization at hospitals that serve a disproportionate share of poor patients.

Additionally, each calendar quarter, we calculate and report an Average Sales Price (ASP) for all products covered by Medicare Part B (primarily injectable or infused products). We submit ASP information for each such product within 30 days of the end of each calendar quarter. This information is then used to set reimbursement levels to reimburse Part B providers for the drugs and biologicals dispensed to Medicare Part B participants.

Furthermore, pursuant to the Veterans Health Care Act, a Non-Federal Average Manufacturer Price is calculated each quarter and a Federal Ceiling Price is calculated each year for every Covered Drug marketed by us. These prices are used to set pricing for purchases by the military arm of the government.

These price reporting obligations are complicated and often involve decisions regarding issues for which there is no clear-cut guidance from the government. Failure to submit correct pricing data can subject us to civil, administrative, and criminal penalties, and could have a material adverse effect on our business, financial condition and results of operations.

***We are subject to continuing potential product liability risks, which could harm our business.***

Risks relating to product liability claims are inherent in the development, manufacturing and marketing of our products. Any person who is injured while using one of our products may have a product liability claim against us. Since we distribute and sell our products to a wide number of end users, the risk of such claims could be material. Persons who participate in clinical trials involving our products may also bring product liability claims.

We currently do not maintain product liability insurance for the first \$25.0 million of aggregate claims, but do maintain coverage for the next \$150.0 million with our insurers. Our insurance coverage may not be sufficient to

cover fully all potential claims.

If our claims experience results in higher rates, or if product liability insurance otherwise becomes costlier because of general economic, market or industry conditions, then we may not be able to maintain product liability coverage on acceptable terms. If sales of our products increase materially, or if we add significant products to our portfolio, then we will require increased coverage and may not be able to secure such coverage at reasonable rates.

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***We and some of our officers and directors have been named as defendants in putative class actions; an adverse outcome in the class actions could have a material adverse effect on us.***

We and some of our officers and directors have been named as defendants in putative class actions filed in 2005. The class action complaints allege claims under the U.S. federal securities laws and state laws. The complaints allege that we caused the release of materially false or misleading information regarding *Tysabri*. The complaints seek damages and other relief that the courts may deem just and proper. We believe that the claims in the lawsuits are without merit and intend to defend against them vigorously.

An adverse result in the lawsuits could have a material adverse effect on us.

***Our stock price is volatile, which could result in substantial losses for investors purchasing shares.***

The market prices for our shares and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, on February 28, 2005, we lost approximately 70% of our market capitalization and on March 31, 2005, we lost more than 50% of our market capitalization. The market price of our shares likely will continue to fluctuate due to a variety of factors, including:

Material public announcements by us;

Developments regarding *Tysabri*;

The timing of new product launches by others and us;

Events related to our marketed products and those of our competitors;

Regulatory issues affecting us;

Availability and level of third-party reimbursement;

Developments relating to patents and other intellectual property rights;

Results of clinical trials with respect to our products under development and those of our competitors;

Political developments and proposed legislation affecting the pharmaceutical industry;

Economic and other external factors;

Hedge or arbitrage activities by holders of our securities;

Period-to-period fluctuations in our financial results or results that do not meet or exceed market expectations; and

Market trends relating to or affecting stock prices across our industry, whether or not related to results or news regarding our competitors or us.

***Certain provisions of agreements to which we are a party may discourage or prevent a third party from acquiring us and could prevent shareholders from receiving a premium for their shares.***

We are a party to agreements that may discourage a takeover attempt that might be viewed as beneficial to shareholders who wish to receive a premium for their shares from a potential bidder. For example:

Our collaboration agreement with Biogen Idec provides Biogen Idec with an option to buy the rights to *Tysabri* in the event that we undergo a change of control, which may limit our attractiveness to potential acquirers;

Until June 20, 2010, Biogen Idec and its affiliates are, subject to limited exceptions, restricted from, among other things, seeking to acquire or acquiring control of us;

Under the terms of indentures governing much of our debt, any acquirer would be required to make an offer to repurchase the debt for cash in connection with some change of control events; and

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Our collaboration agreement with Wyeth restricts Wyeth and its subsidiaries from seeking to acquire us in some circumstances.

**Item 4. Information on the Company.**

**A. History and Development of Elan**

Elan, an Irish public limited company, is a neuroscience-based biotechnology company headquartered in Dublin, Ireland.

We were incorporated as a private limited company in Ireland in December 1969 and became a public limited company in January 1984. Our principal executive offices are located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland and our telephone number is 353-1-709-4000. Our principal research and development, manufacturing and marketing facilities are located in Ireland, the United States and the United Kingdom.

**B. Business Overview**

Our business is organized into two business units: Biopharmaceuticals and Elan Drug Technologies (EDT). Biopharmaceuticals engages in research, development and commercial activities and includes our activities in the areas of autoimmune diseases, neurodegenerative diseases, and our specialty business group. EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry.

In the area of autoimmune diseases, we continue to research and develop novel therapies that may help patients who suffer from diseases where an immune reaction is mistakenly directed at cells, tissues and organs in different parts of the body. Currently there are few autoimmune diseases for which the disease can be reversed or cured; autoimmune diseases are, therefore, often chronic, requiring life-long care.

The wide range of autoimmune diseases includes MS, Crohn's disease (CD), ulcerative colitis (UC) and rheumatoid arthritis (RA). Worldwide it is estimated that one million people suffer from the different forms of MS; and more than a million people suffer from CD and UC.

*Tysabri*, an alpha 4 integrin antagonist, is the first in a new class of adhesion molecule inhibitors for the treatment of MS. *Tysabri* is designed to inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue where they may cause or maintain inflammation. *Tysabri* is being developed and commercialized by us in collaboration with Biogen Idec.

On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

The PCNS Advisory Committee review regarding *Tysabri* culminated a 13-month process focused on reviewing the safety of the therapy and encompassing the following events:

On February 28, 2005, Elan and Biogen Idec announced the voluntary suspension of the marketing and dosing in clinical trials of *Tysabri*, which had been granted accelerated approval for the treatment of MS in November 2004. Our suspension of *Tysabri* was based on two reports of PML, one of which was fatal, in patients treated

for more than two years with *Tysabri* in combination with Avonex in clinical trials. PML is a rare and potentially fatal, demyelinating disease of the central nervous system.

We and Biogen Idec subsequently initiated a comprehensive safety evaluation of *Tysabri* and any possible link to PML. The safety evaluation was comprised of a complete review of all clinical trial data. We and Biogen Idec worked with clinical trial investigators and PML and neurology experts to evaluate more than 3,000 patients in MS, CD and RA trials. The safety evaluation also included a review of any reports of potential PML in patients receiving *Tysabri* in the commercial setting.

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In March 2005, we announced that the safety evaluation had led to a posthumous reassessment of PML in a patient in an open label CD clinical trial. The patient died in December 2003, and the case had originally been reported by a clinical trial investigator as malignant astrocytoma.

In August 2005, we reported that findings from the safety evaluation of *Tysabri* in patients with MS resulted in no new confirmed cases of PML beyond the three previously reported. On October 17, 2005, which marked the completion of the safety review, we reported the same results from our evaluation of patients with CD and RA.

In September 2005, we and Biogen Idec announced that we had submitted an sBLA for *Tysabri* to the FDA for the treatment of MS and would submit a similar data package to the European Medicines Agency (EMA). In November 2005, the sBLA was accepted and designated for Priority Review by the FDA, and the European submission was accepted for review.

On February 15, 2006, Elan and Biogen Idec were informed by the FDA that it had removed the hold on clinical trial dosing of *Tysabri* in MS in the United States, and the companies announced that they expected to begin an open label, multi-center safety extension study of *Tysabri* monotherapy in the United States and internationally.

In the area of neurodegenerative diseases, we continue to build on our discovery and clinical foundation in Alzheimer's disease and Parkinson's disease. In the United States and throughout the world, Alzheimer's disease and related disorders represent a significant unmet medical need.

Alzheimer's disease is a devastating brain degeneration disorder that primarily affects older persons. The disease can begin with forgetfulness and progress into advanced symptoms, including the decline or loss of memory, reasoning, abstraction, and language. Most patients will eventually need complete skilled nursing care, and in the absence of other illnesses, the progressive loss of brain function itself will cause death. In the United States, Alzheimer's disease is estimated to afflict 4.5 million people, with 450,000 new diagnoses every year. Worldwide, 20 to 30 million people may be affected.

Parkinson's disease also typically occurs later in life. Parkinson's disease is a progressive degenerative neurologic movement disorder that destroys nerve cells in the part of the brain responsible for muscle control and movement, creating problems in walking, balance and coordination. In the United States, there are an estimated 500,000 to 1.5 million people with Parkinson's disease, and approximately 50,000 new patients are diagnosed each year. It is estimated that four million people worldwide suffer from Parkinson's disease.

While a number of approved treatment options exist for Alzheimer's disease and Parkinson's disease, current available options do not affect the underlying cause of the disease nor its progression.

Our research and development efforts in Alzheimer's disease and Parkinson's disease span more than two decades, and our work in neurodegeneration diseases is considered unique, especially in the area of immunotherapies targeting Alzheimer's disease.

In a current, industry-leading immunotherapy program, in collaboration with Wyeth, we are conducting clinical trials for the treatment of mild to moderate Alzheimer's disease. AAB-001, an experimental monoclonal antibody, is in Phase 2 studies, and ACC-001, a novel beta amyloid-related active immunization approach, entered Phase 1 studies in late 2005.

Our specialty business group encompasses our commercial activities related to meeting the needs of specialists treating severe bacterial infections in hospitals, and pain specialists addressing severe chronic pain. Currently, these

products are the antibacterial hospital products *Maxipime* and *Azactam*, and *Prialt*, an innovative treatment for severe chronic pain, which we launched in the United States in January 2005.

In February 2005, the European Commission granted marketing authorization for *Prialt* for the treatment of severe, chronic pain in patients who require intrathecal analgesia. *Prialt* has been designated an orphan drug in the European Union. On March 20, 2006, we completed the sale of the European rights to *Prialt* to Eisai, while retaining the product rights in the United States.

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EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry.

Elan has a proud track record of innovation and expertise in drug optimization. For more than 35 years, Elan has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed in more than 40 countries. Today, more than 2.5 million patients worldwide use drug products based on or enhanced by our technologies.

Elan's *NanoCrystal*® technology, a drug optimization technology applicable to poorly water-soluble compounds, was integral to EDT's 2005 results. *NanoCrystal* technology is covered by more than 130 U.S. and international patents and patent applications and is part of a suite of proprietary technologies that EDT offers to third-party clients.

## **AUTOIMMUNE DISEASES**

### ***About Autoimmune Diseases***

In autoimmune diseases, the immune system mistakenly targets the cells, tissues and organs of a person's body, generally causing inflammation. Inflammation is a response of body tissues to trauma, infection, chemical or physical injury, allergic reaction, or other factors. It is usually characterized by a collection of cells and molecules at a target site.

Different autoimmune diseases affect the body in different ways. For example, in MS, the autoimmune reaction is directed against the brain. In CD, it is directed against the gastrointestinal tract; and in RA, it is directed against the joints. Autoimmune diseases are often chronic, affecting millions of people and requiring life-long care. Most autoimmune diseases cannot currently be reversed or cured.

Elan's therapeutic strategy for treating autoimmune diseases is to identify mechanisms common to autoimmune diseases, and develop novel therapeutics that stop the underlying causes of disease.

Alpha 4 integrin is a protein expressed by immune cells that allows those cells to leave the blood stream and invade target tissue. Blocking alpha 4 integrin stops immune cells from entering tissues and therefore stops injury before it can occur.

### ***Tysabri***

*Tysabri*, an alpha 4 integrin antagonist, is the first in a new class of adhesion molecule inhibitors for the treatment of MS. *Tysabri* is designed to inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue where they may cause or maintain inflammation. *Tysabri* is being developed and commercialized by us in collaboration with Biogen Idec.

### ***FDA Review of Tysabri for the Treatment of MS***

On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

In November 2004, the FDA had granted accelerated approval of *Tysabri* as a treatment for relapsing forms of MS to reduce the frequency of clinical relapses, making *Tysabri* the first humanized monoclonal antibody to be approved for the treatment of MS. Revenue from sales of *Tysabri* amounted to \$11.0 million in 2005 (2004: \$6.4 million).

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The PCNS Advisory Committee review regarding *Tysabri* culminated a 13-month process focused on reviewing the safety of the therapy and encompassing the following events:

### *Voluntary Suspension of Tysabri*

In late February 2005, Elan and Biogen Idec suspended the marketing and dosing in clinical trials of *Tysabri*, based on two reports of PML, one of which was fatal, in patients treated for more than two years with *Tysabri* in combination with Avonex in clinical trials. PML is a rare and potentially fatal demyelinating disease of the central nervous system.

We and Biogen Idec initiated a comprehensive safety evaluation of *Tysabri* and any possible link to PML. The safety evaluation was comprised of the review of all clinical trial data. We and Biogen Idec worked with clinical trial investigators and PML and neurology experts to evaluate more than 3,000 patients in MS, CD and RA trials. The safety evaluation also included a review of any reports of potential PML in patients receiving *Tysabri* in the commercial setting.

In March 2005, we and Biogen Idec announced that the safety evaluation had led to a posthumous reassessment of PML in a patient in an open label CD clinical trial. The patient died in December 2003, and the case had originally been reported by a clinical trial investigator as malignant astrocytoma. This diagnosis was confirmed at the time by histopathology. The patient had received eight doses of *Tysabri* over an 18-month period, and prior medication history included multiple courses of immunosuppressant agents.

In August 2005, we and Biogen Idec reported that findings from the safety evaluation of *Tysabri* in patients with MS resulted in no new confirmed cases of PML beyond the three previously reported. On October 17, 2005, which marked the completion of the safety review, we reported the same results from our evaluation of patients with CD and RA.

More than 2,000 MS patients from clinical trials were eligible for the safety evaluation, and more than 91 percent of these patients agreed to participate. More than 1,500 CD and RA patients from clinical trials were eligible for the safety evaluation, and approximately 88 percent of these patients participated.

In September 2005, Elan and Biogen Idec announced that the companies had submitted an sBLA for *Tysabri* to the FDA for the treatment of MS and would submit a similar data package to the EMEA. In November 2005, the sBLA was accepted and designated for Priority Review by the FDA, and the European submission was accepted for review.

The sBLA included two-year data from the Phase 3 AFFIRM monotherapy trial and SENTINEL add-on trial with Avonex in MS, a revised label and risk management plan, and an integrated safety assessment of *Tysabri* clinical trial patients.

### *Redosing of Tysabri in Clinical Trial*

On February 15, 2006, Elan and Biogen Idec were informed by the FDA that it had removed the hold on clinical trial dosing of *Tysabri* in MS in the United States, and the companies announced that they expected to begin an open label, multi-center safety extension study of *Tysabri* monotherapy in the United States and internationally.

### ***AFFIRM Phase 3 Monotherapy Trial***

The AFFIRM trial was a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients conducted in 99 sites worldwide, evaluating the effect of *Tysabri* on the progression of disability in MS at two years and the rate of clinical relapses at one and two years. Patients with relapsing forms of MS, who had experienced at

least one relapse in the previous year, were randomized to receive a 300 milligram intravenous (300 mg IV) infusion of *Tysabri* (n= 627) or placebo (n=315) every four weeks.

At one year, there was a 66 percent relapse rate reduction in the *Tysabri*-treated group versus the placebo-treated group. An annualized relapse rate of 0.25 was seen with *Tysabri*-treated patients versus 0.74 with placebo-treated patients.

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All secondary endpoints were also met. In the *Tysabri*-treated group, 60 percent of patients developed no new or newly enlarging T2 hyperintense lesions compared to 22 percent of placebo-treated patients. On the one-year MRI scan, 96 percent of *Tysabri*-treated patients had no gadolinium enhancing lesions compared to 68 percent of placebo-treated patients. The proportion of patients who remained relapse free was 76 percent in the *Tysabri*-treated group compared to 53 percent in the placebo-treated group.

In February 2005, we and Biogen Idec announced that the AFFIRM monotherapy trial achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of MS. *Tysabri* treatment led to a 42 percent reduction in the risk of disability progression relative to placebo. These data also demonstrated a 67 percent reduction in the rate of clinical relapses over two years, which was sustained and consistent with the previously reported one-year results.

In April 2005, the full two-year AFFIRM monotherapy data was presented at the 57th annual American Academy of Neurology meeting. The data was published in the *New England Journal of Medicine* in March 2006.

### ***SENTINEL Phase 3 Add-on Trial***

The SENTINEL trial, also a two-year study, was a randomized, multi-center, placebo-controlled, double blind study of 1,171 patients in 123 clinical trial sites worldwide. The trial was designed to determine if adding *Tysabri* to ongoing Avonex therapy is more effective than continuing Avonex treatment alone in slowing the rate of disability in MS at two years and in reducing the rate of clinical relapses at one and two years in patients with evidence of relapses despite Avonex therapy.

Patients in the SENTINEL trial were required to have relapsing forms of MS, be on Avonex treatment for at least one year, and have experienced at least one relapse in the previous year. All patients continued to receive once-weekly Avonex and were randomized to add either a 300 mg IV infusion of *Tysabri* (n= 589) or placebo (n=582) every four weeks.

At one year, the addition of *Tysabri* to Avonex resulted in a 54 percent reduction in the rate of clinical relapses over the effect of Avonex alone. An annualized relapse rate of 0.36 was seen with *Tysabri* when added to Avonex versus 0.78 with Avonex plus placebo.

All secondary endpoints were also met. In the group treated with *Tysabri* plus Avonex, 67 percent of patients developed no new or newly enlarging T2 hyperintense lesions compared to 40 percent in the Avonex plus placebo-treated group. On the one-year MRI scan, 96 percent of *Tysabri* plus Avonex-treated patients had no gadolinium-enhancing lesions compared to 76 percent of Avonex plus placebo-treated patients. The proportion of patients who remained relapse-free was 67 percent in the *Tysabri* plus Avonex-treated group compared to 46 percent in the Avonex plus placebo-treated group.

In July 2005, we and Biogen Idec announced that SENTINEL achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of MS. The addition of *Tysabri* to Avonex resulted in a 24 percent reduction in the risk of disability progression compared to the effect provided by Avonex alone. Data from SENTINEL also demonstrated that the addition of *Tysabri* to Avonex led to a 56 percent relative reduction in the rate of clinical relapses compared to that provided by Avonex alone. The reduction in relapse rate was statistically significant and sustained over the entire two-year study period.

Other efficacy data from SENTINEL at two years, including MRI measures and immunogenicity, were similar to previously reported one-year results. Data from SENTINEL was published in the *New England Journal of Medicine* in March 2006.

***Evaluating Tysabri in Crohn's Disease***

In collaboration with Biogen Idec, we are evaluating *Tysabri* as a treatment for CD. In September 2004, we submitted a Marketing Authorization Application to the EMEA for the approval of *Tysabri* for the treatment of CD. The application included induction data and 12-month data from a Phase 3 maintenance trial, ENACT-2, showing sustained response, remission, and withdrawal from corticosteroids in a significant number of patients. In 2006, we expect European regulatory action regarding the potential approval of *Tysabri* in CD, dependent upon completion of

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the regulatory review of *Tysabri* in MS. We expect to file a Biologics License Application (BLA) for *Tysabri* as a treatment for CD in the United States in 2006.

### ***ENCORE Phase 3 Crohn's Disease Trial***

In June 2005, Elan and Biogen Idec reported the topline results of the second Phase 3 induction trial, ENCORE, for the treatment of moderately to severely active CD in patients with evidence of active inflammation. ENCORE met the primary endpoint of clinical response as defined by a 70-point decrease in baseline Crohn's Disease Activity Index (CDAI) score at both weeks 8 and 12.

In addition, ENCORE met all of its secondary endpoints including clinical remission at both weeks 8 and 12. Clinical remission was defined as achieving a CDAI score of equal to or less than 150 at both weeks 8 and 12.

There were no notable differences in the overall rates of adverse events or serious adverse events between the *Tysabri* and the placebo treatment groups. The most common adverse events seen in the trial were headache, nausea, abdominal pain and nasopharyngitis. The full ENCORE data set will be presented during the 2006 Digestive Disease Week (DDW) conference in May.

ENCORE was a Phase 3, international, double-blind, placebo-controlled study of 510 patients at 114 sites to evaluate the safety and efficacy of intravenous *Tysabri* in patients with moderately to severely active CD (based on a confirmed diagnosis of CD and a CDAI score of greater than or equal to 220 and less than or equal to 450) and evidence of active inflammation (as evidenced by elevated C-reactive protein levels of greater than 2.87 mg/l, the upper limit of normal). Patients were randomized 1:1 to treatment with *Tysabri* (300 mg IV) or placebo infusions at weeks 0, 4, and 8. Efficacy and safety assessments were performed at weeks 4, 8 and 12.

At the time of the voluntary suspension of *Tysabri* dosing in all ongoing clinical trials (February 2005), all ENCORE study patients had completed dosing based on the study protocol.

### ***ENACT-2 Phase 3 Crohn's Disease Maintenance Trial***

ENACT-2 was a Phase 3, double-blind, placebo-controlled, international maintenance trial of *Tysabri* in CD enrolled responders from ENACT-1 (a three-month double-blind, placebo-controlled study in patients with moderately to severely active CD). *Tysabri* responders from ENACT-1 (339 patients) were re-randomized after the three-month study to one of two double-blind treatment groups: *Tysabri* (300 mg IV) or placebo, both administered monthly for a total of 12 months. The primary endpoint of ENACT-2 was sustained maintenance of response throughout the first six months of treatment.

We presented six-month data from the ENACT-2 study at the DDW in May 2004. Twelve-month ENACT-2 data was presented as part of a regulatory filing announced and subsequently presented at the 12th Annual United European Gastroenterology Week meeting in September 2004.

The data presented at the DDW showed *Tysabri* maintained clinical response and remission rates throughout six months among patients with Crohn's disease who had previously achieved clinical response. At six months, 61 percent of *Tysabri*-treated patients exhibited significant clinical response versus 28 percent of patients re-randomized to receive placebo, and clinical remission was maintained by 44 percent of patients receiving *Tysabri* versus 26 percent of placebo-treated patients. Forty-nine percent of *Tysabri*-treated patients who were also on chronic corticosteroid therapy were able to withdraw from corticosteroids and maintain response, in contrast to 20 percent of patients on placebo. There were no notable differences in the rate of serious or non-serious adverse events between treatment groups. The most frequently reported adverse events were headache, nasopharyngitis, nausea and abdominal pain.

***Evaluating Tysabri in Rheumatoid Arthritis***

In February 2004, in collaboration with Biogen Idec, we filed an Investigational New Drug (IND) application with the FDA for *Tysabri* for the treatment of RA and initiated a Phase 2 clinical trial in May 2004 to evaluate *Tysabri* in patients with RA. It was a multi-center, double-blind, placebo-controlled study of the efficacy and

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tolerability of intravenous *Tysabri* in patients with moderate-to-severe RA receiving concomitant treatment with methotrexate.

This study was prematurely discontinued in February 2005 due to the voluntary suspension of *Tysabri* dosing in all clinical trials. The available results from the discontinued trial demonstrated biological activity, but less than competitive efficacy results. For this reason, we and Biogen Idec have decided not to pursue the development of *Tysabri* for the treatment of RA at this time.

### ***Autoimmune Diseases Research & Development***

Our ongoing research in autoimmune diseases is based primarily on cell trafficking and focuses on discovering disease-modifying approaches to treating a wide range of autoimmune diseases, including MS, CD and RA. *Tysabri* emerged from this research program.

Since first publishing the hypothesis concerning the therapeutic potential of blocking alpha 4 integrin in 1992, our scientists have been expanding and refining our understanding of how cells enter tissues. We now have a clear understanding of how cells enter the gut, brain, or joints, and cause the damage characteristic of CD, MS, and RA. Through the course of this work we have developed small molecules that can selectively block particular alpha 4 integrin interactions, culminating in the development of ELND001 and ELND002 - two alpha 4 integrin small molecule antagonists targeted at distinct autoimmune diseases. We hope to bring these new therapies into the clinic in 2006.

## **NEURODEGENERATIVE DISEASES**

### ***About Neurodegenerative Diseases***

In addition to Alzheimer's disease and Parkinson's disease, neurodegenerative diseases encompass other disorders that are characterized by changes in normal neuronal function. In most cases of degenerative disease, the risk of these changes increases with age, and the disease progression itself is progressive. Currently, neurodegenerative diseases are generally considered incurable. Several drugs are approved to alleviate some symptoms of some neurodegenerative diseases.

Alzheimer's disease is a degenerative brain disorder that primarily affects older persons. In the United States, an estimated 4.5 million people, most of them over age 65, have Alzheimer's disease, and the disease is thought to afflict half of all Americans over 85. Alzheimer's disease can begin with forgetfulness and progress into more advanced symptoms, including confusion, language disturbances, personality and behavior changes, impaired judgment and profound dementia. As the disease advances, most patients will eventually need complete skilled nursing care, and in the absence of other illnesses, the progressive loss of brain function itself will cause death.

Parkinson's disease is a progressive degenerative neurologic movement disorder that destroys nerve cells in the part of the brain responsible for muscle control and movement. This creates problems walking, maintaining balance and coordination in patients diagnosed with the disease. Parkinson's disease typically occurs later in life, with an average age of onset of slightly over 62 years for U.S. patients. In the United States, there are an estimated 500,000 to 1.5 million people with Parkinson's disease, and approximately 50,000 new patients are diagnosed each year. It is estimated that four million people worldwide suffer from Parkinson's disease.

### ***Our Scientific Approach to Alzheimer's Disease and Related Disorders***

Our scientific approach to treating Alzheimer's disease focuses on the beta amyloid hypothesis, as it is believed that blocking the generation of beta amyloid in the brain or enhancing the clearance of beta amyloid will result in the successful treatment of Alzheimer's disease patients. The beta amyloid hypothesis asserts that beta amyloid is involved in the formation of the plaque that causes the disruption of thinking that is the hallmark of Alzheimer's disease. This hypothesis is also the leading approach to developing therapeutic treatments that may fundamentally alter the progression of the disease, and evidence suggests that clearance of beta amyloid may lead to improved function in Alzheimer's disease patients.

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Beta amyloid, also known as A $\beta$ , is actually a small part of a larger protein called the amyloid precursor protein, or APP. Beta amyloid is formed when certain enzymes called secretases clip (or cleave) APP. It is becoming increasingly clear that once beta amyloid is released, it exists in multiple physical forms with distinct functional activities. It is believed that the toxic effects of these forms are likely responsible for the complex mental disruption characteristic of Alzheimer's disease.

### ***Alzheimer's Research and Development***

Our scientists are investigating three key therapeutic approaches that target the accumulation and production of beta amyloid. In collaboration with Wyeth, we are developing amyloid immunotherapies. Separately, we have research programs focused on small molecule inhibitors of beta secretase and gamma secretase, enzymes whose actions result in the over-production of beta amyloid in the brains of patients with Alzheimer's disease.

### ***Research in Beta Amyloid Immunotherapy***

Beta amyloid immunotherapy pioneered by Elan involves the treatment of Alzheimer's disease by inducing or enhancing the body's own immune response in order to clear beta amyloid from the brain. Active immunization stimulates the body's own immune system to manufacture anti beta amyloid antibodies that may attach to amyloid and clear it from the brain. This, in turn, appears to reduce the build-up of beta amyloid in the brain tissue of patients.

Through a monoclonal antibody approach (passive immunization), synthetically engineered antibodies directed at beta amyloid are injected into the bloodstream and are thought to help reverse beta amyloid accumulation.

Our scientists have developed a series of monoclonal antibodies and active immunization approaches that have the ability to selectively clear a variety of beta amyloid species. These new approaches have the potential to deliver second-generation immunotherapies with improved potency and broader therapeutic activity. Both AAB-001 and AAB-002 have emerged from this important work.

### ***AAB-001***

We, in collaboration with Wyeth, are continuing to pursue beta amyloid immunotherapy for mild to moderate Alzheimer's disease in Phase 2 studies of a humanized monoclonal antibody, AAB-001. This therapeutic antibody, which is thought to bind and clear beta amyloid peptide, is designed to provide antibodies to beta amyloid directly to the patient, rather than requiring patients to mount their own individual responses. This approach, therefore, eliminates the need for the patient to mount an immune response to beta amyloid.

Animal studies have shown that this approach is as effective in clearing beta amyloid from the brain as active immunization methods. By providing such a passive immunization approach for treatment of Alzheimer's disease, the benefits demonstrated with an earlier active immunization study may be retained, while the safety concerns may be greatly reduced or eliminated due to the absence of stimulation of the patient's immune response to beta amyloid.

During the first half of 2005, we initiated two Phase 2 clinical trials with AAB-001. Both trials are randomized, double-blind, placebo-controlled, multiple ascending dose studies. One trial includes 240 patients and the other includes 30 patients, all with mild to moderate Alzheimer's disease. The patients will be followed for 18 months, during which period there will be several interim evaluations of the data. These analyses will be used to decide if and when the program will be moved to the next phase of clinical development.

### ***AAB-002***

We anticipate a potential filing of an IND in the latter half of 2006 for AAB-002, a follow-on antibody program, which is also in collaboration with Wyeth. This antibody has demonstrated unique attributes in our experimental animal models when compared to AAB-001, and therefore represents a potential follow-on candidate to the first-generation passive antibody.

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### ***ACC-001***

We, in collaboration with Wyeth, are also developing ACC-001, a novel beta amyloid-related active immunization approach. ACC-001 is in a Phase 1 clinical study designed to study safety and immunogenicity in patients with mild to moderate Alzheimer's disease. The ACC-001 approach is intended to induce a highly specific antibody response to beta amyloid. The goal is to clear beta amyloid while minimizing side effects such as inflammation of the central nervous system. During the course of 2006, we anticipate generating sufficient data to enter into Phase 2 clinical trials.

### ***Our Secretase Inhibitor Research***

Beta and gamma secretases are proteases (enzymes that break down other proteins) that appear to clip the APP, resulting in the formation of beta amyloid. This is significant because if the clipping of APP could be prevented, the pathology of Alzheimer's disease may be changed. As a result of these discoveries, we have developed and are pursuing advanced discovery programs focused on molecule inhibitors of beta and gamma secretases. We have been at the forefront of research in this area, publishing extensively since 1989, and anticipate moving small molecule secretase antagonists into the clinic in the next two to three years.

### ***Beta Secretase***

Beta secretase is believed to initiate the first step in the formation of beta amyloid, the precursor to plaque development in the brain. We have been an industry leader in beta secretase research for more than 10 years. Our findings concerning the role beta secretase plays in beta amyloid production, published in *Nature* in 1999, are considered a landmark discovery. Today, we continue to be at the center of understanding the complexities of beta secretase and advancing potential disease-modifying agents that inhibit its role in Alzheimer's disease pathology. In 2005, we resolved our dispute with Pfizer Inc. (Pfizer), our former collaborator on the beta secretase program. The settlement allows for both companies to operate with freedom in the beta secretase space. We are aggressively continuing our preclinical drug discovery efforts, including expansion of our strategic industry-leading patent portfolio covering beta secretase small molecule inhibitors.

### ***Gamma Secretase***

Gamma secretase is an unusual multi-protein complex that is thought to play a significant role in the formation of beta amyloid. We have played a critical leadership role in the increased awareness of how gamma secretase may affect Alzheimer's disease pathology. Our finding, published in 2001, that functional gamma secretase inhibitors appear to reduce beta amyloid levels in the brain, was an important step in this area of Alzheimer's disease research. Our gamma secretase research is currently in the preclinical discovery phase.

### ***External Research Collaborations***

As part of our continued emphasis on supporting novel research approaches in academia, we created a new research award program with the Institute for the Study of Aging, Ltd. (ISOA), a biomedical venture philanthropy founded by the Estée Lauder family. The three-year program, entitled *Novel Approaches to Drug Discovery for Alzheimer's Disease*, seeks to catalyze and fund academic and biotechnology industry scientists worldwide to conduct research leading to the discovery of effective therapies for Alzheimer's disease. The first winners of this research award program—four recipients selected from a highly competitive pool of 45 scientists from 12 countries—were announced by ISOA in March 2006.

### ***Parkinson's Research***

Parkinson's disease is believed to be a result of misfolded proteins in the brain. Parkinson's disease is characterized by the accumulation of aggregated alpha-synuclein, or Lewy bodies, in degenerating neurons in particular regions of the brain.

Our early discovery efforts in Parkinson's disease are guided by our expertise and leadership in Alzheimer's disease research. We made significant scientific progress in 2005, identifying unusual modified forms of alpha-

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synuclein in human Parkinson's disease brain tissue. These unique forms have led us to a series of therapeutic targets that will be a focus of our drug discovery efforts over the next few years. Some of our findings were published in the June 2005 edition of the journal *Neuron*.

Our scientists are also studying parkin, a protein found in the brain that has been genetically linked to Parkinson's disease. Parkin may be involved in the elimination of misfolded proteins within neurons. Some familial forms of Parkinson's disease have been linked to mutations in parkin, and we are actively studying the relationship between parkin activity and neurodegeneration. This research is in the drug discovery stage.

### ***Specialty Business Group***

Our specialty business group encompasses our commercial activities related to meeting the needs of specialists treating severe bacterial infections in hospitals, and pain specialists addressing severe chronic pain. Currently, our products are the antibacterial hospital products *Maxipime* and *Azactam*, and *Prialt*, an innovative treatment for severe chronic pain.

### ***About Severe Chronic Pain***

There are many different ways to classify pain, including duration or time, disease base, and whether physiologically the pain is based in nerves that sense and respond to damage to parts of the body (nociceptive), or if the pain is the result of an injury or malfunction in the peripheral or central nervous system (neuropathic).

Chronic pain can be defined as pain that has lasted over six months and is not relieved by medical or surgical care. Chronic pain may result from a previous injury long since healed; or it may be from an ongoing condition, such as back and/or leg pain, cancer pain, complex regional pain syndromes, or painful nerve disorders (neuropathies).

Pain can be classified as severe based on standardized measurements, such as the Visual Analog Scale of Pain Intensity. Severe chronic pain is a significant debilitating condition. Approximately 52,000 patients with severe chronic pain have their condition managed by intrathecal therapy.

### ***Our Focus***

In severe and chronic pain, our efforts focus on inflammatory and neuropathic pain, and pain that is unresponsive to existing therapies.

### ***Prialt A Different Pain Treatment***

On December 28, 2004, the FDA approved *Prialt* for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. *Prialt* is approved for use only in the Medtronic SynchroMed® EL, SynchroMed® II Infusion System and CADD-Micro® ambulatory infusion pump.

*Prialt* is administered through appropriate programmable microinfusion pumps that can be implanted or external, and which release the drug into the fluid surrounding the spinal cord.

*Prialt* has been evaluated as an intrathecal infusion in more than 1,200 patients participating in chronic pain trials. The longest treatment duration to date was more than seven years.

*Prialt* is in a new class of non-opioid analgesics known as N-type calcium channel blockers. It is a synthetic equivalent of a naturally occurring conopeptide found in a marine snail known as *Conus magus*. Research suggests that the novel mechanism of action of *Prialt* works by targeting and blocking N-type calcium channels on nerves that ordinarily transmit pain signals.

*Prialt* represents a unique accomplishment and opportunity for Elan. From a scientific perspective, *Prialt* is an important innovation – a new type of therapy in a field that has not seen a new product in approximately 20 years. The significance of this innovation has received wide industry validation and recognition, including a December 2005 profile in *Popular Science*, which listed *Prialt* as one of the 100 best innovations of the year.

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In January 2005, we launched *Prialt* in the United States. The initial introduction of *Prialt* to the marketplace allowed physicians to gain the necessary experience with this treatment; drove our appropriate responses to reimbursement issues during the year; and clarified the marketing, education and other programs and parameters required to continuously improve patient availability. We believe *Prialt* represents an important therapeutic option addressing an unmet need, and that it has the potential for significant patient impact and market contribution in the area of severe chronic pain. Revenue from sales of *Prialt* totalled \$6.3 million for 2005.

In February 2005, the European Commission granted marketing authorization for *Prialt* for the treatment of severe, chronic pain in patients who require intrathecal analgesia. *Prialt* has been awarded orphan drug status in the European Union, which designates it as a product used for the diagnosis, prevention or treatment of life-threatening or very serious rare disorders or conditions. On March 20, 2006, Elan completed the sale of the *Prialt* rights in Europe to Eisai, while retaining the product rights in the United States.

## **HOSPITAL BUSINESS AND PRODUCTS**

Severe bacterial infections remain a major medical concern, even more so with the rise in resistance and fewer available therapies. We market two products that treat severe bacterial infections, each designed to address specific medical needs within the hospital market. Distinct from the community market, the hospital market is highly specialized and often relies on a team of healthcare professionals that influences the decision-making process. We are committed to meeting the needs of the infectious disease and critical care community within the hospital market.

The Hospital Business actively maintains relationships with 1,035 hospitals throughout the United States, each characterized by unique and complex decision-making processes. Approximately 550 of these are leading academic-teaching institutions. Our hospital sales force maintains key relationships with doctors and other healthcare professionals in the areas of infectious disease, critical care, pulmonary, emergency and pharmacy; and frequently interacts with oncologists.

### ***Maxipime***

We licensed the U.S. marketing rights to *Maxipime* from Bristol-Myers Squibb Company (Bristol-Myers) in January 1999. *Maxipime* is a fourth-generation injectable cephalosporin antibiotic used to treat patients with serious and/or life-threatening infections. Pulmonologists, infectious disease specialists, emergency medicine specialists, surgeons, internal medicine physicians, hematologists and oncologists prescribe *Maxipime* for patients with severe infections requiring hospitalization, such as pneumonia, urinary tract infection and febrile neutropenia. Attributes of *Maxipime* are its broad spectrum of activity, including activity against many pathogens resistant to other antibiotics, ease of use and favorable pharmaco-economic profile. Revenue from sales of *Maxipime* amounted to \$140.3 million for 2005. The basic U.S. patent on *Maxipime* expires in March 2007. However, two other U.S. patents covering *Maxipime* formulations may provide protection until February 2008.

### ***Azactam***

We licensed the U.S. marketing rights to this injectable antibiotic from Bristol-Myers in January 1999. *Azactam* is a monobactam and is principally used by surgeons, infectious disease specialists and internal medicine physicians to treat pneumonia, post-surgical infections and septicemia. Revenue from sales of *Azactam* totalled \$57.7 million for 2005. The basic U.S. patent on *Azactam* expired in October 2005. To date, no generic *Azactam* product has been approved. However, we expect that generic competition to *Azactam* will emerge in 2006.

Please refer to Item 5.A Operating Results for additional information concerning our revenue by category for 2005, 2004 and 2003.



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**ELAN DRUG TECHNOLOGIES**

EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry. EDT offers the industry a suite of proprietary technology-driven solutions.

Our *NanoCrystal* technology was integral to the success of EDT in 2005. Sales by third parties of products incorporating *NanoCrystal* technology grew substantially in 2005, and the fourth *NanoCrystal*-incorporated product was launched in the United States. Important announcements for the year included the signing of a number of development agreements with third parties, as well as a broad license agreement with Roche. We also announced that our *NanoCrystal* technology is being used by Johnson & Johnson Pharmaceutical Research and Development in a Phase 3 clinical trial of a long acting injectable in patients with schizophrenia, and that the Japanese patent office had granted a key *NanoCrystal* technology patent.

***Elan's Patented and Commercialized NanoCrystal Technology***

Elan's *NanoCrystal* technology is a drug optimization technology applicable to poorly water-soluble compounds. It is covered by more than 130 U.S. and international patents and patent applications and is part of a suite of technologies that EDT offers to third-party clients.

Elan's *NanoCrystal* technology has offered tangible patient benefits to a number of compounds. For one product, now commercialized the technology improved bioavailability by up to 600 percent; for another launched product, it allowed a four-time reduction in dosage volume; and for others it eliminated the fed-fasting effects providing clear patient benefits to particular therapies.

Products developed and now commercialized in the United States using Elan's patented *NanoCrystal* technology include:

Emend<sup>®</sup> oral tablet form of aprepitant, a poorly water-soluble compound;

Megace<sup>®</sup> ES concentrated oral suspension, with 75 percent reduced dose and improved dissolution and bioavailability;

Rapamune<sup>®</sup> convenient oral tablet form eliminating reconstitution and refrigerated storage of original compound; and

TriCor<sup>®</sup> new formulation of Abbott's fenofibrate, which can be taken without regard to food.

We currently have more than 30 products in various stages of development from feasibility through to Phase 3 projects.

***About NanoCrystal Technology***

*NanoCrystal* technology involves reducing crystalline drug to particles under 400 nanometers. By reducing particle size, the exposed surface area of the drug is increased and is then stabilized to maintain particle size. The drug in nano-form can be incorporated into common dosage forms, including tablets, capsules, inhalation devices, and sterile forms for injection, with the potential for substantial improvements to clinical performance.

***Manufacturing and Scale-up Activities***

The cohabitation of development and manufacturing capabilities on the same sites in EDT allows for streamlined scale-up and transfer to commercial scale manufacturing activities. EDT's principal manufacturing and development facilities are located in Athlone, Ireland and Gainesville, Georgia, in the United States. In 2005, we expanded the range of services we offer clients, with the completion of a sterile fill and finish facility in our Athlone campus. Our range of services includes formulation development, analytical development, clinical trial manufacturing and scale-up, and product registration support.

The Athlone campus, an FDA/EMEA compliant site, now comprises more than 460,000 square feet under roof, of which 218,000 square feet has dedicated, fully-equipped cGMP compliant manufacturing capacity.

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*Experience, Expertise and Patented Technology Portfolio*

Elan has a proud track record of innovation and expertise in drug optimization. For more than 35 years, Elan has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed in more than 40 countries worldwide. Today, more than 2.5 million patients worldwide use drug products based on or enhanced by our technologies.

Our *NanoCrystal* technology was integral to the success of EDT in 2005. We look forward to more product approvals incorporating this technology in the next few years and to growing our business substantially over this period.

**ENVIRONMENT**

Many factors and elements contribute to the environment in which we conduct our activities. Key factors and elements include the world pharmaceutical market, government regulation, the product approval process, manufacturing, patents and intellectual property rights, competition, distribution, raw materials and product supply, employees and principal properties.

***World Pharmaceutical Market***

IMS audited global pharmaceutical sales increased by 7% from 2004 to \$602.0 billion in 2005. In 2004, IMS audited global pharmaceutical sales also increased by 7% over 2003. Biotech products accounted for 9% of global sales in 2005 and account for 27% of the active research and development pipeline.

North America, Japan and Europe accounted for approximately 82% of global pharmaceutical sales in 2005, compared to 88% as in 2004. North America's pharmaceutical sales grew 5% to \$265.7 billion, representing 44% of all global pharmaceutical sales in 2005.

The U.S. market is our most important market. Please refer to Note 28 to the Consolidated Financial Statements for an analysis of revenue by geographic region. For this reason, the factors discussed below, such as Government Regulation and Product Approval, place emphasis on requirements in the United States.

***Government Regulation***

The pharmaceutical industry is subject to significant regulation by international, national, state and local governmental regulatory agencies. Pharmaceutical product registration is primarily concerned with the safety, efficacy and quality of new drugs and devices, and, in some countries, their pricing. A product must generally undergo extensive clinical trials before it can be approved for marketing. The process of developing a new pharmaceutical product, from idea to commercialization, can take in excess of 10 years. This period varies considerably from case to case and from country to country.

An application for registration includes specific details concerning not only the chemical composition, but also the manufacturing plant and procedures involved in the production of the product. The time from submission of an application to commercialization of the product is typically two years or longer. After a product has been approved by the regulatory authorities and has been launched, it is a condition of the product approval that all aspects relating to its safety, efficacy and quality remain under review.

Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing and marketing of pharmaceutical products. For example, the Federal Food, Drug and Cosmetics Act, the Public Health Service Act, the Controlled Substances Act and other federal

statutes and regulations impose requirements on the clinical and non-clinical testing, safety, effectiveness, manufacturing, labelling, storage, recordkeeping, reporting, advertising, marketing, import, export, distribution and approval of our products in the United States. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions. In addition, administrative remedies can involve requests to recall violative products, the refusal of the government to enter into supply contracts or the refusal to approve pending product approval applications for drugs, biological products, or medical devices, until manufacturing or other alleged deficiencies are brought into

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compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labelling restrictions.

In addition, the U.S. Centers for Disease Control and Prevention regulate select biologics and toxins. This includes registration and inspection of facilities involved in the transfer or receipt of select agents. Select agents are subject to specific regulations for packaging, labelling and transport. Non-compliance with applicable requirements could result in criminal penalties and the disallowance of research and manufacturing of clinical products. Exemptions are provided for select agents used for a legitimate medical purpose or for biomedical research, such as toxins for medical use and vaccines.

The pricing of pharmaceutical products is regulated in many countries. The mechanism of price regulation varies. For example, certain countries regulate the price of individual products while in other countries prices are controlled by limiting overall company profitability. In the United States, while there are limited indirect federal government price controls over private sector purchases of drugs, there have been ongoing discussions on potential reforms of the healthcare system, including the pricing of pharmaceuticals, which could result, directly or indirectly, in the implementation of price controls on a larger number of pharmaceutical products. Certain states are attempting to impose requirements, processes, or systems that would result in indirect price controls. It is not possible to predict future regulatory action on the pricing of pharmaceutical products.

In June 2002, we entered into a settlement with the U.S. Federal Trade Commission (FTC) resolving the FTC's investigation of a licensing arrangement between us and Biovail Corporation (Biovail) relating to nifedipine, a generic version of the hypertension drug Adalat<sup>™</sup> CC (nifedipine). The settlement is reflected in a consent order which, by its terms, does not constitute an admission by us that any law had been violated, and does not provide for monetary fines or penalties. We continue to satisfy all of the terms of the consent order.

In June 2001, we received a letter from the FTC stating that the FTC was conducting a non-public investigation to determine whether Brightstone Pharma, Inc. (Brightstone), Elan Corporation, plc or others may have engaged in an effort to restrain trade by entering into an agreement which may restrict the ability of Brightstone or others to market a bioequivalent or generic version of Naprelan. In October 2001, our counsel met informally with the FTC staff to discuss the matter. No further communication from the FTC was received until December 2002, when we were served with a subpoena duces tecum from the FTC for the production of documents related to Naprelan. We have voluntarily provided documents and witness testimony in response to the subpoena and continue to cooperate with the FTC relating to this investigation. We do not believe that it is feasible to predict or determine the outcome of the investigation and any possible effect on our business, or reasonably to estimate the amounts or potential range of loss, if any, with respect to the resolution of the investigation.

On March 13, 2003, we received notification from the FTC that the FTC's Bureau of Competition was conducting an investigation to determine whether we, King Pharmaceuticals, Inc. (King) or any other person was engaging in unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, including, among other things, by preventing or slowing generic competition to Skelaxin<sup>™</sup> (metaxalone). The FTC's stated focus of the investigation was our listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) of at least one patent for Skelaxin, and other actions with regard to the FDA regulatory process. On May 8, 2003, we received notification from the FTC that it had discontinued that portion of its investigation concerning whether we wrongfully listed a patent for Skelaxin in the Orange Book. We do not believe that it is feasible to predict or determine the outcome of the remaining portion of the investigation and any possible effect on our business, or to reasonably estimate the amounts or potential range of loss, if any, with respect to the resolution of the investigation.

## ***Product Approval***

Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. The results of these studies must be submitted to the FDA as part of an IND before human testing may proceed.

Under U.S. law, an IND must be submitted to the FDA and become effective before human clinical trials may commence. U.S. law further requires that studies conducted to support approval for product marketing be adequate and well controlled. In general, this means that either a placebo or a product already approved for the treatment of

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the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice (GCP) requirements, and adverse event and other reporting requirements must be followed.

The clinical trial process can take three to 10 years or more to complete, and there can be no assurance that the data collected will be in compliance with GCP regulations, will demonstrate that the product is safe or effective, or, in the case of a biologic product, pure and potent, or will provide sufficient data to support FDA approval of the product. The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labelling, are evaluated and, if determined appropriate, submitted to the FDA through a license application such as a New Drug Application (NDA) or a BLA. In certain cases an Abbreviated New Drug Application (ANDA) can be filed in lieu of filing an NDA. An ANDA relies on bioequivalency tests that compare the applicant's drug with an already approved reference drug rather than on clinical safety and efficacy studies. An ANDA might be available to us for a new formulation of a drug for which bioequivalent forms have already been approved by the FDA. In responding to applications for approval, the FDA could grant marketing approval, approve the product for a narrower indication, impose labelling or distribution restrictions, request additional information, require post-approval studies or deny the application. Applications are often referred to an outside FDA advisory committee of independent experts prior to the FDA acting on the application. Similar systems are in place for the testing and approval of biologics and medical devices.

There can be no marketing in the United States of any drug, biologic or device for which a marketing application is required until the application is approved by the FDA. Until an application is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA. Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval. The packaging and labelling of all products developed by us are also subject to FDA approval and ongoing regulation.

In the United States, under the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act, the FDA receives fees for reviewing product applications and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For example, the NDA or BLA review fee alone can exceed \$0.5 million, although certain deferrals, waivers and reductions may be available. Even when user fees are significant, they do not generally constitute a major expense relative to the overall cost associated with product development and regulatory approval.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable regulatory authorities in other countries outside the United States must be obtained prior to the marketing of the product in those countries. The approval procedure varies from country to country. It can involve additional testing and the time required can differ from that required for FDA approval. Although there are procedures for unified filings for EU countries, in general, most other countries have their own procedures and requirements.

Once a product has been approved, significant legal and regulatory requirements apply in order to market a product. In the United States these include, among other things, requirements related to adverse event and other reporting, product advertising and promotion, and ongoing adherence to cGMP requirements, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labelling or manufacturing process. Adverse events that are reported after marketing authorization can result in

additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing authorization, can result in product liability claims against us.

The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and

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Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

### ***Manufacturing***

Each manufacturing establishment, including any contract manufacturers, used to manufacture a product must be listed in the product application for such product. In the United States, this means that each manufacturing establishment must be listed in the drug, biologic, or device application, and must be registered with the FDA. The application will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the product, and determines that the facility is in compliance with cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, the FDA will not grant approval to market the product. All facilities are also subject to periodic regulatory inspections to ensure ongoing compliance with cGMP. At December 31, 2005, we had manufacturing facilities in Ireland and the United States.

At December 31, 2005, we employed 800 people in our manufacturing, supply and drug development activities, over half of these in Athlone, Ireland. This facility is the primary location for the manufacture of oral solid dosage products, including instant, controlled-release and oral micro particulate products. Additional dosage capabilities may be added as required to support future product introductions. Our facility in Gainesville, Georgia, United States, provides additional oral controlled-release dosage product manufacturing capability and is registered with the U.S. Drug Enforcement Administration for the manufacture, packaging and distribution of Schedule II controlled drugs. Capital expenditures at our manufacturing sites amounted to approximately \$38.0 million in 2005 mainly at the Athlone facility, where we have completed construction of a new 41,800 sq ft sterile fill and finish facility which cost approximately \$42.0 million to build. The sterile fill and finish facility is expected to be operational by the second quarter of 2006.

All facilities and manufacturing techniques used for the manufacture of products and devices for clinical use or for sale in the United States must be operated in conformity with cGMP regulations. There are FDA regulations governing the production of pharmaceutical products. Our facilities are also subject to periodic regulatory inspections to ensure ongoing compliance with cGMP regulations.

In May 2001, Elan Holdings, Inc. (Elan Holdings), a wholly owned subsidiary of Elan, the late Donal J. Geaney, then chairman and chief executive officer of Elan, William C. Clark, then president, operations, and two then employees of Elan Holdings, Hal Herring and Cheryl Schuster, entered into a consent decree of permanent injunction with the U.S. Attorney for the Northern District of Georgia, on behalf of the FDA, relating to alleged violations of cGMP at our Gainesville facility. The facility manufactured, and continues to manufacture, verapamil hydrochloride controlled-release capsules used in the treatment of high blood pressure, Avinza<sup>™</sup> once-daily, novel dual release morphine sulphate and RitalinLA<sup>™</sup> once-daily, pulsatile release of methylphenidate. In 2005, FDA approval was granted for the manufacture of Focalin XR<sup>®</sup> once daily dexmethylphenidate for treatment of Attention-Deficit Hyperactivity Disorder. The consent decree does not represent an admission by Elan Holdings of any of the allegations set forth in the decree. Under the terms of the consent decree, which will continue in effect until at least May 2006, Elan Holdings is permanently enjoined from violating cGMP regulations. In addition, Elan Holdings was required to engage an independent expert, subject to FDA approval, to conduct inspections of the facility at least annually through May 2004, in order to ensure the facility's compliance with cGMP.

The first of these inspections was completed and reported upon by the independent expert to the FDA on September 3, 2002. A corrective action plan was prepared and sent to the FDA in response to this inspection. A second independent consultant audit occurred in May 2003 and was reported upon by the independent expert to the FDA on August 14,

2003. In May 2004, the independent expert closed out its third and final audit. The audit report was forwarded to the FDA in August 2004 and this report expressed satisfaction with our corrective action plan and response to date. During the term of the consent decree, we expect that the facility will be subject to increased FDA inspections and, under the terms of the consent decree, we will be required to reimburse the FDA for its costs related to these inspections. We believe that, during the term of the consent decree, the FDA will continue to process approvals for products to be manufactured at the facility. For example, during 2002 the FDA approved Avinza and

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RitalinLA, and Focalin XR<sup>®</sup> was approved in 2005, which are being manufactured at the Gainesville facility. Elan may petition the courts to have the consent decree removed after May 2006.

### ***Patents and Intellectual Property Rights***

Our competitive position depends on our ability to obtain patents on our technologies and products, to defend our patents, to protect our trade secrets and to operate without infringing the valid patents or trade secrets of others. We own or license a number of U.S. and foreign patents.

These patents cover:

Pharmaceutical active ingredients, products containing them and their uses;

Pharmaceutical formulations; and

Product manufacturing processes.

Patents for products extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country.

*Tysabri* is covered by a number of pending patent applications and issued patents in the United States and many foreign countries. Elan has a basic U.S. patent for *Tysabri* covering the humanized antibody and its use to treat MS, which expires in 2014, subject to any available patent term extensions. Additional U.S. patents of Elan and/or its collaborator, Biogen Idec, which cover i) the use of *Tysabri* to treat irritable bowel disease and a variety of other indications and ii) methods of manufacturing *Tysabri* expire generally between 2012 and 2020. Outside the United States, patents on i) the product and methods of manufacturing the product, and ii) methods of treatment generally expire in the 2014-2016 and 2012-2020 timeframe, respectively. If *Tysabri* receives regulatory approval in those jurisdictions, those patents may be eligible for supplemental protection certificates.

In addition to our *Tysabri* collaboration with Biogen Idec, we have entered into licenses covering intellectual property related to *Tysabri*. We will pay royalties under these licenses based upon the level of *Tysabri* sales. We may be required to enter into additional licenses related to *Tysabri* intellectual property. If these licenses are not available, or are not available on reasonable terms, we may be materially and adversely affected.

The fundamental U.S. patent covering the use of *Prialt* to produce analgesia expires in 2011. Two further U.S. patents covering: (i) the commercial, stabilized formulation of *Prialt*, and (ii) a method for preventing progression of neuropathic pain expire in 2015. One of our patents covering *Prialt* may qualify for a U.S. patent term extension of up to five years.

The basic U.S. patent for *Maxipime* expires in March 2007. However, two U.S. patents covering *Maxipime* formulations may provide patent protection until February 2008.

The basic U.S. patent for *Azactam* expired in October 2005. *Azactam* is expected to face generic competition, which is expected to have a substantial adverse effect on our revenues from, and gross margin for, *Azactam*. However, to date, no generic *Azactam* product has been approved.

The primary patents covering Elan's *NanoCrystal* technology expire in the U.S. in 2011 and in countries outside the U.S. in 2012.

We also have more than 130 U.S. and international patents and patent applications that relate to our *NanoCrystal* drug optimization technology applicable to poorly water-soluble compounds.

Our products are sold around the world under brand name, logo and product design trademarks that we consider in the aggregate to be of material importance. Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms.

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### ***Competition***

The pharmaceutical industry is highly competitive. Our principal pharmaceutical competitors consist of major international companies, many of which are larger and have greater financial resources, technical staff, manufacturing, R&D and marketing capabilities than us. We also compete with smaller research companies and generic drug manufacturers.

When *Tysabri* is reintroduced in the United States as a treatment for relapsing forms of MS, it will compete primarily with Avonex marketed by our collaborator Biogen Idec; Betaseron<sup>®</sup> marketed by Berlex Laboratories; Rebif<sup>®</sup> marketed by Serono SA and Pfizer; and Copaxone<sup>®</sup> marketed by Teva Pharmaceuticals Ltd. Many companies are working to develop new therapies or alternative formulations of products for MS, which if successfully developed would compete with *Tysabri*. A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and, thereafter, it may be subject to further competition from generic products. Our product *Azactam* lost its basic U.S. patent protection in October 2005. We expect that generic competition to *Azactam* will emerge in 2006 and will have a material and adverse effect on sales of *Azactam*.

Generic competitors may also challenge existing patent protection or regulatory exclusivity. Governmental and other pressures toward the dispensing of generic products may rapidly and significantly reduce, slow, or reverse the growth in, sales and profitability of any of our products not protected by patents or regulatory exclusivity, and may adversely affect our future results and financial condition. The launch of competitor products, including generic versions of our products, may materially adversely affect our business, financial condition and results of operations.

Our competitive position depends, in part, upon our continuing ability to discover, acquire and develop innovative, cost-effective new products, as well as new indications and product improvements protected by patents and other intellectual property rights. We also compete on the basis of price and product differentiation and through our sales and marketing organization that provides information to medical professionals and launches new products. If we fail to maintain our competitive position, our business, financial condition and results of operations may be materially adversely affected.

### ***Distribution***

We sell our pharmaceutical products primarily to drug wholesalers. Our revenue reflects the demand from these wholesalers to meet the in-market consumption of our products and to reflect the level of inventory that wholesalers of our products carry. Changes in the level of inventory can directly impact our revenue and could result in our revenue not reflecting in-market consumption of our products.

We generally manufacture our drug delivery products for licensees and distributors but do not usually engage in any direct sales of drug delivery products.

### ***Raw Materials and Product Supply***

Raw materials and supplies are generally available in quantities adequate to meet the needs of our business. We have a policy of dual sourcing where practicable but do not have dual sourcing or manufacturing for a number of our raw materials or products. We are also dependent on third party manufacturers for most of the pharmaceutical products that we market. An inability to obtain raw materials or product supply could have a material adverse impact on our business, financial condition and results of operations.

### ***Employees***

On December 31, 2005, we had 1,729 employees worldwide, of whom 471 were engaged in R&D activities, 583 were engaged in manufacturing and supply activities, 310 were engaged in sales and marketing activities and the remainder worked in general and administrative areas.

**Table of Contents****C. Organizational Structure**

At December 31, 2005, we had the following principal subsidiary undertakings:

<b>Company</b>	<b>Nature of Business</b>	<b>Group Share %</b>	<b>Registered Office &amp; Country of Incorporation Operation</b>
Athena Neurosciences, Inc.	Holding company	100	800 Gateway Blvd South San Francisco, CA, United States
Elan Capital Corporation, Ltd.	Financial services company	100	Clarendon House, 2 Church St Hamilton, Bermuda
Elan Drug Delivery, Inc.	R&D	100	3000 Horizon Drive King of Prussia, PA, United States
Elan Finance, plc	Financial services company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Holdings, Inc.	Manufacture pharmaceutical and medical device products	100	1300 Gould Drive Gainesville, GA, United States
Elan Holdings, Ltd.	Holding company	100	Monksland, Athlone Co. Westmeath, Ireland
Elan International Services Ltd	Financial services company	100	Clarendon House, 2 Church St Hamilton, Bermuda
Elan Management, Ltd.	Provision of management services	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Pharma International, Ltd.	R&D, manufacture, sale and distribution of pharmaceutical products and financial services	100	Monksland, Athlone Co. Westmeath, Ireland
Elan Pharmaceuticals, Inc.	R&D and sale of pharmaceutical products	100	800 Gateway Blvd South San Francisco, CA, United States
Neuralab Ltd.	R&D	100	Clarendon House, 2 Church St Hamilton, Bermuda

**D. Property, Plant and Equipment**

We consider that our properties are in good operating condition and that our machinery and equipment has been well maintained. Facilities for the manufacture of products are suitable for their intended purposes and have capacities adequate for current and projected needs.

For additional information, please refer to Note 10 to the Consolidated Financial Statements, which discloses amounts invested in land and buildings and plant and equipment, Note 18 to the Consolidated Financial Statements, which discloses future minimum rental commitments, Note 24 to the Consolidated Financial Statements, which discloses capital commitments for the purchase of property, plant and equipment and dispositions of plant and equipment, and Item 5 B. Liquidity and Capital Resources, which discloses our capital expenditures.

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The following table lists the location, ownership interest, use and size of our principal properties:

<b>Location and Ownership Interest</b>	<b>Use</b>	<b>Size</b>
Owned: Athlone, Ireland	R&D, manufacturing and administration	463,000 Sq. Ft.
Owned: Gainesville, Georgia United States	R&D, manufacturing and administration	84,000 Sq. Ft.
Leased: San Diego, California, United States	Product development, sales and administration	217,700 Sq. Ft.
Leased: South San Francisco, California, United States	R&D and administration	199,250 Sq. Ft.
Leased: King of Prussia, Pennsylvania, United States	R&D, manufacturing, sales and administration	50,000 Sq. Ft.
Leased: Stevenage, United Kingdom	Product development and administration	8,043 Sq. Ft.
Leased: Dublin, Ireland	Corporate administration	19,700 Sq. Ft.
Leased: New York, New York, United States	Corporate administration	14,500 Sq. Ft.

**Item 4A. *Unresolved Staff Comments***

Not applicable.

**Item 5. *Operating and Financial Review and Prospects***

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements, the accompanying notes thereto and other financial information, appearing in Item 18. Consolidated Financial Statements. Prior to the 2004 fiscal year, we prepared our Consolidated Financial Statements, incorporated by reference in our historical Form 20-F, in conformity with Irish GAAP. Beginning with our 2004 fiscal year, we have adopted U.S. GAAP as the basis for the preparation of our Consolidated Financial Statements on this Form 20-F. Accordingly, our Consolidated Financial Statements on this Form 20-F are prepared on the basis of U.S. GAAP for all periods presented.

We also prepared separate Consolidated Financial Statements, included in our Annual Report, in accordance with IFRS, which differ in certain significant respects from U.S. GAAP. The Consolidated Financial Statements included in our Annual Report have been prepared for the first time for the year ended December 31, 2005 under IFRS. Comparative information which was previously presented under Irish GAAP for the year ended December 31, 2004 has been restated under IFRS. The Annual Report under IFRS, which includes a reconciliation of previously reported Irish GAAP financial information to IFRS, is a separate document from this Form 20-F.

This financial review primarily discusses:

Current operations;

Critical accounting policies;

Recently issued accounting pronouncements;

Post balance sheet events;

Results of operations for the year ended December 31, 2005 compared to 2004;

Results of operations for the year ended December 31, 2004 compared to 2003;

Segment analysis;

Risk sharing arrangements; and

Our financial position, including capitalization and liquidity.

Our operating results may be affected by a number of factors, including those described under Item 3. D Risk Factors .

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**CURRENT OPERATIONS**

Our business is organized into two business units: Biopharmaceuticals and EDT. Biopharmaceuticals engages in research, development and commercial activities and includes our activities in the areas of autoimmune diseases, neurodegenerative diseases and our specialty business group. EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry.

For additional information on our current operations, please refer to Item 4 on pages 15 to 35.

**CRITICAL ACCOUNTING POLICIES**

The Consolidated Financial Statements include certain estimates based on management's best judgments. Estimates are used in determining items such as the carrying values of intangible assets, the accounting for contingencies and estimating sales rebates and discounts, among other items. Because of the uncertainties inherent in such estimates, actual results may differ materially from these estimates.

***Goodwill, Other Intangible Assets and Impairment***

We account for goodwill and identifiable intangible assets in accordance with SFAS 142. Effective January 1, 2002, goodwill and identifiable intangible assets with indefinite useful lives are no longer amortized, but instead are tested for impairment at least annually. Intangible assets with estimable useful lives are amortized on a straight-line basis over their respective estimated useful lives to their estimated residual values and reviewed for impairment in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets.

We review our goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. At December 31, 2005, we had no other intangible assets with indefinite lives.

The goodwill impairment test is performed at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment as defined by SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information. We have two reporting units: Biopharmaceuticals and EDT. We compare the fair value of each reporting unit with its carrying value, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired. If the carrying amount of a reporting unit exceeds its fair value, the second step of the goodwill impairment test would be performed to measure the amount of impairment charge, if any. The second step compares the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill, and any excess of the carrying amount over the implied fair value is recognized as an impairment charge. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination is determined, by allocating the fair value of a reporting unit to individual assets and liabilities. The excess of the fair value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. The results of our goodwill impairment tests did not indicate any impairment in 2005.

There were no material impairment charges relating to intangible assets in either 2005 or 2004. In 2003, we recorded an impairment charge to intangible assets of \$32.6 million as a result of the recovery plan that we began in July 2002 and completed in early 2004. For additional information on this impairment charge, please refer to Note 19 to the Consolidated Financial Statements.

Total goodwill and other intangible assets amounted to \$665.5 million at December 31, 2005 (2004: \$753.7 million). If we were to use different estimates, particularly with respect to the likelihood of R&D success, the likelihood and

date of commencement of generic competition or the impact of any reorganization or change of business focus, then an additional material impairment charge could arise. We believe that we have used reasonable estimates in assessing the carrying values of our intangible assets.

***Contingencies Relating to Actual or Potential Administrative and Legal Proceedings***

We are currently involved in certain legal and administrative proceedings, relating to securities matters, patent matters, antitrust matters and other matters, as described in Note 25 to the Consolidated Financial Statements. In

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accordance with SFAS No. 5, Accounting for Contingencies, we assess the likelihood of any adverse outcomes to contingencies, including legal matters, as well as potential ranges of probable losses. We record accruals for such contingencies when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If an unfavorable outcome is probable, but the amount of the loss cannot be reasonably estimated, we estimate the range of probable loss and accrue the most probable loss within the range. If no amount within the range is deemed more probable, we accrue the minimum amount within the range. If neither a range of loss or a minimum amount of loss is estimable, then appropriate disclosure is provided, but no amounts are accrued. As of December 31, 2005, we had accrued \$2.1 million, representing our estimates of costs for the current resolution of these matters. We developed estimates in consultation with outside counsel handling our defense in these matters using the current facts and circumstances known to us. The factors that we consider in developing our legal contingency accrual include the merits and jurisdiction of the litigation, the nature and number of other similar current and past litigation cases, the nature of the product and current assessment of the science subject to the litigation, and the likelihood of settlement and current state of settlement discussions, if any. We believe that the legal contingency accrual that we have established is appropriate based on current factors and circumstances. However, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop a different liability amount. The nature of these matters is highly uncertain and subject to change. As a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the outcome of these matters.

***Revenue Recognition***

We recognize revenue from the sale of our products, royalties earned and contract arrangements in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition, (SAB 104), which requires the deferral and amortization of up-front fees when there is a significant continuing involvement (such as an ongoing product manufacturing contract) by the seller after an asset disposal. We implemented SAB 104 in the fourth quarter of 2000 and recorded a non-cash charge of \$344.0 million for the cumulative effect of this accounting change relating to revenue recognized in periods up to December 31, 1999. Included in contract revenue is \$5.7 million for both 2005 and 2004 and \$10.1 million for 2003 relating to the SAB 104 cumulative adjustment. We defer and amortize up-front license fees to the income statement over the performance period. The performance period is the period over which we expect to provide services to the licensee as determined by the contract provisions. Generally, milestone payments are recognized when earned and non-refundable, and when we have no future legal obligation pursuant to the payment. However, the actual accounting for milestones depends on the facts and circumstances of each contract. We apply the substantive milestone method in accounting for milestone payments. This method requires that substantive effort must have been applied to achieve the milestone prior to revenue recognition. If substantive effort has been applied, the milestone is recognized as revenue, subject to it being earned, non-refundable and not subject to future legal obligation. This requires an examination of the facts and circumstances of each contract. Substantive effort may be demonstrated by various factors, including the risks associated with achieving the milestone, the period of time over which effort was expended to achieve the milestone, the economic basis for the milestone payment and licensing arrangement and the costs and staffing to achieve the milestone. It is expected that the substantive milestone method will be appropriate for most contracts. If we determine the substantive milestone method is not appropriate, we will apply the percentage-of-completion method to the relevant contract. This method recognizes as revenue the percentage of cumulative non-refundable cash payments earned under the contract, based on the percentage of costs incurred to date compared to the total costs expected under the contract.

***Sales Discounts and Allowances***

We recognize revenue on a gross revenue basis and make various deductions to arrive at net revenue as reported in the Consolidated Statements of Operations. These adjustments are referred to as sales discounts and allowances and are described in detail below. Sales discounts and allowances include charge-backs, managed health care and Medicaid

rebates, cash discounts, sales returns and other adjustments. Estimating these sales discounts and allowances is complex and involves significant estimates and judgments, and we use information from both internal and external sources to generate reasonable and reliable estimates. We believe that we have used reasonable judgments in assessing our estimates, and this is borne out by our historical experience. At December 31, 2005, we had total provisions of \$17.2 million for sales discounts and allowances, of which approximately 58.8% and 28.3%

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related to *Maxipime* and *Azactam*, respectively. We have over seven years of experience in relation to these two products.

We do not conduct our sales using the consignment model. All of our product sales transactions are based on normal and customary terms whereby title to the product and substantially all of the risks and rewards transfer to the customer upon either shipment or delivery. Furthermore, we do not have an incentive program which would compensate a wholesaler for the costs of holding inventory above normal inventory levels thereby encouraging wholesalers to hold excess inventory.

We account for sales discounts and allowances in accordance with EITF Issue No. 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products), and SFAS No. 48, Revenue Recognition When Right of Return Exists, (SFAS 48) as applicable.

The table below summarizes our sales discounts and allowances to adjust gross revenue to net revenue for each significant category. An analysis of the separate components of our revenue is set out in Item 5A. Operating Results, and in Note 3 to the Consolidated Financial Statements.

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Gross revenue subject to discounts and allowances	\$ 273.2	\$ 291.7	\$ 530.1
Manufacturing revenue and royalties	207.1	130.9	120.0
Contract revenue	32.2	77.3	98.9
Amortized revenue - Adalat/Avinza	34.0	34.0	34.0
<b>Gross revenue</b>	<b>\$ 546.5</b>	<b>\$ 533.9</b>	<b>\$ 783.0</b>
Sales discounts and allowances:			
Charge-backs	\$ (22.8)	\$ (24.6)	\$ (27.1)
Managed health care rebates and other contract discounts	(2.9)	(5.1)	(11.0)
Medicaid rebates	(1.6)	(8.2)	(25.7)
Cash discounts	(5.5)	(5.6)	(8.9)
Sales returns	(20.9)	(7.1)	(24.6)
Other adjustments	(2.5)	(1.6)	(0.1)
<b>Total sales discounts and allowances</b>	<b>\$ (56.2)</b>	<b>\$ (52.2)</b>	<b>\$ (97.4)</b>
Net revenue subject to discounts and allowances	217.0	239.5	432.7
Manufacturing revenue and royalties	207.1	130.9	120.0
Contract revenue	32.2	77.3	98.9
Amortized revenue - Adalat/Avinza	34.0	34.0	34.0
<b>Net revenue</b>	<b>\$ 490.3</b>	<b>\$ 481.7</b>	<b>\$ 685.6</b>

Total sales discounts and allowances decreased from 18.4% of gross revenue subject to discounts and allowances in 2003 to 17.9% in 2004, and increased to 20.6% in 2005, as detailed in the rollforward below and as further explained in the following paragraphs.

Charge-backs increased as a percentage of gross revenue subject to discounts and allowances from 5.1% in 2003 to 8.4% in 2004, and decreased slightly to 8.3% in 2005. The increase in 2004 is due primarily to changes in the product mix. Several of our divested products were sold through retail pharmacies (principally Skelaxin, Zonegran and Sonata<sup>™</sup> (zaleplon)) and therefore had lower levels of charge-backs in comparison to our retained products.

The reductions in managed health care and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances from year to year are due principally to changes in the product mix. Several of our divested products (principally Skelaxin and Zonegran) were sold through retail pharmacies and therefore had larger components subject to managed health care and Medicaid rebates. Consequently, due primarily to the divestment of

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these products, the managed health care and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances have declined from 2.1% and 4.8%, respectively, in 2003, to 1.7% and 2.8% in 2004, and to 1.1% and 0.6% in 2005.

Cash discounts as a percentage of gross revenue subject to discounts and allowances remained fairly consistent at 1.7% in 2003 compared to 1.9% in 2004, and to 2.0% in 2005. In the United States, we offer cash discounts, generally at 2% of the sales price, as an incentive for prompt payment by our customers.

Sales returns as a percentage of gross revenue subject to discounts and allowances decreased from 4.6% in 2003 to 2.4% in 2004, and increased to 7.6% in 2005. The decrease in 2004, compared to 2003, is due to changes in the product mix as a result of product divestments. The increase in 2005, compared to 2004, is due to the voluntary suspension of *Tysabri* in February 2005, which increased the provision for returns in 2005, and changes in the product mix as a result of product divestments.

The following table sets forth the activities and ending balances of each significant category of adjustments for the sales discounts and allowances (in millions):

	Charge- Backs	Managed Health Care Rebates and Other Contract Discounts	Medicaid Rebates	Cash Discounts	Sales Returns	Other Adjustments	Total
Balance at December 31, 2003	\$ 8.7	\$ 4.9	\$ 21.8	\$ 1.3	\$ 28.5	\$	\$ 65.2
Provision related to sales made in current period	24.4	5.1	8.6	5.6	6.8	1.6	52.1
Provision related to sales made in prior periods	0.2		(0.4)		0.3		0.1
Returns and payments	(24.2)	(6.8)	(23.9)	(6.5)	(19.8)	(0.7)	(81.9)
Divestments	(0.2)	(1.1)	(4.4)		(7.2)	(0.5)	(13.4)
Balance at December 31, 2004	8.9	2.1	1.7	0.4	8.6	0.4	22.1
Provision related to sales made in current period	22.8	2.9	1.6	5.5	22.4	2.5	57.7
Provision related to sales made in prior periods					(1.5)		(1.5)
Returns and payments	(24.9)	(3.3)	(1.9)	(5.0)	(22.8)	(2.4)	(60.3)
Divestments	(0.1)	(0.3)	(0.3)		(0.1)		(0.8)

Balance at														
December 31, 2005	\$	6.7	\$	1.4	\$	1.1	\$	0.9	\$	6.6	\$	0.5	\$	17.2

*(a) Charge-backs*

In the United States, we participate in charge-back programs with a number of entities, principally the U.S. Department of Defense, the U.S. Department of Veterans Affairs, Group Purchasing Organizations and other parties whereby pricing on products is extended below wholesalers' list prices to participating entities. These entities purchase products through wholesalers at the lower negotiated price, and the wholesalers charge the difference between these entities' acquisition cost and the lower negotiated price back to us. We account for charge-backs by reducing accounts receivable in an amount equal to our estimate of charge-back claims attributable to a sale. We determine our estimate of the charge-backs primarily based on historical experience on a product-by-product and program basis, and current contract prices under the charge-back programs. We consider vendor payments, estimated levels of inventory in the distribution channel, and our claim processing time lag and adjust accounts receivable and revenue periodically throughout each year to reflect actual and future estimated experience.

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As described above, there are a number of factors involved in estimating the accrual for charge-backs, but the principal factor relates to our estimate of the levels of inventory in the distribution channel. At December 31, 2005, *Maxipime* and *Azactam* represented approximately 92.2% and 6.9%, respectively, of the total charge-backs accrual balance of \$6.7 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for these products, the accrual for charge-backs would increase/(decrease) by approximately \$2.1 million. We believe that our estimate of the levels of inventory for *Maxipime* and *Azactam* in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

*(b) Managed health care rebates and other contract discounts*

We offer rebates and discounts to managed health care organizations in the United States. We account for managed health care rebates and other contract discounts by establishing an accrual equal to our estimate of the amount attributable to a sale. We determine our estimate of this accrual primarily based on historical experience on a product-by-product and program basis and current contract prices. We consider the sales performance of products subject to managed health care rebates and other contract discounts, processing claim lag time and estimated levels of inventory in the distribution channel, and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the levels of inventory in the distribution channel. At December 31, 2005, *Maxipime* and *Azactam* represented approximately 72.3% and 26.3%, respectively, of the total managed health care rebates and other contract discounts accrual balance of \$1.4 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for these products, the accrual would increase/(decrease) by approximately \$0.3 million. We believe that our estimate of the levels of inventory for *Maxipime* and *Azactam* in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

*(c) Medicaid rebates*

In the United States, we are required by law to participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating state and local government entities. Discounts and rebates provided through these other qualifying federal and state government programs are included in our Medicaid rebate accrual and are considered Medicaid rebates for the purposes of this discussion. We account for Medicaid rebates by establishing an accrual in an amount equal to our estimate of Medicaid rebate claims attributable to a sale. We determine our estimate of the Medicaid rebates accrual primarily based on historical experience regarding Medicaid rebates, legal interpretations of the applicable laws related to the Medicaid and qualifying federal and state government programs, and any new information regarding changes in the Medicaid programs' regulations and guidelines that would impact the amount of the rebates on a product-by-product basis. We consider outstanding Medicaid claims, Medicaid payments, claims processing lag time and estimated levels of inventory in the distribution channel and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

*(d) Cash discounts*

In the United States, we offer cash discounts, generally at 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount of the discounts. We consider

payment performance of each customer and adjust the accrual and revenue periodically throughout each year to reflect actual experience and future estimates.

**Table of Contents***(e) Sales returns*

We account for sales returns in accordance with SFAS 48 by establishing an accrual in an amount equal to our estimate of revenue recorded for which the related products are expected to be returned.

For returns of established products, our sales return accrual is estimated principally based on historical experience, the estimated shelf life of inventory in the distribution channel, price increases, and our return goods policy (goods may only be returned six months prior to expiration date and for up to twelve months after expiration date). We also take into account product recalls and introductions of generic products. All of these factors are used to adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

In the event of a product recall, product discontinuance or introduction of a generic product, we consider a number of factors, including the estimated level of inventory in the distribution channel that could potentially be returned, historical experience, estimates of the severity of generic product impact, estimates of continuing demand and our return goods policy. We consider the reasons for and impact of such actions and adjust the sales returns accrual and revenue as appropriate.

Returns from newly introduced products are significantly more difficult for us to assess. We determine our estimate of the sales return accrual primarily based on the historical sales returns experience of similar products, such as those within the same or similar therapeutic category. We also consider the shelf life of new products and determine whether we believe an adjustment to the sales return accrual is appropriate. The shelf life in connection with new products tends to be shorter than the shelf life for more established products because we may still be developing the optimal stability duration for the new product that would lengthen its shelf life, or an amount of launch quantities may have been manufactured in advance of the launch date to ensure sufficient supply exists to satisfy market demand. In those cases, we assess the reduced shelf life, together with estimated levels of inventory in the distribution channel and projected demand, and determine whether we believe an adjustment to the sales return accrual is appropriate. While it is inherently more difficult to assess returns from newly introduced products than from established products, nevertheless in all instances we believe we have been able to gather sufficient information in order to establish reasonable estimates.

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the shelf life of inventory in the distribution channel. At December 31, 2005, *Maxipime* and *Azactam* represented approximately 35.6% and 57.7%, respectively, of the total sales returns accrual balance of \$6.6 million. At December 31, 2005, we have estimated the gross revenue value of *Maxipime* and *Azactam* inventory in the distribution channel to be approximately \$32.1 million (2004: \$40.0 million) and \$5.5 million (2004: \$17.0 million), respectively. Assuming inventory leaves the distribution channel on a first-in first-out basis, we have estimated that this distribution channel inventory has a shelf life running to various dates during 2006 (gross revenue value approximately \$0.2 million), 2007 (gross revenue value approximately \$1.8 million), and 2008 (gross revenue value approximately \$35.6 million). *Azactam* lost its patent exclusivity in October 2005; however, to date no generic *Azactam* product has been approved. We believe, based upon both the estimated shelf life and also our historical sales returns experience, that the vast majority of this inventory will be sold prior to its expiration date, and accordingly believe that our sales returns accrual is appropriate.

*(f) Other adjustments*

In addition to the significant sales discounts and allowances described above, we make other individually insignificant sales adjustments. We generally account for these other sales discounts and allowances by establishing an accrual in an amount equal to our estimate of the adjustments attributable to the sale. We generally determine our estimates of the accruals for these other adjustments primarily based on historical experience, performance on commitments to

government entities and other relevant factors, including estimated levels of inventory in the distribution channel in some cases, and adjust the accruals and revenue periodically throughout each year to reflect actual experience.

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*(g) Provisions related to sales made in prior periods*

During 2005, we recorded \$1.5 million of adjustments to reduce the discounts and allowances related to sales made in prior periods, primarily due to the availability of additional information relating to the impact of genericization of Zanaflex™ (tizanidine hydrochloride).

*(h) Divestments*

Since the beginning of 2003 we have divested a number of businesses, including principally our primary care franchise, Frova™ (frovatriptan succinate), Zonegran and our European sales and marketing business. The divestment adjustments arise primarily as a result of the negotiated terms of these divestments. For example, we have entered into terms that would either extend or limit our liability for discounts and allowances related to the divested businesses. We have accordingly adjusted our discounts and allowances accruals to reflect the terms of the agreements. Divestment adjustments also include post-divestment revisions resulting from the availability of additional information. Divestment adjustments are recorded as part of the gain/(loss) on sale of businesses, and not as an increase or decrease from gross revenue.

*(i) Use of information from external sources*

We use information from external sources to estimate our significant sales discounts and allowances. Our estimates of inventory at the wholesalers are based on:

The actual and projected prescription demand-based sales for our products and historical inventory experience;

Our analysis of third-party information, including written and oral information obtained from all of the major wholesalers with respect to their inventory levels and sell-through to customers, and third-party market research data; and

Our internal information.

The inventory information received from wholesalers is a product of their record-keeping process and excludes inventory held by intermediaries to whom they sell, such as retailers and hospitals. We receive information from IMS Health, a supplier of market research to the pharmaceutical industry, which we use to project the prescription demand-based sales for our pharmaceutical products. We also use information from external sources to identify prescription trends and patient demand. Up to 2004, we received inventory pipeline data from IMS Health. Since 2004, IMS Health no longer provides this service and we have been receiving such pipeline data directly from the three major wholesalers (McKesson Corp., Cardinal Health, Inc. and AmerisourceBergen Corp.). Our estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information is itself in the form of estimates, and reflect other limitations including lags between the date as of which third-party information is generated and the date on which we receive such information.

**RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS**

In December 2004, the FASB issued Statement No. 123R, *Share-Based Payment* An Amendment of FASB Statements No. 123 and 95, (SFAS 123R), effective for public companies in periods beginning after June 15, 2005. In April 2005, the SEC adopted a rule amendment that delayed the compliance dates for SFAS 123R to the first annual period beginning after June 15, 2005. We will adopt SFAS 123R effective January 1, 2006 and will elect to use the modified prospective transition method. Under the modified prospective transition method, awards that are granted, modified, repurchased or canceled after the date of adoption will be measured and accounted for in accordance with

SFAS 123R. Share-based awards that were granted prior to the effective date will continue to be accounted for in accordance with SFAS 123, except that the expense, based on the fair value of unvested awards, must be recognized in the Consolidated Statement of Operations.

SFAS 123R requires companies to measure all share-based awards to employees using a fair value method and to recognize the expense over the requisite service period. We will elect to recognize compensation cost for an award using a graded-vesting method over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards.

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In March 2005, the SEC issued Staff Accounting Bulletin No. 107 (SAB 107), which provides supplemental implementation guidance for SFAS 123R in a number of areas, including the valuation of share-based payment arrangements.

We expect the adoption of SFAS 123R will have a material adverse impact on our consolidated results of operations. The impact of adoption of SFAS 123R is an estimated increase in expense by between \$40.0 million and \$50.0 million for 2006. This estimate may change materially because it will depend on, among other things, levels of share-based payments granted, the market value of our common stock, and assumptions regarding a number of complex variables. These variables include, but are not limited to, our stock price, volatility and employee stock option exercise behaviors and the related tax impact.

As a result of the anticipated adoption of SFAS 123R and in conjunction with our annual total compensation review in 2005, we adjusted the equity component of our total compensation and, in the beginning of 2006, we began to issue restricted stock units in addition to stock option awards. In addition, for certain employees, we have eliminated the issuance of stock options and replaced such form of compensation with a cash bonus. We also implemented employee equity purchase plans in 2005 for employees in the United States, Ireland and the United Kingdom, which provide eligible employees the opportunity to share in the ownership of the Company by purchasing stock at a discount. See Note 23 to the Consolidated Financial Statements for more information on the employee equity purchase plans.

In November 2004, the FASB issued Statement No. 151, *Inventory Costs: an amendment of ARB No. 43, Chapter 4 (SFAS 151)*, which is effective for public companies prospectively for inventory costs incurred in periods beginning after June 15, 2005. This Statement amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify that accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage) should be recognized as a current period charge and to require the allocation of fixed production overhead to the costs of conversion based on normal capacity of the production facilities. We do not expect that the adoption of SFAS 151 will have a material impact on our financial position or results of operations.

In February 2006, the FASB issued Statement No. 155, *Accounting for Certain Hybrid Financial Instruments*, (SFAS 155), which is effective for public companies for fiscal years beginning after September 15, 2006, with early adoption permitted. SFAS 155 permits fair value measurement for any hybrid financial instrument that contains an embedded derivative that would otherwise require bifurcation and separate accounting. An irrevocable election may be made at inception to measure such a hybrid financial instrument at fair value, with changes in fair value recognized through income. Such an election needs to be supported by concurrent documentation. We do not expect that the adoption of SFAS 155 will have a material impact on our financial position or results of operations.

## **POST BALANCE SHEET EVENTS**

On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

On March 20, 2006, we completed the sale of the European rights to *Prialt* to Eisai, while retaining the product rights in the United States. Under the terms of the agreement, we received \$50.0 million on the closing of the transaction, we will receive a further \$10.0 million on the earlier of two years from closing or launches of *Prialt* in key European markets, and we may receive an additional \$40.0 million contingent on *Prialt* achieving revenue related milestones in Europe.



**Table of Contents****A. OPERATING RESULTS***2005 Compared to 2004 (in millions, except share and per share amounts)*

	2005	2004	% Increase/ (Decrease)
Product revenue	\$ 458.1	\$ 404.4	13%
Contract revenue	32.2	77.3	(58)%
Total revenue	490.3	481.7	2%
Operating expenses:			
Cost of sales	196.1	173.6	13%
Selling, general and administrative expenses	358.4	337.3	6%
Research and development expenses	233.3	257.3	(9)%
Net gain on sale of businesses	(103.4)	(44.2)	134%
Other significant net charges	4.4	59.8	(93)%
Total operating expenses	688.8	783.8	(12)%
Operating loss	(198.5)	(302.1)	(34)%
Net interest and investment (gains) and losses:			
Net interest expense	125.7	109.0	15%
Net investment gains	(16.3)	(114.6)	(86)%
Impairment of investments	23.5	71.8	(67)%
Net charge on debt retirement	51.8		N/A
Charge arising from guarantee to EPIL II noteholders		47.1	(100)%
Net interest and investment losses	184.7	113.3	63%
Loss from continuing operations before provision for/(benefit from) income taxes	(383.2)	(415.4)	(8)%
Provision for/(benefit from) income taxes	1.0	(1.7)	159%
Net loss from continuing operations	(384.2)	(413.7)	(7)%
Net income from discontinued operations (net of tax)	0.6	19.0	(97)%
Net loss	\$ (383.6)	\$ (394.7)	(3)%
Basic and diluted net loss per ordinary share:			
Net loss from continuing operations	\$ (0.93)	\$ (1.06)	(12)%
Net income from discontinued operations (net of tax)		0.05	(100)%
Net loss	\$ (0.93)	\$ (1.01)	(8)%
Weighted average number of Ordinary Shares outstanding	413.5	390.1	



**Table of Contents****Product Revenue**

The increase of 13% in total product revenue in 2005 was primarily due to the growth of product revenue from the core business. Product revenue from our core business increased 34% from 2004 and more than compensated for the loss of revenue from products divested during 2004. The components of product revenue are set out below (in millions):

	2005	2004	% Increase/ (Decrease)
(A) Marketed products			
Maxipime	\$ 140.3	\$ 117.5	19%
Azactam	57.7	50.6	14%
Tysabri	11.0	6.4	72%
Prialt	6.3		N/A
Total revenue from marketed products	215.3	174.5	23%
(B) Manufacturing revenue and royalties	207.1	130.9	58%
(C) Amortized revenue Adalat/Avinza	34.0	34.0	0%
Total product revenue from core business	456.4	339.4	34%
(D) Divested products <sup>(1)</sup>			
European business <sup>(2)</sup>		10.5	(100)%
Zonegran <sup>(3)</sup>		41.2	(100)%
Other	1.7	13.3	(87)%
Total revenue from divested products	1.7	65.0	(97)%
Total product revenue	\$ 458.1	\$ 404.4	13%

<sup>(1)</sup> Products described as *Divested Products* include products or businesses divested since the beginning of 2003.

<sup>(2)</sup> Sold to Zeneus Pharma Ltd. (Zeneus) in February 2004.

<sup>(3)</sup> Sold to Eisai in April 2004.

**(A) Revenue from marketed products**

Total revenue from marketed products increased to \$215.3 million in 2005 from \$174.5 million in 2004. The increase of 23% primarily reflects higher sales of *Maxipime* and *Azactam*, and initial sales of *Tysabri* and *Prialt*. *Azactam* lost its patent exclusivity in October 2005, and the basic patent on *Maxipime* expires in March 2007. Two U.S. patents covering *Maxipime* formulations may provide patent protection until 2008. The expiration of these patents is expected to result in generic competition for these products, which is expected to adversely impact future revenues. However, to date, no generic *Azactam* product has been approved.

*Maxipime* revenue increased from \$117.5 million to \$140.3 million. The 19% increase reflects growth in demand, a price increase of 8% taken at the end of 2004, and improved supply conditions. We experienced third party supply shortages and disruptions with *Maxipime* during 2005. This led to a significant decline in inventories held by our wholesale customers and hospitals and, consequently, affected our ability to meet demand. The supply situation improved beginning in the third quarter of 2005.

As reported by IMS Health Inc., *Azactam* prescription demand for 2005 increased by 6% over 2004, while the corresponding revenues increased from \$50.6 million to \$57.7 million, or 14%. The difference between prescription and revenue growth rates is due to changing wholesaler inventory levels and price increases taken during the period.

The FDA granted accelerated approval of *Tysabri* in late November 2004 for the treatment of patients in the United States with all forms of relapsing remitting MS. Revenue from *Tysabri* amounted to \$11.0 million in 2005 and \$6.4 million in 2004. The marketing and clinical dosing of *Tysabri* was voluntarily suspended in February 2005. On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri*

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be reintroduced as a treatment for relapsing forms of MS. On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

*Prialt*, a new treatment for severe chronic pain, was approved by the FDA in the United States in December 2004 and approved in Europe in February 2005. We began selling *Prialt* in the U.S. market in early 2005 and revenue from sales of *Prialt* was \$6.3 million in 2005 (2004: \$Nil). On March 20, 2006, we completed the sale of the European rights to *Prialt* to Eisai, while retaining the product rights in the United States.

*(B) Manufacturing revenue and royalties*

Manufacturing revenue and royalties are as follows (in millions):

	2005	2004	% Increase/ (Decrease)
Tricor	\$ 45.4	\$ 4.5	909%
Verelan	34.7	27.8	25%
Diltiazem	18.6	19.3	(4)%
Skelaxin	17.9	12.2	47%
Ritalin	13.8	11.8	17%
Avinza	13.4	15.8	(15)%
Zanaflex	11.1		N/A
Other	52.2	39.5	32%
Total	\$ 207.1	\$ 130.9	58%

Manufacturing revenue and royalties from our EDT business comprises revenue earned from products we manufacture for third parties and royalties we earn principally on sales by third parties of products that incorporate our technologies. The increase of 58% was primarily due to increased sales by third parties of products that incorporate Elan's technologies, predominantly Tricor, and increased manufacturing activity for third parties. Except as noted above, no other single product accounted for more than 10% of our manufacturing revenue and royalties in either 2005 or 2004. In 2005, 34% of these revenues consisted of royalties received on products that we do not manufacture, compared to 19% in 2004.

*(C) Amortized revenue Adalat/Avinza*

Amortized revenue of \$34.0 million in both 2005 and 2004 related to the licensing to Watson Pharmaceuticals, Inc. (Watson) of rights to our generic form of Adalat CC (\$9.0 million) and the restructuring of our Avinza license agreement with Ligand Pharmaceuticals, Inc (Ligand) (\$25.0 million). Both of these transactions occurred in 2002. The remaining unamortized revenue on these products of \$35.2 million is included in deferred revenue, due to our ongoing involvement in the manufacturing of these products. Of the remaining \$35.2 million, \$13.5 million of the deferred revenue relates to generic Adalat CC and will be recognized as revenue through June 2007. The remaining deferred revenue of \$21.7 million relates to Avinza and will be recognized as revenue through November 2006.

*(D) Divested products*

During 2004, we sold a number of products and businesses as part of the recovery plan, which commenced in July 2002 and was completed in early 2004, and our subsequent strategic repositioning as a biotechnology company focused on a number of key therapeutic markets. The decrease in revenue from divested products in 2005 was primarily due to the divestment of a number of products and businesses during 2004, principally the European business and Zonegran, which are described below. No divestments occurred in 2005.

In February 2004, we completed the sale of our European sales and marketing business to Zeneus. Revenue for the divested European business was \$Nil for 2005 (2004: \$10.5 million).

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In April 2004, we sold our interests in Zonegran for North America and Europe to Eisai. Zonegran generated revenue of \$Nil for 2005 (2004: \$41.2 million).

**Contract Revenue**

	<b>2005</b>	<b>2004</b>	<b>% Increase/ (Decrease)</b>
	<b>(In millions)</b>		
Amortized fees	\$ 16.4	\$ 17.6	(7)%
Research revenues/milestones	15.8	59.7	(74)%
Total contract revenue	\$ 32.2	\$ 77.3	(58)%

The decrease in contract revenue of 58% in 2005 is principally due to a reduction in research revenue and milestones arising from research and development activities we perform on behalf of third parties. The reduction resulted from, among other things, the timing of milestone receipts, the completion of transitional research and development activities related to certain divested products, and the suspension of activity related to Sonata.

**Cost of Sales**

Cost of sales was \$196.1 million in 2005, compared to \$173.6 million in 2004. The cost of sales as percentage of product revenue was 43% for both 2005 and 2004. The gross margin remained consistent with 2004 because of compensating changes in the mix of product revenues, the impact of the *Tysabri* voluntary suspension and the divestment of products in 2004.

**Selling, General and Administrative Expenses (SG&A)**

SG&A expenses were \$358.4 million in 2005, compared to \$337.3 million in 2004, and included \$84.7 million (2004: \$52.3 million) in relation to *Tysabri*. The increase of 6% reflects the costs of maintaining the *Tysabri* commercial infrastructure in place for the full year 2005 in anticipation of its potential return to market and the marketing cost of launching *Prialit* during 2005, offset by reduced costs in the rest of the business.

**Research and Development Expenses**

R&D expenses were \$233.3 million in 2005, compared to \$257.3 million in 2004, and included \$66.9 million (2004: \$84.2 million) in relation to *Tysabri*. The decrease of 9% reflects cost containment initiatives, the refocusing of research and development efforts on key Alzheimer's disease programs, and reduced spending on *Tysabri* as a result of the completion of clinical trials, offset by the cost of the extensive *Tysabri* safety evaluation.

**Net Gain on Sale of Businesses**

	<b>2005</b>	<b>2004</b>
	<b>(In millions)</b>	
Zonegran	\$ 85.6	\$ 42.9

European business	17.1	(2.9)
Other	0.7	4.2
Total	\$ 103.4	\$ 44.2

In April 2004, we sold our interests in Zonegran in North America and Europe to Eisai for initial net consideration of \$113.5 million at closing. We were also entitled to receive additional consideration of up to \$110.0 million from Eisai through January 1, 2006, primarily contingent on the date of generic Zonegran approval. We received \$85.0 million of this contingent consideration prior to the approval of generic Zonegran in December 2005. Consequently, the total net proceeds received from the sale of Zonegran amounted to \$198.5 million and resulted in a cumulative net gain of \$128.5 million, of which \$85.6 million was recognized in 2005 and \$42.9 million in 2004.

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In February 2004, we sold our European sales and marketing business to Zeneus for initial net cash proceeds of \$93.2 million, resulting in a loss of \$2.9 million in 2004. We received an additional \$6.0 million in February 2005, which was accrued at December 31, 2004, and \$15.0 million of contingent consideration in December 2005, which resulted in a net gain of \$17.1 million in 2005 after the release of contingent liabilities of \$2.1 million, which were not required ultimately. We will not receive any further consideration in respect of this disposal.

***Other Significant Net Charges***

The principal items classified as other significant charges/(gains) include severance, relocation and exit costs, litigation settlement receipts, and losses incurred from litigation or regulatory actions, including shareholder class action litigation and the SEC investigation. These items have been treated consistently from period to period. Our management believes that disclosure of other significant charges/(gains) is meaningful because it provides additional information in relation to these material items.

	2005	2004
	(In millions)	
(A) Pfizer litigation settlement, shareholder litigation, and SEC investigation	\$ (7.4)	\$ 56.0
(B) Severance, relocation and exit costs	14.4	3.0
Other	(2.6)	0.8
Total other significant net charges	4.4	\$ 59.8

***(A) Pfizer litigation settlement, shareholder litigation, and SEC investigation***

During 2005, we recorded a net gain of \$7.4 million related primarily to the Pfizer litigation settlement in which we received a payment of \$7.0 million. The nature of this action and its settlement is described in Note 25 to the Consolidated Financial Statements.

The \$56.0 million charge recorded in 2004 arose primarily as a result of a \$55.0 million provision made in relation to settlements of the SEC investigation and the related shareholder class action lawsuit. We and certain of our former and current officers and directors were named as defendants in a class action filed in early 2002 alleging that our financial statements were not prepared in accordance with GAAP, and that the defendants disseminated materially false and misleading information concerning our business and financial results. We agreed to settle the action in October 2004 and the settlement was formally approved by the U.S. District Court for the Southern District of New York in February 2005. The terms of the class action settlement received final court approval in April 2005. Under the class action settlement, all claims against us and the other named defendants were dismissed with no admission or finding of wrongdoing on the part of any defendant. The principal terms of the settlement provide for an aggregate cash payment to class members of \$75.0 million, out of which the court awarded attorneys' fees to plaintiffs' counsel, and \$35.0 million was paid by our insurance carrier.

We were also the subject of an investigation by the SEC's Division of Enforcement regarding matters similar to those alleged in the class action. We provisionally settled the investigation in October 2004 and the SEC formally approved the settlement in February 2005. Under the settlement agreement reached with the SEC, we neither admitted nor denied the allegations contained in the SEC's civil complaint, which included allegations of violations of certain provisions of the federal securities laws. The settlement contains a final judgment restraining and enjoining us from future violations of these provisions. In addition, under the final judgment, we paid a civil penalty of \$15.0 million. In

connection with the settlement, we were not required to restate or adjust any of our historical financial results or information.

For additional information on litigation which we are involved in, please refer to Note 25 to the Consolidated Financial Statements.

*(B) Severance, relocation and exit costs*

During 2005, we incurred severance, relocation and exit costs of \$14.4 million arising from the realignment of our resources to meet our current business structure. These expenses arose from termination of certain operating leases and a reduction in employee headcount.

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During 2004, we incurred severance, relocation and exit costs arising from the implementation of our recovery plan of \$3.0 million. The recovery plan, which commenced in July 2002 and was completed in February 2004, involved the restructuring of our businesses, assets and balance sheet. These expenses arose from a reduction in the scope of our activities and a reduction in employee headcount.

***Net Interest Expense***

Net interest expense was \$125.7 million in 2005, compared to \$109.0 million in 2004. The increase of 15% primarily reflects the interest costs associated with the issuance of \$850.0 million of 7.75% senior fixed rate notes (7.75% Notes) and \$300.0 million of senior floating rate notes (Floating Rate Notes) in November 2004, partially offset by the impact of the repayment of the Elan Pharmaceutical Investments III Ltd. (EPIL III) Series B and C guaranteed notes (collectively, EPIL III Notes) in November 2004, the early retirement of \$36.8 million of the 7.25% senior notes (Athena Notes) due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of 6.5% Convertible Notes due in 2008 in the second quarter of 2005, and increased interest income associated with higher cash balances and interest rates.

***Net Investment Gains***

Net investment gains were \$16.3 million in 2005, compared to \$114.6 million in 2004, a decrease of 86%. In 2005, we raised \$62.7 million (2004: \$255.5 million) in net cash proceeds from the disposal of investments and marketable investment securities. The net investment gains of \$16.3 million in 2005 includes gains on the sale of securities of Allergy Therapeutics plc of \$10.0 million, Iomai Corporation of \$3.2 million and Emisphere Technologies, Inc. of \$1.8 million. The net investment gains in 2004 of \$114.6 million included a gain on the sale of securities of Warner Chilcott plc of \$43.6 million, DOV Pharmaceutical, Inc. of \$22.6 million, Curis, Inc. of \$15.3 million and Atrix Laboratories of \$13.1 million.

***Impairment of Investments***

During 2005, investment impairment charges of \$23.5 million (2004: \$71.8 million) reflect other-than-temporary impairments to the value of a number of investments, primarily in privately-held biotech companies.

***Net Charge on Debt Retirement***

In June 2005, we incurred a net charge of \$51.8 million (2004: \$Nil) associated with the early retirement of \$36.8 million of the Athena Notes due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of the 6.5% Convertible Notes due in 2008. This reduced our debt by \$242.8 million and our annualized interest expenses by approximately \$16.0 million.

***Charge Arising from Guarantee to EPIL II Noteholders***

We had guaranteed EPIL II loan notes (EPIL II Notes) to the extent that the investments held by EPIL II were insufficient to repay the EPIL II Notes and accrued interest. EPIL II was a qualifying special purpose entity and was not consolidated under U.S. GAAP. On June 28, 2004, the EPIL II Notes of \$450.0 million, together with accrued interest for the period from December 31, 2003 to June 28, 2004 of \$21.5 million, were repaid. Of the aggregate payment of \$471.5 million, \$79.7 million was funded from the cash resources in EPIL II and through the sale of EPIL II's entire investment portfolio. We funded the balance of \$391.8 million under our guarantee. This resulted in a charge of \$47.1 million in 2004, arising from interest of \$21.5 million and investment losses of \$25.6 million incurred by EPIL II during the first half of 2004.

***Provision for/(Benefit from) Income Taxes***

We had a net tax provision of \$1.0 million for 2005, compared to a net tax benefit of \$1.7 million for 2004. The overall tax provision for 2005 was \$0.4 million. Of this amount, \$0.6 million has been credited to shareholders' equity to reflect utilization of stock option deductions. The remaining \$1.0 million provision is allocated to ordinary activities. The tax provision reflected tax at standard rates in the jurisdictions in which we operate, income derived from Irish patents, foreign withholding tax and the availability of tax losses. Our Irish patent derived income was

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exempt from taxation pursuant to Irish legislation, which exempts from Irish taxation income derived from qualifying patents. Currently, there is no termination date in effect for such exemption. For additional information regarding taxation, please refer to Note 17 to the Consolidated Financial Statements.

***Net Income/(Loss) from Discontinued Operations***

Net income from discontinued operations was \$0.6 million in 2005, compared to a net income from discontinued operations of \$19.0 million in 2004. The net income from discontinued operations includes a net gain on sale of businesses of \$0.5 million (2004: \$11.5 million). During the course of the completed recovery plan, we sold a number of products and businesses, including Athena Diagnostics, Elan Diagnostics, a portfolio of pain products (the Pain Portfolio), Actiq<sup>™</sup> (oral transmucosal fentanyl citrate), the dermatology portfolio of products, Abelcet<sup>™</sup> (amorphotericin B lipid complex) U.S./Canada, Myobloc<sup>™</sup> (botulinum toxin type B), Myambutol<sup>™</sup> (ethambutal hydrochloride) and Frova, which are included in discontinued operations. We have recorded the results and gains or losses on the divestment of these operations within discontinued operations in the Consolidated Statement of Operations.

***Net Loss and Net Loss per Ordinary Share***

Net loss for the year was \$383.6 million for 2005, compared to a net loss of \$394.7 million for 2004. Basic and diluted net loss per share was \$0.93 for 2005, compared to \$1.01 for 2004. Basic and diluted net loss from continuing operations was \$0.93 per share for 2005, compared to \$1.06 per share for 2004. Basic and diluted net income from discontinued operations was \$Nil per share for 2005, compared to basic and diluted net income per share of \$0.05 for 2004.

**Table of Contents****2004 Compared to 2003 (in millions, except share and per share amounts)**

	<b>2004</b>	<b>2003</b>	<b>% Increase/ (Decrease)</b>
Product revenue	\$ 404.4	\$ 586.7	(31)%
Contract revenue	77.3	98.9	(22)%
Total revenue	481.7	685.6	(30)%
Operating expenses:			
Cost of sales	173.6	248.9	(30)%
Selling, general and administrative expenses	337.3	384.2	(12)%
Research and development expenses	257.3	277.6	(7)%
Net gain on sale of businesses	(44.2)	(267.8)	(83)%
Other significant net charges	59.8	403.2	(85)%
Total operating expenses	783.8	1,046.1	(25)%
Operating loss	(302.1)	(360.5)	(16)%
Net interest and investment (gains) and losses:			
Net interest expense	109.0	103.8	5%
Net investment gains	(114.6)	(103.4)	11%
Impairment of investments	71.8	87.5	(18)%
Charge arising from guarantee to EPIL II noteholders	47.1	49.0	(4)%
Net interest and investment losses:	113.3	136.9	(17)%
Loss from continuing operations before provision for/(benefit from) income taxes	(415.4)	(497.4)	(16)%
Benefit from income taxes	(1.7)	(22.8)	(93)%
Net loss from continuing operations	(413.7)	(474.6)	(13)%
Net income/(loss) from discontinued operations (net of tax)	19.0	(31.5)	(160)%
Net loss	\$ (394.7)	\$ (506.1)	(22)%
Basic and diluted net loss per ordinary share:			
Net loss from continuing operations	\$ (1.06)	\$ (1.33)	(20)%
Net income/(loss) from discontinued operations (net of tax)	0.05	(0.09)	(156)%
Net loss	\$ (1.01)	\$ (1.42)	(29)%
Weighted average number of Ordinary Shares outstanding	390.1	356.0	

**Table of Contents****Product Revenue**

The decrease in product revenue in 2004 was primarily due to the divestment of a number of products and businesses during 2003 and 2004, principally Zonegran, Skelaxin, Sonata and the European business, offset by 10% growth in revenue from the core business. The components of product revenue are set out below (in millions):

	2004	2003	% Increase/ (Decrease)
(A) Marketed products			
Maxipime	\$ 117.5	\$ 109.1	8%
Azactam	50.6	45.1	12%
Tysabri	6.4		N/A
Total revenue from marketed products	174.5	154.2	13%
(B) Manufacturing revenue and royalties	130.9	120.0	9%
(C) Amortized revenue Adalat/Avinza	34.0	34.0	0%
Total product revenue from core business	339.4	308.2	10%
(D) Divested products <sup>(1)</sup>			
European business <sup>(2)</sup>	10.5	89.0	(88)%
Zonegran <sup>(3)</sup>	41.2	80.7	(49)%
Skelaxin <sup>(4)</sup>		60.2	(100)%
Sonata <sup>(4)</sup>		48.2	(100)%
Other	13.3	0.4	
Total divested products revenue	65.0	278.5	(77)%
Total product revenue	\$ 404.4	\$ 586.7	(31)%

<sup>(1)</sup> Products described as *Divested Products* include products or businesses divested since the beginning of 2003.

<sup>(2)</sup> Sold to Zeneus in February 2004.

<sup>(3)</sup> Sold to Eisai in April 2004.

<sup>(4)</sup> Sold to King in June 2003.

**(A) Marketed products**

Total revenue from marketed products increased to \$174.5 million in 2004 from \$154.2 million in 2003. The increase of 13% primarily reflected the growth in prescriptions and demand for *Maxipime* and *Azactam*, and initial sales of *Tysabri*. The basic patent on *Maxipime* expires in March 2007 and the basic patent on *Azactam* expired in October 2005. Two U.S. patents covering *Maxipime* formulations may provide patent protection until 2008. The expiration of

these patents is expected to result in generic competition for these products, which could adversely impact future revenues. To date no *Azactam* generic has been approved.

As reported by IMS Health National Sales Perspectives, *Maxipime* prescription demand for 2004 increased by 14% over 2003, while revenues increased from \$109.1 million to \$117.5 million, or 8%. *Azactam* prescription demand for 2004 increased by 12% over the same period in 2003, corresponding to increased revenues from \$45.1 million to \$50.6 million. The difference between prescription and revenue growth rates is due to changing wholesaler inventory levels.

The FDA granted accelerated approval of *Tysabri* in late November 2004 for the treatment of patients in the United States with all forms of relapsing remitting MS. Revenue from *Tysabri* amounted to \$6.4 million in 2004. The marketing and clinical dosing of *Tysabri* was voluntarily suspended in February 2005. On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. On March 21, 2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the

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*Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

*(B) Manufacturing revenue and royalties*

Manufacturing revenue and royalties are as follows (in millions):

	2004	2003	% Increase/ (Decrease)
Verelan	\$ 27.8	\$ 38.2	(27)%
Diltiazem	19.3	23.6	(18)%
Skelaxin	12.2	7.4	65%
Other	71.6	50.8	41%
Total	\$ 130.9	\$ 120.0	9%

Manufacturing revenue and royalties comprises of revenue earned from products we manufacture for third parties, and royalties we earned on sales by third parties of products that incorporate our technologies. The increase of 9% in 2004 was primarily related to additional manufacturing activities. Aside from Verelan and Diltiazem, no other single product accounted for more than 10% of our manufacturing revenue and royalties in either 2004 or 2003. In 2004, 19% of these revenues consisted of royalties received on products that we do not manufacture, compared to 12% in 2003.

*(C) Amortized revenue Adalat/Avinza*

Amortized revenue of \$34.0 million in both 2004 and 2003 related to the licensing to Watson of rights to our generic form of Adalat CC (\$9.0 million) and the restructuring of our Avinza license agreement with Ligand (\$25.0 million). Both of the transactions occurred in 2002. The remaining unamortized revenue on these products of \$69.2 million is included in deferred revenue, due to our ongoing involvement in the manufacturing of these products. Of the remaining \$69.2 million, \$22.5 million of the deferred revenue relates to generic Adalat CC and will be recognized as revenue through June 2007. The remaining deferred revenue of \$46.7 million relates to Avinza and will be recognized as revenue through November 2006.

*(D) Divested products*

During 2003 and 2004, we sold a number of products and businesses as part of the recovery plan, and our subsequent strategic repositioning as a biotechnology company focused on a number of key therapeutic markets. The decrease in product revenue in 2004 was primarily due to the divestment of a number of products and businesses during 2003 and 2004, principally the European business, Zonegran, Skelaxin and Sonata, which are described below.

In February 2004, we completed the sale of our European sales and marketing business to Zeneus. Revenue for the divested European business was \$10.5 million for 2004 (2003: \$89.0 million).

In April 2004, we sold our interests in Zonegran for North America and Europe to Eisai. Zonegran generated revenue of \$41.2 million for 2004 (2003: \$80.7 million).

In June 2003, we completed the sale of our primary care franchise, principally our rights to Skelaxin and Sonata, to King. We did not report any product revenue from sales by us of Skelaxin and Sonata during 2004 (2003: \$108.4 million). Following divestment, we earn royalties on sales of Skelaxin by King. This amounted to \$12.2 million in 2004 (2003: \$7.4 million).

**Table of Contents*****Contract Revenue***

	<b>2004</b>	<b>2003</b>	<b>% Increase/ (Decrease)</b>
	<b>(In millions)</b>		
Amortized fees	\$ 17.6	\$ 49.6	(65)%
Research revenues/milestones	59.7	49.3	21%
Total contract revenue	\$ 77.3	\$ 98.9	(22)%

Included in amortized fees for 2003 is \$35.2 million related to the business ventures that were restructured or terminated as part of our recovery plan. There were no revenues related to the business ventures in 2004 and, consequently, amortized fees for 2004 decreased by 65% from 2003.

The increase in research revenues/milestones primarily reflects increased activity coupled with the timing of the achievement of milestones.

***Cost of Sales***

Cost of sales was \$173.6 million in 2004, compare to \$248.9 million in 2003. The cost of sales as percentage of product revenue was 43% for 2004 and 42% for 2003. The margin remained consistent with 2003 despite the change in the mix of product revenues. This was due primarily to the divestment of a number of products and businesses with higher margins and was offset by the elimination of royalties paid to Pharma Marketing Ltd. (Pharma Marketing) in 2004 (2003: \$43.3 million). There were no direct costs of sales related to our royalty revenue in 2004 and 2003.

***Selling, General and Administrative Expenses (SG&A)***

SG&A expenses were \$337.3 million in 2004 compared to \$384.2 million in 2003. The decrease of 12% reflects the overall reduction in our activities as a result of the business and product divestments in both 2004 and 2003, offset by the costs of certain commercialization activities related to the launch of *Tysabri*. We incurred \$52.3 million of launch costs in 2004 on *Tysabri*.

***Research and Development Expenses***

R&D expenses were \$257.3 million in 2004 compared to \$277.6 million in 2003. The decrease of 7% reflects the reduction in the scope of our R&D activities as a result of the divestment of certain businesses and products, the termination of certain R&D activities, and the refocusing of our efforts on key programs: *Tysabri*, *Prialt* and Alzheimer's disease.

***Net Gain on Sale of Businesses***

	<b>2004</b>	<b>2003</b>
	<b>(In millions)</b>	
Zonegran	\$ 42.9	\$

European business	(2.9)	
Primary care franchise		264.4
Other	4.2	3.4
Total	\$ 44.2	\$ 267.8

In April 2004, we completed the sale of our interests in Zonegran in North America and Europe to Eisai for initial net consideration of \$113.5 million at closing. The gain from this transaction amounted to \$42.9 million in 2004. We were also entitled to receive additional consideration of up to \$110.0 million from Eisai through January 1, 2006, primarily contingent on the date of generic Zonegran approval. We had received \$85.0 million of this contingent consideration prior to the approval of generic Zonegran in December 2005. Consequently, the total net

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proceeds received from the sale of Zonegran amounted to \$198.5 million and resulted in a cumulative net gain of \$128.5 million, of which \$85.6 million was recognized in 2005 and \$42.9 million in 2004.

In February 2004, we sold our European sales and marketing business to Zeneus for net cash proceeds of \$93.2 million, resulting in a loss of \$2.9 million. We received an additional \$6.0 million in February 2005, which was accrued at December 31, 2004, and \$15.0 million December 2005, which resulted in a net gain of \$17.1 million in 2005 after the release of contingent liabilities of \$2.1 million, which were not required ultimately. Approximately 180 employees of our European sales and marketing business transferred to Zeneus.

In 2003, a net gain of \$264.4 million was recognized on the divestment of the primary care franchise to King (principally our rights to Sonata and Skelaxin). In June 2003, King paid gross consideration on closing of \$749.8 million, which included the transfer to King of Sonata and Skelaxin inventory with a value of approximately \$40.0 million and obligations related to Sonata of \$218.8 million that were assumed by King at closing. In addition, in January 2004, we received an additional \$25.0 million payment, which was contingent on the ongoing patent exclusivity of Skelaxin through December 31, 2003. The amount was included in the gain recorded in 2003 as the contingency was resolved by December 31, 2003.

***Other significant net charges***

The principal items classified as other significant net charges/(gains) include asset impairments, purchase of royalty rights, severance, relocation and exit costs, and costs incurred from litigation or regulatory actions, including shareholder class action litigation and the SEC investigation. These items have been treated consistently from period to period. Our management believes that disclosure of other charges is meaningful because it provides additional information in relation to these material, infrequent and often non-recurring items.

	<b>2004</b>	<b>2003</b>
	<b>(In millions)</b>	
(A) Shareholder litigation and SEC investigation	\$ 56.0	\$ 10.7
(B) Severance, relocation and exit costs	3.0	29.7
(C) Purchase of royalty rights		297.6
(D) Asset impairments		32.6
(E) EPIL II/EPIL III waiver fee		16.8
Other	0.8	15.8
Total other charges	\$ 59.8	\$ 403.2

***(A) Shareholder litigation and SEC investigation***

During 2004, we recorded \$56.0 million (2003: \$10.7 million) related to litigation provisions and costs related to the SEC investigation and shareholder class action lawsuit. The expense recorded in 2004 arose primarily as a result of a \$55.0 million provision made in relation to settlement of the SEC investigation and the related shareholder class action lawsuit.

We and certain of our former and current officers and directors were named as defendants in a class action filed in early 2002 alleging that our financial statements were not prepared in accordance with GAAP, and that the defendants disseminated materially false and misleading information concerning our business and financial results. We agreed to

settle the action in October 2004 and the settlement was formally approved by the U.S. District Court for the Southern District of New York in February 2005. Under the class action settlement, all claims against us and the other named defendants were dismissed with no admission or finding of wrongdoing on the part of any defendant. The principal terms of the settlement provide for an aggregate cash payment to class members of \$75.0 million, out of which the court awarded attorneys' fees to plaintiffs' counsel, and \$35.0 million was paid by our insurance carrier.

We were also the subject of an investigation by the SEC's Division of Enforcement regarding matters similar to those alleged in the class action. We provisionally settled the investigation in October 2004 and the SEC formally approved the settlement in February 2005. The terms of the class action settlement received final court approval in

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April 2005. Under the settlement agreement reached with the SEC, we neither admitted nor denied the allegations contained in the SEC's civil complaint, which included allegations of violations of certain provisions of the federal securities laws. The settlement contains a final judgment restraining and enjoining us from future violations of these provisions. In addition, under the final judgment, we paid a civil penalty of \$15.0 million. In connection with the settlement, we were not required to restate or adjust any of our historical financial results or information.

The expense incurred in 2003 relates to legal expenses incurred on the SEC investigation and shareholder class action lawsuit.

For additional information on litigation which we are involved in, please refer to Note 25 to the Consolidated Financial Statements.

### *(B) Severance, relocation and exit costs*

During 2004, we incurred severance, relocation and exit costs arising from the implementation of our recovery plan of \$3.0 million (2003: \$29.7 million). The recovery plan, which commenced in July 2002 and was completed in February 2004, involved the restructuring of our businesses, assets and balance sheet. These expenses arose from a reduction in the scope of our activities and a reduction in employee headcount.

### *(C) Purchase of royalty rights*

During 2003, we repurchased royalty rights related to certain of our current and former products from Pharma Marketing. For additional information on the purchase of royalty rights from Pharma Marketing, please refer to Item 5. Risk Sharing Arrangements.

### *(D) Asset impairments*

As part of our recovery plan, we identified a range of businesses and products that we intended to sell in the near term, and other assets that we intended to cease using. In many cases, we had received indicative offers for these assets and wrote-down the assets to their fair value. In other cases, the impairment arose because of changes to the forecast profitability of these assets. The impairments of \$32.6 million in 2003 related principally to our European sales and marketing business (sold to Zeneus in February 2004), a manufacturing and R&D business based in Switzerland (sold in February 2004), and to certain R&D technology platforms that we ceased using.

### *(E) EPIL II/EPIL III waiver fee*

In November 2003, we successfully completed a private offering of \$460.0 million in aggregate principal amount of 6.5% Convertible Notes and gross proceeds of \$173.2 million from the sale of 35 million Ordinary Shares. In connection with this offering, we paid a waiver fee of \$16.8 million to the holders of the EPIL II and EPIL III Notes.

## ***Net Interest Expense***

Net interest expense was \$109.0 million in 2004, compared to \$103.8 million in 2003, an increase of 5%. The increase was primarily a result of the issuance of the \$850.0 million of 7.75% Notes and \$300.0 million of Floating Rate Notes in November 2004, offset by the repurchase of \$351.0 million of the EPIL III Notes and by lower interest expense due to the Liquid Yield Option Notes (LYONs) repurchases during 2003. In addition, the \$460.0 million 6.5% Convertible Notes, which were issued in November 2003, were outstanding throughout 2004.

## ***Net Investment Gains***

Net investment gains were \$114.6 million in 2004, compared to \$103.4 million in 2003, an increase of 11%. In 2004, we raised \$255.5 million (2003: \$238.2 million) in net cash proceeds from the disposal of investments and marketable investment securities. The net investment gains of \$114.6 million in 2004 included gains on the sale of securities of Warner Chilcott plc of \$43.6 million, Atrix Laboratories of \$13.1 million, Curis, Inc. of \$15.3 million and DOV Pharmaceutical, Inc. of \$22.6 million. The gains in 2003 of \$103.4 million included a gain on the sale of

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securities of Ligand of \$72.2 million and a gain from the movement in fair value of derivative instruments of \$26.1 million.

***Impairment of Investments***

During 2004, impairment charges of \$71.8 million (2003: \$87.5 million) reflect other-than-temporary impairments to the value of a number of investments, mainly in privately-held biotech companies.

***Charge Arising from Guarantee to EPIL II Noteholders***

We had guaranteed the EPIL II Notes to the extent that the investments held by EPIL II were insufficient to repay the EPIL II Notes and accrued interest. EPIL II was a qualifying special purpose entity and was not consolidated under U.S. GAAP. On June 28, 2004, the EPIL II Notes of \$450.0 million, together with accrued interest for the period from December 31, 2003 to June 28, 2004 of \$21.5 million, were repaid. Of the aggregate payment of \$471.5 million, \$79.7 million was funded from the cash resources in EPIL II and through the sale of EPIL II's entire investment portfolio. We funded the balance of \$391.8 million under our guarantee. This resulted in a charge in 2004 of \$47.1 million, arising from interest of \$21.5 million and investment losses of \$25.6 million incurred by EPIL II during the first half of 2004. During 2003, a charge of \$49.0 million arose under the EPIL II guarantee, reflecting the increase during the year of the excess of the principal and accrued interest expense of the EPIL II Notes over the value of EPIL II's assets.

***Provision for Income Taxes***

We had a net tax benefit of \$1.7 million for 2004, compared to a net tax benefit of \$22.8 million for 2003. The overall tax benefit to us for 2004 was \$4.4 million. Of this amount, \$2.7 million has been credited to shareholders' equity to reflect utilization of stock option deductions. The remaining \$1.7 million benefit is allocated to ordinary activities. The tax benefit reflected tax at standard rates in the jurisdictions in which we operate, income derived from Irish patents, foreign withholding tax and the availability of tax losses. Our Irish patent derived income was exempt from taxation pursuant to Irish legislation, which exempts from Irish taxation income derived from qualifying patents. Currently, there is no termination date in effect for such exemption. For additional information regarding taxation, please refer to Note 17 to the Consolidated Financial Statements.

***Net Income/(Loss) from Discontinued Operations***

Net income from discontinued operations was \$19.0 million in 2004, compared to a net loss from discontinued operations of \$31.5 million in 2003. The net income/(loss) from discontinued operations includes a net gain on sale of businesses of \$11.5 million (2003: \$22.9 million) and other charges of \$Nil (2003: \$58.4 million). During the course of the recovery plan, we sold a number of products and businesses, including Athena Diagnostics, Elan Diagnostics, a portfolio of pain products (the Pain Portfolio), Actiq<sup>™</sup> (oral transmucosal fentanyl citrate), the dermatology portfolio of products, Abelcet<sup>™</sup> (amorphotericin B lipid complex) U.S./Canada, Myobloc<sup>™</sup> (botulinum toxin type B), Myambutol and Frova, which are included in discontinued operations. We have recorded the results and gains or losses on the divestment of these operations within discontinued operations in the income statement. For additional information on discontinued operations, please refer to Note 20 to the Consolidated Financial Statements.

***Net Loss and Net Loss per Ordinary Share***

Net loss for the year was \$394.7 million for 2004, compared to net loss of \$506.1 million for 2003. Basic and diluted net loss per share was \$1.01 for 2004, compared to \$1.42 per share for 2003. Basic and diluted net loss from continuing operations was \$1.06 per share for 2004, compared to \$1.33 per share for 2003. Basic and diluted net

income from discontinued operations was \$0.05 per share for 2004, compared to basic and diluted net loss per share of \$0.09 for 2003.

**Table of Contents****SEGMENT ANALYSIS**

Our business is organized into two segments: Biopharmaceuticals and EDT (formerly known as Global Services and Operations). Biopharmaceuticals engages in research, development and commercial activities and includes our activities in the areas of autoimmune diseases, neurodegenerative diseases, and our specialty business group. EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry.

Our total revenue of \$490.3 million in 2005 (2004: \$481.7 million; 2003: \$685.6 million) was comprised of revenue from Biopharmaceuticals of \$250.8 million (2004: \$275.1 million; 2003: \$479.7 million) and EDT of \$239.5 million (2004: \$206.6 million; 2003: \$205.9 million). Our total operating loss of \$198.5 million in 2005 (2004: \$302.1 million; 2003: \$360.5 million) was comprised primarily of operating losses incurred by Biopharmaceuticals of \$225.4 million (2004: \$253.2 million; 2003: \$318.1 million), partially offset by operating income from EDT of \$27.6 million (2004: \$14.2 million; 2003: \$5.7 million).

Biopharmaceuticals revenue decreased 9% to \$250.8 million in 2005 from \$275.1 million in 2004 and 48% from \$479.7 million in 2003. The decrease is primarily due to the decrease in revenue from divested products, offset by increased sales of *Maxipime* and *Azactam*. Biopharmaceuticals operating loss decreased 11% to \$225.4 from \$253.2 million in 2004 and 29% from \$318.1 million in 2003. The decrease in the operating loss was principally due to the increase in the gain on sale of businesses, offset by a decrease in revenues. Biopharmaceuticals net gain on sale of businesses increased from \$41.2 million in 2004 to \$103.1 million in 2005, primarily related to the gain on sale of Zonegran and our European business, principally due to the receipt of contingent considerations in 2005. Biopharmaceuticals other significant net charges increased from \$0.2 million in 2004 to \$5.6 million in 2005, primarily due to severance, relocation, and exit costs incurred relating to the realignment of our resources to meet our current business structure. In 2003, Biopharmaceuticals incurred net significant other charges of \$343.7 million, which primarily related to the purchase of royalty rights from Pharma Marketing.

EDT revenue increased to \$239.5 million in 2005 from \$206.6 million in 2004 and increased 16% from \$205.9 million in 2003. The increase from 2004 was primarily due to increased sales by third parties that incorporate Elan's technologies. EDT operating income increased to \$27.6 million in 2005 from \$14.2 million in 2004, primarily due to the increase in revenues. EDT gain on sale of businesses decreased from a \$3.0 million gain in 2004 to a \$0.3 million gain in 2005. EDT did not incur material other significant net charges in either 2005 or 2004. In 2003, EDT incurred net significant other charges of \$13.9 million, which related primarily to asset impairments.

**RISK-SHARING AGREEMENTS**

In June 2000, we disposed of royalty rights on certain products and development projects to Pharma Marketing. Pharma Marketing completed a private placement of its common shares to a group of institutional investors, resulting in gross proceeds of \$275.0 million. We held no investment in Pharma Marketing and had no representative on its board of directors. Concurrent with the private placement, Pharma Marketing entered into a Program Agreement with us. The Program Agreement, which substantially regulated our relationship, was a risk-sharing arrangement between us and Pharma Marketing. Under the terms of the Program Agreement, Pharma Marketing acquired certain royalty rights to each of the following products for the designated indications (including any other product that contained the active ingredient included in such product for any other designation): (i) Frova, for the treatment of migraines; (ii) Myobloc, for the treatment of cervical dystonia; (iii) *Prialt*, for the treatment of acute pain and severe chronic pain; (iv) Zanaflex, for the treatment of spasticity and painful spasms; and (v) Zonegran, for the treatment of epilepsy. Pharma Marketing agreed to make payments to us in amounts equal to expenditures made by us in connection with the commercialization and development expenditures for these products, subject to certain limitations. These payments had been made on a quarterly basis based on the actual costs incurred by us. We did not receive a margin on the

payments.

We received no revenue from Pharma Marketing in either 2005, 2004, or 2003. Pursuant to the Program Agreement, Pharma Marketing utilized all of its available funding by mid-2002. We will not receive any future revenue from Pharma Marketing. In 2003, the royalty rate on net sales of all designated products was 28% on the

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first \$122.9 million of net sales and 53% for net sales above \$122.9 million. We paid aggregate royalties of \$43.3 million in 2003. This was recorded as a cost of sales.

In December 2001, the Program Agreement was amended such that we re-acquired the royalty rights to Myobloc and disposed of the royalty rights on Sonata to Pharma Marketing. The amendment was transacted at estimated fair value. The board of directors and shareholders of Pharma Marketing approved this amendment. The estimated difference in relative fair value between the royalty rights of Sonata and the royalty rights of Myobloc was \$60.0 million. We paid this amount to Pharma Marketing in cash and capitalized it as an intangible asset.

Under the original agreements, we could have, at our option at any time prior to June 30, 2003, acquired the royalty rights by initiating an auction process. This date was extended to January 3, 2005 under the settlement with Pharma Marketing and Pharma Operating Ltd. (Pharma Operating) described below. In addition, the holders of Pharma Marketing common shares were entitled to initiate the auction process earlier upon the occurrence of certain events. Pursuant to the auction process, the parties were to negotiate in good faith to agree on a purchase price, subject to our right to re-acquire the royalty rights at a maximum purchase price. The maximum purchase price was approximately \$413.0 million at December 31, 2002 and increased by approximately 25% annually (less royalty payments). The purchase price was reduced under the settlement with Pharma Marketing and Pharma Operating as described below.

On January 17, 2003, we announced that Pharma Operating had filed a lawsuit in the Supreme Court of the State of New York against us and certain of our subsidiaries in connection with the risk-sharing arrangement between the parties. The lawsuit sought, among other things, a court determination that Pharma Operating's approval would be required in the event of a sale by us of our interest in Sonata to a third party. On January 30, 2003, we, Pharma Operating and its parent Pharma Marketing, agreed to settle the lawsuit and, under the terms of the settlement agreement, Pharma Operating dismissed the litigation between the parties without prejudice. Pursuant to the settlement agreement, effective upon the sale of Sonata to King in June 2003: (1) we paid Pharma Operating \$196.4 million in cash (representing \$225.0 million less royalty payments on all related products paid or due to Pharma Operating from January 1, 2003 through June 12, 2003) to acquire Pharma Operating's royalty rights with respect to Sonata and *Prialit*; and (2) our maximum purchase price for the remaining products in the arrangement, Zonegran, Frova and Zanaflex, was reduced to \$110.0 million, which increased at a rate of 15% per annum from June 12, 2003 (less royalty payments made for periods after June 12, 2003). The parties also agreed to extend our purchase option termination date to January 3, 2005 from the original termination date of June 30, 2003.

In connection with the settlement agreement, we agreed that we would cause certain subsidiaries in the United States, Ireland, the United Kingdom, Germany, France, Spain and Italy to pledge their accounts receivable from commercial sales of pharmaceutical products and services to Pharma Operating as collateral to secure our obligations in relation to royalty payments under the Pharma Marketing arrangement and the settlement agreement. We also agreed that, following the closing of a sale of Sonata, we would grant Pharma Operating additional collateral to the extent that the aggregate value of the collateral package, which was to be tested on a quarterly basis, was less than the maximum purchase price for the royalty rights on Zonegran, Frova and Zanaflex. On March 6, 2003, Elan Pharmaceuticals, Inc. (EPI) and Pharma Operating entered into a security agreement pursuant to which EPI granted Pharma Operating a first priority security interest in its accounts receivable from commercial sales of pharmaceutical products in the United States. On that same date, we and Pharma Operating agreed to the terms of the additional collateral mechanism. On May 20, 2003, Elan Pharma Limited (EPL) and Pharma Operating entered into a security agreement pursuant to which EPL granted Pharma Operating a security interest in its accounts receivable from commercial sales of pharmaceutical products and services in the United Kingdom. A similar agreement was entered into in relation to Ireland by Elan Pharma (Ireland) Limited on June 10, 2003.

In November 2003, we exercised our option to purchase the remaining royalty rights of Zonegran, Frova and Zanaflex from Pharma Operating for \$101.2 million and all of our agreements with Pharma Marketing were terminated. During

2003, we expensed \$297.6 million for the acquisition of royalty rights from Pharma Operating.

**Table of Contents****B. Liquidity and Capital Resources*****Cash and Cash Equivalents, Liquid and Capital Resources***

Our liquid and capital resources at December 31 were as follows (in millions):

	2005	2004	Increase/ (Decrease)
Cash and cash equivalents	\$ 1,080.7	\$ 1,347.6	(20)%
Restricted cash (current)	20.4	189.3	(89)%
Short-term marketable investments	10.0	65.5	(85)%
Shareholders' equity	16.9	205.0	(92)%

We have historically financed our operating and capital resource requirements through cash flows from operations, sales of equity securities and borrowings. We consider all highly liquid deposits with an original maturity of three months or less to be cash equivalents. Our primary source of funds as of December 31, 2005 consisted of cash and cash equivalents of \$1,080.7 million, which excludes restricted cash of \$24.9 million (current and non-current), and short-term marketable securities of \$10.0 million.

At December 31, 2005, our shareholders' equity was \$16.9 million, compared to \$205.0 million at December 31, 2004. The decrease is due primarily to the net loss incurred during the year, offset by the conversion of convertible debt and proceeds from stock option exercises.

***Cash Flows Summary***

	2005	2004 (In millions)	2003
Net cash used in operating activities	\$ (283.5)	\$ (347.9)	\$ (428.5)
Net cash provided by investing activities	120.9	474.2	369.6
Net cash provided by/(used in) financing activities	(99.7)	441.5	(175.7)
Effect of exchange rate changes on cash	(4.6)	1.6	12.5
Net increase/(decrease) in cash and cash equivalents	(266.9)	569.4	(222.1)
Cash and cash equivalents at beginning of year	1,347.6	778.2	1,000.3
Cash and cash equivalents at end of year	\$ 1,080.7	\$ 1,347.6	\$ 778.2

The results of our cash flow activities for 2005 and 2004 are described below.

***2005***

Net cash used in operating activities was \$283.5 million in 2005. The primary components of cash used in operating activities were the net loss (adjusted to exclude non-cash charges and benefits) and changes in working capital

accounts. The changes in working capital accounts include the net decrease in trade receivables and prepaid and other assets of \$159.4 million (principally related to the release of restricted cash of \$168.9 million), the decrease in inventory of \$3.5 million, and the net decrease of \$111.8 million in accounts payable and accrued and other liabilities.

Net cash provided by investing activities was \$120.9 million in 2005. The major component of cash generated from investing activities includes net proceeds of \$45.6 million from the disposal of investments, \$17.1 million from sale and maturity of marketable investment securities and \$108.8 million from business disposals (primarily Zonegran and the European business), partially offset by \$50.1 million for capital expenditures. As of December 31, 2005, we did not have any significant commitments to purchase property, plant and equipment, except for committed additional capital expenditures of \$7.1 million.

Net cash used in financing activities totalled \$99.7 million in 2005, primarily reflecting \$39.0 million for the repayment of EPIL III Notes and \$87.8 million for the early retirement of \$36.8 million of the Athena Notes and

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early conversion of \$206.0 million in aggregate principle amount 6.5% Convertible Notes, offset by \$23.8 million of net proceeds from employee stock option exercises and \$4.0 million of proceeds from government grants.

We believe that our current liquid asset position will be sufficient to meet our needs for at least the next twelve months.

*2004*

Net cash used in operating activities was \$347.9 million in 2004. The components of cash used in operating activities were the net loss, adjusted to exclude non-cash charges and benefits, and changes in working capital accounts. The changes in working capital accounts include the net increase in trade receivables and prepaid and other assets of \$15.4 million, the decrease in inventory of \$17.1 million, and the net decrease of \$26.7 million in accounts payable and accrued and other liabilities.

Net cash provided by investing activities was \$474.2 million in 2004. The major component of cash generated from investing activities includes net proceeds of \$76.6 million from the disposal of investments, \$178.9 million from sale and maturity of marketable investment securities, \$274.6 million from business disposals (primarily the European business, Zonegran and Frova), and \$44.2 million from the disposals of property, plant and equipment, partially offset by \$57.9 million for capital expenditures and \$41.1 million for the purchase of intangible and other assets.

Net cash provided by financing activities totalled \$441.5 million in 2004, primarily reflecting \$1,125.1 million from the issuance of 7.75% Notes and Floating Rate Notes in November 2004 and \$70.6 million of net proceeds from employee stock option exercises, partially offset by \$351.0 million for the repayment of EPIL III Notes and \$391.8 million for the EPIL II guarantee payment.

***Debt Facilities***

At December 31, 2005, we had long-term and convertible debts outstanding of \$2,017.2 million which consists of the following:

	<b>(in millions)</b>
6.5% Convertible notes due 2008	\$ 254.0
Athena notes due 2008	613.2
7.75% Notes due 2011	850.0
Floating rate notes due 2011	300.0
	<b>\$ 2,017.2</b>

During 2005, as of December 31, 2005, and, as of the date of filing of this Form 20-F, we were not in violation of any of our debt covenants.

We may, at any time after December 1, 2006, redeem all or part of the 6.5% Convertible Notes then outstanding at par, with interest accrued to the redemption date provided that, within a period of 30 consecutive trading days ending five trading days prior to the date on which the relevant notice of redemption is published, the official closing price per share of the ADSs on the NYSE for 20 trading days shall have been at least 150% of the conversion price deemed to be in effect on each of such trading days.

For additional information regarding our outstanding debt, please refer to Note 14 to the Consolidated Financial Statements.

*Commitments and Contingencies*

For information regarding commitments and contingencies, please refer to Notes 24 and 25 to the Consolidated Financial Statements.

**Table of Contents****Capital Expenditures**

We believe that our current and planned manufacturing, research, product development and corporate facilities will adequately meet our current and projected needs. We will use our resources to make capital expenditures as necessary from time to time and also to make investments in the purchase or licensing of products and technologies and in marketing and other alliances with third parties to support our long-term strategic objectives.

**C. Research and Development, Patents and Licenses, etc.**

See Item 4. B Business Overview for information on our R&D, patents and licenses, etc.

**D. Trend Information**

Please see Item 4. B Business Overview and Item 5. A Operating Results for trend information.

**E. Off-Balance Sheet Arrangements**

As of December 31, 2005, we have no unconsolidated special purpose financing or partnership entities or other off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, that are material to investors.

**F. Tabular Disclosure of Contractual Obligations**

The following table sets out, at December 31, 2005, our main contractual obligations due by period for debt principal and interest repayments and capital and operating leases. These represent the major contractual, future payments that may be made by us. The table does not include items such as expected capital expenditures on plant and equipment or future investments in financial assets. As of December 31, 2005, the directors had authorized capital commitments for the purchase of property, plant and equipment of \$7.1 million (2004: \$15.9 million).

	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>After 5 Years</b>
Athena Notes due 2008	\$ 613.2	\$	\$ 613.2	\$	\$
6.5% Convertible Notes due 2008 <sup>(1)</sup>	254.0		254.0		
7.75% Notes due 2011	850.0				850.0
Floating Rate Notes due 2011	300.0				300.0
Total debt principal obligations	2,017.2		867.2		1,150.0
Debt interest payments <sup>(2)</sup>	682.4	153.4	265.7	183.0	80.3
Capital lease obligations <sup>(3)</sup>	8.0	5.3	2.7		
Operating lease obligations	138.9	18.0	30.3	40.9	49.7
Total contractual obligations	\$ 2,846.5	\$ 176.7	\$ 1,165.9	\$ 223.9	\$ 1,280.0

- (1) *We may, at any time after December 1, 2006, redeem all or part of the 6.5% Convertible Notes then outstanding at par, with interest accrued to the redemption date provided that, within a period of 30 consecutive trading days ending five trading days prior to the date on which the relevant notice of redemption is published, the official closing price per share of the ADSs on the NYSE for 20 trading days shall have been at least 150% of the conversion price deemed to be in effect on each of such trading days.*
- (2) *The Floating Rate Notes bear interest at a rate, adjusted quarterly, equal to three-month London Interbank Offer Rate (LIBOR) plus 4.0%. To calculate our interest payment obligation, we used the LIBOR at December 31, 2005.*
- (3) *In prior years, we disposed of plant and equipment and subsequently leased them back and also entered into an arrangement with a third party bank, the substance of which allows us to require a net settlement of our obligations under the leases. The related assets and liabilities of these previous sale and leaseback transactions have been offset in the Consolidated Financial Statements in the amount of \$51.8 million at December 31, 2005 (2004: \$64.3 million).*

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At December 31, 2005, we had commitments to invest \$2.4 million (2004: \$3.2 million) in healthcare managed funds.

In disposing of assets or businesses, we often provide customary representations, warranties and indemnities (if any) to cover various risks. We do not have the ability to estimate the potential liability from such indemnities because they relate to unknown conditions. However, we have no reason to believe that these uncertainties would have a material adverse effect on our financial condition or results of operations.

The two major rating agencies covering our debt rate it as sub-investment grade debt. None of our debt has a rating trigger that would accelerate the repayment date upon a change in rating.

Our debt ratings as of December 31, 2005 and 2004 were as follows:

	<b>Standard &amp; Poor's Rating Services</b>	<b>Moody's Investors Service</b>
Athena Notes	B	B3
6.5% Convertible Notes	CCC+	Not rated
7.75% Notes	B	B3
Floating Rate Notes	B	B3

We believe that we have sufficient current cash, liquid resources, realizable assets and investments to meet our liquidity requirements for at least the next twelve months. Longer-term liquidity requirements and debt repayments will need to be met out of future operating cash flows, financial and other asset realizations and future financing. However, events, including a material deterioration in our operating performance as a result of our inability to reintroduce *Tysabri* to the market, or, even if it were reintroduced to the market, a substantial delay in such reintroduction or, even if *Tysabri* is timely reintroduced, a material impairment in our ability to sell significant amounts of *Tysabri*, material adverse legal judgments, fines, penalties or settlements arising from litigation or governmental investigations, failure to receive marketing approval for products under development or the occurrence of other circumstances or events described under Risk Factors , could materially adversely affect our ability to meet our longer-term liquidity requirements.

We commit substantial resources to our R&D activities, including collaborations with third parties such as Biogen Idec for the development of *Tysabri* and Wyeth for Alzheimer's disease. We expect to commit significant cash resources to the development and commercialization of products in our development pipeline.

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital, restructure or refinance outstanding debt, repurchase material amounts of outstanding debt (including the Athena Notes, the 6.5% Convertible Notes, and the 7.75% Notes and the Floating Rate Notes), consider the sale of interests in subsidiaries, marketable investment securities or other assets or the rationalization of products, or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps, including any repurchase of outstanding debt, could be material. In the normal course of business, we may investigate, evaluate, discuss and engage in future company or product acquisitions, capital expenditures, investments and other business opportunities. In the event of any future acquisitions, capital expenditures, investments or other business opportunities, we may consider using available cash

or raising additional capital, including the issuance of additional debt.

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**Item 6. Directors, Senior Management and Employees**

**A. Directors and Senior Management**

***Directors***

*Kyran McLaughlin (61)* was appointed a director of Elan in January 1998 and was appointed chairman of Elan in January 2005. He is deputy chairman and head of capital markets at Davy Stockbrokers, Ireland's largest stockbroker firm. He is also a director of Ryanair Holdings, plc and is a director of a number of private companies.

*Göran Ando, MD (57)* was appointed a director of Elan in May 2005. He was formerly executive vice president and president, R&D of Pharmacia (now Pfizer). He is a director of a number of public and private companies. Dr. Ando is a Specialist in General Medicine and a Founding Fellow of the American College of Rheumatology.

*Garo H. Armen, PhD (53)* was appointed a director of Elan in February 1994, and served as chairman of Elan from July 2002 until January 2005. He is Chairman and Chief Executive Officer of Antigenics Inc., the biotechnology company he co-founded with Pramod Srivastava in 1994. Dr. Armen also serves on the Board of Directors of Color Kinetics Incorporated, a company that designs, markets and licenses intelligent solid-state lighting systems. Dr. Armen is also the founder and President of the Children of Armenia Fund, a charitable organization established in 2000 that is dedicated to the positive development of the children and youth of Armenia.

*Shane Cooke (43)* was appointed a director of Elan in May 2005. He joined Elan as executive vice president and chief financial officer in July 2001. Prior to joining Elan, Mr. Cooke was chief executive of Pembroke Capital Limited, an aviation leasing company, and prior to that held a number of senior positions in finance in the banking and aviation industries. Mr. Cooke is a chartered accountant and a graduate of University College Dublin.

*Laurence G. Crowley (69)* was appointed a director of Elan in March 1996. He was governor (chairman) of the Bank of Ireland until his retirement in July 2005. He is presently chairman of PJ Carroll & Co. and is a director of a number of private companies.

*William F. Daniel (54)* was appointed a director of Elan in February 2003. He has served as the company secretary since December 2001, having joined Elan in March 1994 as group financial controller. In July 1996, he was appointed group vice president, finance, group controller and principal accounting officer. From 1990 to 1992, Mr. Daniel was financial director of Xtravision, plc. Mr. Daniel is a chartered accountant and a graduate of University College Dublin.

*Lars Ekman, MD, PhD (56)* was appointed a director of Elan in May 2005 and joined Elan as executive vice president and president, global R&D in 2001. Prior to joining Elan, he was EVP, R&D, at Schwarz Pharma AG since 1997. From 1984 to 1997, Dr. Ekman was employed in a variety of senior scientific and clinical functions at Pharmacia (now Pfizer). Dr. Ekman is a board certified surgeon with a PhD in experimental biology and has held several clinical and academic positions in both the United States and Europe. He obtained his PhD and MD from the University of Gothenburg, Sweden.

*Alan R. Gillespie, CBE, PhD (55)* was appointed a director of Elan in March 1996. He is chairman of Ulster Bank Limited and chairman of the International Finance Facility. From November 1999 until November 2002, he was chief executive officer of CDC Group, plc and was previously a managing director of Goldman Sachs International.

*Ann Maynard Gray (60)* was appointed a director of Elan in February 2001. She was formerly president of Diversified Publishing Group of Capital Cities/ABC, Inc. Ms. Gray is also a director of Duke Energy Corporation and The Phoenix Companies, Inc.

*Gary Kennedy (48)* was appointed a director of Elan in May 2005. From May 1997 to December 2005, he was Group Director, Finance & Enterprise Technology at Allied Irish Banks, plc (AIB) and a member of the main Board of AIB and was also on the Board of M&T, AIB's associate in the United States. Prior to that, Mr. Kennedy was group vice president at Nortel Networks Europe after starting his management career at Deloitte & Touche. He served on the Board of the Industrial Development Authority of Ireland for 10 years until he retired in December 2005. Currently as an independent business consultant, he is a member of the NUI Galway Development Board.

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*Nancy Lurker (48)* was appointed a director of Elan in May 2005. She has been chief executive officer and president of ImpactRX since 2003 and was previously group vice president, Global Prescription Business, at Pharmacia (now Pfizer). Ms. Lurker also served as a member of the Pharmacia Operating Committee.

*G. Kelly Martin (47)* was appointed a director of Elan in February 2003 following his appointment as president and chief executive officer. He was formerly president of the International Private Client Group and a member of the executive management and operating committee of Merrill Lynch & Co., Inc. He spent over 20 years at Merrill Lynch & Co., Inc. in a broad array of operating and executive responsibilities on a global basis.

*Kieran McGowan (62)* was appointed a director of Elan in December 1998. From 1990 until his retirement in December 1998, he was chief executive of the Industrial Development Authority of Ireland. He is chairman of the Governing Authority of University College Dublin and is a director of CRH, plc, Irish Life and Permanent, plc, United Drug, plc, Enterprise Ireland, and a number of private companies.

*Kevin M. McIntyre, MD (70)* was appointed a director of Elan in February 1984. He is an associate clinical professor of medicine at Harvard Medical School and has served as a consultant to the National Academy of Sciences.

*Dennis J. Selkoe, MD (62)* was appointed a director of Elan in July 1996, following our acquisition of Athena Neurosciences, where he served as a director since July 1995. Dr. Selkoe was a founder of, and consultant to, Athena Neurosciences. Dr. Selkoe, a neurologist, is a professor of neurology and neuroscience at Harvard Medical School. He also serves as co-director of the Center for Neurologic Disease at The Brigham and Women's Hospital.

Outside directors of Elan are compensated with fee payments and stock options (with additional payments where directors are members of board committees) and are reimbursed for travel expenses to and from board meetings.

***Senior Management***

*Paul Breen (49)* is executive vice president, EDT. He joined Elan in July 2001. Prior to joining Elan, he was vice president and joint managing director of Pfizer Pharmaceuticals Ireland. Prior thereto, he was vice president and managing director of Warner-Lambert Company's Irish operations. He is Chairman of the governing body of the Athlone Institute of Technology. Mr. Breen holds a degree in science and is a graduate of University College Dublin.

*Nigel Clerkin (32)* was appointed senior vice president, finance and group controller in January 2004, having previously held a number of financial and strategic planning positions since joining Elan in January 1998. He is also our principal accounting officer. Mr. Clerkin is a chartered accountant and a graduate of Queen's University Belfast.

*Richard Collier (52)* joined Elan as executive vice president and general counsel in November 2004. Prior to joining Elan, Mr. Collier was senior counsel at Morgan, Lewis & Bockius LLP. Prior to joining Morgan Lewis, he was senior vice president and general counsel at Pharmacia (now Pfizer), after serving in that same position at Pharmacia & Upjohn. Prior to his experience at Pharmacia, Mr. Collier spent 11 years at Rhone-Poulenc Rorer, Inc. Previously, he was in private practice after having served with the U.S. Federal Trade Commission and U.S. Department of Justice. Mr. Collier is a graduate of Temple University and also earned his Juris Doctor at Temple University.

*Allison Hulme, PhD (42)* was appointed executive vice president, autoimmune, *Tysabri*, global development, in January 2005. Previously, Dr. Hulme held the positions of executive vice president, *Tysabri* business enterprise, and senior vice president, head of global development. Prior to joining Elan in October 1995, Dr. Hulme held several positions in Clinical Research at Glaxo Wellcome Pharmaceuticals (United Kingdom) and served as Lecturer at Luton University. She holds a degree in science from Luton University and earned her PhD from Cranfield Institute of Technology.

*Karen S. Kim (43)* was appointed executive vice president, corporate strategy & alliances, communications, branding and specialty group, in January 2005. She joined Elan in September 2003 as senior vice president, head of global corporate strategy and strategic alliances. Prior to joining Elan, Ms. Kim held senior management positions at Merrill Lynch & Co., which she joined in 1998, and where she was most recently head of Client Development in the International Private Client Group. Previously she held senior management positions at the Cambridge Group and

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The MAC Group/Gemini Consulting. She is a graduate of Wellesley College and earned her MBA from the Harvard Graduate School of Business Administration.

*Ivan Lieberburg, MD, PhD (56)* is executive vice president and chief medical officer of Elan, where he has held a number of senior positions, most recently senior vice president of research. Prior to joining Athena Neurosciences in 1987, Dr. Lieberburg held faculty positions at the Albert Einstein College of Medicine and Mt. Sinai School of Medicine in New York. He received an AB from Cornell University and earned his PhD in Neurobiology from The Rockefeller University. Dr. Lieberburg was a Postdoctoral Fellow in Neurobiology at Rockefeller University. He earned his MD from the University of Miami. Dr. Lieberburg was a Research Endocrine Fellow at the University of California, San Francisco.

*Kathleen Martorano (44)* was appointed executive vice president, strategic human resources, and a member of the office of the chief executive officer, in January 2005. She joined Elan in May 2003 as senior vice president, corporate marketing & communications. Prior to joining Elan, Ms. Martorano held senior management positions at Merrill Lynch & Co., which she joined in 1996, and where she was most recently first vice president of Marketing and Communications for the International Private Client Group. Previously, she held senior management positions with Salomon Brothers. Ms. Martorano holds a Bachelor of Science degree from Villanova University.

*Dale Schenk, PhD (48)* was appointed senior vice president and Elan's chief scientific officer in June 2003. From 1999 to 2003, Dr. Schenk was senior vice president of discovery research at Elan, and from 1998 to 1999, he was the company's vice president of neurobiology. Previously, Dr. Schenk was director of neurobiology for Athena Neurosciences from 1994 to 1998. Earlier at Athena, from 1987 to 1994, Dr. Schenk served as the leader of several research programs. Dr. Schenk earned his Bachelor's degree in Biology from the University of California, San Diego and a PhD in Physiology and Pharmacology from the University of California, San Diego.

*Ted Yednock, PhD (48)* was appointed senior vice president, head of global research, in September 2005. Dr. Yednock joined Athena Neurosciences in 1990 to initiate work on MS. He has contributed to a number of research efforts since that time in the areas of both autoimmune and neurodegeneration, and has held a number of scientific and management positions within the organization. Most recently, Dr. Yednock served as vice president, biology. He earned his Bachelor's degree in Biology and Chemistry from the University of Illinois and his PhD in Immunology from the University of California, San Francisco.

Officers serve at the discretion of the board of directors. No director or officer has a family relationship with any other director or officer.

**B. Compensation**

***Executive Officers and Directors Remuneration***

For the year ended December 31, 2005, all executive officers and outside directors as a group (21 persons) received total compensation of \$8.5 million. We reimburse officers and outside directors for their actual business-related expenses. For the year ended December 31, 2005, an aggregate of \$0.2 million was accrued to provide pension, retirement and other similar benefits for directors and officers. We also maintain certain health and medical benefit plans for our employees in which our officers participate.

***Directors Remuneration***

**Year Ended December 31**

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<b>Executive Directors:</b>	<b>2005 Salary/Fees</b>	<b>2005 Annual Bonus</b>	<b>2005 Pension</b>	<b>2005 Benefit in Kind</b>	<b>2005 Total</b>	<b>2004 Total</b>
G. Kelly Martin	\$ 804,139	\$ 880,000	\$ 6,300	\$ 102,876	\$ 1,793,315	\$ 858,252 <sup>(1)</sup>
Shane Cooke <sup>(2)</sup>	357,900	390,605			748,505	
William Daniel	396,409	205,400	45,028	21,428	668,265	612,880
Lars Ekman, MD, PhD <sup>(2)</sup>	265,529	233,333	6,186	270,833 <sup>(3)</sup>	775,881	
<b>Total</b>	<b>\$ 1,823,977</b>	<b>\$ 1,709,338</b>	<b>\$ 57,514</b>	<b>\$ 395,137</b>	<b>\$ 3,985,966</b>	<b>\$ 1,471,132</b>

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- (1) On March 10, 2005, Mr. Martin waived his 2004 performance cash bonus, which would have been paid in 2005, in lieu of 200,000 shares of stock options. The options were granted with an estimated fair value of \$900,000 at an exercise price of \$7.47 per share. Mr. Martin also received an annual grant of 80,000 stock options on the same date. For additional information on directors' options, please refer to pages 73 and 74.
- (2) Appointed as director on May 26, 2005; and the remuneration has been pro-rated for the period from May 26, 2005 to December 31, 2005.
- (3) Includes \$240,000 for loan fully forgiven in December 2005. For additional information, please refer to Note 26 to the Consolidated Financial Statements.

	Year Ended December 31					
	2005	2005 Annual	2005	2005 Benefit in Kind	2005 Total	2004 Total
<b>Non-Executive Directors:</b>	<b>Fees</b>	<b>Bonus</b>	<b>Pension</b>			
Kyran McLaughlin	\$ 300,000	\$	\$	\$	\$ 300,000	\$ 96,250
Göran Ando, MD <sup>(2)</sup>	36,661				36,661	
Garo H. Armen, PhD	55,000				55,000	300,000
Brendan E. Boushel <sup>(1)</sup>	22,211				22,211	51,250
Laurence G. Crowley	68,802				68,802	76,250
Alan R. Gillespie, CBE PhD	67,500				67,500	63,750
Ann Maynard Gray	77,464				77,464	88,750
John Groom <sup>(1)</sup>	22,211		83,333		105,544	251,250
Gary Kennedy <sup>(2)</sup>	36,661				36,661	
Nancy Lurker <sup>(2)</sup>	36,661				36,661	
Kieran McGowan	82,333				82,333	76,250
Kevin M. McIntyre, MD	68,281				68,281	71,250
Dennis J. Selkoe, MD	97,916				97,916	51,250
Richard L. Thornburgh <sup>(1)</sup>	29,134				29,134	71,250
<b>Total</b>	<b>\$ 1,000,835</b>	<b>\$</b>	<b>\$ 83,333</b>	<b>\$</b>	<b>\$ 1,084,168</b>	<b>\$ 1,197,500</b>
Average number of non-executive directors					11	12

(1) Retired as director on May 26, 2005.

(2) Appointed as director on May 26, 2005.

On February 12, 2002, we entered into a consultancy agreement with Mr. Groom. Mr. Groom received \$200,000 in 2002 under this consultancy agreement. Effective July 1, 2003, the consultancy agreement was cancelled and we entered into a pension agreement of \$200,000 per annum payable to Mr. Groom until May 16, 2008.



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On May 20, 2004, EPI entered into a consultancy agreement with Dr. Selkoe. Dr. Selkoe is also a party to a consultancy agreement with Athena Neurosciences. Under consultancy agreements, Dr. Selkoe received \$25,000 in 2005 and \$76,200 in 2004.

<b>Payments to Former Directors:</b>	<b>2005</b>	<b>2004</b>
<i>Salaries:</i>		
Donal Geaney	\$	\$ 660,304
Thomas Lynch		459,615
		1,119,919
<i>Legal settlement:</i>		
Donal Geaney	4,375,000	
<i>Pensions:</i>		
John Groom	116,667	
Donald Panoz	26,667	160,000
Nancy Panoz	4,166	25,000
	147,500	185,000
Total	\$ 4,522,500	\$ 1,304,919

On July 9, 2002, the late Mr. Geaney and Mr. Lynch resigned as chairman and vice-chairman of the board, respectively, as well as from their respective positions as officers of Elan. Under the terms of the agreements, Mr. Geaney and Mr. Lynch continued as employees of Elan as senior advisers to the chairman until July 31, 2004 at their then current base salaries and were entitled to continue to receive the pension and other benefits to which they were then entitled. They were not entitled to any bonuses during that time.

On June 13, 2005, we settled an action taken by Mr. Geaney for a sum of 3.5 million Euros (\$4.4 million) plus an agreed sum of legal fees. For additional information, see Note 26 to the Consolidated Financial Statements.

**C. Board Practices*****The Board***

The roles of the chairman and chief executive officer (CEO) are separated. The chairman of the board is responsible for the leadership and management of the board. Our CEO is responsible for the operation of the business of the Company. Other significant commitments of the chairman are set out on page 64. These commitments did not change during 2005. Under our guidelines, two-thirds of the board is independent. The board currently includes ten independent, non-executive directors who constitute two-thirds of the board. We adopted a definition of independence based on the rules of the New York Stock Exchange (NYSE), the exchange on which the majority of our shares are traded.

The board regularly reviews its responsibilities and those of its committees and management. The board meets regularly throughout the year, and all of the directors have full and timely access to the information necessary to enable them to discharge their duties. All directors also have access to the advice and services of the Company

Secretary.

The board has reserved certain matters to its exclusive jurisdiction, thereby maintaining control of the Company and its future direction. All directors are appointed by the board, as nominated by its nominating committee, and subsequently elected by the shareholders. Procedures are in place where directors and committees, in furtherance of their duties, may take independent professional advice, if necessary, at our expense. The board held six scheduled meetings during 2005.

Our Guidelines require that the board will conduct a self-evaluation at least annually to determine whether it and its committees are functioning effectively. An evaluation of the performance of the board, the board

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committees, and individual directors was conducted during the year by the Lead Independent Director through meetings with each member of the board. The results were presented to the Nominating Committee and to the board. The board concluded that it and its committees had operated satisfactorily during the past year.

The board has delegated authority over certain areas of our activities to three standing committees, as more fully described below.

### ***Audit Committee***

The audit committee, composed entirely of non-executive directors, helps the board in its general oversight of our accounting and financial reporting practices, internal controls and audit functions, and is directly responsible for the appointment, compensation and oversight of the work of our independent auditors. The audit committee periodically reviews the effectiveness of the system of internal control. It monitors the adequacy of internal accounting practices, procedures and controls, and reviews all significant changes in accounting policies. The committee meets regularly with the internal and external auditors and addresses all issues raised and recommendations made by them. The members of the committee in 2005 were Dr. Gillespie (chairman), Mr. Kennedy (appointed September 9, 2005), Mr. McGowan and Ms. Gray, who was appointed to the audit committee on February 3, 2005, and served on the committee until Mr. Kennedy's appointment. Mr. Kennedy qualifies as an audit committee financial expert. The audit committee held seven formal meetings during 2005. For additional information on the audit committee, please refer to Item 16A. Audit Committee Financial Expert and Item 16C. Audit Committee.

As part of our code of conduct, we have put in place a confidential email and telephone hot-line to allow employees to report potential violations of laws, rules, regulations or ethical standards. The audit committee reviews these arrangements, and the investigation and follow-up of any reported matters.

### ***Leadership Development and Compensation Committee***

The leadership, development and compensation committee (LDCC), composed entirely of non-executive directors, reviews our compensation philosophy and policies with respect to executive compensation, fringe benefits and other compensation matters. The committee determines the compensation of the chief executive officer and other executive directors and reviews the compensation of the other members of the executive management. The members of the committee are Dr. Selkoe (chairman), Dr. Ando (appointed September 9, 2005), Mr. Crowley, Ms. Lurker (appointed September 9, 2005) and Dr. McIntyre. The committee held six meetings during 2005.

### ***Nominating Committee***

The nominating committee, composed entirely of non-executive directors, reviews on an ongoing basis the membership of the board of directors and of the board committees and the performance of the directors. It recommends new appointments to fill any vacancy that is anticipated or arises on the board of directors. The committee reviews and recommends changes in the functions of the various committees of the board. The Guidelines and the charter of the committee set out the manner in which the performance evaluation of the board, its committees and the directors is to be performed and by whom. The members of the committees are Mr. McGowan (Chairman and Lead Independent Director), Ms. Gray and Mr. McLaughlin. The committee held four meetings during 2005.

**Table of Contents****Board and Board Committee Meetings**

The number of scheduled board and board committee meetings held and attended by each director during the year was as follows:

	<b>Board</b>	<b>Audit Committee</b>	<b>LDCC</b>	<b>Nominating Committee</b>
Kyran McLaughlin	6/6			4/4
Göran Ando, MD <sup>(2)</sup>	2/2		0/1	
Garo H. Armen, PhD	6/6			
Brendan E. Boushel <sup>(1)</sup>	2/3			
Shane Cooke	2/2			
Laurence G. Crowley	5/6		6/6	
William F. Daniel	6/6	7/7 <sup>(3)</sup>	6/6 <sup>(3)</sup>	4/4 <sup>(3)</sup>
Lars Ekman, MD, PhD	2/2			
Alan R. Gillespie, CBE PhD	5/6	7/7		
Ann Maynard Gray	5/6	3/3		4/4
John Groom <sup>(1)</sup>	3/3			
Gary Kennedy <sup>(2)</sup>	2/2	3/3		
Nancy Lurker <sup>(2)</sup>	2/2		1/1	
G. Kelly Martin	6/6			
Kieran McGowan	6/6	6/7		4/4
Kevin M. McIntyre, MD	6/6		6/6	
Dennis J. Selkoe, MD	6/6		6/6	
Richard L. Thornburgh <sup>(1)</sup>	3/3			

<sup>(1)</sup> Retired as director on May 26, 2005.

<sup>(2)</sup> Appointed as director on May 26, 2005.

<sup>(3)</sup> William Daniel was secretary on these committees.

**Relations with Shareholders**

We communicate regularly with our shareholders throughout the year, specifically following the release of quarterly and annual results, and after major developments. Our general meetings and analyst briefings are webcast and are available on our website (www.elan.com). All shareholders are given adequate notice of the annual meeting. The board periodically receives a presentation by external advisers on investor perceptions and external brokers' reports are circulated to all directors. All directors normally attend the Annual General Meeting and shareholders are invited to ask questions during the meeting and to meet with directors after the formal proceedings have ended.

**Internal Control**

The board of directors has overall responsibility for our system of internal control and for monitoring its effectiveness. The system of internal control is designed to provide reasonable, but not absolute, assurance against material misstatement or loss. The key procedures that have been established to provide effective internal control include:

A clear focus on business objectives is set by the board having considered the risk profile of Elan;

A formalized risk reporting system. Significant business risks are addressed at each board meeting;

A clearly defined organizational structure under the day-to-day direction of our chief executive officer. Defined lines of responsibility and delegation of authority have been established within which our activities are planned, executed, controlled and monitored to achieve the strategic objectives which the board has adopted for us;

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A comprehensive system for reporting financial results to the board. This includes a budgeting system with an annual budget approved by the board;

A system of management and financial reporting, treasury management and project appraisal the system of reporting covers trading activities, operational issues, financial performance, working capital, cash flow and asset management; and

To support our system of internal control, we have separate Corporate Compliance, Internal Audit and Internal Control Departments. Each of these departments report periodically to the Audit Committee. The Internal Control function, which was established at the beginning of 2004, is primarily responsible for the Company's compliance with Section 404 of the Sarbanes-Oxley Act 2002. Our Internal Audit function was re-established in the latter part of 2005 and is now fully coordinated with the other control functions outlined above.

The directors reviewed our system of internal control and also examined the full range of risks affecting us and the appropriateness of the internal control structures to manage and monitor these risks. This process involved a confirmation that appropriate systems of internal control were in place throughout the financial year and up to the date of signing of these financial statements. It also involved an assessment of the ongoing process for the identification, management and control of the individual risks and of the role of the various risk management functions and the extent to which areas of significant challenges facing us are understood and are being addressed. No material unaddressed issues emerged from this assessment. The directors confirm that they have reviewed, in accordance with the Turnbull Guidance, the effectiveness of our systems of internal control for the year ended December 31, 2005. Section 404 of the Sarbanes-Oxley Act will require that our Annual Report on Form 20-F for the year ending December 31, 2006 contain a report stating that it is the responsibility of management to establish and maintain adequate internal control over financial reporting and assessing the effectiveness of our internal control over financial reporting. Although we are not required to report compliance in this 2005 Form 20-F, management has undertaken a process to be in a position to comply with the mandates of Section 404 of the Sarbanes-Oxley Act by December 31, 2006.

### ***Going Concern***

The directors, having made inquiries, believe that we have adequate resources to continue in operational existence for at least the next twelve months and that it is appropriate to continue to adopt the going concern basis in preparing our Consolidated Financial Statements.

### ***Report of the Leadership Development and Compensation Committee***

The terms of reference for the committee are to determine the compensation, terms and conditions of employment of the chief executive officer and other executive directors and to review the recommendations of the chief executive officer with respect to the remuneration and terms and conditions of employment of our senior management. The committee also exercises all the powers of the board of directors to issue Ordinary Shares on the exercise of stock options and to generally administer our stock option plans.

Each member of the committee is nominated to serve for a three-year term subject to a maximum of two terms of continuous service.

### ***Remuneration Policy***

Our policy on executive directors' remuneration is to set remuneration levels that are appropriate for our senior executives having regard to their substantial responsibilities, their individual performance and our performance as a whole. The committee sets remuneration levels after reviewing remuneration packages of executives in the pharmaceutical industry. The committee takes external advice from independent benefit consultants and considers Section B of the Code of Best Practice of The Combined Code as issued by the London and Irish Stock Exchanges.

The typical elements of the remuneration package for executive directors include basic salary and benefits, annual cash incentive bonus, pensions and participation in equity award plans.

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The committee grants equity awards to encourage identification with shareholders' interests and to link performance to the long-term share price performance of Elan.

### *Executive Directors' Basic Salary*

The basic salaries of executive directors are reviewed annually having regard to personal performance, company performance and market practice.

### *Annual Cash Incentive Bonus*

An annual cash incentive bonus, which is not pensionable, is paid on the recommendation of the committee to executive directors. Bonus determination is not based on specific financial or operational targets, but on individual and company performance.

### *Stock Option Plans*

It is the committee's policy, in common with other companies operating in the pharmaceutical industry, to award stock options to management and employees. The options generally vest between one and four years. These plans do not contain any performance conditions.

### *Restricted Stock Units*

In June 2004, our shareholders and board of directors approved a Restricted Stock Unit Plan (RSU Plan). The first grants under the RSU Plan were made by the committee in February 2006. The grants vest between one and four years and do not contain any performance conditions.

### *Employee Equity Purchase Plans*

In June 2004, our shareholders approved a qualified Employee Equity Purchase Plan (U.S. Purchase Plan), under Sections 421 and 423 of the Internal Revenue Code (IRC), which became effective on January 1, 2005 for eligible employees based in the United States. The plan allows eligible employees to purchase common stock at 85% of the lower of the fair market value at the start of the offering period or the fair market value on the last trading day of the offering period. Purchases are limited to \$25,000 per calendar year, 1,000 shares per offering period, and subject to certain IRC restrictions.

The board of directors approved the Irish Sharesave Option Scheme 2004 and U.K. Sharesave Option Plan 2004, effective January 1, 2005, for employees based in Ireland and the United Kingdom, respectively (the Irish/U.K. Sharesave Plans). In total, 1,500,000 shares were reserved for issuance under the Irish/U.K. Sharesave Plans and U.S. Purchase Plan combined. The Irish/U.K. Sharesave Plans allow eligible employees to purchase shares at no lower than 85% of the fair market value at the start of the thirty-six month saving period. The plan allows eligible employees to save up to 320 Euro per month under the Irish Scheme or 250 pounds Sterling under the U.K. Plan and they may purchase shares anytime within six months after the end of the saving period.

In 2005, 542,429 shares were issued under the U.S. Purchase Plan (2004: Nil) and as of December 31, 2005, 957,571 shares (2004: 1,500,000 shares) were reserved for future issuance under the U.S. Purchase Plan and Irish/U.K. Sharesave Plans.

## **D. Employees**

See Item 4.B Business Overview Employees for information on our employees.

**Table of Contents****E. Share Ownership****Directors Ordinary Shares**

The beneficial interests of those persons who were directors and the secretary of Elan Corporation, plc at December 31, 2005, including their spouses and children under eighteen years of age, were as follows:

	<b>Ordinary Shares; Par Value 5 Euro Cents Each</b>	
	<b>2005</b>	<b>2004</b>
Kyran McLaughlin	150,000	
Göran Ando, MD	1,500	
Garo H. Armen, PhD	270,000	270,000
Shane Cooke	250,000	
Laurence G. Crowley	12,000	12,000
William F. Daniel	50,000	50,000
Lars Ekman, MD, PhD	30,100	12,100
Alan R. Gillespie, CBE PhD	132,000	132,000
Ann Maynard Gray	3,500	3,500
Gary Kennedy	2,800	
Nancy Lurker		
G. Kelly Martin	257,500	257,500
Kieran McGowan	1,200	1,200
Kevin M. McIntyre, MD	179,356	179,356
Dennis J. Selkoe, MD	163,175	163,175

**Directors Options**

	<b>At</b>				<b>Weighted Average Market Price of Shares at Exercise Date</b>	<b>At</b>		<b>Weighted Average Exercise Price</b>
	<b>December 31,</b>					<b>December 31,</b>		
	<b>2004</b>	<b>Granted</b>	<b>Expired</b>	<b>Exercised</b>	<b>Date</b>	<b>2005</b>		
Kyran McLaughlin	55,000	7,500				62,500	\$ 19.83	
Göran Ando, MD		15,000				15,000	\$ 8.05	
Garo H. Armen, PhD	1,075,000		10,000	200,000	\$ 8.12	865,000	\$ 4.10	
Shane Cooke	640,500	210,000	227,500	413,000	\$ 8.20	210,000	\$ 7.28	
Laurence G. Crowley	65,000	7,500	10,000			62,500	\$ 19.83	
William F. Daniel	356,705	50,000				406,705	\$ 16.18	
	635,000	60,000				695,000	\$ 13.29	

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Lars Ekman, MD, PhD					
Alan R. Gillespie, CBE PhD	65,000	7,500	10,000	62,500	\$ 19.83
Ann Maynard Gray	45,000	7,500		52,500	\$ 18.69
Gary Kennedy		15,000		15,000	\$ 8.05
Nancy Lurker		15,000		15,000	\$ 8.05
G. Kelly Martin	2,060,000	1,030,000		3,090,000	\$ 6.87
Kieran McGowan	55,000	7,500		62,500	\$ 19.83
Kevin M. McIntyre, MD	65,000	7,500	10,000	62,500	\$ 19.83
Dennis J. Selkoe, MD	65,000	7,500	10,000	62,500	\$ 19.83

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Options outstanding at December 31, 2005 are exercisable at various dates between January 2006 and December 2015. During the year ended December 31, 2005, the closing market price ranged from \$3.24 to \$29.00 per ADS. The closing market price at March 17, 2006, on the NYSE of our ADSs was \$15.01.

The following changes in directors' interests occurred between December 31, 2005 and March 17, 2006:

	<b>Grant Date</b>	<b>Price</b>	<b>Options</b>	<b>Restricted Stock Units</b>
Kyran McLaughlin	February 1, 2006	\$ 15.90	10,000	
Göran Ando, MD	February 1, 2006	15.90	10,000	
Garó H. Armen, PhD	February 1, 2006	15.90	10,000	
Shane Cooke	February 1, 2006	15.90	63,899	12,579
Laurence G. Crowley	February 1, 2006	15.90	10,000	
William F. Daniel	February 1, 2006	15.90	47,925	9,434
Lars Ekman, MD, PhD	February 1, 2006	15.90	127,799	25,157
Alan R. Gillespie, CBE PhD	February 1, 2006	15.90	10,000	
Ann Maynard Gray	February 1, 2006	15.90	10,000	
Gary Kennedy	February 1, 2006	15.90	10,000	
Nancy Lurker	February 1, 2006	15.90	10,000	
Kieran McGowan	February 1, 2006	15.90	10,000	
Kevin M. McIntyre, MD	February 1, 2006	15.90	10,000	
Dennis Selkoe, MD	February 1, 2006	15.90	10,000	

	<b>Date</b>	<b>Options Exercised</b>	<b>ADR Purchased</b>	<b>ADR Sold</b>
Nancy Lurker	February 2, 2006		2,810	
Garó H. Armen, PhD	February 2, 2006			250,000
Garó H. Armen, PhD	February 6, 2006	250,000		
Kyran McLaughlin	February 6, 2006		40,000	
Alan R. Gillespie, CBE PhD	February 10, 2006		200,000	
Lars Ekman, MD, PhD	March 8, 2006	30,000		30,000

**Item 7. Major Shareholders and Related Party Transactions.****A. Major Shareholders**

The following table sets forth certain information regarding the beneficial ownership of Ordinary Shares or American Depository Shares at March 17, 2006 by major shareholders (based solely upon information disclosed to us in accordance with Section 67 of the Companies Act, 1990 and public filings) and all of our directors and officers as a group (either directly or by virtue of ownership of our ADSs):

<b>No. of</b>	<b>Percent of</b>
---------------	-------------------

<b>Name of Owner or Identity of Group</b>	<b>Shares</b>	<b>Date of Disclosure<sup>(1)</sup></b>	<b>Class<sup>(2)</sup></b>
Susquehanna International Group, LLP	22,310,489	February 14, 2006	5.1%
Fidelity Management and Research Company	21,963,200	March 17, 2006	5.1%
All directors and officers as a group (18 persons)	6,201,191 <sup>(3)</sup>		1.4%

*(1) Since the date of disclosure to the Company, the interest of any person listed above in the Ordinary Shares of the Company may have increased or decreased. No requirement to notify the Company of any change would have arisen unless the holding moved up or down through a whole number percentage level.*

*(2) Based on 429.8 million Ordinary Shares outstanding on March 17, 2006 and 4.4 million Ordinary Shares issuable upon the exercise of currently exercisable options held by directors and officers as a group as of March 17, 2006.*

*(3) Includes 4.4 million Ordinary Shares issuable upon exercise of currently exercisable options held by directors and officers as a group as of March 17, 2006.*

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Except for these interests, we have not been notified at March 17, 2006 of any interest of 3% or more of our issued share capital. Neither Susquehanna International Group, LLC or Fidelity Management and Research Company has voting rights different from other shareholders.

We, to our knowledge, are not directly or indirectly owned or controlled by another entity or by any government. We do not know of any arrangements, the operation of which might result in a change of control of us.

A total of 429,790,036 Ordinary Shares of Elan were issued and outstanding at March 17, 2006, of which 6,154 Ordinary Shares were held by holders of record in the United States, excluding shares held in the form of ADRs. 366,843,391 Ordinary Shares were represented by our ADSs, evidenced by ADRs, issued by The Bank of New York, as depositary, pursuant to a deposit agreement. At March 17, 2006, the number of holders of record of Ordinary Shares was 13,128, which includes 17 holders of record in the United States, and the number of registered holders of ADRs in the United States was 3,630. Because certain of these Ordinary Shares and ADRs were held by brokers or other nominees, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

**B. Related Party Transactions**

There were no significant transactions with related parties during the year ended December 31, 2005 other than as outlined in Note 26 to the Consolidated Financial Statements.

***Transactions with Directors and Executive Officers***

Except as set out below, there are no service contracts in existence between any of the directors and Elan:

On July 1, 2003, we entered into a pension agreement with Mr. John Groom, a former director of Elan Corporation, plc, whereby we shall pay him a pension of \$200,000 per annum, monthly in arrears, until May 16, 2008 in respect of his former senior executive roles.

On January 7, 2003, we and EPI entered into an agreement with Mr. G. Kelly Martin such that Mr. Martin was appointed president and chief executive officer effective February 3, 2003. Mr. Martin was granted an initial option to purchase 1,000,000 Ordinary Shares with an exercise price of \$3.85 and vesting in three equal installments on December 31, 2003, December 31, 2004 and December 31, 2005. In accordance with the terms of his contract, in October 2003, Mr. Martin was granted an additional option to purchase 1,000,000 Ordinary Shares with an exercise price of \$5.28, equal to the fair market value of the shares on the date of grant, vesting on the same basis and dates as the initial option grant.

Mr. Martin has received additional option grants consistent with our annual option grant practices.

Effective December 3, 2004, Mr. Martin's employment agreement was amended to modify the benefits to be received by Mr. Martin in the event of an involuntary termination, extend severance payments to three years (from two) in the event of an involuntary termination following a change in control, modify the indemnification provisions of the employment agreement, and add an attorneys' fees provision.

Effective December 7, 2005, we and EPI entered into a new employment agreement with Mr. Martin, under which Mr. Martin continues to serve as our president and chief executive officer with an initial base annual salary of \$798,000. Mr. Martin is eligible to participate in our annual bonus plan, performance based stock awards and merit award plans. Under the new agreement, Mr. Martin was granted an option to purchase 750,000 Ordinary Shares with

an exercise price per share of \$12.03, vesting in three equal annual installments (2005 Options).

The agreement continues until Mr. Martin resigns, is involuntarily terminated, is terminated for cause or dies, or is disabled.

In general, if Mr. Martin's employment is involuntarily terminated (other than for cause, death or disability) or Mr. Martin leaves for good reason, we will pay Mr. Martin a lump sum equal to two (three, in the event of a change in control) times his salary and target bonus and his 2005 options will vest and be exercisable for the following two years (three, in the event of a change in control).

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In the event of such an involuntary termination (other than as the result of a change in control), Mr. Martin will, for a period of two years (three years in the event of a change in control), or until Mr. Martin obtains other employment, continue to participate in our health and medical plans or we shall pay him a lump sum equal to the present value of the cost of such coverage and we shall pay Mr. Martin a lump sum of \$50,000 to cover other costs and expenses. Mr. Martin will also be entitled to career transition assistance and the use of an office and the services of a full time secretary for a reasonable period of time not to exceed two years (three years in the event of a change in control).

In addition, if it is determined that any payment or distribution to Mr. Martin would be subject to excise tax under Section 4999 of the U.S. Internal Revenue Code, or any interest or penalties are incurred by Mr. Martin with respect to such excise tax, then Mr. Martin shall be entitled to an additional payment in an amount such that after payment by Mr. Martin of all taxes on such additional payment, Mr. Martin retains an amount of such additional payment equal to such excise tax amount.

The agreement also obligates us to indemnify Mr. Martin if he is sued or threatened with suit as the result of serving as our officer or director. We will be obligated to pay Mr. Martin's attorney's fees if he has to bring an action to enforce any of his rights under the employment agreement.

Mr. Martin is eligible to participate in the pension, medical, disability and life insurance plans applicable to senior executives in accordance with the terms of those plans. He may also receive financial planning and tax support and advice from the provider of his choice at a reasonable and customary annual cost.

On July 1, 1986, Athena Neurosciences entered into a consultancy agreement with Dr. Dennis J. Selkoe, whereby Dr. Selkoe agreed to provide certain consultancy services in the field of Alzheimer's disease for a fee to be fixed annually, together with the reimbursement of all reasonable travel and other expenses incurred. The consultancy agreement renews automatically, unless notice of termination is provided 60 days prior to the anniversary date. No such notice has been provided.

On May 20, 2004, EPI entered into a consultancy agreement with Dr. Selkoe whereby Dr. Selkoe agreed to provide review and advice on the merit of our research and development programs, with payments not to exceed \$10,000 in the aggregate over the terms of the agreement, which is to expire in 2007.

Dr. Lars Ekman had a forgivable loan from Elan which amounted to \$240,000 at May 26, 2005. This loan was fully forgiven at the end of December 2005.

Mr. Paul Breen has a forgivable loan from Elan that he received on May 29, 2001. During 2005 there was \$31,700 outstanding under the loan, of which \$15,850 was forgiven. The remaining \$15,850 outstanding under the loan will be forgiven on July 1, 2006 if Mr. Breen remains an employee of Elan through that date. The loan does not bear interest.

In relation to Dr. Garo Armen's retirement from the board, we have agreed to vest on his retirement 25,000 options that would otherwise have expired unvested on his retirement date, and have extended the exercise term of 50,000 options from ninety days to one year post-retirement.

**C. Interest of Experts and Counsel**

Not applicable.

**Item 8. *Financial Information.***

**A. Consolidated Statements and Other Financial Information**

See item 18.

**B. Significant Changes**

None.

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**Item 9. *The Offer and Listing.***

**A. Offer and Listing Details**

See item 9C.

**B. Plan of Distribution**

Not applicable.

**C. Markets**

The principal trading markets for our Ordinary Shares are the Irish Stock Exchange and the London Stock Exchange. Our ADSs, each representing one Ordinary Share and evidenced by one American Depositary Receipt (ADR), are traded on the NYSE under the symbol `ELN`. The ADR depository is The Bank of New York.

Our corporate governance practices do not differ in any significant way from those required of domestic companies under NYSE listing standards. A comparison of NYSE and Elan corporate governance standards is available on our website at [www.elan.com](http://www.elan.com).

In accordance with Section 303A.12(a) of the NYSE Listed Company Manual, the Chief Executive Officer of the Company submits annual certifications to the NYSE stating that he is not aware of any violations by the Company of the NYSE corporate governance listing standards, qualifying the certification to the extent necessary. The last such annual certification was submitted on August 29, 2005.

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The following table sets forth the high and low sales prices of the Ordinary Shares during the periods indicated, based upon mid-market prices at close of business on the Irish Stock Exchange and the high and low sales prices of the ADSs, as reported in published financial sources:

	<b>0.05 Ordinary Shares</b>		<b>American Depository Shares<sup>(1)</sup></b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
	<b>( )</b>		<b>(\$)</b>	
<b>Year ended December 31</b>				
2001	73.80	44.60	65.00	39.35
2002	50.27	1.23	45.18	1.03
2003	7.25	2.33	9.02	2.25
2004	23.80	5.40	30.09	7.06
2005	22.25	2.42	29.00	3.24
<b>Calendar Year</b>				
2004				
Quarter 1	16.70	5.40	20.62	7.06
Quarter 2	20.89	16.60	24.74	19.70
Quarter 3	20.62	13.40	25.39	17.14
Quarter 4	23.80	17.00	30.09	20.53
2005				
Quarter 1	22.25	2.42	29.00	3.24
Quarter 2	6.42	2.64	8.05	3.38
Quarter 3	7.40	5.46	9.25	6.77
Quarter 4	11.54	6.47	14.23	7.70
<b>Month Ended</b>				
September 2005	7.40	6.40	9.25	7.80
October 2005	7.35	6.47	8.42	7.70
November 2005	9.25	6.87	10.96	8.32
December 2005	11.54	8.55	14.23	10.30
January 2006	13.49	11.12	16.78	13.66
February 2006	12.85	11.11	15.90	12.70

<sup>(1)</sup> An American Depository Share represents one Ordinary Share, par value 5 Euro cents.

In connection with the acquisition of Dura Pharmaceuticals, Inc., we acquired warrants to purchase the Company ADSs, trading on Nasdaq under the symbols ELANZ (Z-Series Warrants), formerly traded under the symbol DURAZ, and ELANW (W-Series Warrants), formerly traded under the symbol DURAW. Each Z-Series Warrant was exercisable for 0.1276 of an ADS at an exercise price of \$26.72 per ADS. The Z-Series warrants expired on August 31, 2005. Each W-Series Warrant was exercisable for 0.1679 of an ADS at an exercise price of \$81.67 per ADS. The W-Series Warrants expired on December 31, 2002.

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The table on the following page sets forth the high and low sales prices for Z-Series Warrants for the periods indicated as reported in published financial sources.

	<b>Z-Series</b>	
	<b>High</b>	<b>Low</b>
	<b>\$</b>	<b>\$</b>
2004		
Quarter 1	2.15	0.19
Quarter 2	1.15	0.58
Quarter 3	0.94	0.43
Quarter 4	0.99	0.50
2005		
Quarter 1	0.75	0.17
Quarter 2	0.21	0.07
Quarter 3 <sup>(1)</sup>	0.16	0.03

<sup>(1)</sup> Expired on August 31, 2005

**D. Selling Shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the Issue**

Not applicable.

**Item 10. Additional Information.****A. Share Capital**

Not applicable.

**B. Memorandum and Articles of Association****Objects**

Our objects, which are detailed in its Memorandum of Association include, but are not limited to, manufacturing, buying, selling and distributing pharmaceutical products.

**Directors**

Subject to certain limited exceptions, directors may not vote on matters in which they have a material interest. In the absence of an independent quorum, the directors may not vote compensation to themselves or any member of the board of directors. Directors are entitled to remuneration as shall, from time to time, be voted to them by ordinary resolution of the shareholders and to be paid such expenses as may be incurred by them in the course of the performance of their duties as directors. Directors who take on additional committee assignments or otherwise perform additional services for us, outside the scope of their ordinary duties as directors, shall be entitled to receive such additional remuneration as the board may determine. The directors may exercise all of the powers of Elan to borrow money. These powers may be amended by special resolution of the shareholders. There is no requirement for a director to hold shares.

Under the terms of our Articles of Association, one-third of the directors or, if their number is not a multiple of three, then the number nearest to one-third shall retire from office at each Annual General Meeting. The effect of

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this provision is that each of our directors retires no less than every third year and, occasionally, after two years. Directors are not required to retire at any set age and may offer themselves for re-election at any Annual General Meeting where they are deemed to have retired by rotation.

In accordance with our Articles of Association, Dr. Armen, Mr. Crowley, Mr. Daniel, Mr. Martin and Dr. McIntyre will retire at the 2006 Annual General Meeting. Mr. Crowley, Mr. Daniel and Mr. Martin, being eligible, offer themselves for re-election. Dr. Armen and Dr. McIntyre will not be seeking re-election and so will be retiring from the board effective from the conclusion of the 2006 Annual General Meeting.

### ***Meetings***

The Annual General Meeting shall be held in such place and at such time as shall be determined by the board, but no more than 15 months shall pass between the dates of consecutive Annual General Meetings. Directors may call Extraordinary General Meetings at any time. The members, in accordance with our Articles of Association and Irish company law, may also requisition extraordinary General Meetings. Notice of an Annual General Meeting (or any special resolution) must be given at least 21 clear days prior to the scheduled date and, in the case of any other general meeting, with not less than 14 clear days notice.

### ***Rights, Preferences and Dividends Attaching to Shares***

All unclaimed dividends may be invested or otherwise made use of by the directors for the benefit of Elan until claimed. All shareholders entitled to attend and vote at the Annual General Meeting are likewise entitled to vote on the re-election of directors. We are permitted under our Memorandum and Articles of Association to issue redeemable shares on such terms and in such manner as the shareholders may determine by special resolution. The liability of the shareholders to further capital calls is limited to the amounts remaining unpaid on shares.

### ***Liquidation Rights***

In the event of the Company being wound up, the liquidator may, with the authority of a special resolution, divide among the holders of Ordinary Shares the whole or any part of the net assets of the company (after the return of capital on the non-voting Executive shares), and may set such values as he deems fair upon each kind of property to be so divided and determine how such division will be carried out.

### ***Actions Necessary to Change the Rights of Shareholders***

The rights attaching to the different classes of shares may be varied by special resolution passed at a class meeting of that class of shareholders. The additional issuance of further shares ranking *pari passu* with, or subordinate to, an existing class shall not, unless specified by the Articles or the conditions of issue of that class of shares, be deemed to be a variation of the special rights attaching to that class of shares.

### ***Limitations on the Right to Own Shares***

There are no limitations on the right to own shares in the Memorandum and Articles of Association. However, there are some restrictions on financial transfers between Ireland and other specified countries, more particularly described in the section on Exchange Controls and Other Limitations Affecting Security Holders .

### ***Other Provisions of the Memorandum and Articles of Association***

There are no provisions in the Memorandum and Articles of Association:

Delaying or prohibiting a change in control of Elan that operate only with respect to a merger, acquisition or corporate restructuring;

Discriminating against any existing or prospective holder of shares as a result of such shareholder owning a substantial number of shares; or

Governing changes in capital, where such provisions are more stringent than those required by law.

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We incorporate by reference all other information concerning our Memorandum and Articles of Association from the section entitled "Description of Ordinary Shares" in the Registration Statement on Form 8-A/A3 (SEC File No. 001-13896) we filed with the SEC on December 6, 2004.

**C. Material Contracts*****Indenture***

Indentures governing the 7.75% Notes, the Floating Rate Notes, and the Athena Notes contain covenants that restrict or prohibit our ability to engage in or enter into a variety of transactions. These restrictions and prohibitions could have a material and adverse effect on us. For additional information with respect to the restrictive covenants contained in our indentures, see Note 14 to the Consolidated Financial Statements.

***Development and Marketing Collaboration Agreement with Biogen Idec***

In August 2000, we entered into a development and marketing collaboration agreement with Biogen Idec, successor to Biogen, Inc., to collaborate in the development and commercialization of *Tysabri*. Along with Biogen Idec, we are developing *Tysabri* for MS and Crohn's disease, with Biogen Idec acting as the lead party for MS and Elan acting as the lead party for Crohn's disease.

In November 2004, *Tysabri* received regulatory approval in the United States for the treatment of relapsing forms of MS. Biogen Idec paid us a \$7.0 million approval-based milestone. The approval milestone payment, together with other milestone payments related to the collaboration agreement of \$45.0 million, are recognized as revenue based on the percentage-of-completion method, which is based on the percentage of costs incurred to date compared to the total costs expected under the contract.

Biogen Idec manufactures *Tysabri*. We purchase *Tysabri* from Biogen Idec for distribution to third parties in the United States. We recorded \$11.0 million in product revenue from *Tysabri* in 2005 (2004: \$6.4 million). In general, we share with Biogen Idec most development and commercialization costs. At December 31, 2005, we owed Biogen Idec \$21.4 million (2004: \$34.4 million) for the reimbursement of costs related to development and commercialization.

In February 2005, Elan and Biogen Idec voluntarily suspended the marketing and dosing in clinical trials of *Tysabri*. This decision was based on reports of two serious adverse events, one of which was fatal, in patients treated with *Tysabri* in combination with Avonex in clinical trials. These events involved two cases of PML, a rare and potentially fatal, demyelinating disease of the central nervous system. Both patients received more than two years of *Tysabri* therapy in combination with Avonex. In March 2005, the companies announced that their ongoing safety evaluation of *Tysabri* led to a previously diagnosed case of malignant astrocytoma being reassessed as PML, in a patient in an open label Crohn's disease clinical trial. The patient had received eight doses of *Tysabri* over an 18-month period. The patient died in December 2003.

Elan and Biogen Idec performed a comprehensive safety evaluation of more than 3,000 *Tysabri* patients in collaboration with leading experts in PML and neurology. The results of the safety evaluation yielded no new confirmed cases of PML beyond the three previously reported.

In September 2005, Elan and Biogen Idec submitted to the FDA an sBLA for *Tysabri*, which the FDA subsequently designated for Priority Review. On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. On March 21,

2006, we and Biogen Idec were informed by the FDA that the agency would extend its regulatory review of *Tysabri* by up to 90 days in order to complete a full review of the *Tysabri* risk management plan. Under the revised timeline, we anticipate an action from the FDA about the reintroduction of *Tysabri* as a treatment for relapsing forms of MS on or before June 28, 2006.

**Table of Contents*****Wyeth Collaboration Agreement***

Under our collaboration agreement with Wyeth, we are developing amyloid immunotherapies to attempt to treat Alzheimer's disease. See Item 4. B Business Overview for additional information regarding our Wyeth collaboration.

**D. Exchange Controls**

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of Ireland dealing in domestic securities, which includes shares or depositary receipts of Irish companies such as us. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to make provision for the restriction of financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the EU. The acquisition or disposal of ADSs or ADRs representing shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and Associated Persons, Burma/Myanmar, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, Osama bin Laden, Al-Qaida and the Taliban of Afghanistan, Democratic Republic of Congo, Iraq, Côte d'Ivoire, Liberia, Zimbabwe, Uzbekistan, Sudan, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, an ADS involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. We do not anticipate that orders under the Financial Transfers Act, 1992, or United Nations sanctions implemented into Irish law will have a material effect on our business.

**E. Taxation**

The following is a general description of Irish taxation inclusive of certain Irish tax consequences to U.S. Holders (as defined below) of the purchase, ownership and disposition of ADSs or Ordinary Shares. As used herein, references to the Ordinary Shares include ADSs representing such Ordinary Shares, unless the tax treatment of the ADSs and Ordinary Shares has been specifically differentiated. This description is for general information purposes only and does not purport to be a comprehensive description of all the Irish tax considerations that may be relevant in a U.S. Holder's decision to purchase, hold or dispose of Ordinary Shares of us. It is based on the various Irish Taxation Acts, all as in effect on March 17, 2006 and all of which are subject to change (possibly on a retroactive basis). The Irish tax treatment of a U.S. Holder of Ordinary Shares may vary depending upon such holder's particular situation, and holders or prospective purchasers of Ordinary Shares are advised to consult their own tax advisors as to the Irish or other tax consequences of the purchase, ownership and disposition of Ordinary Shares.

For the purposes of this tax description, a U.S. Holder is a holder of Ordinary Shares that is: (i) a citizen or resident of the United States; (ii) a corporation or partnership created or organized in or under the laws of the United States or of any political subdivision thereof; (iii) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust, if a U.S. court is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust.

***Taxation of Corporate Income***

We are a public limited company incorporated, and resident for tax purposes, in Ireland. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. The Taxes Consolidation Act, 1997, provides

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that a company that is resident in Ireland and is not resident elsewhere shall be entitled to have any income from a qualifying patent disregarded for taxation purposes. The legislation does not provide a termination date for this relief. A qualifying patent means a patent in relation to which the research, planning, processing, experimenting, testing, devising, designing, developing or similar activities leading to the invention that is the subject of the patent were carried out in Ireland. Income from a qualifying patent means any royalty or other sum paid in respect of the use of the invention to which the qualifying patent relates, including any sum paid for the grant of a license to exercise rights under such patent, where that royalty or other sum is paid, for the purpose of activities that would be regarded under Irish law as the manufacture of goods (to the extent that the payment does not exceed an arms-length rate), or by a person who is not connected with us. Accordingly, our income from such qualifying patents is disregarded for taxation purposes in Ireland. Any Irish manufacturing income of Elan and its subsidiaries is taxable at the rate of 10% in Ireland until December 31, 2010. Income arising from qualifying activities in our Shannon-certified subsidiary is taxable at the rate of 10% in Ireland until December 31, 2005. From January 1, 2006, such income is taxable at a rate of 12.5%. Any trading income that does not qualify for the patent exemption or the 10% rate of tax is taxable at the Irish corporation tax rate of 12.5% in respect of trading income for the years 2003 and thereafter. Non-trading income is taxable at 25%.

***Taxation of Capital Gains and Dividends***

A person who is neither resident nor ordinarily resident in Ireland and who does not carry on a trade in Ireland through a branch or agency will not be subject to Irish capital gains tax on the disposal of Ordinary Shares. Unless exempted, all dividends paid by us other than dividends paid out of exempt patent income, will be subject to Irish withholding tax at the standard rate of income tax in force at the time the dividend is paid, currently 20%. An individual shareholder resident in a country with which Ireland has a double tax treaty, which includes the United States, or in a member state of the European Union, other than Ireland (together, a Relevant Territory), will be exempt from withholding tax provided he or she makes the requisite declaration.

Corporate shareholders who: (i) are ultimately controlled by residents of a Relevant Territory; (ii) are resident in a Relevant Territory and are not controlled by Irish residents; (iii) have the principal class of their shares, or of a 75% parent, traded on a stock exchange in a Relevant Territory; or (iv) are wholly owned by two or more companies, each of whose principal class of shares is substantially and regularly traded on one or more recognized stock exchanges in a Relevant Territory or Territories, will be exempt from withholding tax on the production of the appropriate certificates and declarations.

Holders of our ADSs will be exempt from withholding tax if they are beneficially entitled to the dividend and their address on the register of depositary shares maintained by the depositary is in the United States, provided that the depositary has been authorized by the Irish Revenue Commissioners as a qualifying intermediary and provided the appropriate declaration is made by the holders of the ADSs. Where such withholding is made, it will satisfy the liability to Irish tax of the shareholder except in certain circumstances where an individual shareholder may have an additional liability. A charge to Irish social security taxes and other levies can arise for individuals. However, under the Social Welfare Agreement between Ireland and the United States, an individual who is liable for U.S. social security contributions can normally claim exemption from these taxes and levies.

***Irish Capital Acquisitions Tax***

A gift or inheritance of Ordinary Shares will be and, in the case of our warrants or American Depositary Warrant Shares (ADWSs) representing such warrants, may be, within the charge to Irish capital acquisitions tax, notwithstanding that the person from whom the gift or inheritance is received is domiciled or resident outside Ireland. Capital acquisitions tax is charged at the rate of 20% above a tax-free threshold. This tax-free threshold is determined by the relationship between the donor and the successor or donee. It is also affected by the amount of the current

benefit and previous benefits taken since December 5, 1991 from persons within the same capital acquisitions tax relationship category. Gifts and inheritances between spouses are not subject to capital acquisitions tax.

The Estate Tax Convention between Ireland and the United States generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited against tax payable in the United States and for

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tax paid in the United States to be credited against tax payable in Ireland, based on priority rules set forth in the Estate Tax Convention, in a case where warrants, ADWSs, ADSs or Ordinary Shares are subject to both Irish capital acquisitions tax with respect to inheritance and U.S. Federal estate tax. The Estate Tax Convention does not apply to Irish capital acquisitions tax paid on gifts.

### ***Irish Stamp Duty***

Under current Irish law, no stamp duty, currently at the rate and on the amount referred to below, will be payable by U.S. Holders on the issue of ADSs, Ordinary Shares or ADWSs of Elan. Under current Irish law, no stamp duty will be payable on the acquisition of ADWSs or ADSs by persons purchasing such ADWSs or ADSs, or on any subsequent transfer of an ADWS or ADS of us. A transfer of Ordinary Shares, whether on sale, in contemplation of a sale or by way of gift will attract duty at the rate of 1% on the consideration given or, where the purchase price is inadequate or unascertainable, on the market value of the shares. Similarly, any such transfer of a warrant may attract duty at the rate of 1%. Transfers of Ordinary Shares that are not liable to duty at the rate of 1% are exempt unless the transfer is by way of security, in which event there is a potential maximum charge of Euro 630. The person accountable for payment of stamp duty is the transferee or, in the case of a transfer by way of gift or for a consideration less than the market value, all parties to the transfer. Stamp duty is normally payable within 30 days after the date of execution of the transfer. Late or inadequate payment of stamp duty will result in a liability to pay interest penalties and fines.

### **F. Dividends and Paying Agents**

Not applicable.

### **G. Statement by Experts**

Not applicable.

### **H. Documents on Display**

The Company is subject to the reporting requirements of the Exchange Act. In accordance with these requirements, the Company files Annual Reports on Form 20-F with, and furnishes Reports of Foreign Issuer on Form 6-K to, the SEC. These materials, including our Annual Report on Form 20-F for the fiscal year ended December 31, 2005 and the exhibits thereto, may be inspected and copied at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington D.C. 20549. Copies of the materials may be obtained from the Public Reference Room of the SEC at 100 F Street, NE, Room 1580, Washington, D.C. at prescribed rates. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. As a foreign private issuer, all documents which were filed or submitted after November 4, 2002 on the SEC's EDGAR system are available for retrieval on the website maintained by the SEC at <http://www.sec.gov>. These filings and submissions are also available from commercial document retrieval services.

Copies of our Memorandum and Articles of Association may be obtained at no cost by writing or telephoning the Company at our principal executive offices. Our Memorandum and Articles of Association are filed with the SEC as Exhibit 3 of our Registration Statement on Form 8-A/A3 (SEC File No. 001-13896) filed with the SEC on December 6, 2004. You may also inspect or obtain a copy of our Memorandum and Articles of Association using the procedures prescribed above.

### **I. Subsidiary Information**

Not applicable.

**Item 11. *Quantitative and Qualitative Disclosures about Market Risk.***

Market risk is the risk of loss from adverse changes in market prices, interest rates and foreign exchange rates. Our future earnings and cash flows are dependent upon prevailing market rates. Accordingly, we manage our market risk by matching projected cash inflows from operating, investing and financing activities with projected cash

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outflows for debt service, capital expenditures and other cash requirements. The majority of our outstanding debt has fixed interest rates, which minimizes the risk of fluctuating interest rates. Our exposure to market risk includes interest rate fluctuations in connection with our variable rate borrowings and our ability to incur more debt, thereby increasing our debt service obligations, which could adversely affect our cash flows.

***Inflation Risk***

Inflation had no material impact on our operations during the year.

***Exchange Risk***

We are a multinational business operating in a number of countries and the U.S. dollar is the primary currency in which we conduct business. The U.S. dollar is used for planning and budgetary purposes and as the presentation currency for financial reporting. We do, however, have revenues, costs, assets and liabilities denominated in currencies other than U.S. dollars. Consequently, we enter into derivative financial instruments to manage our non-U.S. dollar foreign exchange risk. We use derivative financial instruments primarily to reduce exposures to market fluctuations in foreign exchange rates. We do not enter into derivative financial instruments for trading or speculative purposes. All derivative contracts entered into are in liquid markets with credit-approved parties. The treasury function operates within strict terms of reference that have been approved by our board of directors.

The U.S. dollar is the base currency against which all identified transactional foreign exchange exposures are managed and hedged. The principal risks to which we are exposed are movements in the exchange rates of the U.S. dollar against the Euro, Sterling and Japanese Yen. The main exposures are net costs in Euro arising from a manufacturing and research presence in Ireland and the sourcing of raw materials in European markets.

At December 31, 2005, we had entered into a number of forward foreign exchange contracts at various rates of exchange in the normal course of business. The nominal value of forward foreign exchange contracts to sell U.S. dollars for Euro at December 31, 2005 had a total contract amount of \$77.0 million (2004: \$9.0 million) and these contracts had a fair value loss of \$1.7 million (2004: \$1.2 million gain). These contracts all expire on various dates through December 2006. The forward foreign exchange contracts to sell Japanese Yen for U.S. dollars at December 31, 2005 had a total contract amount of \$Nil (2004: \$9.4 million) and these contracts had a fair value loss of \$Nil (2004: \$0.4 million).

During 2005, average exchange rates were \$1.25 = EUR1. We sell U.S. dollars to buy Euro for costs incurred in Euro.

***Interest Rate Risk on Debt***

Our long-term debt is primarily at fixed rates, except for the \$300.0 million of Floating Rate Notes issued in November 2004 and interest rate swaps entered into to convert \$300.0 million of our fixed rate interest obligations related to the Athena Notes to variable rate interest obligations. Interest rate changes affect the amount of interest on our variable rate debt.

The table below summarizes the market risks associated with our fixed and variable rate long-term and convertible debt outstanding at December 31, 2005 (in millions):

	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>Thereafter</b>	<b>Total</b>
Fixed rate debt <sup>(1)</sup>	\$	\$	\$ 867.2	\$	\$	\$ 850.0	\$ 1,717.2

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Average interest rate			7.03%			7.75%	7.39%
Variable rate debt <sup>(2)(3)</sup>	\$	\$	\$	\$	\$	300.0	\$ 300.0
Average interest rate						7.33%	7.33%
Total long-term and convertible debt	\$	\$	\$ 867.2	\$	\$	1,150.0	\$ 2,017.2
Average interest rate			7.03%			7.64%	7.38%

*(1) Represents 85.1% of all outstanding long-term and convertible debt.*

*(2) Represents 14.9% of all outstanding long-term and convertible debt.*

*(3) Variable interest rates are based on LIBOR.*

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*If market rates of interest on our variable rate debt, including the effect of the \$300.0 million interest rate swaps, increased by 10%, then the increase in interest expense on the variable rate debt would be \$4.8 million annually. As of December 31, 2005, the fair value of our total convertible debt and guaranteed notes was \$2,174.7 million. See Note 15 to the Consolidated Financial Statements for additional information on the fair values of debt instruments.*

We held three interest rate derivatives associated with our fixed-rate, long-term debt outstanding at December 31, 2005 (in millions):

	2006	2007	2008	2009	2010	Thereafter	Total	Fair Value
Interest Rate Swaps								
Fixed to Variable	\$	\$	\$ 300.0	\$	\$	\$	\$ 300.0	\$ (5.1)
Average pay rate			7.57%				7.57%	
Receive rate			7.25%				7.25%	

**Interest Rate Risk on Investments**

Our liquid funds are invested primarily in U.S. dollars except for the working capital balances of subsidiaries operating outside of the United States. Interest rate changes affect the returns on our investment funds. Our exposure to interest rate risk on liquid funds is actively monitored and managed with an average duration of less than three months. By calculating an overall exposure to interest rate risk rather than a series of individual instrument cash flow exposures, we can more readily monitor and hedge these risks. Duration analysis recognizes the time value of money and in particular, prevailing interest rates by discounting future cash flows.

The interest rate risk profile of our investments at December 31, 2005 was as follows (in millions):

	Fixed	Floating	No Interest	Total
Cash and cash equivalents	\$	\$ 1,080.7	\$	\$ 1,080.7
Restricted cash	\$	\$ 24.9	\$	\$ 24.9
Marketable investment securities (current)	\$	\$	\$ 10.0	\$ 10.0
Marketable investment securities (non-current)	\$ 2.3	\$	\$ 10.8	\$ 13.1

Fixed interest rates on investments have a weighted average interest rate of 7.0% (2004: 7.5%), maturing in 2006.

Variable interest rates on cash and liquid resources are generally based on the appropriate Euro Interbank Offered Rate, LIBOR or bank rates dependent on principal amounts on deposit.

**Credit Risk**

Our treasury function transacts business with counterparties that are considered to be low investment risk. Credit limits are established commensurate with the credit rating of the financial institution that business is being transacted with. We only enter into contracts with parties that have at least an A or equivalent credit rating. The counterparties to these contracts are major financial institutions. The maximum exposure to credit risk is represented by the carrying amount of each financial asset, including derivative financial instruments, in the balance sheet. We believe that the risk of any net loss from counterparty risk is remote.

For customers, we have a credit policy in place which involves credit evaluation and ongoing account monitoring.

We do not currently transact significant business in countries that are subject to major political and economic uncertainty. As a result, we are not materially exposed to any sovereign risk or payment difficulties.

At the balance sheet date, we have a significant concentration of credit risk given that our three main customers, McKesson, Amerisource Bergen, and Cardinal Health, account for 44% of our gross accounts receivable balance at December 31, 2005. However, we do not believe our credit risk in relation with these three customers is significant, as they each have an A credit rating.

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***Equity Price Risk***

We are exposed to equity price risks primarily on our available for sale securities, which consist of equity investments in quoted companies. At December 31, 2005, current available-for-sale securities had a fair value of \$10.0 million and had a cost of \$10.3 million. These investments are primarily in emerging pharmaceutical and biotechnology companies. An adverse change in equity prices could result in a material impact in the fair value of our available for sale equity securities.

**Item 12. *Description of Securities Other than Equity Securities.***

Not applicable.

**Part II**

**Item 13. *Defaults, Dividend Arrearages and Delinquencies.***

None.

**Item 14. *Material Modifications to the Rights of Security Holders and Use of Proceeds.***

None.

**Item 15. *Controls and Procedures***

***Disclosure Controls and Procedures***

As of the end of the fiscal year ended December 31, 2005, we conducted an evaluation (under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer), pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934, as amended, of the effectiveness of our disclosure controls and procedures.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable, rather than absolute, assurance of achieving the desired control objectives and management necessarily was required to apply its judgment in evaluating the cost- benefit relationship of possible controls and procedures. Based on the evaluation conducted, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that as of the end of the fiscal year such disclosure controls and procedures were reasonably designed and operating effectively.

**Item 16. *Reserved.***

**Item 16A. *Audit Committee Financial Expert***

The board of directors of Elan has determined that Mr. Kennedy qualifies as an audit committee financial expert and as an independent director within the meaning of the NYSE listing standards.

**Item 16B. *Code of Ethics***

Our board of directors adopted a code of conduct that applies to our directors, officers and employees. There have been no material modifications to, or waivers from, the provisions of such code. This code is available on our website

at the following address: [http://elan.com/governance/code\\_of\\_conduct](http://elan.com/governance/code_of_conduct).

**Table of Contents****Item 16C. Principal Accountant Fees and Services**

Our principal accountants are KPMG. The table below summarizes the fees for professional services rendered by KPMG for the audit of our Consolidated Financial Statements and fees billed for other services rendered by KPMG (in millions):

	<b>2005</b>	<b>2004</b>
Auditors remuneration:		
Audit fees <sup>(1)</sup>	\$ 2.9	\$ 3.6
Audit related fees <sup>(2)</sup>		
Total audit and audit-related fees	\$ 2.9	3.6
Tax fees	0.8	0.8
All other fees		
Total auditors remuneration	\$ 3.7	\$ 4.4

<sup>(1)</sup> *Audit services include audit of our Consolidated Financial Statements, as well as work that generally only the independent auditor can reasonably be expected to provide, including comfort letters, statutory audits, and discussions surrounding the proper application of financial accounting or reporting standards.*

<sup>(2)</sup> *Audit related services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.*

***Audit Committee***

The audit committee, composed entirely of non-executive directors, helps the board in its general oversight of our accounting and financial reporting practices, internal controls and audit functions, and is directly responsible for the appointment, compensation and oversight of our independent auditors. The audit committee periodically reviews the effectiveness of the system of internal control. It monitors the adequacy of internal accounting practices, procedures and controls, and reviews all significant changes in accounting policies. The committee meets regularly with the internal and external auditors and addresses all issues raised and recommendations made by them. The members of the committee in 2005 were Dr. Gillespie (chairman), Mr. Kennedy (appointed September 9, 2005), Mr. McGowan and Ms. Gray, who was appointed to the audit committee on February 3, 2005, and served on the committee until Mr. Kennedy's appointment. Mr. Kennedy qualifies as an audit committee financial expert.

Consistent with SEC policies regarding auditor independence, the audit committee has responsibility for appointing, setting compensation, overseeing the work of and ensuring the independence of the independent auditor. In recognition of this responsibility, the audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent auditor. Prior to engagement of the independent auditor for the next year's audit, management will submit a list of services and related fees expected to be rendered during that year within each of four categories of services to the audit committee for approval: audit services; audit-related services; tax

services; and other fees.

Prior to engagement, the audit committee pre-approves all independent auditor services within each category. The fees are budgeted and the audit committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent auditor for additional services not contemplated in the original pre-approval categories. In those instances, the audit committee requires specific pre-approval before engaging the independent auditor.

The audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated reports any pre-approval decisions to the audit committee at its next scheduled meeting.

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**Item 16D. *Exemptions from the Listing Standards for Audit Committees***

Not applicable.

**Item 16E. *Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

Not applicable.

**Part III**

**Item 17. *Consolidated Financial Statements.***

Not applicable.

**Item 18. *Consolidated Financial Statements.***

Report of Independent Registered Public Accounting Firm

Consolidated Financial Statements of Elan Corporation, plc and subsidiaries

Notes to the Consolidated Financial Statements

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Directors and Shareholders of Elan Corporation, plc

We have audited the accompanying consolidated balance sheets of Elan Corporation, plc and subsidiaries as of December 31, 2005 and 2004 and the related consolidated statements of operations, shareholders' equity and other comprehensive income/(loss) and cash flows for each of the years in the three-year period ended December 31, 2005. We have also audited the accompanying financial statement schedule. These Consolidated Financial Statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these Consolidated Financial Statements and financial statement schedule based on our audits.

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

In our opinion, the Consolidated Financial Statements referred to above present fairly, in all material respects, the consolidated financial position of Elan Corporation, plc and subsidiaries as of December 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States (U.S. GAAP). Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

KPMG

Dublin, Ireland  
March 28, 2006

**Table of Contents****Elan Corporation, plc****Consolidated Statements of Operations  
For the Years Ended December 31, 2005, 2004 and 2003**

	Notes	2005	2004	2003
		(In millions, except per share data)		
Product revenue		\$ 458.1	\$ 404.4	\$ 586.7
Contract revenue		32.2	77.3	98.9
Total revenue	3	490.3	481.7	685.6
Operating expenses:				
Cost of sales		196.1	173.6	248.9
Selling, general and administrative expenses		358.4	337.3	384.2
Research and development expenses		233.3	257.3	277.6
Net gain on sale of businesses	20	(103.4)	(44.2)	(267.8)
Other significant net charges	19	4.4	59.8	403.2
Total operating expenses		688.8	783.8	1,046.1
Operating loss		(198.5)	(302.1)	(360.5)
Net interest and investment (gains)/losses:				
Net interest expense	14	125.7	109.0	103.8
Net investment gains	7	(16.3)	(114.6)	(103.4)
Impairment of investments	7	23.5	71.8	87.5
Net charge on debt retirement	14	51.8		
Charge arising from guarantee to EPIL II noteholders			47.1	49.0
Net interest and investment losses		184.7	113.3	136.9
Loss from continuing operations before provision for/(benefit from) income taxes		(383.2)	(415.4)	(497.4)
Provision for/(benefit from) income taxes	17	1.0	(1.7)	(22.8)
Net loss from continuing operations		(384.2)	(413.7)	(474.6)
Net income/(loss) from discontinued operations (net of tax)	20	0.6	19.0	(31.5)
Net loss		\$ (383.6)	\$ (394.7)	\$ (506.1)
Basic and diluted loss per Ordinary Share:				
Net loss from continuing operations		\$ (0.93)	\$ (1.06)	\$ (1.33)
Net income/(loss) from discontinued operations (net of tax)			0.05	(0.09)
Net loss	4	\$ (0.93)	\$ (1.01)	\$ (1.42)

Weighted average number of Ordinary Shares outstanding	4	413.5	390.1	356.0
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The accompanying notes are an integral part of these Consolidated Financial Statements.

**Table of Contents****Elan Corporation, plc****Consolidated Balance Sheets  
As of December 31, 2005 and 2004**

	Notes	2005	2004
	(In millions, except shares and par values)		
<b>ASSETS</b>			
Current Assets:			
Cash and cash equivalents		\$ 1,080.7	\$ 1,347.6
Restricted cash	5	20.4	189.3
Accounts receivable, net	6	81.8	41.5
Marketable investment securities	7	10.0	65.5
Inventory	8	25.3	29.0
Held for sale assets	20	11.2	10.3
Prepaid and other current assets	9	23.0	82.0
Total current assets		1,252.4	1,765.2
Property, plant and equipment, net	10	353.6	346.2
Goodwill and other intangible assets, net	11	665.5	753.7
Marketable investment securities	7	13.1	39.0
Restricted cash	5	4.5	3.4
Other assets	12	51.8	68.4
Total assets		2,340.9	\$ 2,975.9
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>			
Current Liabilities:			
Accounts payable		31.5	\$ 55.0
Accrued and other current liabilities	13	172.0	260.4
EPIL III Notes			39.0
Deferred revenue	16	43.1	55.8
Total current liabilities		246.6	410.2
Long term and convertible debts	14	2,017.2	2,260.0
Deferred revenue	16	17.0	54.6
Other liabilities	13	43.2	46.1
Total liabilities		2,324.0	2,770.9
Shareholders Equity:			
Ordinary shares, 0.05 par value, 600,000,000 shares authorized, 428,832,534 and 395,072,974 shares issued and outstanding at December 31, 2005 and 2004, respectively	21	24.7	22.6
	21		

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Executive shares, 1.25 par value, 1,000 shares authorized, 1,000 shares issued and outstanding at December 31, 2005 and 2004			
B Executive shares, 0.05 par value, 25,000 shares authorized, 21,375 shares issued and outstanding at December 31, 2005 and 2004	21		
Additional paid-in capital		5,024.5	4,796.4
Treasury Stock	21	(17.4)	(17.4)
Accumulated deficit		(4,988.3)	(4,604.7)
Accumulated other comprehensive income/(loss)	22	(26.6)	8.1
Shareholders' equity		16.9	205.0
Total liabilities and shareholders' equity		\$ 2,340.9	\$ 2,975.9

The accompanying notes are an integral part of these Consolidated Financial Statements.

**Table of Contents****Elan Corporation, plc****Consolidated Statements of Shareholders' Equity and Other Comprehensive Income/(Loss)  
For the Years Ended December 31, 2005, 2004 and 2003**

	<b>Number of Shares</b>	<b>Share Capital</b>	<b>Additional Paid-in Capital</b>	<b>Treasury Stock (In millions)</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Income/(Loss)</b>	<b>Total Shareholders' Equity</b>
December 31, 2002	350.4	\$ 19.9	\$ 4,557.8	\$ (17.4)	\$ (3,703.9)	\$ (13.3)	\$ 843.1
Comprehensive loss:							
Net loss					(506.1)		(506.1)
Unrealized gain on securities						90.9	90.9
Reclassification adjustment for net gains included in net loss						(1.3)	(1.3)
Currency translation adjustments						12.4	12.4
Minimum pension liability adjustment						9.8	9.8
Total comprehensive loss							(394.3)
Stock issued, net of issuance costs	35.8	2.1	167.0				169.1
December 31, 2003	386.2	22.0	4,724.8	(17.4)	(4,210.0)	98.5	617.9
Comprehensive loss:							
Net loss					(394.7)		(394.7)
Unrealized loss on securities						(12.1)	(12.1)
Reclassification adjustment for net gains included in net loss						(77.5)	(77.5)
Currency translation adjustments						(0.8)	(0.8)
Total comprehensive loss							(485.1)
			2.7				2.7

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Tax benefit of stock option deductions							
Stock issued, net of issuance costs	8.9	0.6	68.9				69.5
December 31, 2004	395.1	22.6	4,796.4	(17.4)	(4,604.7)	8.1	205.0
Comprehensive loss:							
Net loss					(383.6)		(383.6)
Unrealized loss on securities						(24.9)	(24.9)
Reclassification adjustment for net losses included in net loss						3.6	3.6
Minimum pension liability adjustment						(10.7)	(10.7)
Currency translation adjustments							

&nbsp;