ELAN CORP PLC
Form 20-F
April 11, 2005
United States
Securities and Exchange Commission,
Washington, D.C. 20549
FORM 20-F

(Mark One)

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: December 31, 2004

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from to .

Commission file number: 1-13896

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")	New York Stock Exchange
Ordinary Shares	New York Stock Exchange

Securities registered or to be registered pursuant to Section 12(g) of the Act:
Warrants to purchase ADSs, Series Z

(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: 395,072,974 Ordinary Shares.

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 which financial statement item the registrant has elected to follow:
Item 17 Item 18

TABLE OF CONTENTS

General

As used herein, "we", "our", "us", "Elan" and the "Company" refer to Elan Corporation, plc (public limited company) and its 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 have adopted accounting principles generally accepted in the United States ("U.S. GAAP") as the basis for the preparation of our Consolidated Financial Statements contained in this Form 20-F. 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 prepare separate Consolidated Financial Statements, included in our Annual Report, in accordance with Irish GAAP, which differs in certain significant respects from U.S. GAAP. The Annual Report under Irish GAAP 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. You can identify these statements by the fact that they use words such as "anticipate", "estimate", "project", "intend", "plan", "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: (1) whether and when we will be able to resume marketing and developing Tysabri® (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 Prialt® (ziconotide intrathecal infusion) as an intrathecal treatment for severe pain; (4) our ability to maintain sufficient cash, liquid resources, 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 antikickback 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.

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.

Years Ended December 31,	2004	2003 (restated)	2002 (restated)	2001 (restated)	2000 (restated)
		(in millions, except per share data)			
Income Statement Data:					
Total revenue	$ 481.7	$ 685.6	$ 1,093.1	$ 1,576.3	$ 1,307.3
Operating income/(loss)	$ (302.1)[1]	$ (360.5)[2]	$ (608.7)[3]	$ 268.5[4]	$ (62.8)[5]
Net income/(loss) from continuing operations before cumulative effect of changes in accounting principles	$ (413.7)	$ (474.6)	$ (2,169.6)	$ 285.0	$ 71.2
Net income/(loss) from discontinued operations before cumulative effect of changes in accounting principles	19.0	(31.5)	(188.6)	(20.3)	(13.2)
	—	—	—	7.8	(344.0)

Cumulative effect of changes in accounting principles					
Net income/(loss)	$ (394.7)[1]	$ (506.1)[6]	$(2,358.2)[7]	$ 272.5[4]	$ (286.0)[8]
Basic earnings/(loss) per Ordinary Share [9]					
from continuing operations	$ (1.06)	$ (1.33)	$ (6.20)	$ 0.85	$ 0.25
from discontinued operations	0.05	(0.09)	(0.54)	(0.06)	(0.05)
cumulative effect of changes in accounting principles	—	—	—	0.02	(1.20)
Total basic earnings/(loss) per Ordinary Share	$ (1.01)	$ (1.42)	$ (6.74)	$ 0.81[10]	$ (1.00)[10]
Diluted earnings/(loss) per Ordinary Share [9]					
from continuing operations	$ (1.06)	$ (1.33)	$ (6.20)	$ 0.79	$ 0.23
from discontinued operations	0.05	(0.09)	(0.54)	(0.06)	(0.04)
cumulative effect of changes in accounting principles	—	—	—	0.02	(1.11)
Total diluted earnings/(loss) per Ordinary Share	$ (1.01)	$ (1.42)	$ (6.74)	$ 0.76[10]	$ (0.92)[10]

December 31,	2004	2003 (restated)	2002 (restated)	2001 (restated)	2000 (restated)
			(in millions)		
Balance Sheet Data:					
Cash and cash equivalents	$ 1,347.6	$ 778.2	$ 984.5	$ 1,478.5	$ 692.4
Restricted cash	$ 192.7	$ 33.1	$ 29.4	$ 120.9	$ 110.1
Current marketable investment securities	$ 65.5	$ 349.4	$ 450.6	$ 943.3	$ 447.6
Total assets	$ 2,975.9	$ 3,029.8	$ 4,031.7	$ 6,840.4	$ 4,661.5
Long term and convertible debt	$ 2,260.0	$ 1,500.0	$ 1,046.3	$ 2,227.4	$ 1,375.6
Total Shareholders' equity	$ 205.0	$ 617.9	$ 843.1	$ 3,211.0	$ 2,285.4
Weighted-average number of shares outstanding —Basic	390.1	356.0	349.7	336.0	287.1
Weighted-average number of shares outstanding —Diluted	390.1	356.0	349.7	359.3	309.6

(1)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 o businesses.

(2)After net other charges of $403.2 million, primarily relating to asset impairments of $32.6 million, severance, relocation an 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.

(3)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.

(4)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.

(5)After net other charges of $424.9 million, primarily relating to acquired in-process research and development ("IPR&D") c $158.1 million and merger costs, integration and similar costs of $177.0 million.

(6)

After net other charges of $403.2 million, primarily relating to asset impairments of $32.6 million, severance, relocation an 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").

(7) 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.

(8) After net other charges of $424.9 million, primarily relating to acquired IPR&D of $158.1 million and merger costs, integration and similar costs of $177.0 million; and after $344.0 million relating to the cumulative adjustment for the implementation of SEC's Staff Accounting Bulletin No. 104, Revenue Recognition, ("SAB 104").

(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 amortize for that year. Basic and diluted (loss) per share for 2000 would have been $(0.85) if goodwill was not amortized for that year. This disclosure is provided as SFAS No. 142, "Goodwill and Other Intangible Assets," ("SFAS No. 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.

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.

On February 28, 2005, we 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 in patients treated with Tysabri in combination with Biogen Idec's product Avonex® (interferon beta-1) in clinical trials. These events involved two cases of progressive multifocal leukoencepalopathy ("PML"), a rare and frequently fatal demyelinating disease of the central nervous system. On March 30, 2005, we and Biogen Idec announced that a patient who had received eight infusions of Tysabri in a Crohn's trial had died of PML in December 2003. If it is determined that these serious adverse events were 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 and clinical dosing of 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's commercial potential remains substantially impaired, we will be materially and adversely affected.

Excluding Tysabri, we only market three products and we have only one potential product in clinical development, and it is only in the early stages of clinical development. Our future success depends upon the successful commercialization of Tysabri, the development and commercialization of additional indications for Tysabri and the development and 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 labeling changes that may be mandated by regulatory agencies, may substantially 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 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, 2004, we had $2,299.0 million of debt. At such date, we had cash and cash equivalents and restricted cash of approximately $1,540.3 million. Our substantial indebtness 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 working capital, capital expenditures, acquisitions and 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 incur operating losses in 2005 and 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 on a timely basis, or at all, 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 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. Other competitors also consist of 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.

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 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.

U.S. basic patents that expire in March 2007 and October 2005 cover two of our products, Maxipime™ (cefepime hydrochloride) for injection and Azactam™(aztreonam for injection, USP), respectively. Two formulation U.S. patents covering Maxipime expire in 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 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 ("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, 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.

We require supplies of raw materials for the manufacture of our products. Currently, we do not have dual sourcing of our required raw materials. Our 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, which may adversely affect our profitability.

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 U.S., 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 payors, 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. In the meantime, a temporary drug discount card program was established for 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 antikickback and false claims laws in the United States.

In addition to the United States Food and Drug Administration ("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 antikickback statutes and false claims statutes.

The federal health care program antikickback 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 antikickback 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 antikickback 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 payor. 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.

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, labeling, 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 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 labeling 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 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.

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. Medicaid rebate program, as well as several state Medicaid supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program 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 also includes a penalty if our prices increase faster than the rate of inflation.

As a manufacturer of single source, innovator multiple source 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, 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 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 rebates 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 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 Federal Ceiling Price is calculated each year for every Covered Drug marketed by us. The Federal Ceiling Price is used to set pricing for purchases by government agencies.

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 maintain an aggregate $150.0 million of product liability insurance, with the first $25.0 million of aggregate claims not covered, the next $125.0 million covered by our insurers, the next $25.0 million not covered and the next $25.0 million covered by 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.

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
- 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 focus on discovering, developing, manufacturing and marketing advanced therapies in autoimmune diseases, including pain, and neurodegenerative diseases.

We incorporated as a private limited company in Ireland on December 18, 1969 and became a public limited company on January 3, 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 R&D, manufacturing and marketing facilities are located in Ireland, the United States and the United Kingdom.

B. Business Overview

In February 2004, we announced the formal completion of our recovery plan. The recovery plan, which was announced in July 2002, was initiated in response to a number of setbacks we suffered in rapid succession earlier in 2002, including the cessation of dosing in a Phase IIA clinical trial of AN-1792, an experimental immunotherapeutic that was under development for the treatment of Alzheimer's disease, the announcement of a profit warning and an investigation by the SEC. These disappointments ultimately led to a loss of confidence in the Company, and we began a recovery plan in July 2002 to restructure our business in order to meet our financial commitments. The recovery plan involved the restructuring of our businesses, assets and balance sheet, and resulted in gross consideration of $2.1

billion, ahead of the target of $1.5 billion.

With the completion of the recovery plan, the operations of Core Elan and Elan Enterprises were reorganized into two business units: Biopharmaceuticals and Global Services and Operations ("GS&O"). Biopharmaceuticals engages in research, development and commercial activities and includes our autoimmune diseases franchise, our pain franchise, our neurodegenerative diseases franchise, and our commercial group for hospital products. Elan Enterprises ended operations in February 2004. Its remaining businesses, comprised principally of drug delivery businesses, were amalgamated with the drug delivery business from Core Elan to form GS&O.

We are studying and developing ways to provide therapies for a wide range of autoimmune diseases, including multiple sclerosis ("MS"), Crohn's disease and rheumatoid arthritis. In November 2004, the FDA granted accelerated approval of Tysabri for the treatment of MS.

On February 28, 2005, we and Biogen Idec announced the voluntary suspension of the marketing and dosing in clinical trials of Tysabri. This decision was based on reports of two serious adverse events in patients treated with Tysabri in combination with Avonex in clinical trials. These events involved two cases of PML, a rare and frequently fatal demyelinating disease of the central nervous system. Both patients received more than two years of Tysabri therapy in combination with Avonex.

On March 30, 2005, we and Biogen Idec announced that our 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.

We are working with leading experts, regulatory agencies and the clinical investigators to investigate these serious adverse events and to determine the appropriate path forward.

In neurodegenerative diseases, we are focused on building upon our breakthrough research and extensive experience in Alzheimer's disease and are also studying other neurodegenerative diseases, including Parkinson's disease. In collaboration with Wyeth, we are currently conducting clinical trials with an experimental monoclonal antibody, AAB-001, designed and engineered to neutralize the neurotoxic beta-amyloid peptide that accumulates in the brains of patients with Alzheimer's disease.

GS&O encompasses our initiatives in supply chain management, small molecule optimization and manufacturing, drug delivery technology and biologics, including planned sterile fill finish and monoclonal antibody process development and productions. Our drug delivery business, which includes our proprietary NanoCrystal® and oral controlled technologies, engages in the development and commercialization of pharmaceutical products for ourselves and for third parties.

AUTOIMMUNE DISEASES

In autoimmune diseases, the immune system mistakenly targets the cells, tissues and organs of a person's own 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 targeted against the brain. In Crohn's disease, it is targeted against the gastrointestinal tract; and in rheumatoid arthritis, 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.

Tysabri

Tysabri, formerly referred to as Antegren, is the first humanized monoclonal antibody approved for the treatment of MS. Tysabri is an alpha 4 antagonist 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 marketed by us in collaboration with Biogen Idec. The marketing and clinical dosing of Tysabri has been voluntarily suspended.

Tysabri for the Treatment of MS

In November 2004, the FDA granted accelerated approval of Tysabri as a treatment for relapsing forms of MS to reduce the frequency of clinical relapses. The FDA approval followed the agency's priority review of Tysabri based on one-year data from two Phase III studies ("AFFIRM" and "SENTINEL"). The AFFIRM was a monotherapy trial and the SENTINEL was an add-on trial with Avonex. Revenue from sales of Tysabri amounted to $6.4 million in 2004. The marketing of Tysabri was voluntarily suspended in February 2005.

Phase III MS Trials

The one-year results of AFFIRM and SENTINEL were announced in conjunction with the FDA approval of Tysabri.

The AFFIRM trial is 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.

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. This 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.

The SENTINEL trial, also a two-year study, is an ongoing, randomized, multi-center, placebo-controlled, double-blind study of approximately 1,171 patients in 123 clinical trial sites worldwide. The trial is designed to determine if adding Tysabri to Avonex is more effective than 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.

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.

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. Dosing in all Tysabri clinical trials has been voluntarily suspended.

Evaluating Tysabri in Crohn's Disease

In collaboration with Biogen Idec, we are evaluating Tysabri as a treatment for Crohn's disease. In 2004, we presented six-month data from a key Phase III Crohn's disease maintenance study and initiated a further three-month Phase III Crohn's disease induction trial in April. In September, we submitted a Marketing Approval Authorisation to the European Medicines Agency for the approval of Tysabri for the treatment of Crohn's disease. Dosing in all Tysabri clinical trials has been voluntarily suspended.

Phase III Crohn's Disease Trial—ENACT-2

ENACT-2 is a Phase III, double-blind, placebo-controlled, international maintenance trial of Tysabri in Crohn's disease enrolled responders from ENACT-1 (a three-month double-blind, placebo-controlled study in patients with moderately to severely active Crohn's disease). 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 Digestive Disease Week 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 Digestive Disease Week showed Tysabri maintained clinical response and remission rates throughout six months among patients with Crohn's disease who had previously achieved clinical response. A majority of Tysabri treated patients who were also on chronic corticosteroid therapy were able to withdraw from corticosteroids and maintain response in contrast to those patients on placebo. Additional findings included:

- 61 percent (103/168) of Tysabri treated patients exhibited significant clinical response versus 28 percent (48/170) of patients re-randomized to receive placebo; and
- Clinical remission at six months was maintained by 44 percent (57/130) of patients receiving Tysabri versus 26 percent (31/120) of placebo-treated patients.

Twelve-month ENACT-2 data presented at the United European Gastroenterology Week meeting confirmed the six-month primary endpoint data, showing:

- 54 percent (90/168) of patients treated with Tysabri continued to respond to treatment compared with 20 percent (34/170) of patients treated with placebo;
- 39 percent (51/130) of Tysabri treated patients maintained clinical remission versus 15 percent (18/120) of patients on placebo;
- 49 percent of Tysabri treated patients (33/67) taking corticosteroids in ENACT-1, re-randomized to Tysabri in ENACT-2, were able to be withdrawn from steroids, compared to 20 percent (15/76) who were re-randomized to placebo;
- Patients taking Tysabri maintained clinical response as well as remission at significantly higher rates than patients on placebo; and
- 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, we filed an Investigational New Drug ("IND") application, with the FDA, for Tysabri for the treatment of rheumatoid arthritis and initiated a Phase II clinical trial in May 2004 to evaluate Tysabri in patients with rheumatoid arthritis. It is a multi-center, double-blind, placebo-controlled study of the efficacy and tolerability of intravenous Tysabri in patients with moderate-to-severe rheumatoid arthritis receiving concomitant treatment with methotrexate. Dosing in all Tysabri clinical trials has been voluntarily suspended.

Autoimmune Diseases Research

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. Tysabri emerged from this research program.

SEVERE CHRONIC PAIN

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

About Severe 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, or if the pain is the result of an injury or malfunction in the peripheral or central nervous system. Chronic pain can be defined as pain that has lasted over six months and is not relieved by medical or surgical care. Pain can be classified as "severe" based on standardized measurements, such as the Visual Analog Scale of Pain Intensity.

Prialt

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

Prialt—A New Treatment for Severe Chronic Pain

On December 28, 2004, the FDA approved Prialt for the management of severe chronic pain in patients for whom intrathecal ("IT") therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine. Prialt was launched in the United States in January 2005.

In February 2005, the European Medicines Agency granted marketing authorization for Prialt for the treatment of severe, chronic pain in patients who require IT analgesia, in all 25 member states as well as Norway and Iceland.

Prialt is approved for use only in the Medtronic SynchroMed® EL, SynchroMed® II Infusion System and Simms Deltec Cadd Micro® External Microinfusion Device and Catheter.

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 IT infusion in more that 1,200 patients participating in chronic pain trials. The longest treatment duration to date was more than seven years.

Severe psychiatric symptoms and neurological impairment may occur during treatment with Prialt. Patients with a pre-existing history of psychosis should not be treated with Prialt. All patients should be monitored frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Prialt therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms.

The most frequently reported adverse events associated with the drug in clinical trials were asthenia, nausea, vomiting, abnormal gait, ataxia, confusion, dizziness, memory impairment, nystagmus, abnormal vision, and urinary retention. It is recommended that Prialt be administered intrathecally by or under the direction of a physician experienced in the technique of IT administration and who is familiar with the drug and device labeling. Prialt is not a substitute for opioids. If opiate withdrawal is required, patients must be withdrawn slowly from opiates when initiating therapy with Prialt.

HOSPITAL PRODUCTS

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

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, urologists, internal medicine physicians, hematologists and oncologists prescribe Maxipime for patients with severe hospital-based respiratory and non-respiratory conditions such as pneumonia, urinary tract infection and febrile neutropenia. An important attribute of Maxipime is its broad spectrum of activity, including activity against many pathogens resistant to other antibiotics. Revenue from sales of Maxipime amounted to $117.5 million for 2004. Our 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 product 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 totaled $50.6 million for 2004. Our basic U.S. patent on Azactam expires in October 2005.

See Item 5 A. "Operating Results" for additional information concerning our revenue by category in 2004, 2003 and 2002.

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.

About Alzheimer's Disease

Alzheimer's disease is a degenerative brain disorder that primarily affects older persons. In the United States, an estimated four 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.

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 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 development of 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 patients.

Beta amyloid, also known as Abeta, is actually a small part of a larger protein called the amyloid precursor protein ("APP"). Beta amyloid is formed when certain enzymes called secretases clip (or cleave) APP.

Alzheimer's Research and Development

Our scientists are investigating three key therapeutic approaches that target the 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 are thought to affect the accumulation of amyloid plaques in the brains of patients with Alzheimer's disease.

Research and Development in Beta Amyloid Immunotherapy

Beta amyloid immunotherapy is 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.

AAB-001

We, in collaboration with Wyeth, are continuing to pursue beta amyloid immunotherapy for mild to moderate Alzheimer's disease in a Phase II study of a humanized monoclonal antibody, AAB-001. This therapeutic antibody, which is thought to bind to 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. It is believed that this approach may eliminate the need for the patient to mount an immune response to beta amyloid.

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

ACC-001

We, in collaboration with Wyeth, are also developing ACC-001, a novel beta amyloid-related active immunization approach. This 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. This research is in the late preclinical discovery phase.

AN-1792

In July 2004, at the 9th International Conference on Alzheimer's Disease and Related Disorders, we, along with Wyeth, announced several key findings from our Phase IIA clinical trial of an investigational Alzheimer's disease treatment,

AN-1792. AN-1792 is a synthetic form of the beta amyloid peptide that pathologically builds up in the brains of persons with Alzheimer's disease. Although dosing with AN-1792 was halted in January 2002 after reports of encephalitis in a subset of patients, the trial remained blinded and the patients were followed in the study until December 2002.

While clinical development of AN-1792 has been terminated, the results presented in July 2004 support the beta amyloid immunotherapy approach, which is thought to treat Alzheimer's disease using an immunologic approach to clear beta amyloid from the brain. The results include less worsening on a neuropsychological test battery, including the memory component at 12 months in patients who developed an antibody response to AN-1792 compared to the placebo group. In addition, in three autopsy examinations of patients treated with AN-1792, reduction of beta amyloid plaque was observed.

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 identifying and developing small molecule inhibitors of beta and gamma secretases. We have been at the forefront of research in this area.

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, published in Nature in 1999, concerning the role beta secretase plays in beta amyloid production is 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. This program is in the preclinical discovery phase.

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.

About Parkinson's Disease

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, and 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.

Parkinson's Research

For more than two decades, we have been a recognized leader in neurodegeneration research, including Alzheimer's and Parkinson's disease. The goal of our Parkinson's disease discovery efforts is to identify a novel therapeutic target that prevents the neurodegenerative cascade associated with the disease. Our scientists are examining the underlying cause of Parkinson's disease in an attempt to develop disease-modifying therapies.

Our early stage discovery efforts are guided by the pathology and genetics of Parkinson's disease. Our scientists are studying synuclein in Lewy bodies to understand how it might play a potential role in the pathology of the disease. Our researchers are examining alpha-synuclein, a protein that accumulates in degenerating neurons in people with Parkinson's disease, as well as the role of genetically linked molecules, such as parkin, and their potential role in the development of the disease.

Our scientists, together with collaborators, are employing innovative strategies to identify and validate novel therapeutic approaches to reduce or halt the progression of Parkinson's disease. These efforts include an extensive biochemical analysis of the pathological lesions associated with Parkinson's disease, and the investigation of cellular, yeast, Drosophila and transgenic mouse model systems. For example, forward genetic studies in Drosophila have identified genes that suppress or enhance dopaminergic neuron as possible targets for therapeutic intervention in Parkinson's disease.

GLOBAL SERVICES & OPERATIONS

Drug Delivery and Manufacturing

Our drug delivery and manufacturing businesses engage in the development and commercialization of pharmaceutical products for clients through the application of drug delivery technologies. Our track record of innovation and expertise in drug optimization and delivery encompasses a full range of addressing industry challenges—from solving problems of poor solubility to customizing release profiles for oral dosage forms.

Drug delivery technologies can improve the performance of existing marketed drugs or drugs under development and can improve the efficacy of R&D processes. We have a long and established history in the manufacture and development of pharmaceutical dosage forms for pharmaceutical markets worldwide, with dozens of products successfully launched in more than 40 countries in North America, Asia and Europe. Our GS&O unit also assists companies with their pharmaceutical manufacturing, scale-up and development requirements.

GS&O also provides professional management services for our marketed products, including global supply chain management, strategic sourcing, demand planning, package design and control, and contract product procurement.

For more than 30 years, we have been applying our skills and knowledge to meet the challenges of drug delivery and enhance the performance of numerous drugs that have subsequently been marketed worldwide. We provide a range of services including formulation development, analytical development, clinical trial manufacturing and scale-up and

product registration support. The co-habitation of development and manufacturing capabilities on the same sites allows for streamlined scale-up and transfer to commercial scale manufacturing activities.

Products developed by others using our patented technologies that are on the market include:

- Avinza™ – once-daily, novel dual release morphine sulphate, marketed in the United States
- Emend® – oral capsule form of aprepitant, a poorly water soluble compound, marketed worldwide
- Herbesser® – once-daily, high-potency, sustained-release diltazem for Japanese and other Asian markets
- Naprelan™ – once-daily, sustained-release naproxen sodium, marketed in the United States
- Rapamune® – oral tablet form of rapamycin, marketed in the United States
- RitalinLA™ – once-daily, pulsatile release of methylphenidate marketed in the United States and other territories
- Theo-Dur® – twice-daily, sustained-release theophylline for Japanese market
- Verelan® – once-daily, sustained-release verapamil marketed worldwide
- Verelan® PM – modified release, chronotherapeutic verapamil marketed in the United States
- TriCor® – oral tablet form of fenofibrate, marketed in the United States

Our GS&O business has its principal manufacturing and development facilities located in Athlone, Ireland, where in 2004 we completed a $178.0 million investment and also in 2004, commenced building a $42.0 million sterile fill finish facility. The Athlone campus, an FDA/European Medicines Agency approved site, now comprises 421,000 square feet in total, of which 138,000 square feet has dedicated, fully-equipped cGMP compliant manufacturing capacity. See Item 5 B. "Liquidity and Capital Resources" for further information about our capital expenditures during 2004, 2003 and 2002.

We also have a manufacturing, scale-up and development facility approved for the manufacture of controlled substances (through Schedule II), in Gainesville, Georgia. Our development and scale-up facility in King of Prussia, Pennsylvania is a primary site for the utilization of our proprietary NanoCrystal technology, an innovative approach for delivering poorly water-soluble compounds.

About NanoCrystal Technology

NanoCrystal technology may enhance the clinical performance of poorly water-soluble drugs by transforming them into nanometer-sized particles. An increasing number of the drug candidates synthesized each year by pharmaceutical companies are poorly water-soluble. Many of these potentially innovative drug candidates are often abandoned because

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of poor pharmacokinetic properties including absorption, distribution, metabolism and excretion. NanoCrystal technology has the potential to rescue a significant percentage of these chemical compounds. 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. Our NanoCrystal technology is protected by more than 130 U.S. and foreign patents and patent applications.

COMPLETED TRANSACTIONS

Completion of Recovery Plan

In February 2004, we announced the formal completion of our recovery plan. The recovery plan, which was announced in July 2002, involved the restructuring of our businesses, assets and balance sheet; and resulted in gross consideration of $2.1 billion, exceeding the target of $1.5 billion. The principal elements and outcomes of the recovery plan are further described in Item 5. "Operating and Financial Review and Prospects."

2004 Divestments

During 2004 we divested a number of products and businesses, including our European sales and marketing business, Zonegran and Frova.

European Sales and Marketing Business

In February 2004, we completed the sale of our European sales and marketing business to Zeneus Pharma Ltd. ("Zeneus") (formerly Medeus Pharma Ltd.), a U.K. pharmaceutical company backed by Apax Partners Funds, for net proceeds of $93.2 million. We received an additional $6.0 million in February 2005. Approximately 180 employees of our European sales and marketing business transferred their employment to Zeneus. We realized a loss of $2.9 million on this transaction.

Zonegran

In April 2004, we sold our interests in Zonegran™ (zonisamide) in North America and Europe to Eisai Co. Ltd. ("Eisai") for $130.5 million before making a $17.0 million payment to Dainippon Pharmaceutical Co., Ltd. ("Dainippon") related to the assignment of the Zonegran license agreements. The gain from this transaction amounted to $42.9 million. With respect to Zonegran, we expect to receive additional consideration of up to $110.0 million from Eisai through January 1, 2006. The deferred consideration will be recorded as a gain if and when it is earned and entitled to be received. These payments are contingent on Zonegran receiving marketing approval in Europe ($25.0 million) and no generic zonisamide being introduced in the U.S. market before January 1, 2006 ($85.0 million). The $85.0 million will become due in installments on various dates up to January 1, 2006, assuming no generic zonisamide has been introduced in the U.S. market as of such dates. On March 16, 2005, Eisai announced the EU has granted marketing authorization approval for Zonegran and, as a result, we received $25.0 million from Eisai in March 2005. In addition, as no generic zonisamide had been introduced in the U.S. market by March 31, 2005, we received $17.0 million of the $85.0 million from Eisai in April 2005.

Frova

In March 2004, we terminated our development and license agreements with Vernalis plc ("Vernalis") regarding Frova™ (frovatriptan succinate). Vernalis agreed to purchase our commercialization rights in North America for Frova for $55.0 million, comprising $5.0 million received on closing in May 2004; $20.0 million and $25.0 million to be received on December 31, 2004 and December 31, 2005, respectively; and, no later than December 31, 2004, we were to receive a payment for our Frova inventory, estimated at approximately $5.0 million. In August, we agreed to settle the remaining consideration for approximately $44.0 million as a full payment for Frova. Our co-promotion agreement with UCB Pharma, Inc. ("UCB") was terminated at closing, and we paid UCB approximately $10.0 million as a result of the termination. We realized a gain of $7.9 million on the sale of Frova. The results of operations related to Frova have been included in discontinued operations as we have no significant continuing involvement with this business.

See Note 21 to the Consolidated Financial Statements for additional information on our divestments in 2004, 2003 and 2002.

Debt Refinancing

During 2004 and early 2005, we successfully completed the repositioning of our balance sheet by refinancing existing debt at lower average interest rates and with longer maturities. As a consequence, we now have no debt maturing until 2008, except for $39.0 million of Elan Pharmaceuticals Investments III Ltd. ("EPIL III") Series B and C guaranteed notes (collectively, "EPIL III Notes"), which matured and were repaid in March 2005.

In November 2004, we completed the offering of $1.15 billion aggregate principal amount of senior notes, consisting 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"), both due 2011. A portion of the proceeds from the offering was used to complete the repurchase of approximately $351.0 million of EPIL III Notes.

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 loan notes and related 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 of EPIL II and through the sale of EPIL II's entire investment portfolio. We funded the balance of $391.8 million under our guarantee arrangement.

Resolution of SEC Investigation and Shareholder Class Action

On October 25, 2004, we announced that we had reached a provisional agreement to settle the investigation by the SEC's Division of Enforcement that commenced in February 2002, and that we had reached an agreement to settle the related shareholder class action. On February 8, 2005, we announced that the SEC had given final approval to the previously announced provisional agreement. The approved settlement concluded all aspects of the investigation with respect to us and our current and former directors and officers and included a $15.0 million civil penalty.

Under the proposed class action settlement, all claims against us and the other named defendants would be dismissed with no admission or finding of wrongdoing on the part of any defendant. The principal terms of the proposed settlement provide for an aggregate cash payment to class members of $75.0 million, out of which the court would award attorneys' fees to plaintiffs' counsel, and $35.0 million of which would be paid by our insurance carrier. The terms of the settlement are subject to final court approval. For additional information, please refer to Note 26 to the Consolidated Financial Statements.

ENVIRONMENT

World Pharmaceutical Market

IMS audited global pharmaceutical sales increased by 7% from 2003 to $550.0 billion in 2004. In 2003, IMS audited global pharmaceutical sales increased by 9% over 2002. Biotech products accounted for 10% of global sales in 2004 and account for 27% of the active R&D pipeline.

North America, Japan and Europe accounted for approximately 88% of global pharmaceutical sales in 2004, the same level as in 2003. North America's pharmaceutical sales grew 8% to $248.0 billion, representing 45% of all global pharmaceutical sales in 2004.

The U.S. market is our most important market. Please refer to Note 31 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 Process," 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 ten 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 ("FDCA"), 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, labeling, storage, record-keeping, 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 compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions.

In addition, the U.S. Centers for Disease Control and Prevention regulate select biologics and toxins, including registration and inspection of facilities involved in the transfer or receipt of select agents. Select agents are subject to specific regulations for packaging, labeling 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.

Certain in vitro diagnostic products and certain delivery systems are regulated or potentially regulated in the United States under the FDCA as medical devices. These products are subject to pre-marketing and post-marketing requirements. Among other things, medical devices are subject to quality system requirements, including design control and good manufacturing practices, and to requirements for adverse event reporting by manufacturers, distributors and user facilities. The failure to adhere to these requirements can result in a refusal of permission to market and the imposition of sanctions, including seizure, recall notification, replacement or refund, injunction, and civil and criminal penalties. Additionally, as a condition to marketing or continued marketing, the FDA could impose certain post-market surveillance or tracking requirements, which could significantly increase the regulatory costs

associated with a product. Under the FDCA, it is also possible for a given product to be regulated both as a drug and a medical device or as a biologic and medical device. In vitro diagnostic products are also subject to certain requirements under the Clinical Laboratory Improvement Act of 1988, as amended, relating to test complexity and risk.

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 relating to nifedipine, a generic version of the hypertension drug Adalat 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 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™ (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 its 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 Process

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. The stages of testing required before a pharmaceutical product can be marketed in the United States are generally as follows:

Phase of Development	Description
Preclinical	Studies and laboratory tests to evaluate safety and efficacy, demonstrate activity of a product candidate and identify its chemical and physical properties
Phase I	Clinical studies to test safety profile of drug in humans
Phase II	Clinical studies conducted with groups of patients to determine preliminary efficacy, dosage and expanded evidence of safety
Phase III	Larger scale clinical studies conducted in patients to provide sufficient data for statistical proof of efficacy and safety

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 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 ten 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 (described in the table below), along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a license application such as a New Drug Application ("NDA") or a Biologics License Application ("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 labeling 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 labeling 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 labeling 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 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, 2004, we had manufacturing facilities in Ireland and the United States.

At December 31, 2004, we employed 735 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 $41.0 million in 2004, mainly at the Athlone facility. In addition, at Athlone we have commenced the building of a new 41,800 sq ft sterile fill finish facility which is expected to cost approximately $42.0 million to build. The sterile fill finish facility is expected to be completed by the first 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, a wholly owned subsidiary of Elan, 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. 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 is 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 RitalinLA, which are being manufactured at the Gainesville facility.

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. We have a basic U.S. patent for Tysabri covering the humanized antibody and its use to treat MS, which expires in 2014. This patent may qualify for a patent term extension of up to an additional 3 years. Additional U.S. patents covering the use of Tysabri to treat irritable bowel disease and to inhibit brain inflammation expire in 2012 and 2017, respectively. In Japan and the countries of the EU, primary patent coverage for the active ingredient in Tysabri expires in the 2015-2016 timeframe. If Tysabri receives regulatory approval in those jurisdictions, those patents may be eligible for some form of patent term extension of up to an additional 5 years.

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.

We have patents granted in the EU and other foreign countries related to the use and formulation of Prialt. The patents related to the use of Prialt expire in 2012 and those related to the formulation of Prialt expire in 2016.

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

Our basic U.S. patent for Azactam expires in October 2005. Following the expiration of this patent Azactam may face generic competition, which would have a substantial adverse effect on our revenues from, and gross margin for, Azactam.

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.

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. Other competitors consist of smaller research companies and generic drug manufacturers.

Tysabri, which was approved for marketing in the United States in November 2004 for the treatment of MS, would compete primarily with Avonex, marketed by our collaborator Biogen Idec; Betaseron®, marketed by Berlex Laboratories; Rebif®, marketed by Serono and Pfizer, Inc.; and Copaxone®, marketed by Teva Pharmaceutical Industries, Ltd. Many companies are working to develop new therapies or alternative formulations of products for MS,

which if successfully developed, would compete with Tysabri. In February 2005, the marketing and clinical dosing of Tysabri was voluntarily suspended.

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.

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 levels 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 all 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, 2004, we had 1,899 employees worldwide, of whom 575 were engaged in R&D activities, 571 were engaged in manufacturing and supply activities, 314 were engaged in sales and marketing activities and the remainder worked in general and administrative areas. The number of employees has been reduced from 2,159 employees at December 31, 2003 as a result of the continued implementation and completion of the recovery plan.

C. Organizational Structure

At December 31, 2004, we had the following principal subsidiary undertakings:

Company	Nature of Business	Group Share %	Registered Office & Country of Incorporation & Operation
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, marketing and distribution of 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, Ltd	Manufacture of pharmaceutical products	100	Monksland, Athlone Co. Westmeath, Ireland
Elan Pharma International, Ltd	R&D, manufacture, sale and distribution of pharmaceutical products and financial services	100	WIL House, Shannon Business Park, Co Clare, Ireland
Elan Pharmaceuticals, Inc.	R&D and sale of pharmaceutical products	100	800 Gateway Blvd South San Francisco, CA, United States
Elan Pharmaceutical Investments, III, Ltd	Investment holding company	100	Clarendon House, 2 Church St Hamilton, Bermuda
Monksland Holdings BV	Financial services company	100	Amsteldijk 166 6th Floor 1079 LH Amsterdam The Netherlands

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 19 to the Consolidated Financial Statements, which discloses future minimum rental commitments, Note 25 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.

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

Location and Ownership Interest	Use	Size
Owned: Athlone, Ireland	R&D, manufacturing and administration	421,000 Sq. Ft.
Owned: Gainesville, Georgia United States	Manufacturing and administration	71,200 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	194,500 Sq. Ft.
Leased: King of Prussia, Pennsylvania, United States	R&D, sales and administration	47,000 Sq. Ft.
Leased: Stevenage, United Kingdom	Product development and administration	35,800 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 5. Operating and Financial Review and Prospects

We are engaged in biopharmaceutical R&D activities, pharmaceutical commercial activities and pharmaceutical manufacturing activities. Biopharmaceutical R&D activities include the discovery and development of products in the therapeutic areas of neurodegenerative diseases, autoimmune diseases and severe pain. Our pharmaceutical commercial activities include the marketing of neurodegenerative and pain management products and hospital products. Our initiatives in product development, optimization and manufacturing are encompassed by GS&O, which is focused on providing technology platforms that address the drug delivery challenges of the pharmaceutical industry.

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements, 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 prepare separate Consolidated Financial Statements, included in our Annual Report, in accordance with Irish GAAP, which differs in certain significant respects from U.S. GAAP. The Annual Report under Irish GAAP is a separate document from this Form 20-F.

This financial review primarily discusses:

- Completion of recovery plan;
- Current focus of operations;
- Critical accounting policies;
- Restatements;
- Post balance sheet events;
- Results of operations for the year ended December 31, 2004 compared to 2003;
- Results of operations for the year ended December 31, 2003 compared to 2002;
- 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".

Completion of Recovery Plan

In February 2004, we completed the restructuring of our business in order to meet our financial commitments. The principal elements and outcome of the recovery plan were:

- A focus on three core therapeutic areas: neurodegenerative diseases, autoimmune diseases and severe pain;
- The divestment of financial assets, non-core businesses, products and assets targeting proceeds of $1.0 billion in the first nine months of the recovery plan and a further $500.0 million by the end of 2003. The total target of $1.5 billion was exceeded six months ahead of schedule, and by the end of the recovery plan gross consideration of $2.1 billion was achieved;
- To meet our financial obligations. Contractual and potential future payments were reduced by $2.5 billion during the course of the recovery plan;
- The implementation of a cost reduction program through headcount and infrastructure reductions and business rationalizations. At the completion of the recovery plan, headcount had been reduced to less than 2,000 from approximately 4,700 in July 2002; and
- A review of our business venture portfolio to conserve cash and reflect the reduced scope of our activities. As a result, we decided to restructure or terminate substantially all of our business ventures with the aim of substantially reducing or eliminating future cash outlays. All business ventures have been terminated, restructured or are now inactive. As a consequence, we do not expect to provide any additional financing to the business ventures and business venture parents. For additional information on the business ventures, please refer to Note 29 to the Consolidated Financial Statements.

Current Focus of Operations

We are now focused clearly on three core therapeutic areas: neurodegenerative diseases, autoimmune diseases and severe pain. Due to the number of product and business divestments since the beginning of 2002, our financial performance in historical years is of limited comparable relevance to an understanding of our future prospects. Near term, we are focusing our development, sales and marketing resources on Tysabri for MS and Crohn's disease, and Prialt, for severe pain. In November and December 2004, the FDA approved Tysabri for MS treatment and Prialt for severe pain treatment, respectively. In February 2005, the European Commission granted marketing approval for

Prialt for the treatment of severe, chronic pain in patients who require intrathecal analgesia. In addition, we are continuing our research of neurodegenerative diseases, including MS, rheumatoid arthritis, Alzheimer's disease and Parkinson's disease.

On February 28, 2005, we and Biogen Idec announced the voluntary suspension of marketing and clinical dosing of Tysabri. On March 30, 2005, we and Biogen Idec announced that our 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.

We are working with leading experts, regulatory agencies and the clinical investigators to investigate these serious adverse events and to determine the appropriate path forward.

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 carrying values of financial 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 No. 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, or based on their projected cash flows for certain intangible assets, 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, 2004, 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 GS&O. 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 impairment tests did not indicate any impairment in 2004.

In July 2002, we began a recovery plan. As a result of certain actions relating to the plan, we recorded material impairment charges to intangible assets of $Nil, $32.6 million and $266.1 million in 2004, 2003 and 2002, respectively. For additional information on these impairment charges, please refer to Note 20 to the Consolidated Financial Statements. Where the carrying value of intangible assets exceeded their fair values, the carrying values of those intangible assets have been written down to their fair values. Total goodwill and other intangible assets amounted to $780.8 million at December 31, 2004 (2003: $907.8 million). If we were to use different estimates, particularly with respect to expected proceeds from divestments, 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.

At December 31, 2004, we have $19.9 million of other intangible assets and $1.9 million of inventory relating to Tysabri. Tysabri is included in our Biopharmaceuticals segment, which has goodwill with a carrying value of $218.3 million at December 31, 2004. Biopharmaceuticals engages in research, development and commercial activities and includes our autoimmune diseases franchise, our pain franchise (including Prialt), our neurodegenerative diseases franchise (including our Alzheimer's disease programs), and our commercial group for hospital products (including Maxipime and Azactam). As a result of the voluntary suspension of the marketing and clinical dosing of Tysabri in February 2005, we have reassessed our periodic review of goodwill and other intangible assets for impairment. Our reassessment does not indicate impairment at this stage in relation to these assets. For goodwill, the fair value of our Biopharmaceutical reporting unit exceeds its carrying value and, therefore, we believe goodwill is properly valued as of the date of the filing of our 2004 Form 20-F. However, should new information arise, we may need to reassess goodwill and other intangible assets in light of the new information and we may then be required to take impairment charges related to goodwill and/or other intangible assets.

Investment Securities and Impairment

Our investment portfolio consists primarily of marketable equity securities, convertible preferred stock and interest-bearing debt of other biotechnology companies. Marketable equity and debt securities are accounted for as trading or as available-for-sale investments as described below. Non-marketable equity and debt securities are carried at cost. We periodically monitor the liquidity and financing activities of the respective issuers to determine if impairment write-downs are necessary.

Marketable equity and debt securities are classified into one of three categories in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," held-to-maturity, available-for-sale or trading. Marketable securities are considered held-to-maturity when we have the positive intent and ability to hold the securities to maturity. Marketable securities are considered trading when purchased principally for the purpose of selling in the near term. These securities are recorded as short-term investments and are carried at market value. Unrealized holding gains and losses on trading securities are included in other income. We have no held-to-maturity or trading securities at December 31, 2004. Securities not classified as held-to-maturity or as trading are considered available-for-sale. These securities are recorded as either short-term or long-term investments and are carried at fair value with unrealized gains

and losses included in accumulated other comprehensive income in stockholders' equity. Non-marketable equity and debt securities are carried at cost, less write-downs for impairments. The assessment for impairment is based on established financial methodologies, including quoted market prices for quoted equity securities. Non-marketable

securities are carried at cost and are adjusted for impairment based on methodologies, including the Black-Scholes option-pricing model, the valuation achieved in the most recent private placement by an investee, an assessment of the impact of general private equity market conditions, and discounted projected future cash flows. The factors affecting the assessment of impairments include both general financial market conditions for pharmaceutical and biotechnology companies and factors specific to a particular company. For additional information on these investment securities, please refer to Note 7 to the Consolidated Financial Statements.

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 26 to the Consolidated Financial Statements. In 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, 2004, we had accrued $63.4 million (which includes $55.0 million in relation to settlement of the SEC investigation and shareholder class actions), representing our estimate of the costs for the current resolution of these matters. We developed these 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

SAB 104 provides guidance on revenue recognition. SAB 104 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 revenues is $5.7 million, $10.1 million and $45.2 million for 2004, 2003 and 2002, respectively, 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. This is subject to the milestone being earned, non-refundable and not subject to future legal obligation.

Revenue—Discounts, Sales Returns, Rebates and Charge-backs

Estimated sales returns, pursuant to rights of return granted to our customers, are reflected as a reduction of revenue in the same period that the related sales are recorded. The sales returns provisions are based on actual experience, although in certain situations, for example, a new product launch or at patent expiry, further judgment may be required. Additionally, revenue is also recorded net of provision, made at the time of sale, for estimated cash discounts, rebates and charge-backs. These amounts are included in other current liabilities (rebates) or deducted from trade receivables (other discounts). Discounts, sales returns, rebates and charge-backs that require the use of judgment in the establishment of the accrual include Medicaid, managed care, long-term care, hospital and various other government programs. We enter into contracts with managed care organizations to provide access to our products. Based on a managed care organization's market share performance and utilization of our products, the organization receives rebates from us. In addition, we are bound by certain laws and regulations to provide products at a discounted rate to Medicaid recipients. Medicaid rebates are paid to each state in the United States based on claims filed by pharmacies that provide our products to Medicaid recipients at the reduced rate. Charge-backs are reimbursements to wholesalers for sales to third parties at reduced prices based on contracts that we negotiate. Cash discounts are provided to customers that pay their invoice within a certain time period. Discounts, sales returns, rebates and charge-backs are primarily based upon historical rebate and discount payments made to our customer segment groups. These amounts are calculated based upon a percentage of sales for each of our products as defined by the statutory rates and the contracts with our various customer groups. The nature of estimating discounts, sales returns, rebates and charge-backs is complex and subject to change. However, we believe that we have used reasonable judgements in assessing our estimates.

For additional information regarding our significant accounting policies, please refer to Note 2 to the Consolidated Financial Statements.

Restatements

Insurance Deposit

In this 2004 Form 20-F, we have adjusted our previously announced unaudited financial information under U.S. GAAP for the fiscal year ended December 31, 2004, and have restated our financial results previously reflected in the U.S. GAAP reconciliation footnote to our previously issued financial statements under Irish GAAP as of and for the years ended December 31, 2003 and 2002, to account for the termination of a historical product liability insurance program, which was established in 2000. As a result of termination of the program in December 2004, we received $21.0 million from the insurance provider, representing a refund of all of our previously paid premiums which had been expensed as paid, plus a return on the amount deposited less administrative costs. Due to the receipt of the refund upon termination of the program, we determined that the program had not resulted in a transfer of risk; therefore, the premiums paid should have been accounted for under the deposit method. Under the deposit method, insurance premiums paid that do not involve risk transfer should be capitalized as a deposit rather than expensed. We currently have no other similar insurance programs in place.

This adjustment increased our previously announced unaudited net loss under U.S. GAAP for 2004 by $18.8 million, from $375.9 million to $394.7 million, and reduced our reported net loss previously reflected in the U.S. GAAP reconciliation footnote to our previously issued financial statements under Irish GAAP for 2003 and 2002 by $2.6 million and $4.1 million, respectively, from $508.7 million to $506.1 million for 2003 and from $2,362.3 million to $2,358.2 million for 2002. In addition, the adjustment increased our previously reported shareholders' equity at December 31, 2003 by $18.8 million, from $599.1 million to $617.9 million, but had no impact on the previously announced unaudited shareholders' equity at December 31, 2004. This restatement had no effect on our previously reported results and shareholders' equity under Irish GAAP as the historical accounting for the insurance program is in conformity with Irish GAAP.

Income Taxes

In our 2003 Annual Report and Form 20-F/A, we restated our U.S. GAAP financial results previously reflected in the U.S. GAAP reconciliation footnote to our previously issued financial statements under Irish GAAP as of and for the year ended December 31, 2003 following a reassessment of net operating loss carryforwards expected to be recognized on a probable basis. This correction reduced our previously reported tax expense by $26.7 million, resulting in a tax benefit of $22.8 million and a net loss of $508.7 million for 2003 (prior to the restatement described above).

Post Balance Sheet Events

On February 28, 2005, we and Biogen Idec announced the voluntary suspension of the marketing and dosing in clinical trials of Tysabri. This decision was based on reports of two serious adverse events in patients treated with Tysabri in combination with Avonex in clinical trials. These events involved two cases of PML, a rare and frequently fatal demyelinating disease of the central nervous system. Both patients received more than two years of Tysabri therapy in combination with Avonex.

On March 30, 2005, we and Biogen Idec announced that our 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.

We are working with leading experts, regulatory agencies and the clinical investigators to investigate these serious adverse events and to determine the appropriate path forward.

A. Operating Results

2004 Compared to 2003 (in millions, except share and per share amounts)

	2004	2003 (restated)	% increase/ (decrease)
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	170.4	248.9	(32%)
Selling, general and administrative expenses	340.5	384.2	(11%)
Research and development expenses	257.3	277.6	(7%)
Gain on sale of businesses	(44.2)	(267.8)	(83%)
Restructuring and other charges, net	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	107.8	103.8	4%
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:	112.1	136.9	(18%)
Loss from continuing operations before provision for/(benefit from) income taxes	(414.2)	(497.4)	(17%)
Provision for/(benefit from) income taxes	(0.5)	(22.8)	(98%)
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	

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 Skelaxin, Sonatan™ and the European business, offset by 11% growth in revenue from retained products. The components of product revenue are set out below (in millions):

	2004	2003	% increase/ (decrease)
(A) Retained products [1]			
Maxipime	$ 117.5	$ 109.1	8%
Azactam	50.6	45.1	12%
Tysabri	6.4	—	100%
Contract manufacturing and royalties	130.9	120.0	9%
Total retained products' revenue	305.4	274.2	11%
(B) Amortized revenue — Adalat/Avinza	34.0	34.0	0%
(C) Divested products [2]			

European business [3]	10.5	89.0	(88%)
Zonegran [4]	41.2	80.7	(49%)
Skelaxin [5]	—	60.2	(100%)
Sonata [5]	—	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%)

(1) Products described as "Retained Products" include products or businesses not divested and not subject to divestment agreements.
(2) Products described as "Divested Products" include products or businesses divested since the beginning of 2003.
(3) Sold to Zeneus in February 2004.
(4) Sold to Eisai in April 2004.
(5) Sold to King in June 2003.
(A) Retained products

Total revenue from retained products increased to $305.4 million in 2004 from $274.2 million in 2003, an increase of 11%. The increase primarily reflected the growth in prescriptions and demand for Maxipime and Azactam, growth in contract manufacturing and royalties and initial sales of Tysabri. The basic patent on Maxipime expires in March 2007 and the basic patent on Azactam expires 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.

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.

Contract manufacturing and royalty revenues are as follows (in millions):

	2004	2003	% increase/ (decrease)
Verelan	$ 27.8	$ 38.2	(27)%
Diltiazem	15.9	20.3	(22)%
Skelaxin	12.2	7.4	65%
Other	75.0	54.1	39%
Total	$ 130.9	$ 120.0	9%

Contract manufacturing and royalty revenue comprises of revenue earned from products we manufacture for third parties, and royalties we earn on sales by third parties of products that incorporate our technologies. Contract manufacturing and royalty revenues increased 9% from $120.0 million in 2003 to $130.9 million in 2004. The increase was primarily related to additional manufacturing activities. Aside from Verelan and Diltiazem, no other single product accounted for more than 10% of our contract manufacturing and royalty revenues in either 2004 or 2003.

(B) Amortized revenue — Adalat/Avinza

Amortized revenue of $34.0 million in both 2004 and 2003 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). The transactions both occurred in 2002. The remaining unamortized revenue on these products of $69.2 million, which is included in deferred revenue, will be recognized as revenue through June 2007 (generic Adalat CC), $22.5 million and November 2006 (Avinza), $46.7 million, reflecting our ongoing involvement in the manufacturing of these products.

(C) 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).

Contract Revenue

	2004	2003	% increase/ (decrease)
	(in millions)		
License fees	$ 17.6	$ 49.6	(65%)
Research revenues/milestones	59.7	49.3	21%
Total contract revenue	$ 77.3	$ 98.9	(22%)

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

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 $170.4 million in 2004, compared to $248.9 million in 2003. The cost of sales as percentage of product revenue was 42% for both 2004 and 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 $340.5 million in 2004 compared to $384.2 million in 2003, a decrease of 11%. The decrease 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 approximately $35.0 million of launch costs in the fourth quarter of 2004 on Tysabri.

Research and Development Expenses

R&D expenses were $257.3 million in 2004 compared to $277.6 million in 2003, a decrease of 7%. The decrease 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.

Gain on Sale of Businesses

	2004	2003
	(in millions)	
Zonegran	$ 42.9	$ —
European business	(2.9)	—
Primary care franchise	—	264.4
Other	4.2	3.4
Total	$ 44.2	$ 267.8

In March 2004, we announced an agreement with Eisai for the sale of our interests in Zonegran in North America and Europe. The sale of Zonegran to Eisai closed in April 2004 for a total consideration of $130.5 million before making a $17.0 million payment to Dainippon related to the assignment of the Zonegran license agreements. The gain from this transaction amounted to $42.9 million. We may receive additional consideration related to Zonegran of up to $110.0 million from Eisai through January 1, 2006. The deferred consideration will be recorded as a gain if and when it is earned and entitled to be received. These payments are contingent on Zonegran receiving marketing approval in Europe ($25.0 million) and no generic zonisamide being introduced in the U.S. market before January 1, 2006 ($85.0 million). The $85.0 million will be paid in installments on various dates up to January 1, 2006, assuming no generic zonisamide has been introduced in the U.S. market as of such dates. On March 16, 2005, Eisai announced the EU

granted marketing authorization approval for Zonegran and, as a result, we received $25.0 million from Eisai in March 2005. In addition, as no generic zonisamide had been launched in the U.S. market by March 31, 2005, we received $17.0 million of the $85.0 million from Eisai in April 2005.

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. 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. We will also continue to receive royalties on net sales of Skelaxin until 2021.

Restructuring and other charges

The principal items classified as restructuring and other charges include asset impairments, purchase of royalty rights, severance and relocation costs, and losses incurred from litigation or regulatory actions, including shareholder class action

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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 items.

	2004	2003
	(in millions)	
(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, with respect to our investments in certain business ventures and business venture parents and the license fees and research revenues received from the business ventures; the accounting for proceeds from our sale of certain product lines and disclosure concerning those sales; the accounting for certain risk-sharing arrangements that we entered into and disclosure concerning those arrangements; the accounting for certain qualified special purpose entities and disclosure concerning those entities; the disclosure of compensation of certain of our officers; and certain alleged related-party transactions. We agreed to settle the action in October 2004. Under the proposed class action settlement, all claims against us and the other named defendants would be dismissed with no admission or finding of wrongdoing on the part of any defendant. The principal terms of the proposed settlement provide for an aggregate cash payment to class members of $75.0 million, out of which the court would award attorneys' fees to plaintiffs' counsel, and $35.0 million would be paid by our insurance carrier. The terms of the settlement are subject to final court approval.

We were also the subject of an investigation by the SEC's Division of Enforcement regarding matters similar to those alleged in such class action. We provisionally settled the investigation in October 2004. The SEC formally approved the settlement in February 2005. Under the 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 26 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 Note 30 to the Consolidated Financial Statements.

(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% Guaranteed Convertible Notes ("6.5% Convertible Notes") due 2008. 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 $107.8 million in 2004, compared to $103.8 million in 2003, an increase of 4%. 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 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 $0.5 million for 2004, compared to a net tax benefit of $22.8 million for 2003. The overall tax benefit to us for 2004 was $3.2 million. Of this amount, $2.7 million has been credited to shareholders' equity to reflect utilization of stock option deductions. The remaining $0.5 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 18 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 Athena Diagnostics, Elan Diagnostics, a portfolio of pain products (the "Pain Portfolio"), Actiq™ (oral transmucosal fetanyl citrate), the dermatology portfolio of products, Abelcet™ (amorphotericin B lipid complex) U.S./Canada, Myobloc™ (botulinum toxin type B), Myambutol (ethambutol 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 income statement. For additional information on discontinued operations, please refer to Note 21 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.

2003 Compared to 2002 (in millions, except share and per share amounts)

	2003 (restated)	2002 (restated)	% increase/ (decrease)
Product revenue	$ 586.7	$ 742.4	(21%)
Contract revenue	98.9	350.7	(72%)
Total revenue	685.6	1,093.1	(37%)
Costs and expenses:			
Cost of sales	248.9	305.6	(19%)
Selling, general and administrative expenses	384.2	541.6	(29%)

Research and development expenses	277.6	353.9	(22%)
Gain on sale of businesses	(267.8)	—	100%
Restructuring and other charges, net	403.2	500.7	(19%)
Total operating expenses	1,046.1	1,701.8	(39%)
Operating loss	(360.5)	(608.7)	(41%)
Net interest and investment (gains) and losses:			
Net interest expense	103.8	70.7	47%
Net investment (gains)/losses	(103.4)	39.2	364%
Impairment of investments	87.5	1,006.0	(91%)
Loss on sale of investments by EPIL III/Shelly Bay Holdings Ltd. ("Shelly Bay") transaction	—	141.6	(100%)
Charge arising from guarantee to EPIL II noteholders	49.0	295.4	(83%)
Net interest and investment losses	136.9	1,552.9	(91%)
Loss from continuing operations before provision for/(benefit from) income taxes	(497.4)	(2,161.6)	(77%)
Provision for/(benefit from) income taxes	(22.8)	8.0	385%
Net loss from continuing operations	(474.6)	(2,169.6)	(78%)
Net loss from discontinued operations (net of tax)	(31.5)	(188.6)	(83%)
Net loss	$ (506.1)	$ (2,358.2)	(79%)
Basic and diluted net loss per ordinary share:			
Net loss from continuing operations	$ (1.33)	$ (6.20)	79%
Net loss from discontinued operations (net of tax)	$ (0.09)	$ (0.54)	83%
Net loss	$ (1.42)	$ (6.74)	79%
Weighted average number of Ordinary Shares outstanding	356.0	349.7	

Product Revenue

The decrease in product revenue in 2003 was due mainly to the divestment of a number of products and businesses since the beginning of 2002, and the impact of generic competition on sales of Zanaflex (tizanidine hydrochloride), compensated for, in part, by growth of 19% in sales of those products retained.

	2003	2002	% increase/ (decrease)
	(in millions)		
(A) Retained products [1]			
Maxipime	$ 109.1	$ 79.2	38%
Azactam	$ 45.1	$ 33.0	37%
Contract manufacturing and royalties	$ 120.0	$ 118.5	1%
Total retained products' revenue	$ 274.2	$ 230.7	19%
(B) Amortized revenue— Adalat/Avinza	$ 34.0	$ 7.8	336%
(C) Divested products [2]			
European business [3]	$ 89.0	$ 81.7	9%

Zonegran [4]	$ 80.7	$ 43.1	87%
Skelaxin [5]	$ 60.2	$ 145.4	(59%)
Sonata [5]	$ 48.2	$ 92.5	(48%)
Zanaflex [6]	$ (5.2)	$ 56.8	(109%)
Other	$ 5.6	$ 21.6	(74%)
Total divested products' revenue	$ 278.5	$ 441.1	(37%)
(D) Co-promotion fees	$ —	$ 62.8	(100%)
Total product revenue	$ 586.7	$ 742.4	(21%)

(1) Products described as "Retained Products" include products or businesses not divested and not subject to divestment agreements.

(2) Products described as "Divested Products" include products or businesses divested since the beginning of 2002.

(3) Sold to Zeneus in February 2004.

(4) Sold to Eisai in April 2004.

(5) Sold to King in June 2003.

(6) Sold to Acorda Therapeutics, Inc. ("Acorda") in July 2004.

(A) Retained products

Revenue from retained products was $274.2 million in 2003, compared to $230.7 million in 2002, an increase of 19%. The increase was due to growth in prescriptions and demand for our retained products, principally Maxipime and Azactam. Sales of Maxipime and Azactam increased 37% in 2003, reflecting stronger demand and the negative impact on the sales of these products in 2002 due to a change in our discounting strategy and short-term supply issues resulting from third party manufacturing constraints.

Contract manufacturing and royalty revenues are as follows:

	2003	2002	% increase/ (decrease)
	(in millions)		
Verelan	$ 38.2	$ 39.0	(2)%
Diltiazem	20.3	6.3	222%
Skelaxin	7.4	—	100%
Other	54.1	73.2	(26)%
Total	$ 120.0	$ 118.5	1%

Contract manufacturing and royalty revenue comprises of revenue earned from products we manufacture for third parties, and royalties we earn on sales by third parties of products that incorporate our technologies. Contract

manufacturing and royalty revenues for 2003 remained consistent with 2002. Aside from Verelan and Diltiazem, no other single product accounted for more than 10% of the contract manufacturing and royalty revenues in either 2003 or 2002.

(B) Amortized revenue— Adalat/Avinza

Amortized revenue of $34.0 million (2002: $7.8 million) related to the licensing to Watson of rights to our generic form of Adalat CC ($9.0 million; 2002: $4.5 million) and the restructuring of our Avinza license agreement with Ligand ($25.0 million; 2002: $3.3 million). The remaining unamortized revenue on these products of $103.2 million at December 31, 2003 will be recognized as revenue through June 2007 (generic Adalat CC), $31.5 million and November 2006 (Avinza), $71.7 million, reflecting our ongoing involvement in the manufacturing of these products.

(C) 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. The decrease in product revenue in 2003 was primarily due to the divestment of a number of products and businesses, principally the European business, Zonegran, Skelaxin, Sonata and Zanaflex, 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 $89.0 million for 2003 (2002: $81.7 million).

In April 2004, we sold our interests in North America and Europe for Zonegran to Eisai. Zonegran generated revenue of $80.7 million for 2003 (2002: $43.1 million).

In June 2003, we completed the sale of our primary care franchise, principally our rights to Skelaxin and Sonata, to King. Product revenue from Skelaxin and Sonata in 2003 was $108.4 million (2002: $237.9 million).

In July 2004, we sold our interest in Zanaflex to Acorda. Product revenue from Zanaflex was negative $5.2 million in 2003 (2002: $56.8 million). The negative revenue in 2003 was a result of the adjustment to the discounts and allowance related to Zanaflex. Sales of Zanaflex declined significantly after the introduction of generic tizanidine into the U.S. market in June 2002.

(D) Co-promotion fees

Product revenue from product co-promotion and marketing activities, which resulted from our risk-sharing arrangements with Pharma Marketing and Autoimmune Diseases Research & Development Corp. Ltd. ("Autoimmune"), was $Nil for 2003 compared to $62.8 million for 2002. We will not receive any future revenue from either Pharma Marketing or Autoimmune as a result of the termination of the agreements. For additional information on Pharma Marketing and Autoimmune, please refer to Note 30 to the Consolidated Financial Statements.

Contract Revenue

	2003	2002	% increase/ (decrease)
	(in millions)		
License fees	$ 49.6	$ 234.7	(79%)
Risk-sharing arrangements	—	37.2	(100%)
Research revenues/milestones	49.3	78.8	(37%)

Total contract revenue	$ 98.9	$ 350.7	(72%)

License fee revenue for 2003 includes $35.2 million related to amortization of license fees earned from the business venture program, compared to $203.8 million for 2002. As part of the recovery plan, we terminated or restructured all of our business ventures. The reduction in amortized fees arose primarily from the restructuring and termination of business ventures, which started in 2002. There were no remaining unamortized fees from the business ventures at December 31, 2003.

Contract revenue also decreased as no revenue was received from either the Pharma Marketing or Autoimmune risk-sharing arrangements in 2003. We terminated our risk-sharing arrangements and will not receive any future revenue from either Pharma Marketing or Autoimmune. For additional information on Pharma Marketing and Autoimmune, please refer to Note 30 to the Consolidated Financial Statements.

The reduction in research revenues and milestones reflects a lower level of activity in 2003 coupled with the timing of the achievement of milestones.

Cost of Sales

The cost of sales was $248.9 million in 2003, compared to $305.6 million in 2002. The cost of sales as a percentage of product revenue in 2003 was 42%, compared to 41% for 2002. Although the margin in 2003 and 2002 remained relatively consistent, it was affected by various factors, including the change in the mix of product revenues, the divestment of a number of products and businesses over the period of the recovery plan and under-utilization of capacity at our manufacturing facility in Athlone. In addition, during 2003, royalties of $43.3 million (2002: $24.1 million) were paid to Pharma Marketing. Royalties paid were charged to cost of sales. In 2002, we recorded a charge of $43.3 million related to the write-off of Zanaflex inventories due to the impact of generic competition during 2002. There were no direct cost of sales related to our royalty revenue in 2003 and 2002.

Selling, General and Administrative Expenses

SG&A expenses were $384.2 million in 2003, compared to $541.6 million in 2002, a decrease of 29%. The decrease reflects the overall reduction in our activities as a result of the business and product divestments in both 2003 and 2002.

Research and Development Expenses

R&D expenses were $277.6 million in 2003, compared to $353.9 million in 2002, a decrease of 22%. The reduction in R&D expenses reflects the refocusing of R&D efforts on our key programs: Tysabri, Prialt and Alzheimer's disease.

Gain on Sale of Businesses

	2003	2002
	(in millions)	
Primary care franchise	$ 264.4	$ —

Other	3.4	—
Total	$ 267.8	$ —

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 as of December 31, 2003. We will also continue to receive royalties on net sales of Skelaxin until 2021.

We did not dispose of any businesses in 2002.

Restructuring and Other Charges, Net

	2003	2002
	(in millions)	
(A) Shareholder litigation and SEC investigation	$ 10.7	$ 22.6
(B) Severance, relocation and exit costs	29.7	77.8
(C) Purchase of royalty rights	297.6	121.0
(D) EPIL II/EPIL III waiver fee	16.8	—
(E) Asset impairments and write-off	32.6	266.1
(F) Gain on repurchase of LYONs	(1.6)	(37.7)
(G) Other litigation provisions	—	18.0
(H) 401(K) rescission offer	—	13.5
Other	17.4	19.4
Total restructuring and other charges, net	$ 403.2	$ 500.7

45

(A) Shareholder litigation and SEC investigation

During 2003, we recorded $10.7 million (2002: $22.6 million) related to legal costs incurred in the SEC investigation and shareholder class action lawsuit discussed above. For additional information on litigation, please refer to Note 26 to the Consolidated Financial Statements.

(B) Severance, relocation and exit costs

During 2003, we incurred severance, relocation and exit costs arising from the implementation of our recovery plan of $29.7 million (2002: $77.8 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 the employee headcount.

(C) Purchase of royalty rights

During 2003 and 2002, we repurchased royalty rights related to certain of our current and former products from Pharma Marketing and Autoimmune, respectively. For additional information on the purchase of royalty rights from Pharma Marketing and Autoimmune, please refer to Note 30 to the Consolidated Financial Statements.

(D) 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 due 2008. 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.

(E) Asset impairments and write-off

During 2003, we recorded $32.6 million (2002: $266.1 million) related to the impairment of tangible and intangible assets. 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.

	2003	2002
	(in millions)	
Quadrant Healthcare, plc ("Quadrant")	$ —	$ 59.5
Delsys Pharmaceutical Corporation ("Delsys")	—	45.7
Naprelan	—	34.2
Marketing technology	—	20.8
Other	32.6	105.9
Total	$ 32.6	$ 266.1

2003

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.

2002

We acquired Quadrant in December 2000 for $86.0 million. Quadrant was a drug delivery company with proprietary formulation technology applicable to pulmonary, oral and parenteral routes of administration. In 2002, we wrote-off the intangible assets arising from the acquisition of Quadrant by $59.5 million, as under our recovery plan, we decided to dispose of or close the Quadrant business. We subsequently sold this business to a company managed by former employees of the business in July 2003.

In September 2001, we acquired Delsys for $50.0 million. Delsys was formed in 1995 and engaged in developing novel manufacturing technology. During 2002, we recorded an impairment charge for the intangible assets relating to Delsys of $45.7 million, as under our recovery plan, we decided to close Delsys.

The intangible asset associated with Naprelan was written-down by $45.7 million due to the impact of generic competition in 2002 and reduced projected revenue and profitability.

During 2002, we also recorded an impairment charge of $20.8 million related to the write-off of a marketing technology platform that we ceased using.

Other asset impairments in 2002 related to the write-off or impairment of a number of less significant products, technologies and other assets.

(F) Gain on repurchase of LYONs

In December 1998, we, through our wholly owned subsidiary, Elan Finance Capital ("EFC") issued, in a private placement at a substantial discount, LYONs due in 2018 in the principal amount of $1,643.5 million at maturity. The issuance price of the LYON was $524.78 per $1,000 in principle amount at maturity and the gross proceeds amounted to $862.5 million. The expense related to the transaction amounted $23.1 million. The LYONs were exchangeable at anytime at the option of holder into 13.75 Elan ADSs per each $1,000 amount at maturity.

During 2003, we repurchased $1,323.4 million in principal amount at maturity of the LYONs. These LYONs, having an accreted value of $810.5 million at the date of purchase, were purchased at an aggregate cost of $803.4 million, resulting in a gain of $1.6 million, net of the related costs.

During 2002, we repurchased $318.6 million in principal amount at maturity of the LYONs. These LYONs, having an accreted value of $190.1 million at the date of purchase, were purchased at an aggregate cost of $149.8 million, resulting in a gain of $37.7 million after related costs.

(G) Other litigation provisions

We recorded a provision during 2002 of $18.0 million relating to litigation with Schwarz Pharma, Inc. ("Schwarz") Allergan, Inc. and Allergan Sales, LLC (collectively "Allergan"), and shareholder derivative actions. For additional information on litigation, please refer to Note 26 to the Consolidated Financial Statements.

(H) 401(K) rescission offer

In November 2002, we commenced a rescission offer with respect to 462,900 of our ADSs purchased by employees who participated in the Elan Pharmaceuticals, Inc. ("EPI") 401(k) plan between 1998 and 2001. The sale of these ADSs to the participants in the 401(k) plan was not registered under the Securities Act of 1933. The failure to register such sales necessitated the rescission offer. We recorded a charge of $13.5 million in 2002 as the result of the rescission offer.

Net Interest Expense

Net interest expense was $103.8 million in 2003, compared to $70.7 million in 2002, an increase of 47%. The increase reflects lower interest income earned on cash deposits and other investments and the interest costs associated with the $460.0 million 6.5% Convertible Notes issued in the fourth quarter of 2003, partially offset by lower interest expense due to the LYONs repurchases during 2002 and 2003.

Net Investment (Gains)/Losses

Net investment gains were $103.4 million in 2003, compared to net investment losses of $39.2 million in 2002. In 2003, we raised $238.2 million (2002: $233.0 million) in net cash proceeds from the disposal of investments and marketable investment securities. The principal gains in 2003 included a gain on the sale of securities of Ligand of $72.2 million and a gain from the movement in fair value of derivative instruments of $26.1 million. The principal losses in 2002 included business venture funding of $23.9 million and a loss on Maximus, a biotechnology investment fund, of $15.6 million.

Impairment of Investments

During 2003, impairment charges of $87.5 million reflected other-than-temporary impairments to the value of a number of investments, mainly in privately held biotech companies. Investment impairments of $1,006.0 million in 2002 resulted from a significant decline in the biotech sector overall, the impact on the value of smaller biotech companies (that make up a significant part of our portfolio) of difficult financing markets, and the impact of the business venture restructuring program initiated in the third quarter of 2002.

Loss on Sale of Investments by EPIL III/Shelly Bay Transaction

In March 2001, we transferred a portfolio of equity and debt securities to EPIL III, our wholly owned subsidiary. EPIL III issued $160.0 million in aggregate principal amount of Series A Guaranteed Notes, $190.0 million in aggregate principal amount of Series B Guaranteed Notes and $200.0 million in aggregate principal amount of Series C Guaranteed Notes. The Series A Guaranteed Notes matured on June 29, 2002. To fund the repayment of the notes, on June 29, 2002, EPIL III transferred certain investments, consisting of certain of the securities included in the portfolio transferred to EPIL III, to Shelly Bay and Shelly Bay made a $148.0 million cash payment to EPIL III. EPIL III used the proceeds from the payment by Shelly Bay, together with existing cash of $12.0 million, to repay the Series A Guaranteed Notes.

The documents that established EPIL III required that EPIL III dispose of investments in order to repay the Series A Guaranteed Notes at maturity. The documents also mandated the order in which the assets were to be sold prior to the maturity date for the Series A Guaranteed Notes. However, due to a number of factors, including the inability of Elan and EPIL III to locate the list mandating the order of disposal of the investments, the disposal process was commenced and completed over the one-week period ending on June 29, 2002. Although we, as servicing agent for EPIL III, contacted a number of third parties regarding their potential interest in purchasing investments from EPIL III, each of those parties indicated that they would not be able to complete a due diligence analysis of the issuers of the investments to be sold, or to receive all necessary internal approvals to complete the purchase, on a timely basis.

Therefore, in an effort to enable EPIL III to dispose of the investments, we determined that it would be necessary to provide non-recourse credit support to third parties who would agree to purchase investments from EPIL III. Credit support was offered to a number of potential purchasers of the investments. However, ultimately, only Shelly Bay possessed the ability to complete the transaction on a timely basis.

We established Shelly Bay specifically for the purpose of acquiring investments from EPIL III. All of the capital stock of Shelly Bay was issued to its sole shareholder. We did not own any capital stock of Shelly Bay and did not have a representative on Shelly Bay's board of directors. In addition, we had no previous relationship with the sole shareholder of Shelly Bay. However, as further described below, we possessed all of the financial risk of the Shelly Bay transaction. Similar to all other potential purchasers contacted by us, the sole shareholder of Shelly Bay was

unwilling to invest capital to acquire the investments until a due diligence analysis of the issuers of the investments had been completed. Therefore, the sole shareholder of Shelly Bay made no substantive capital investment in Shelly Bay and, although Shelly Bay possessed all of the potential financial benefits of the transaction, neither Shelly Bay nor its sole shareholder had any financial risk in the transaction.

We believed that any failure by EPIL III to dispose of the investments prior to June 29, 2002 could potentially adversely impact the non-consolidated accounting status of EPIL III under U.S. GAAP and could result in defaults under our debt instruments.

Under the terms of the transaction, Shelly Bay acquired certain investments from EPIL III on June 29, 2002 and made a cash payment to EPIL III of $148.0 million. Shelly Bay financed the entire purchase price of the investments, together with the funds necessary to pay interest and other costs on the loan to its maturity date, through borrowings under a $153.0 million non-recourse bank loan facility maturing on September 30, 2002. We provided a full and unconditional guarantee to the bank to support Shelly Bay's obligation to repay the loan and provided $153.0 million in cash collateral to the bank to secure our obligations under the guarantee. Upon the closing of the transaction, we paid to Shelly Bay approximately $1.0 million to reimburse Shelly Bay for the expenses expected to be incurred by it in connection with the transaction. In addition, we irrevocably waived all rights of recourse against Shelly Bay in the event that it failed to repay the bank loan at maturity.

The cash payment made by Shelly Bay in connection with its acquisition of the investments was based upon a valuation we conducted. The valuation utilized customary, widely accepted valuation methodologies and required that we make certain judgments and assumptions regarding the investments. We did not receive any independent verification of the valuation at the time of the transaction. In addition, EPIL III did not receive any bids for the investments to be disposed of.

Upon the closing of the transaction, Shelly Bay's assets consisted solely of the investments purchased from EPIL III. Under the terms of the transaction, Shelly Bay was required to complete a due diligence analysis of the issuers of the securities prior to September 15, 2002. Shelly Bay had the right to either elect, on or prior to 15 September 2002, to retain the investments on a long-term basis or to dispose of the investments prior to September 30, 2002.

In the event that Shelly Bay elected to retain the investments, it was required, within 15 days of the election, to obtain alternative financing in an amount equal to the value, as of June 29, 2002, of the assets being retained, as determined by

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an independent appraiser engaged by Shelly Bay. The net cash proceeds received by Shelly Bay from any alternative financing were required to be applied to repay amounts outstanding under Shelly Bay's bank loan.

In the event that Shelly Bay elected to dispose of the investments prior to September 30, 2002, Shelly Bay was required to apply the net proceeds from the dispositions to repay amounts outstanding under its bank loan. The transaction agreements contained no limitation on the price at which Shelly Bay or the party to whom any investment could be sold. In addition, we agreed that we had no right to object to the disposition of any investment, the party to whom it was disposed or the price obtained for the disposition.

Given the non-recourse nature of the Shelly Bay bank loan, we possessed all of the financial risk of the transaction under our guarantee of the bank loan, and the cash collateral that we provided to secure the guarantee, in the event of

any shortfall in the aggregate proceeds received by Shelly Bay from the refinancing or disposition of the investments. Although Shelly Bay possessed all of the potential financial benefits of the transaction, neither Shelly Bay nor its sole shareholder had any financial risk in the transaction.

As required by the terms of the transaction, Shelly Bay engaged an independent appraiser to value the investments as of June 29, 2002. The appraisal, which was prepared in early September 2002, valued the investments at $8.2 million.

Shelly Bay did not elect, under the terms of the transaction, to retain any of the investments and obtain alternative financing in an amount equal to the independent appraiser's valuation. Rather, by September 30, 2002, Shelly Bay had disposed of all of the investments for aggregate net proceeds of $9.3 million. A number of the investments were disposed of, for net proceeds of $1.8 million, to an affiliate of Shelly Bay. The remainder of the investments were sold to third parties in open market transactions. As described above, the transaction agreements contained no limitation on the price at which Shelly Bay or the party to whom any investment could be sold, including to an affiliate of Shelly Bay. In addition, we agreed that we had no right to object to the disposition of any investment, the party to whom it was disposed of or the price obtained for the disposition.

As a result of the disposition of the investments by Shelly Bay for aggregate net proceeds of $9.3 million, on September 30, 2002, we made a cash payment of $141.6 million to satisfy its obligation under its guarantee. Under the terms of the transaction agreements, we have no further obligation under the guarantee and have no recourse to Shelly Bay or to its sole shareholder arising from our payment under the guarantee.

Charge Arising from Guarantee to EPIL II Noteholders

We had guaranteed the EPIL II Notes, issued by EPIL II, to the extent that the investments held by EPIL II were insufficient to repay the EPIL II Notes and accrued interest. During 2003, a charge of $49.0 million (2002: $295.4 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. The charge in 2002 resulted from a significant decline in the biotech sector overall, the impact on the value of smaller biotech companies that made-up a significant part of EPIL II's portfolio, difficult financing markets and the impact of the business venture restructuring program initiated in the third quarter of 2002.

Provision for Income Taxes

We had a net tax benefit of $22.8 million for 2003, compared to a net tax expense of $8.0 million for 2002. The tax benefit for 2003 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 18 to the Consolidated Financial Statements.

Net Loss from Discontinued Operations

Net loss from discontinued operations was $31.5 million in 2003, compared to $188.6 million in 2002. The net loss from discontinued operations includes gains on sale of businesses of $22.9 million (2002: $177.9 million) and other charges of $58.4 million (2002: $344.2 million). During the course of the recovery plan, we sold a number of products and businesses (including Athena Diagnostics, Elan Diagnostics, the Pain Portfolio, Actiq, the dermatology portfolio of products, Abelcet U.S./Canada, Myobloc, 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 21 to the Consolidated Financial Statements.

Net Loss and Net Loss per Ordinary Share

Net loss for 2003 was $506.1 million, compared to net loss of $2,358.2 million for 2002. Basic and diluted net loss per share was $1.42 for 2003, compared to $6.74 per share for 2002. Basic and diluted net loss from continuing operations was $1.33 per share for 2003, compared to $6.20 per share for 2002. Basic and diluted net loss from discontinued operations was $0.09 per share for 2004, compared to $0.54 per share for 2002.

Segment Analysis

In 2002, we suffered a number of setbacks in rapid succession, including the cessation of dosing in a Phase IIA clinical trial of AN-1792, an experimental immunotherapeutic that was under development for the treatment of Alzheimer's disease, and the announcement of a profit warning and an investigation by the SEC. These disappointments ultimately led to a loss of confidence in us. To address these issues, we began a recovery plan in July 2002 to restructure our business in order to meet our financial commitments.

In February 2004, we announced the formal completion of our recovery plan. The recovery plan, which was announced on July 31, 2002, involved the restructuring of our businesses, assets and balance sheet; and resulted in gross consideration of $2.1 billion, ahead of the target of $1.5 billion. With the completion of the recovery plan, the operations of Core Elan and Elan Enterprises were reorganized into two business units: Biopharmaceuticals and GS&O. In this reorganization, our Core Elan business, with the exception of its drug delivery businesses, now forms the Biopharmaceuticals business unit. The remaining businesses in Elan Enterprises, comprising principally drug delivery businesses, were amalgamated with the drug delivery business from Core Elan, to form GS&O.

Biopharmaceuticals engages in research, development and commercial activities and includes our autoimmune diseases franchise, our pain franchise, our neurodegenerative diseases franchise, and our commercial group for hospital products. GS&O focuses on product development and manufacturing to provide technology platforms that address drug delivery challenges of the pharmaceutical industry.

All prior period financial information has been reclassified to reflect the new basis of segmentation.

Our total revenue of $481.7 million in 2004 (2003: $685.6 million; 2002: $1,093.1 million) was comprised of revenue from Biopharmaceuticals of $275.1 million (2003: $479.7 million; 2002: $688.5 million) and GS&O of $206.6 million (2003: $205.9 million; 2002: $404.6 million), respectively. Our total operating loss of $302.1 million in 2004 (2003: $360.5 million; 2002: $608.7 million) was comprised primarily of operating losses incurred by Biopharmaceuticals of $253.2 million (2003: $318.1 million; 2002: $582.8 million), partially offset by operating income from GS&O of $14.2 million (2003: $5.7 million; 2002: $32.9 million), respectively.

Biopharmaceuticals' revenue decreased 43% to $275.1 million in 2004 from $479.7 million in 2003 and 60% from $688.5 million in 2002. The decrease is primarily due to product and business disposals. Biopharmaceuticals operating loss decreased 20% to $253.2 million from $318.1 million in 2003 and 57% from $582.8 million in 2002. The decrease was due to the cost cutting initiative and the disposal of products and businesses. Biopharmaceuticals' net gain on sale of businesses decreased from $271.2 million in 2003 to $41.2 million in 2004, primarily related to the gain on sale of the primary care business in 2003. Biopharmaceuticals' restructuring and other charges decreased from $343.7 million in 2003 to $0.2 million in 2004, primarily relating to the purchase of royalty rights from Pharma Marketing in 2003. Biopharmaceuticals' other charges increased from $319.1 million in 2002 to $343.7 million in

2003, primarily relating to the purchase of royalty rights from Autoimmune and asset impairments.

GS&O revenue increased to $206.6 million in 2004 from $205.9 million in 2003 and decreased 49% from $404.6 million in 2002. The decrease from 2002 was primarily due to the disposals of products and businesses since the inception of the recovery plan in early 2002. GS&O operating income increased to $14.2 million in 2004 from $5.7 million in 2003, primarily due to the decrease in our expenses as a result of the business and product divestments in both 2004 and 2003. GS&O gain on sale of businesses increased from a $3.4 million loss in 2003 to a $3.0 million gain in 2004. GS&O restructuring and other charges decreased from $127.0 million in 2002 to $13.9 million in 2003, primarily related to asset impairments.

For additional information regarding our reportable segments, please refer to Note 31 to the Consolidated Financial Statements.

Risk Sharing Arrangements

Pharma Marketing

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 were 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 2004 or 2003. Our revenue from Pharma Marketing was $31.3 million in 2002, consisting of $24.0 million for commercialization expenditures, which has been recorded as product revenue, and $7.3 million for development expenditures, which has been recorded as contract revenue. 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 first $122.9 million of net sales and 53% for net sales above $122.9 million. In 2002, the royalty rate on net sales of all designated products was 16% on the first $122.9 million of net sales and 4% for net sales above $122.9 million. We paid aggregate royalties of $43.3 million in 2003 (2002: $24.1 million). 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 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 Prialt; 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, 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 Limited (Ireland) 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.

Autoimmune

In December 2001, Autoimmune completed a private placement of its common shares to a group of institutional investors, resulting in gross proceeds to Autoimmune of $95.0 million. In the same initial tranche, we purchased non-voting preferred shares of Autoimmune's subsidiary for an aggregate purchase price of $37.5 million. We had no representative on the board of directors of Autoimmune. We also committed to a second investment in the same amount to be completed in April 2003, subject to certain conditions. The related Program Agreement was a risk-sharing arrangement among the companies. Under the terms of the Program Agreement, Autoimmune acquired royalty rights to each of the following products and development projects for the designated indications: (i) Tysabri, for the treatment of relapsing forms of MS, moderate-to-severe inflammatory bowel disease, including Crohn's disease and ulcerative colitis, and moderate-to-severe rheumatoid arthritis; (ii) Maxipime, for the treatment of infection; (iii) Azactam, for the treatment of infection; and (iv) Abelcet, for the treatment of severe fungal infection. Autoimmune also acquired royalty rights on certain development projects, as well as any other product subsequently developed or acquired by us that had an indication substantially the same as Maxipime, Azactam or Abelcet and that would be in direct competition with Maxipime, Azactam or Abelcet. Autoimmune agreed to make payments to us in amounts equal to expenditures we incurred in connection with the commercialization and development of these products, subject to certain limitations. These payments were to be made on a quarterly basis based on actual costs incurred by us. We did not receive a margin on these payments. Our revenue from Autoimmune was $68.7 million for 2002, consisting of $38.8 million for commercialization expenditures, which has been recorded as product revenue, and $29.9 million for development expenditures, which has been recorded as contract revenue. We have received no revenue from Autoimmune since June 2002. We will not receive any future revenue from Autoimmune. No royalties were payable to Autoimmune by us in 2004, 2003, or 2002.

Under the original agreement, we could, at our option at any time prior to April 2005, acquire the royalty rights by initiating an auction process. In addition, the holders of the Autoimmune common shares could initiate the auction process earlier upon the occurrence of certain events. If the auction process had not been initiated prior to October 2004, it would have automatically commenced. Pursuant to the auction process, Autoimmune and we would have negotiated in good faith to agree on a purchase price, subject to our right to re-acquire the royalty rights at a maximum purchase price. This maximum purchase price increased at various rates, approximately 25% annually, subject to certain conditions.

In July 2002, we announced the termination of all agreements relating to the risk-sharing arrangement with Autoimmune. The royalty obligations to Autoimmune were terminated. The total consideration for the royalty rights was $121.0 million, which, after taking account of the redemption of our investment of $38.5 million in Autoimmune, resulted in a net cash cost of $82.5 million. We expensed $121.0 million as an other charge arising from the acquisition of royalty rights from Autoimmune.

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):

	2004	2003 (restated)	Increase/ (Decrease)

Cash and cash equivalents	$ 1,347.6	$ 778.2	73%
Restricted cash (current)	164.3	—	100%
Short-term marketable investments	65.5	349.4	(81%)
Shareholders' equity	205.0	617.9	(67%)

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, 2004 consisted of cash and cash equivalents of $1,347.6 million, which excludes restricted cash of $192.7 million (current and non-current), and short-term marketable securities of $65.5 million.

At December 31, 2004, our working capital was $1,286.2 million, which increased 85% from $697.1 million at December 31, 2003. The increase is primarily due to the $1.1 billion of net additional borrowings raised in November 2004, partially offset by the $351.0 million repayment of EPIL III Notes and the $391.8 million payment under the EPIL II guarantee.

At December 31, 2004, our shareholders' equity was $205.0 million, compared to $617.9 million at December 31, 2003. The decrease is due primarily to our significant net loss from operations incurred during the year.

Cash Flows

	2004	2003 (restated)	2002 (restated)
		(in millions)	
Net cash provided by/(used in) operating activities	$ (347.9)	$ (428.5)	$ 137.2
Net cash provided by/(used in) investing activities	474.2	369.6	(65.6)
Net cash provided by/(used in) financing activities	441.5	(175.7)	(681.9)
Effect of exchange rate changes on cash	1.6	12.5	11.2
Net increase/(decrease) in cash and cash equivalents	569.4	(222.1)	(599.1)
Cash and cash equivalents at beginning of year	778.2	1,000.3	1,599.4
Cash and cash equivalents at end of year	$ 1,347.6	$ 778.2	$ 1,000.3

The results of our cash flow activities for 2004 and 2003 are described below.

2004

Net cash used in operating activities was $347.9 million in 2004. 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 increase in trade receivable and prepaid and other current assets of $21.3 million, the decrease in inventory of $17.1 million, and the net decrease of $26.7 million in accounts payable and accrued and other current 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 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 assets, primarily relating to payments for Maxipime and Azactam intangible assets of $35.6 million. As of December 31, 2004, we did not have any significant commitments to purchase property, plant and equipment, except for committed additional capital

expenditures of approximately $40.0 million.

Net cash provided by financing activities totaled $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. With the completion of the debt financing in November 2004, we have no debt due until 2008, other than $39.0 million of the EPIL III Notes, which were repaid in full in March 2005.

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

2003

Net cash used in operating activities was $428.5 million. The primary components of cash used in operating activities were net loss, adjusted to exclude non-cash charges and benefits, and changes in working capital accounts. The changes in working capital accounts include a net decrease in trade receivables and prepaid and other current assets of $16.8 million, decrease in inventory of $9.9 million, and a net decrease of other working capital accounts of $243.8 million, driven primarily by the decrease in accounts payable and accrued and other current liabilities. The changes in working capital in 2003 primarily relate to a decrease in accounts payable and accrued liabilities as a result of the completion of the recovery plan, and a reduction in debt interest accruals mainly due to payment of accrued interest on LYONs. Also included in our operating cash flows was the sale of investments previously received by us as a result of the sale of product rights to third parties for $79.0 million, of which $61.5 million related to the sale of our investments in Xcel Pharmaceuticals, Inc. ("Xcel") to Xcel. We had originally received these investments from Xcel in 2001 in exchange for the sale of two of our former products to Xcel.

Net cash provided by investing activities was $369.6 million in 2003. The primary components include proceeds of $593.0 million from business disposals (mainly related to the primary care franchise), $53.1 million from the disposal of investments, $185.1 million from the sale and maturity of marketable investment securities and $27.9 million from the disposal of property, plant and equipment. These proceeds were offset by cash outflows of $144.8 million for purchases of intangible assets, $33.7 million for capital expenditures, and the $297.6 million payment made to acquire product royalty rights from Pharma Marketing.

Net cash used in financing activities amounted to $175.7 million in 2003, primarily consisting of $770.7 million for the repurchases of LYONs, offset by $167.9 million of net proceeds from the sale of common stock and $443.9 million of net proceeds of from the issuance of the 6.5% Convertible Notes.

Debt Facilities

At December 31, 2004, we had long-term and convertible debt outstanding of $2,260.0 million, excluding $39.0 million of EPIL III Notes due and repaid in full in March 2005, under borrowing facilities:

- 6.5% Convertible Notes due 2008 — $460.0 million;
- 7.25% senior notes ("Athena Notes") due 2008 — $650.0 million;
- 7.75% Notes due 2011 — $850.0 million; and

- Floating Rate Notes due 2011 — $300.0 million

During 2004, as of December 31, 2004, and, as of the date of filing of this Form 20-F, we were not in violation of any of our debt covenants. At December 31, 2004, we had no undrawn debt facilities.

For additional information regarding our outstanding debt, please refer to Note 15 to the Consolidated Financial Statements.

Commitments and Contingencies

For information regarding commitments and contingencies, please refer to Notes 25 and 26 to the Consolidated Financial Statements.

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

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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, 2004, 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, 2004, 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.

	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
EPIL III Notes	$ 39.0	$ 39.0	$ —	$ —	$ —
Athena Notes due 2008	650.0	—	—	650.0	—
6.5% Convertible Notes due 2008	460.0	—	—	460.0	—
7.75% Notes due 2011	850.0	—	—	—	850.0
Floating Rate Notes due 2011	300.0	—	—	—	300.0
Total debt principal obligations	2,299.0	39.0	—	1,110.0	1,150.0
Debt interest payments [1]	840.1	158.6	315.8	204.0	161.7
Capital lease obligations[2]	15.6	6.9	8.7	—	—
Operating lease obligations	150.1	18.4	30.8	34.1	66.8
Total contractual obligations	$ 3,304.8	$ 222.9	$ 355.3	$ 1,348.1	$1,378.5

[1] 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, 2004.

[2] 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 $64.3 million at December 31, 2004 (2003: $63.8 million).

As of December 31, 2004, the directors had authorized the following capital commitments for the purchase of property, plant and equipment (in millions):

Contracted for	$15.9
Not-contracted for	24.1
Total	$40.0

At December 31, 2004, we had commitments to invest $3.2 million (2003: $3.8 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 March 31, 2005 are as follows:

Standard & Poor's Rating	Moody's Investors Service

	Services	
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 and 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. 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, 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.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Directors

Kyran McLaughlin (60) was appointed a director of Elan Corporation, plc in January 1998 and was appointed chairman of Elan Corporation, plc 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.

Garo H. Armen, PhD (52) was appointed a director of Elan Corporation, plc in February 1994 and served as chairman from July 2002 until January 2005. He has been chairman and chief executive officer of Antigenics, Inc. ("Antigenics") since its initial public offering in February 2000 and held the same positions in its predecessor, Antigenics, LLC since its formation in 1994. Previously, Dr. Armen was with Dean Witter Reynolds as a senior vice president of research and with E.F. Hutton & Company as first vice president, research.

Brendan E. Boushel (74) was appointed a director of Elan Corporation, plc in January 1980. From 1966 until his retirement in 1994, Mr. Boushel was a partner in the Irish law firm of T.T.L. Overend McCarron & Gibbons. Mr. Boushel also holds a number of private company directorships.

Laurence G. Crowley (68) was appointed a director of Elan Corporation, plc in March 1996. He is governor (chairman) of the Bank of Ireland. He is presently chairman of PJ Carroll & Co. and is a director of a number of private companies.

William F. Daniel (53) was appointed a director of Elan Corporation, plc in February 2003. He has served as our secretary since December 2001, having joined us 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.

Alan R. Gillespie, C.B.E. PhD (54) was appointed a director of Elan Corporation, plc in March 1996. He is chairman of Ulster Bank Limited. 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 (59) was appointed a director of Elan Corporation, plc 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.

John Groom (66) was appointed a director of Elan Corporation, plc in July 1996 and served as president and chief operating officer from then until his retirement in January 2001. Mr. Groom was president, chief executive officer and director of Athena Neurosciences Inc., ("Athena Neurosciences") prior to its acquisition by us in 1996. Mr. Groom serves on the boards of Neuronyx Inc., Ligand, CV Therapeutics and Amarin Corporation plc ("Amarin").

G. Kelly Martin (46) was appointed a director of Elan Corporation, plc 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 (61) was appointed a director of Elan Corporation, plc in December 1998. From 1990 until his retirement in December 1998, he was chief executive of IDA 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, An Post National Lottery Company Ltd., and a number of private companies.

Kevin M. McIntyre, MD (69) was appointed a director of Elan Corporation, plc 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 (61) was appointed a director of Elan Corporation, plc 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.

The Honorable Richard L. Thornburgh (72) was appointed a director of Elan Corporation, plc in March 1996. He served as governor of Pennsylvania for two terms and as attorney general of the United States from 1988 to 1991. He is presently of counsel to the law firm of Kirkpatrick & Lockhart LLP in Washington, D.C. He was appointed lead independent director of Elan in May 2002.

Officers serve at the discretion of the board of directors. Directors of Elan Corporation, plc 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 (48) is executive vice president, global services and operations. 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. Mr. Breen holds a degree in science and is a graduate of University College Dublin.

Nigel Clerkin (31) 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 (51) 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 Corporation ("Pharmacia"), 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.

Shane Cooke (42) 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.

Lars Ekman MD, PhD (55) was appointed executive vice president and president, global R&D since joining Elan 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.

Allison Hulme, PhD (41) was appointed executive vice president, therapeutic franchise group for Elan 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.

Karen S. Kim (42) was appointed executive vice president, strategy, business development, brand management & communications, 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, which she joined in 1998, and where she most recently was head of Client Development in the International Private Client Group. Previously, she held senior management positions with the Cambridge Group and The MAC Group/Gemini Consulting.

Ivan Lieberburg, MD, PhD (55) 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.

Kathleen Martorano (43) 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, which she joined in 1996, and where she most recently was first vice president of Marketing and Communications for the International Private Client Group. Previously, she held senior management positions with Salomon Brothers.

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, 2004, all executive officers and directors as a group (19 persons) received total compensation of $6.4 million.

We reimburse officers and directors for their actual business-related expenses. For the year ended December 31, 2004, an aggregate of $0.4 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					
Executive Directors:	2004 Salary/Fees	2004 Annual Bonus	2004 Pension	2004 Benefit In Kind	2004 Total	2003 Total
G. Kelly Martin	$ 834,831	$ (1)	$ 6,150	$ 17,271	$ 858,252	$1,580,540
William Daniel	310,819	238,578	42,912	20,571	612,880	464,191
Total	$1,145,650	$ 238,578	$ 49,062	$ 37,842	$1,471,132	$2,044,731

(1)Mr. Martin waived his 2004 performance cash bonus and on March 10, 2005 was granted 200,000 stock options with an estimated fair value of $900,000 at an exercise price of $7.47 per share in lieu of his cash bonus. 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 page 64.

	Year Ended December 31					
Non-Executive Directors:	2004 Fees	2004 Annual Bonus	2004 Pension	2004 Benefit in Kind	2004 Total	2003 Total
Kyran McLaughlin	$ 96,250	$ —	$ —	$ —	$ 96,250	$ 85,000
Garo H. Armen, PhD.	300,000	—	—	—	300,000	240,000
Brendan E. Boushel	51,250	—	—	—	51,250	40,000
Laurence G. Crowley	76,250	—	—	—	76,250	65,000
Alan R. Gillespie, C.B.E. PhD.	63,750	—	—	—	63,750	53,859
Ann Maynard Gray	88,750	—	—	—	88,750	77,500
John Groom	51,250	—	200,000	—	251,250	240,000
Kieran McGowan	76,250	—	—	—	76,250	65,000
Kevin M. McIntyre, MD.	71,250	—	—	—	71,250	60,000
Dennis J. Selkoe, MD.	51,250	—	—	—	51,250	65,000
Richard L. Thornburgh	71,250	—	—	—	71,250	60,000
Daniel P. Tully[(1)]	88,750	—	—	—	88,750	77,500
Total	$ 1,086,250	$ —	$ 200,000	$ —	$ 1,286,250	$ 1,128,859
Average number of non-executive directors					12	12

(1)Daniel P. Tully resigned as director on November 1, 2004.

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.

On April 1, 2002, we 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 $76,200 in 2004 and $25,000 in 2003.

Payments to Former Directors:	2004	2003
Donal Geaney	$ 660,304	$ 1,122,082
Thomas Lynch	459,615	899,955
Donald Panoz	160,000	160,000
Nancy Panoz	25,000	25,000
Total	$ 1,304,919	$ 2,207,037

On July 9, 2002, 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.

C. Board Practices

The Board

The roles of chairman and chief executive officer are separated. Under our Corporate Governance Guidelines, two-thirds of the board is independent. The board currently includes 9 independent, non-executive directors who constitute in excess of 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. 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 has delegated authority over certain areas of our activities to four standing committees, as more fully described below, during 2004. The board held 12 meetings during 2004.

Executive Committee

The executive committee exercised the authority of the board during the interval between board meetings, except to the extent that the board had delegated authority to another committee or to other persons, or had reserved authority to itself or as limited by Irish law. The members of the committee were Dr. Armen, chairman, Mr. McLaughlin, Mr. Crowley, Ms. Gray and Mr. Martin. The executive committee held one formal meeting during 2004. Dr. Armen retired as chairman on January 7, 2005 and Mr. McLaughlin was appointed chairman. On February 3, 2005, the board terminated the executive committee.

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 2004 were Mr. McLaughlin, chairman, Dr. Gillespie and Mr. McGowan. The audit committee held 9 formal meetings during 2004. In January 2005, Mr. McLaughlin retired from the committee and Dr. Gillespie was appointed as chairman. On February 3, 2005, Ms. Gray was appointed to the committee. 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 such reported matters.

Leadership Development and Compensation Committee

The leadership development and compensation committee (the "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 committee

also administers our stock option plans. The members of the committee in 2004 were Mr. McIntyre, chairman, Mr. Crowley, Ms. Gray and Mr. Tully (until November 1, 2004). The LDCC held 12 formal meetings during 2004. On February 3, 2005, Dr. McIntyre stepped down as chairman and Dr. Selkoe was appointed as chairman of the committee and Ms. Gray retired as a member of the committee. Please also refer to the report of the LDCC on pages 62-63.

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. During 2004, the Nominating Committee initiated the search for the new chairman of Elan Corporation, plc, which lead to the appointment of Mr. Kyran McLaughlin in January 2005. This involved a process of identifying the skills and experience required for this position. This Committee reviews and recommends changes in respect of the functions of the various committees of the board. Elan's Corporate Governance Guidelines and the charter of the Nominating 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. Such evaluations have not been carried out in a formal manner to date. It is currently anticipated that such formal evaluation process will be implemented during 2005. During 2004, members of the committee were Mr. Thornburgh, chairman, Ms. Gray, Mr. McGowan, Mr. McLaughlin and Mr. Tully (until November 1, 2004). The nominating committee held 6 formal meetings during 2004. On March 9, 2005, Mr. Thornburgh stepped down as chairman, and as lead independent director. The directors expect to appoint a new lead independent director in the near future.

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

	Board	Executive Committee	Audit Committee	LDCC	Nominating Committee
Garo H. Armen, PhD.	12/12	1/1	—	—	—
Brendan E. Boushel	11/12	—	—	—	—
Laurence G. Crowley	8/12	1/1	—	9/12	—
William F. Daniel	12/12	1/1[1]	9/9[1]	12/12[1]	6/6[1]
Alan R. Gillespie, C.B.E. PhD.	8/12	—	9/9	—	—
Ann Maynard Gray	9/12	0/1	—	12/12	5/6
John Groom	11/12	—	—	—	—
G. Kelly Martin	12/12	1/1	—	—	—
Kieran McGowan	8/12	—	9/9	—	6/6
Kevin M. McIntyre, MD.	12/12	—	—	12/12	—
Kyran McLaughlin	10/12	1/1	9/9	—	6/6
Dennis J. Selkoe, MD.	11/12	—	—	—	—
Richard L. Thornburgh	8/12	—	—	—	5/6
Daniel P. Tully[2]	5/11	0/1	—	9/11	4/5

(1)William Daniel was secretary on these committees.
(2)Daniel Tully resigned as director on 1 November 2004.

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. Management is responsible for the planning and implementation of the system of internal control and ensuring that we apply these controls consistently. Such a system is designed to manage rather than eliminate the risk of failure to achieve business objectives and can only provide reasonable and not absolute assurance against material misstatement or loss.

To provide effective internal control, focus on business objectives and to consider risk, we have:

- 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 that the board has adopted for us;

- A comprehensive system for reporting financial results to the board. This includes a budgeting system with an annual budget approved by the board. The board compares actual results with budgeted results regularly. Management accounts are prepared on a timely basis. They include a profit and loss account, balance sheet, cash flow statement and capital expenditure report, together with an analysis of performance of key operating divisions and subsidiaries;
- A system of management and financial reporting, treasury management and project appraisal. Management is responsible for reporting to the board on its progress in achieving objectives. The system of reporting covers trading activities, operational issues, financial performance, working capital, cash flow and asset management. We report in a timely and regular manner. In this context, progress is monitored against annual budgets and longer term objectives; and
- Corporate compliance and internal controls departments that review key systems and controls.

Following certain changes in our financial functions, the separate internal audit function ceased in September 2004. At the beginning of 2004, we established a separate internal control department primarily responsible for our Sarbanes-Oxley 404 project. In addition, we continue to have a separate corporate compliance function, which is responsible for all aspects of compliance within Elan. Both these functions report to the board audit committee. We are currently moving to re-instate our internal audit function in a manner that is fully co-ordinated 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 Consolidated 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, 2004.

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.

The chief executive officer attends meetings of the committee except when his own remuneration is being considered.

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 stock option plans.

The committee grants options 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 five years. These plans do not contain any performance conditions.

Employee Equity Purchase Plans

In June 2004, our shareholders and board of directors approved a qualified Employee Equity Purchase Plan (the "U.S. Purchase Plan"), under Sections 421 and 423 of the Internal Revenue Code ("IRS"), which became effective on January 1, 2005 for eligible employees based in the U.S. 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 IRS restrictions.

Also in June 2004, in connection with the U.S. Purchase Plan, our shareholders and 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"). As of December 31, 2004, 1,500,000 shares have been 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 at no lower than 85% of the fair market value at the start of the thirty-six month offering period. The plan allows eligible employees to save up to 320 Euros 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 savings period.

D. Employees

We employed 1,899 people at December 31, 2004.

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, 2004, including their spouses and children under eighteen years of age, were as follows:

	Ordinary Shares; Par Value 5 Euro Cents Each	
	2004	2003
Kyran McLaughlin	—	—
Garo H. Armen, PhD.	270,000	270,000
Brendan E. Boushel	838,698	838,698
Laurence G. Crowley	12,000	—

William F. Daniel	50,000	50,000
Alan R. Gillespie, C.B.E. PhD.	132,000	120,000
Ann Maynard Gray	3,500	3,500
John Groom	776,720	510,000
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
Richard L. Thornburgh	12,200	200

Directors' Options

	At December 31, 2003	Granted	Exercised	At December 31, 2004	Weighted Average Exercise Price
Kyran McLaughlin	15,000	40,000	—	55,000	21.51
Garo H. Armen, PhD.	1,025,000	50,000	—	1,075,000	4.27
Brendan E. Boushel	25,000	40,000	—	65,000	22.35
Laurence G. Crowley	37,000	40,000	(12,000)	65,000	22.35
William F. Daniel	326,000	30,705	—	356,705	17.40
Alan R. Gillespie, C.B.E. PhD.	37,000	40,000	(12,000)	65,000	22.35
Ann Maynard Gray	5,000	40,000	—	45,000	20.56
John Groom	316,720	40,000	(266,720)	90,000	27.89
G. Kelly Martin	2,000,000	60,000	—	2,060,000	4.91
Kieran McGowan	15,000	40,000	—	55,000	21.51
Kevin M. McIntyre, MD.	25,000	40,000	—	65,000	22.35
Dennis J. Selkoe, MD.	108,648	40,000	(83,648)	65,000	22.35
Richard L. Thornburgh	37,000	40,000	(12,000)	65,000	22.35

Options outstanding at December 31, 2004 are exercisable at various dates between January 2005 and March 2014. During the year ended December 31, 2004, the closing market price ranged from $7.06 to $30.09 per ADS. The closing market price at March 31, 2005, on the NYSE of our ADSs was $3.24.

The following changes in directors' interests occurred between December 31, 2004 and March 31, 2005. On February 9, 2005, Mr. McLaughlin purchased 10,000 American Depository Shares ("ADSs"), representing ordinary shares par value €0.05 each ("Ordinary Shares"). On March 10, 2005, options to purchase ordinary shares were granted to the following directors at the then market price of $7.47 per share: Mr. Martin 280,000 options; Dr. Armen, Mr. Boushel, Mr. Crowley, Dr. Gillespie, Ms. Gray, Mr. Groom, Mr. McGowan, Dr. McIntyre, Mr. McLaughlin, Dr. Selkoe and Mr. Thornburgh 7,500 options each and Mr. Daniel 50,000 options.

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 at March 31, 2005 by major shareholders (based solely upon information obtained from SEC filings) and all of our directors and officers as a group (either directly or by virtue of ownership of our ADSs):

Name of Owner or Identity of Group	No. of Shares	Percent of Class [1]
Capital Research and Management Company ("Capital Research")	32,880,300	8.3%
Fidelity Management and Research Company ("Fidelity Management")	19,369,730	4.9%
T. Rowe Price Associates, Inc. ("T. Rowe Price")	14,510,829	3.7%
All directors and officers as a group (18 persons)[2]	6,801,533	1.7%

(1) Based on 396.7 million Ordinary Shares outstanding on March 31, 2005 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 31, 2005.

(2) Includes 4.4 million Ordinary Shares issuable upon exercise of currently exercisable options held by directors and officers as a group as of March 31, 2005.

Except for these interests, we are not aware of any person who, directly or indirectly, holds 3% or more of our issued share capital. Neither Capital Research, Fidelity Management nor T. Rowe Price have 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.

B. Related Party Transactions

There were no significant transactions with related parties during the year ended December 31, 2004 other than as outlined in Note 27 to the Consolidated Financial Statements.

Service Contracts

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 director of Elan Corporation, plc, whereby we shall pay 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's annual salary under this agreement is $798,000. He is eligible for an annual bonus in a target amount equal to his salary depending on the achievement of established performance goals. 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.

The agreement continues until December 31, 2005 and will be extended for a further year on each anniversary of that date thereafter unless Mr. Martin or we give 90 days notice prior to the applicable anniversary date. In general, if Mr. Martin's employment is involuntarily terminated (other than for cause or disability) or Mr. Martin leaves for good reason, we will continue to pay his salary and target bonus for the following two years and his outstanding options will immediately accelerate and remain outstanding for the following two years.

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 April 1, 2002, EPI entered into a consultancy agreement with Dr. Selkoe whereby Dr. Selkoe agreed to provide certain consultancy services, including services in the field of immunological approaches to the treatment of Alzheimer's disease for a period of one year for a fee not to exceed $12,000.

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.

Item 9. The Offer and Listing.

A. Offer and Listing Details

Not applicable.

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 depositary is The Bank of New York.

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:

	€0.05 Ordinary Shares		American Depository Shares [1]	
	High	Low	High	Low
Year ended December 31	(€)		($)	
2000	66.75	26.35	60.13	26.00
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
Calendar Year				
2003				
Quarter 1	4.40	2.33	4.98	2.25
Quarter 2	7.25	2.60	9.02	2.70
Quarter 3	5.60	3.88	6.46	4.05
Quarter 4	4.95	4.25	5.97	4.72
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
Month Ended				
January 2005	22.25	20.00	29.00	25.50
February 2005	22.04	6.49	28.36	8.00
March 2005	6.33	2.40	7.97	3.24

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

A total of 396,726,822 Ordinary Shares of Elan were issued and outstanding at March 31, 2005, of which 4,847 Ordinary Shares were held by holders of record in the United States, excluding shares held in the form of ADRs. 342,621,984 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 31, 2005, the number of holders of record of Ordinary Shares was 7,874, which includes 11 holders of record in the United States, and the number of registered holders of ADRs in the United States was 4,817. 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.

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 is exercisable for 0.1276 of an ADS at an exercise price of $26.72 per ADS. The Z-Series warrants expire 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.

In connection with the acquisition of Liposome, we issued Contingent Value Rights (CVRs"). The CVRs began trading on May 15, 2000. CVRs traded on the Nasdaq under the symbol "LCVRZ". The CVRs were delisted from the Nasdaq on September 25, 2002 for failure to comply with the minimum market value of publicly traded units requirement of the Nasdaq Marketplace Rules. The CVRs expired on the termination of the Contingent Value Rights Agreement on March 31, 2003.

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

	Z-SERIES		CVRs	
	HIGH	LOW	HIGH	LOW
	$	$	$	$
2003 – Quarter 1	0.70	0.10	0.005	0.0001
– Quarter 2	0.42	0.10	—	—
– Quarter 3	0.23	0.10	—	—
– Quarter 4	0.32	0.08	—	—
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 – January	0.75	0.60	—	—
– February	0.69	0.25	—	—
– March	0.41	0.17	—	—

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 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. Gillespie, Ms. Gray, Mr. McGowan and Mr. Thornburgh will retire at the 2005 Annual General Meeting. Dr. Gillespie, Ms. Gray and Mr. McGowan being eligible, offer themselves for re-election. Mr. Thornburgh will not be seeking re-election and so will be retiring from the board effective from the conclusion of the 2005 Annual General Meeting. In addition to Mr. Thornburgh, Mr. Boushel and Mr. Groom have notified the Company that they will be retiring from the board effective from the conclusion of the 2005 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 us until claimed. All of the 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.

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.

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

Under an Indenture dated November 16, 2004 with The Bank of New York, as Trustee, two of our subsidiaries co-issued senior notes consisting of $850.0 million aggregate principal amount of 7.75% Notes due 2011 and $300.0 million aggregate principal amount of Floating Rate Notes due 2011. The Floating Rate Notes bear interest at a rate, adjusted quarterly, equal to three-month LIBOR plus 4.0%, except the first interest payment, which bears interest at a rate equal to six-month LIBOR plus 4.0%. Most of our subsidiaries and we guarantee the 7.75% Notes, the Floating Rate Notes, and the Athena Notes.

See Note 15 to the Consolidated Financial Statements for additional information concerning our outstanding debt.

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, manufaturing and commercialization of Tysabri. Along with Biogen Idec, we are developing Tysabri for MS, Crohn's disease and RA, with Biogen Idec acting as the lead party for MS and Elan acting as the lead party for Crohn's disease and RA.

In November 2004, Tysabri received regulatory approval in the U.S. 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 U.S. We recorded $6.4 million in product revenue from Tysabri in 2004. In general, we share with Biogen Idec most development and commercialization costs. At December 31, 2004, we owed Biogen Idec $34.4 million for the reimbursement of costs related to development and commercialization.

On February 28, 2005, we and Biogen Idec announced the voluntary suspension of the marketing and dosing in clinical trials of Tysabri. This decision was based on reports of two serious adverse events in patients treated with Tysabri in combination with Avonex in clinical trials. These events involved two cases of PML, a rare and frequently fatal demyelinating disease of the central nervous system. Both patients received more than two years of Tysabri therapy in combination with Avonex. On March 30, 2005, we and Biogen Idec announced that our 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.

We are working with leading experts, regulatory authorities and the clinical investigators to investigate these serious adverse events and to determine the appropriate path forward.

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 Iraq, the Federal Republic of Yugoslavia, the Republic of Serbia, Zimbabwe, the Taliban of Afghanistan, Osama bin Laden and Al-Qaeda, Burma/Myanmar, Slobodan Milosevic, Associated Persons, Liberia 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. The following countries and persons are currently the subject of such sanctions: Federal Republic of Yugoslavia, Republic of Serbia, Iraq, Liberia, Burma/Myanmar, Zimbabwe, the Taliban of Afghanistan, Osama bin Laden and Al-Qaeda and Slobodan Milosevic. 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 31, 2005 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 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, it is anticipated, based on Irish legislation currently enacted, that such income will be 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

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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 EU, 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 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 5 December 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 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

We have not paid cash dividends on our Ordinary Shares in the past and our debt obligations restrict us from paying cash dividends on our capital stock. Although we do not anticipate that we will be able to pay any cash dividends on our Ordinary Shares in the foreseeable future, we expect that the board of directors will review our dividend policy on a

regular basis. Dividends may be paid on our Executive Shares and B" Executive Shares at a time when no dividends are being paid on the Ordinary Shares. For additional information regarding the Executive Shares and B" Executive Shares, please refer to Note 22 to the Consolidated Financial Statements.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the reporting requirements of the Exchange Act. In accordance with these requirements, we file Annual Reports on Form 20-F with, and furnish 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, 2004 and the exhibits thereto, may be inspected and copied at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington D.C. 20549 and at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511, and 233 Broadway, New York, New York 10274. Copies of the materials may be obtained from the Public Reference Room of the SEC at

450 Fifth Street, N.W., 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 us 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 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 many countries. 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 currency for financial reporting. We have revenues, costs, assets and liabilities denominated in currencies other than U.S. dollars. We manage our non-U.S. dollar foreign exchange risk through derivative financial instruments. 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 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, 2004, 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 Japanese Yen for U.S. dollars at that date was $9.4 million and these contracts had a fair value loss of $0.4 million. These contracts all expire on various dates through December 2005. The nominal value of forward foreign exchange contracts to sell U.S. dollars for Euro at December 31, 2004 was $9.0 million and these contracts had a fair value gain of $1.2 million. These contracts all expire on various dates through June 2005.

During 2004, average exchange rates were $1.24 = EUR1. We sell U.S. dollars to buy Euro for costs incurred in Euro. The recent strengthening of the Euro against the U.S. dollar will result in a higher reported cost related to our Euro cost base in 2005 compared to 2004.

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, 2004 (in millions):

	2005	2006	2007	2008	2009	Thereafter	Total
Fixed rate debt [1]	$ —	$ —	$ —	$ 1,110.0	$ —	$ 850.0	$ 1,960.0
Average interest rate				6.94%		7.75%	7.29%
Variable rate debt [2][3]	$ —	$ —	$ —	$ —	$ —	$ 300.0	$ 300.0