

ELAN CORP PLC  
Form 20-F/A  
September 09, 2005  
United States  
Securities and Exchange Commission,  
Washington, D.C. 20549  
FORM 20-F/A  
(Amendment No. 1)

(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

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(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:  
None

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(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

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#### Explanatory Note

This Amendment No. 1 to Elan Corporation plc's ("Elan") Annual Report on Form 20-F for the fiscal year ended December 31, 2004 (this "Amendment") is being filed solely to amend Items 5 and 18 and Schedule II. Elan's Annual Report on Form 20-F for the fiscal year ended December 31, 2004 (the "Form 20-F") was originally filed with the U.S. Securities and Exchange Commission (the "SEC") on April 11, 2005. This Amendment:

- Provides additional, expanded disclosure regarding Elan's sales discounts and allowances;
- Includes additional disclosure regarding segment information set out in Note 31, to the Consolidated Financial Statements; and
- Includes an amended Schedule II "Valuation and Qualifying Accounts and Reserves" to correct numbers for sales discounts and allowances previously disclosed in the roll forward table.

For the convenience of the reader, this Amendment includes the complete text of all Items of the Form 20-F, including the complete text of Items 5 and 18 and Schedule II, as amended. However, other than the amendments described above, no changes have been made to these or any other Items to the Form 20-F as originally filed. This Amendment continues to speak as of the date of the original filing of the Form 20-F and, except as described above, does not purport to amend or update the information contained in the Form 20-F filed on April 11, 2005, or reflect any events that have occurred after the Form 20-F was filed.

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## 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.

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#### 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)				
<b>Income Statement Data:</b>					
Total revenue	\$ 481.7	\$ 685.6	\$ 1,093.1	\$ 1,576.3	\$ 1,307.3
Operating income/(loss)	\$ (302.1) <sup>(1)</sup>	\$ (360.5) <sup>(2)</sup>	\$ (608.7) <sup>(3)</sup>	\$ 268.5 <sup>(4)</sup>	\$ (62.8) <sup>(5)</sup>
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)
Cumulative effect of changes in accounting principles	—	—	—	7.8	(344.0)
Net income/(loss)	\$ (394.7) <sup>(1)</sup>	\$ (506.1) <sup>(6)</sup>	\$ (2,358.2) <sup>(7)</sup>	\$ 272.5 <sup>(4)</sup>	\$ (286.0) <sup>(8)</sup>
<b>Basic earnings/(loss) per Ordinary Share</b> <sup>(9)</sup>					
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 <sup>(10)</sup>	\$ (1.00) <sup>(10)</sup>
<b>Diluted earnings/(loss) per Ordinary Share</b> <sup>(9)</sup>					
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 <sup>(10)</sup>	\$ (0.92) <sup>(10)</sup>
<b>Balance Sheet Data:</b>					
December 31,	2004	2003 (restated)	2002 (restated)	2001 (restated)	2000 (restated)
	(in millions)				
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

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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

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- (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 of businesses.
  - (2) After net other charges of \$403.2 million, primarily relating to asset impairments of \$32.6 million, severance, relocation and exit costs of \$29.7 million, EPIL III/EPIL II waiver fee of \$16.8 million, and the purchase of royalty rights of \$297.6 million; and after a net gain of \$267.8 million on the sale of businesses and repurchase of debt.
  - (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") of \$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 and exit costs of \$29.7 million and the purchase of royalty rights of \$297.6 million, offset by a net gain of \$267.8 million on the sale of businesses and repurchase of debt; and after charges of \$136.5 million, primarily relating to investments and the guarantee issued to the noteholders of Elan Pharmaceutical Investments II, Ltd. ("EPIL II").
  - (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 amortized 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<sup>®</sup> (interferon beta-1) in clinical trials. These events involved two cases of progressive multifocal leukoencephalopathy ("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.

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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 indebtedness could have important consequences to us. For example, it could:

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- 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

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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

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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

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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;

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- 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.

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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.

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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:

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- 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
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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.

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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 than 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.

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### 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 A $\beta$ , 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,

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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.

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## 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
- Herbesse® – 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
- Rapamun® – 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-Du® – 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
- TriCo® – 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.

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#### 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.

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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

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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.

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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

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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.

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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<sup>®</sup>, marketed by Berlex Laboratories; Rebif<sup>®</sup>, marketed by Serono and Pfizer, Inc.; and Copaxone<sup>®</sup>, 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.

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#### 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.		100	

	Manufacture, marketing and distribution of pharmaceutical and medical device products		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.

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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."

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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

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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.

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### Revenue Recognition— Sales Discounts and Allowances

As described further below and in our significant accounting policies in Note 2 to the Consolidated Financial Statements, we recognize revenue on a gross revenue basis and make various deductions to arrive at net revenue as reported in the Consolidated Statements of Operations. These adjustments are referred to as sales discounts and

allowances and are described in detail below. Sales discounts and allowances include charge-backs, managed health care and Medicaid rebates, cash discounts, sales returns and other adjustments. Estimating these sales discounts and allowances is complex and involves significant estimates and judgments, and we use information from both internal and external sources to generate reasonable and reliable estimates. We believe that we have used reasonable judgments in assessing our estimates, and this is borne out by our historical experience. At December 31, 2004, we had total reserves of \$22.1 million for sales discounts and allowances, of which approximately 57% and 21% related to Maxipime and Azactam, respectively. We have over six years' experience in relation to these two products.

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

(a) Sales discounts and allowances

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

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

	Years ended December 31,		
	2004	2003	2002
	(US\$ in millions)		
Gross revenue subject to discounts and allowances	291.7	530.1	779.8
Contract manufacturing and royalties	130.9	120.0	118.5
Contract revenue	77.3	98.9	350.7
Amortized revenue – Adalat/Avinza	34.0	34.0	7.8
Co-promotion fees	—	—	62.8
Gross revenue	533.9	783.0	1,319.6
Sales discounts and allowances:			
Charge-backs	(24.6)	(27.1)	(22.7)
Managed health care rebates and other contract discounts	(5.1)	(11.0)	(21.3)
Medicaid rebates	(8.2)	(25.7)	(51.3)
Cash discounts	(5.6)	(8.9)	(38.1)
Sales returns	(7.1)	(24.6)	(92.8)
Other adjustments	(1.6)	(0.1)	(0.3)
Total sales discounts and allowances	(52.2)	(97.4)	(226.5)
Net revenue subject to discounts and allowances	239.5	432.7	553.3
Contract manufacturing and royalties	130.9	120.0	118.5
Contract revenue	77.3	98.9	350.7
Amortized revenue – Adalat/Avinza	34.0	34.0	7.8
Co-promotion fees	—	—	62.8
Net revenue	481.7	685.6	1,093.1

Total sales discounts and allowances have decreased from 29.0% of gross revenue subject to discounts and allowances in 2002 to 18.4% in 2003, and to 17.9% in 2004, as detailed in the rollforward below and as further explained in the following paragraphs.

Charge-backs increased as a percentage of gross revenue subject to discounts and allowances from 2.9% in 2002 to 5.1% in 2003, and to 8.4% in 2004. The increase is due primarily to changes in the product mix. Several of our divested products were sold through retail pharmacies (principally Skelaxin, Zonegran and Sonata) and therefore had lower levels of charge-backs in comparison to our retained products.

The reductions in managed health care and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances from year to year are due principally to changes in the product mix. Several of our divested products (principally Skelaxin, Zonegran and Zanaflex) were sold through retail pharmacies and therefore had larger components subject to managed health care and Medicaid rebates. Consequently, due primarily to the divestment of these products, the managed health care and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances have declined from 2.7% and 6.6%, respectively, in 2002, to 2.1% and 4.8% in 2003, and to 1.7% and 2.8% in 2004.

Cash discounts as a percentage of gross revenue subject to discounts and allowances decreased from 4.9% in 2002 to 1.7% in 2003, and to 1.9% in 2004. The decrease is due principally to a change in our discounting strategy during 2002 as we concentrated on improving margins at the expense of volumes for certain of our key product lines.

Sales returns as a percentage of gross revenue subject to discounts and allowances decreased from 11.9% in 2002 to 4.6% in 2003, and to 2.4% in 2004 due to a number of factors, primarily the genericization of a number of our products in 2002 (principally Zanaflex), which increased the provision for returns in that year, and changes in the product mix as a result of product divestments.

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

	Charge-backs	Managed Health Care Rebates and Other Contract Discounts	Medicaid Rebates	Cash Discounts	Sales Returns	Other Adjustments	Total
Balance at December 31, 2002	\$ 7.2	\$ 11.2	\$ 28.0	\$ 1.9	\$ 72.9	\$ 0.5	\$ 121.7
Provision related to sales made in current period	27.3	11.0	25.7	8.9	17.6	0.1	90.6
Provision related to sales made in prior periods	(0.2)	—	—	—	7.0	—	6.8
Returns and payments	(25.7)	(20.4)	(34.4)	(9.5)	(68.0)	(0.6)	(158.6)
Divestments	0.1	3.1	2.5	—	(1.0)	—	4.7
	8.7	4.9	21.8	1.3	28.5	—	65.2

Balance at December 31, 2003												
Provision related to sales made in current period	24.4	5.1	8.6	5.6	6.8	1.6	52.1					
Provision related to sales made in prior periods	0.2	—	(0.4)	—	0.3	—	0.1					
Returns and payments	(24.2)	(6.8)	(23.9)	(6.5)	(19.8)	(0.7)	(81.9)					
Divestments	(0.2)	(1.1)	(4.4)	—	(7.2)	(0.5)	(13.4)					
Balance at December 31, 2004	\$ 8.9	\$ 2.1	\$ 1.7	\$ 0.4	\$ 8.6	\$ 0.4	\$ 22.1					

## (b) Charge-backs

In the United States, we participate in charge-back programs with a number of entities, principally the U.S. Department of Defense, the U.S. Department of Veterans Affairs, Group Purchasing Organizations and other parties whereby pricing on products is extended below wholesaler's list price to participating entities. These entities purchase products through wholesalers at the lower negotiated price, and the wholesalers charge the difference between their acquisition cost and the lower negotiated price back to us. We account for charge-backs by reducing accounts receivable in an amount equal

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to our estimate of charge-back claims attributable to a sale. We determine our estimate of the charge-backs primarily based on historical experience on a product-by-product and program basis, and current contract prices under the charge-back programs. We consider vendor payments, estimated levels of inventory in the distribution channel, and our claim processing time lag and adjust accounts receivable and revenue periodically throughout each year to reflect actual and future estimated experience.

As described above, there are a number of factors involved in estimating the accrual for charge-backs, but the principal factor relates to our estimate of the levels of inventory in the distribution channel. At December 31, 2004, Maxipime and Azactam represented approximately 90% and 8%, respectively, of the total charge-backs accrual balance of \$8.9 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for these products, the accrual for charge-backs would increase/(decrease) by approximately \$2.2 million. We believe that our estimate of the levels of inventory for Maxipime and Azactam in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

## (c) Managed health care rebates and other contract discounts

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

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the levels of inventory in the distribution channel. At December 31, 2004, Maxipime and Azactam represented approximately 58% and 24%, respectively, of the total managed health care rebates and other contract discounts accrual balance of \$2.1 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for these products, the accrual would increase/(decrease) by approximately \$0.3 million. We believe that our estimate of the levels of inventory for Maxipime and Azactam in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

(d) Medicaid rebates

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

(e) Cash discounts

In the United States, we offer cash discounts, generally at 2% of the sales price, as an incentive for prompt payment. Prior to our change in discounting strategy during 2002, we also offered additional incentive cash discounts to customers who purchased product between certain time intervals or with certain minimum volumes. While these discounts were designed to encourage volume, they were not in the nature of incentives to compensate wholesalers for holding excess inventory. We discontinued these discounts during the third quarter of 2002 as we took a commercial decision to improve product margins at the expense of volumes. We no longer offer such discounts to any of our customers. Principally, as a consequence of this change in discounting strategy, cash discounts as a percentage of gross revenue subject to discounts

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and allowances decreased from 4.9% in 2002 to 1.7% in 2003, and 1.9% in 2004. We account for cash discounts by reducing accounts receivable by the full amount of the discounts. We consider payment performance of each customer and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

(f) Sales returns

We account for sales returns in accordance with SFAS No. 48 by establishing an accrual in an amount equal to our estimate of revenue recorded for which the related products are expected to be returned.

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

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

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

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the shelf life of inventory in the distribution channel. At December 31, 2004, Maxipime and Azactam represented approximately 35% and 34%, respectively, of the total sales returns accrual balance of \$8.6 million. At December 31, 2004, we have estimated the gross revenue value of Maxipime and Azactam inventory in the distribution channel to be approximately \$40 million and \$17 million, respectively. Assuming inventory leaves the distribution channel on a first-in first-out basis, we have estimated that this distribution channel inventory has a shelf life running to various dates during 2006 (gross revenue value approximately \$11 million) and 2007 (gross revenue value approximately \$46 million). We believe, based upon both the estimated shelf life and also our historical sales returns experience, that the vast majority of this inventory will be sold prior to its expiration date, and accordingly believe that our sales returns accrual is appropriate.

(g) Other adjustments

In addition to the significant sales discounts and allowances described above, we make other individually insignificant sales adjustments. We generally account for these other sales discounts and allowances by establishing an accrual in an amount equal to our estimate of the adjustments attributable to the sale. We generally determine our estimates of the accruals for these other adjustments primarily based on historical experience, performance on commitments to government entities and other relevant factors, including estimated levels of inventory in the distribution channel in some cases, and adjust the accruals and revenue periodically throughout each year to reflect actual experience.

(h) Provisions related to sales made in prior periods

During 2003 we recorded \$6.8 million of additional discounts and allowances related to sales made in prior periods, primarily due to the availability of additional information relating to the impact of genericization of a number of our products (principally Zanaflex).

(i) Divestments

Since the beginning of 2003 we have divested a number of businesses, including principally our primary care franchise, Zonegran and our European sales and marketing business. The divestment adjustments arise primarily as a result of the

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negotiated terms of these divestments. For example, we have entered into terms that would either extend or limit our liability for discounts and allowances related to the divested businesses. We have accordingly adjusted our discounts and allowances accruals to reflect the terms of the agreements. Divestment adjustments also include post-divestment revisions resulting from the availability of additional information. Divestment adjustments are recorded as part of the gain/(loss) on sale of businesses, and not as an increase or decrease from gross revenue.

(j) Use of information from external sources

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

- The projected prescription demand-based sales for our products and historical inventory experience;
- Our analysis of third-party information, including written and oral information obtained from all of the major wholesalers with respect to their inventory levels and sell-through to customers, and third-party market research data; and
- Our internal information.

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

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

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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	

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## 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<sup>TM</sup> 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 <sup>(1)</sup>			
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 <sup>(2)</sup>			
European business <sup>(3)</sup>	10.5	89.0	(88%)
Zonegran <sup>(4)</sup>	41.2	80.7	(49%)
Skelaxin <sup>(5)</sup>	—	60.2	(100%)
Sonata <sup>(5)</sup>	—	48.2	(100%)
Other	13.3	0.4	—
Total divested products revenue	65.0	278.5	(77%)
Total product revenue	\$ 404.4	\$ 586.7	(31%)

(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.

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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%)
	59.7	49.3	21%

## Research

## revenues/milestones

Total contract revenue	\$	77.3	\$	98.9	(22%)
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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

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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&amp;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.

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(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.

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#### 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<sup>TM</sup> (oral transmucosal fentanyl citrate), the dermatology portfolio of products, Abelcet<sup>TM</sup> (amorphotericin B lipid complex) U.S./Canada, Myobloc<sup>TM</sup> (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.

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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	

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### 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 <sup>(1)</sup>			
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 <sup>(2)</sup>			
European business <sup>(3)</sup>	\$ 89.0	\$ 81.7	9%
Zonegran <sup>(4)</sup>	\$ 80.7	\$ 43.1	87%
Skelaxin <sup>(5)</sup>	\$ 60.2	\$ 145.4	(59%)
Sonata <sup>(5)</sup>	\$ 48.2	\$ 92.5	(48%)
Zanaflex <sup>(6)</sup>	\$ (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)
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	(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

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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.

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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

## (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.

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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.

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#### 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 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

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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.

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#### 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.

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## 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.

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## 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)



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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.

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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 <sup>(1)</sup>	840.1	158.6	315.8	204.0	161.7
Capital lease obligations <sup>(2)</sup>	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

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.

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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 Services	Moody's Investors Service
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.

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## 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.

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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.

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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					
	2004	2004	2004	2004	2004	2003
Executive Directors:	Salary/Fees	Annual Bonus	Pension	Benefit In Kind	Total	Total
G. Kelly Martin	\$ 834,831	\$ — <sup>(1)</sup>	\$ 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 69.

	Year Ended December 31					
	2004	2004	2004	2004	2004	2003
Non-Executive Directors:	Fees	Annual Bonus	Pension	Benefit in Kind	Total	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 <sup>(1)</sup>	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.

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## 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 67-68.

#### 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

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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 led 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 <sup>(1)</sup>	9/9 <sup>(1)</sup>	12/12 <sup>(1)</sup>	6/6 <sup>(1)</sup>
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 <sup>(2)</sup>	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](http://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.

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#### 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

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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

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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 <sup>(1)</sup>
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) <sup>(2)</sup>	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.

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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 depository 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		American	
	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
<b>Calendar Year</b>				
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 Depositary 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",

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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 following table 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

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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:

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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.

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## 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, manufacturing 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.

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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

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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.

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#### 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):

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	2005	2006	2007	2008	2009	Thereafter	Total
Fixed rate debt <sup>(1)</sup>	\$ —	\$ —	\$ —	\$ 1,110.0	\$ —	\$ 850.0	\$ 1,960.0
Average interest rate				6.94%		7.75%	7.29%
Variable rate debt <sup>(2)(3)</sup>	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 300.0	\$ 300.0
Average interest rate						6.50%	6.50%
Total long-term and convertible debt	\$ —	\$ —	\$ —	\$ 1,110.0	\$ —	\$ 1,150.0	\$ 2,260.0
Average interest rate				6.94%		7.42%	7.19%

(1)Represents 86.7% of all outstanding long-term and convertible debt.

(2)Represents 13.3% of all outstanding long-term and convertible debt.

(3)Variable interest rates are based on LIBOR.

If market rates of interest on our variable rate debt, including the effect of the \$300.0 million interest rate swap, increased by 10%, then the increase in interest expense on the variable rate debt would be \$0.6 million annually. As of December 31, 2004, the fair value of our total convertible debt and guaranteed notes was \$3,700.0 million. The fair values of the debt instruments has decreased significantly with our voluntary suspension of the marketing and clinical dosing ofTysabri in February 2005 to \$1,769.0 million at March 31, 2005 primarily due to the decrease in the option value of the 6.5% Convertible Notes. See Note 16 to the Consolidated Financial Statements for additional information on the fair values of debt instruments.

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We held three interest rate derivatives associated with our fixed-rate, long-term debt outstanding at December 31, 2004 (in millions):

	2005	2006	2007	2008	2009	Thereafter	Total	Fair Value
Interest Rate Swaps								
Fixed to Variable	\$ —	\$ —	\$ —	\$ 300.0	\$ —	\$ —	\$ 300.0	\$ 2.7
Average pay rate				5.55%			5.55%	
Average receive rate				7.25%			7.25%	

#### Interest Rate Risk on Investments

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

The interest rate risk profile of our investments at December 31, 2004 was as follows (in million):

Fixed	Floating	No Interest	Total
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Cash and cash equivalents	\$	—	\$	1,372.6	\$	—	\$	1,372.6
Restricted cash	\$	—	\$	192.7	\$	—	\$	192.7
Marketable Investment Securities (current)	\$	12.5	\$	—	\$	53.0	\$	65.5
Marketable investment securities (non-current)	\$	3.1	\$	—	\$	35.9	\$	39.0

Fixed interest rates on investments have a weighted average interest rate of 7.5% (2003: 8.4%), maturing in 2005. The weighted average life of the fixed interest rate investments is 0.1 years (2003: 0.1 years).

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

#### Credit Risk

Our treasury function transacts business with counterparties that are considered to be low investment risk. Credit limits are established commensurate with the credit rating of the financial institution that business is being transacted with. We do not believe that we have a significant exposure to any one financial counterparty.

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

#### Equity Price Risk

We are exposed to equity price risks primarily on our available for sale securities, which consist of equity investments in quoted companies. At December 31, 2004, current available-for-sale securities had a fair value of \$65.5 million and had a cost of \$44.6 million. These investments are primarily in emerging pharmaceutical and biotechnology companies. An adverse change in equity prices could result in a material impact in the fair value of our available for sale equity securities.

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

Not applicable.

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#### Part II

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

None.

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

None.

#### Item 15. Controls and Procedures

## Disclosure Controls and Procedures

We have disclosure controls and procedures (Disclosure Controls") that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the 1934 Act"), such as our Annual Report on Form 20-F, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Disclosure Controls are also designed to ensure that the information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. Please refer to our officers' certifications included as Exhibits 12.1 and 12.2.

Item 16. Reserved.

## Item 16A. Audit Committee Financial Expert

Our board of directors does not have an audit committee financial expert, within the meaning of such phrase under applicable regulations of the SEC, serving on its audit committee. The board of directors believes that all members of its audit committee are financially literate, experienced in business matters, capable of analyzing and evaluating our Consolidated Financial Statements, understanding internal controls and procedures for financial reporting purposes and understanding audit committee functions. The board of directors is seeking an appropriate individual to serve on the board of directors and the audit committee who will meet the requirements necessary to be an audit committee financial expert.

## Item 16B. Code of Ethics

Our board of directors adopted a code of conduct that applies to our directors, officers and employees. There have been no material modifications to, or waivers from, the provisions of such code. This code is available on our website at the following address: [http://elan.com/governance/code\\_of\\_conduct](http://elan.com/governance/code_of_conduct).

## Item 16C. Principal Accountant Fees and Services

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

	2004	2003
Auditors' remuneration:		
Audit fees <sup>(1)</sup>	\$ 3.6	\$ 5.3
Audit related fees <sup>(2)</sup>	—	1.2
Total audit and audit-related fees	3.6	6.5
Tax fees	0.8	0.1
All other fees	—	—
Total auditors' remuneration	\$ 4.4	\$ 6.6

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

(2) Audit related services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

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## 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.

Consistent with SEC policies regarding auditor independence, the audit committee has responsibility for appointing, setting compensation and overseeing the work of the independent auditor. In recognition of this responsibility, the audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent auditor. Prior to engagement of the independent auditor for the next year's audit, management will submit a list of services and related fees expected to be rendered during that year within each of four categories of services to the audit committee for approval: audit services; audit-related services; tax services; and other fees.

Prior to engagement, the audit committee pre-approves all independent auditor services within each category. The fees are budgeted and the audit committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent auditor for additional services not contemplated in the original pre-approval categories. In those instances, the audit committee requires specific pre-approval before engaging the independent auditor.

The audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the audit committee at its next scheduled meeting.

### Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

### Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

## Part III

### Item 17. Consolidated Financial Statements.

Not applicable.

### Item 18. Consolidated Financial Statements.

Report of Independent Registered Public Accounting Firm

Consolidated Financial Statements of Elan Corporation, plc and subsidiaries

Notes to the Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Directors and Shareholders of Elan Corporation, plc

We have audited the accompanying consolidated balance sheets of Elan Corporation, plc and subsidiaries as of December 31, 2004 and 2003 and the related consolidated statements of operations, shareholders' equity and other comprehensive income/(loss) and cash flows for each of the years in the three-year period ended December 31, 2004. We have also audited the accompanying financial statement schedule. These Consolidated Financial Statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these Consolidated Financial Statements and the financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the Consolidated Financial Statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the Consolidated Financial Statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the Consolidated Financial Statements referred to above present fairly, in all material respects, the consolidated financial position of Elan Corporation, plc and subsidiaries as of December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

In the fiscal years prior to 2004, the Company prepared its financial statements in conformity with accounting principles generally accepted in Ireland ("Irish GAAP"), and presented in a footnote to such financial statements a reconciliation of shareholders' equity and net income under Irish GAAP to shareholders' equity and net income under U.S. GAAP. As disclosed in Note 2, "Restatements", to the Consolidated Financial Statements, shareholders' equity and net loss under U.S. GAAP for the years ended December 31, 2003 and 2002, as previously disclosed, have been restated to reflect the correction of an error in accounting for an insurance program that did not involve risk transfer and an error in accounting for the income tax effect of net operating loss carryforwards. As disclosed in Note 2, "Restatements", to the Consolidated Financial Statements, the segmental disclosures in Note 31 have been restated by including a table titled "Revenue analysis by segment".

KPMG

Dublin, Ireland

April 8, 2005, except for Note 2(d) Restatements—Segmental Disclosures, the table titled "Revenue analysis by

segment" in Note 31 and Schedule II, which are as of September 9, 2005

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Elan Corporation, plc  
Consolidated Statements of Operations  
For the Years Ended December 31, 2004, 2003 and 2002  
(in millions, except per share data)

	Notes	2004	2003 (restated)	2002 (restated)
Product revenue		\$ 404.4	\$ 586.7	\$ 742.4
Contract revenue		77.3	98.9	350.7
Total revenue	3	481.7	685.6	1,093.1
Operating expenses:				
Cost of sales		170.4	248.9	305.6
Selling, general and administrative expenses		340.5	384.2	541.6
Research and development expenses		257.3	277.6	353.9
Gain on sale of businesses	21	(44.2)	(267.8)	—
Restructuring and other charges, net	20	59.8	403.2	500.7
Total operating expenses		783.8	1,046.1	1,701.8
Operating loss		(302.1)	(360.5)	(608.7)
Net interest and investment (gains)/losses:				
Net interest expense	15	107.8	103.8	70.7
Net investment (gains)/losses	7	(114.6)	(103.4)	39.2
Impairment of investments	7	71.8	87.5	1,006.0
Loss on sale of investments by EPIL III/Shelly Bay transaction	15	—	—	141.6
Charge arising from guarantee to EPIL II noteholders	14	47.1	49.0	295.4
Net interest and investment losses		112.1	136.9	1,552.9
Loss from continuing operations before provision for/(benefit from) income taxes		(414.2)	(497.4)	(2,161.6)
Provision for/(benefit from) income taxes	18	(0.5)	(22.8)	8.0
Net loss from continuing operations		(413.7)	(474.6)	(2,169.6)
Net income/(loss) from discontinued operations (net of tax)	21	19.0	(31.5)	(188.6)
Net loss		\$ (394.7)	\$ (506.1)	\$ (2,358.2)
Basic and diluted loss per Ordinary Share:				
Net loss from continuing operations		\$ (1.06)	\$ (1.33)	\$ (6.20)
Net income/(loss) from discontinued operations (net of tax)		0.05	(0.09)	(0.54)
Net loss	4	\$ (1.01)	\$ (1.42)	\$ (6.74)
	4	390.1	356.0	349.7



Weighted average number of Ordinary Shares  
outstanding

The accompanying notes are an integral part of these Consolidated Financial Statements.

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Elan Corporation, plc  
Consolidated Balance Sheets  
As of December 31, 2004 and 2003  
(in millions, except shares and par values)

Assets	Notes	2004	2003 (restated)
Current Assets:			
Cash and cash equivalents		\$ 1,347.6	\$ 778.2
Restricted cash	5	164.3	—
Accounts receivable, net	6	41.5	37.9
Marketable investment securities	7	65.5	349.4
Inventory	8	29.0	69.5
Held for sale assets	21	—	135.2
Prepaid and other current assets	9	78.6	124.2
Total current assets		1,726.5	1,494.4
Property, plant and equipment	10	346.2	369.1
Goodwill and other intangible assets	11	780.8	907.8
Marketable investment securities	7	39.0	192.9
Restricted cash	5	28.4	33.1
Other assets	12	55.0	32.5
Total assets		\$ 2,975.9	\$ 3,029.8
Liabilities and Shareholders' Equity			
Current Liabilities:			
Accounts payable		\$ 55.0	\$ 26.2
Accrued and other current liabilities	13	290.5	337.2
EPIL III Notes	15	39.0	—
EPIL II guarantee provision	14	—	344.5
Deferred revenue	17	55.8	61.5
Held for sale liabilities	21	—	27.9
Total current liabilities		440.3	797.3
Long term and convertible debt	15	2,260.0	1,500.0
Deferred revenue	17	54.6	93.3
Other liabilities		16.0	21.3
Total liabilities		2,770.9	2,411.9
Shareholders' Equity:	22	22.6	22.0

Ordinary shares, €0.05 par value, 600,000,000 shares authorized, 395,072,974 and 386,182,274 shares issued and Outstanding at December 31, 2004 and 2003, respectively

Executive shares, €1.25 par value, 1,000 shares authorized, 1,000 shares issued and outstanding at December 31, 2004 and 2003

"B" Executive shares, €0.05 par value, 25,000 shares authorized, 21,375 shares issued and outstanding at December 31, 2004 and 2003

Additional paid-in capital		4,796.4	4,724.8
Treasury Stock	22	(17.4)	(17.4)
Accumulated deficit		(4,604.7)	(4,210.0)
Accumulated other comprehensive income	23	8.1	98.5
Shareholders' equity		205.0	617.9
Total liabilities and shareholders' equity		\$ 2,975.9	\$ 3,029.8

The accompanying notes are an integral part of these Consolidated Financial Statements.

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Elan Corporation, plc

Consolidated Statements of Shareholders' Equity and Other Comprehensive Income/(Loss)

For the Years Ended December 31, 2004, 2003 and 2002

(in millions)

	Number of Shares	Share Capital	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit (restated)	Accumulated Other Comprehensive Income/(Loss)	Total Shareholders' Equity (restated)
December 31, 2001	349.8	\$ 19.9	\$ 4,551.9	\$ (17.4)	\$ (1,345.7)	\$ 2.3	\$ 3,211.0
Comprehensive loss:							
Net loss	—	—	—	—	(2,358.2)	—	(2,358.2)
Unrealized gain on securities	—	—	—	—	—	9.4	9.4
Reclassification adjustment for gains included in net loss	—	—	—	—	—	(30.1)	(30.1)
Currency translation adjustments	—	—	—	—	—	14.9	14.9
Minimum pension liability	—	—	—	—	—	(9.8)	(9.8)
Total comprehensive loss							(2,373.8)
Stock issued, net of issuance costs	0.6	—	5.9	—	—	—	5.9
December 31, 2002	350.4	19.9	4,557.8	(17.4)	(3,703.9)	(13.3)	843.1
Comprehensive loss:							

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Net loss	—	—	—	—	(506.1)	—	(506.1)
Unrealized gain on securities	—	—	—	—	—	90.9	90.9
Reclassification adjustment for gains included in net loss	—	—	—	—	—	(1.3)	(1.3)
Currency translation adjustments	—	—	—	—	—	12.4	12.4
Minimum pension liability	—	—	—	—	—	9.8	9.8
Total comprehensive loss							(394.3)
Stock issued, net of issuance costs	35.8	2.1	167.0	—	—	—	169.1
December 31, 2003	386.2	22.0	4,724.8	(17.4)	(4,210.0)	98.5	617.9
Comprehensive loss:							
Net loss	—	—	—	—	(394.7)	—	(394.7)
Unrealized loss on securities	—	—	—	—	—	(12.1)	(12.1)
Reclassification adjustment for gains included in net loss	—	—	—	—	—	(77.5)	(77.5)
Currency translation adjustments	—	—	—	—	—	(0.8)	(0.8)
Total comprehensive loss							(485.1)
Tax benefit of stock option deductions	—	—	2.7	—	—	—	2.7
Stock issued, net of issuance costs	8.9	0.6	68.9	—	—	—	69.5
Balance at December 31, 2004	395.1	\$ 22.6	\$ 4,796.4	\$ (17.4)	\$ (4,604.7)	\$ 8.1	\$ 205.0

The accompanying notes are an integral part of these Consolidated Financial Statements.

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Elan Corporation, plc  
Consolidated Statements of Cash Flows  
For the Years Ended December 31, 2004, 2003 and 2002  
(in millions)

	2004	2003 (restated)	2002 (restated)
Cash flows from operating activities:			
Net loss	\$ (394.7)	\$ (506.1)	\$ (2,358.2)
Adjustments to reconcile net loss to net cash provided by/(used in) operating activities:			
Amortization of deferred revenue	(55.6)	(87.5)	(62.8)
Amortization of financing costs	5.5	13.6	9.7
Depreciation and amortization	123.6	174.1	196.6

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(Gain)/loss on sale of investments	(114.6)	(103.4)	39.2
Impairment of investments	71.8	87.5	1,006.0
Provision for EPIL II guarantee	47.1	49.0	295.4
Disposals/write-down of other assets	10.2	72.2	660.2
Purchase of product royalty rights	—	297.6	121.0
Gain on sale of businesses	(55.7)	(290.7)	(177.9)
Gain on repurchase of LYONs	—	(1.6)	(37.7)
Loss on sale of investments by EPIL III/Shelly Bay	—	—	141.6
Waiver fee to EPIL II/III noteholders	—	16.8	—
Receipts from sale of product rights	16.5	79.0	2.5
Other	23.0	(25.2)	56.1
Net changes in assets and liabilities:			
Decrease in accounts receivables	5.9	13.3	242.2
Decrease/(increase) in prepaid and other current assets	(21.3)	16.8	(49.8)
Decrease/(increase) in inventory	17.1	9.9	(13.0)
Decrease in accounts payable and accruals and other liabilities	(26.7)	(243.8)	66.1
Net cash provided by/(used in) operating activities	(347.9)	(428.5)	137.2
Cash flows from investing activities:			
Proceeds from disposal of property, plant and equipment	44.2	27.9	8.6
Purchase of property, plant and equipment	(57.9)	(33.7)	(170.2)
Purchase of investments	(1.4)	(11.8)	(117.1)
Proceeds from disposal of investments	76.6	53.1	10.4
Purchase of marketable investment securities	—	(2.1)	(83.7)
Sale and maturity of marketable investment securities	178.9	185.1	222.6
Purchase of intangible assets	(41.1)	(144.8)	(315.5)
Proceeds from disposal of intangible assets	0.3	0.5	9.4
Proceeds of business disposals	274.6	593.0	443.1
Purchase of product royalty rights	—	(297.6)	(121.0)
Redemption of investment in Autoimmune	—	—	38.5
Sale of EPIL III assets	—	—	9.3
Net cash provided by/(used in) investing activities	474.2	369.6	(65.6)
Cash flows from financing activities:			
Proceeds from issue of share capital	70.6	167.9	5.7
Payment under EPIL II guarantee	(391.8)	—	—
Repayment of EPIL III Notes	(351.0)	—	(160.0)
Repayment of loans	(11.4)	(770.7)	(527.6)
Net proceeds from debt issuance	1,125.1	443.9	—
Waiver fee to EPIL II/III noteholders	—	(16.8)	—
Shelly Bay bank loan	—	—	148.0
Repayment of Shelly Bay bank loan	—	—	(148.0)
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
Supplemental cash flow information:			
Cash paid for interest	(110.2)	(100.6)	(116.5)
Cash paid for income taxes	(0.6)	(8.9)	(18.6)

The accompanying notes are an integral part of these Consolidated Financial Statements.

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Elan Corporation, plc

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Elan Corporation, plc, an Irish public limited company ("we", "our", "us", "Elan" or the "Company"), is a neuroscience-based biotechnology company headquartered in Dublin, Ireland that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurodegenerative diseases, autoimmune diseases and severe pain.

In February 2004, we announced the formal completion of our recovery plan. The recovery plan had been announced in July 2002 to restructure our businesses, assets and balance sheet in order to enable us to meet our financial commitments. As a cornerstone of the recovery plan, we turned our focus to three core therapeutic areas: neurodegenerative diseases, autoimmune diseases and severe pain. During the course of the recovery plan, we were organized into two business units, Core Elan and Elan Enterprises. With the completion of the recovery plan, we announced the end of operations for our Elan Enterprises business unit. The implementation of the recovery plan resulted in the discontinuation and disposal of many of our products, operations and assets. See Note 21 for additional information.

In February 2004, our operations were reorganized into two business units: Biopharmaceuticals and Global Services and Operations ("GS&O"). Biopharmaceuticals engages in biopharmaceutical research and development ("R&D") activities, and pharmaceutical commercial 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. GS&O focuses on product development and manufacturing to provide technology platforms that address the drug delivery challenges of the pharmaceutical industry. All prior period financial information reflects this change in segmentation. See Note 31 for additional information.

Between 1996 and mid-2001, we pursued collaborations with biotechnology, drug delivery and pharmaceutical companies through a program referred to as "the business venture program". We have not entered into any new business ventures under the business venture program since mid-2001. 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. See Note 29 for additional information on business ventures.

We have in the past entered into risk-sharing arrangements. Please refer to Note 30 for information on risk-sharing arrangements. These arrangements have been terminated and we will not earn any revenues from these risk-sharing arrangements or upfront license fees from business ventures in the future.

The composition of our revenue for 2004, 2003 and 2002 is described below in Note 3.

2. Significant Accounting Policies

The following accounting policies have been applied in the preparation of our Consolidated Financial Statements.

(a) Basis of consolidation and presentation of financial information

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 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.

Unless otherwise indicated, our financial statements and other financial data contained in this Form 20-F are presented in United States dollars ("\$"). The accompanying Consolidated Financial Statements include our financial position, results of operations and cash flows and those of our wholly owned subsidiaries. All significant intercompany amounts have been eliminated.

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We have incurred significant losses during the last three fiscal years and anticipate continuing losses for the foreseeable future. However, our directors 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 prepare our Consolidated Financial Statements on a going concern basis.

(b) Use of estimates

The preparation of the Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures in these Consolidated Financial Statements. Actual results could differ from those estimates.

(c) Reclassifications

Certain items in the Consolidated Financial Statements for prior periods have been reclassified to conform to current classifications.

(d) 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 reconciliation to 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 (prior to the restatement described above).

#### Segmental Disclosures

In our 2004 Form 20-F/A we have restated our segmental disclosures by including a table titled "Revenue analysis by segment" as required by paragraph 37 of SFAS 131 "Disclosures about Segments of an Enterprise and Related Information".

#### (e) Cash and cash equivalents

Highly liquid debt instruments purchased with an original maturity of three months or less are classified as cash equivalents.

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#### (f) Investments and marketable 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 classified into one of three categories in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," ("SFAS No. 115"): including trading, available-for-sale, or held-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 trading securities at December 31, 2004.
- Marketable securities not classified as trading or held-to-maturity 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/(loss) in stockholders' equity. The assessment for impairment of marketable securities classified as available-for-sale is based on established financial methodologies, including quoted market prices for quoted equity securities.
- Marketable debt securities are considered held-to-maturity when we have the positive intent and ability to hold the securities to maturity. These securities are carried at cost, less any write-downs for impairments. We have no held-to-maturity securities at December 31, 2004.

Non-marketable equity and debt securities are carried at cost, less write-down-for-impairments, 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.

Equity accounting applies where we hold equity in the investee and have the ability to exercise significant influence over the operating and financial policies of the investee. Significant influence is presumed to exist if we own 20% of the investee's common stock and common stock equivalents, but may also exist in situations when we own less than 20% depending on the existence of factors such as representation on the board of directors, participation in policy making processes, material intercompany transactions, interchange of managerial personnel or technological dependency. Certain circumstances, such as majority ownership by another company, can offset the impact of such factors. The determination to use cost or equity accounting requires a significant degree of judgment of the facts and circumstances of a particular investment. Financial asset investments which are accounted for under the equity method are stated at cost, adjusted for our share of the earnings or losses and distributions of the investee after the date of investment, less any provision for impairment in value.

(g) Inventory

Inventory is valued at the lower of cost or market value. In the case of raw materials and supplies, cost is calculated on a first-in, first-out basis and includes the purchase price, including import duties, transport and handling costs and any other directly attributable costs, less trade discounts. In the case of work-in-progress and finished goods, costs include direct labor, material costs and related overhead.

(h) Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on estimated useful lives as follows:

Buildings	15-40 years
Leasehold improvements	Shorter of expected useful life or lease term
Plant and equipment	3-10 years

Where events or circumstances indicate that the carrying amount of a tangible asset may not be recoverable, we compare the carrying amount of the asset to its fair value. The carrying amount of the asset is not deemed recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of that



asset. In such event, an impairment loss is measured as the excess of the carrying amount over the asset's fair value.

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(i) Leasing

Property, plant and equipment acquired under a lease that transfers substantially all of the risks and rewards of ownership to us, are capitalized. Amounts payable under such leases (capital leases), net of finance charges, are shown as current or long-term liabilities as appropriate. Finance charges on capital leases are charged to expense over the term of the lease to give a constant rate of charge in proportion to the capital balances outstanding. Rentals on operating leases are charged to expense on a straight-line basis.

(j) Goodwill, other intangible assets and impairment

We account for goodwill and identifiable intangible assets in accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," ("SFAS No. 142"). Effective January 1, 2002, goodwill and identifiable intangible assets with indefinite useful lives are no longer amortized, but are instead 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" ("SFAS No. 144"). Other intangible assets with useful lives ranging from 2 to 20 years are amortized on a straight-line basis.

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 result of our impairment tests did not indicate any impairment in 2004.

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.

(k) Financing costs

Debt financing costs are included in other assets and are amortized to interest expense over the term of the related debt at a constant rate on the carrying amount.

(l) Derivative financial instruments

We enter into transactions in the normal course of business using a variety of financial instruments in order to hedge against exposures to fluctuating exchange and interest rates. We use derivative financial instruments to reduce exposure to fluctuations in foreign exchange rates and interest rates. Derivative instruments are contractual agreements whose value reflects price movements in an underlying asset or liability. We do not enter into derivative financial instruments

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for trading or speculative purposes. Our forward currency contracts do not qualify for hedge accounting under SFAS No. 133, "Accounting for Derivative Instruments in Hedging Activities" ("SFAS No. 133"), and are marked to market at each balance sheet date, with the resulting gains and losses recognized in income. Gains and losses on derivative financial instruments that qualify as fair value hedges under SFAS No. 133 are recognized as an offset to the related income or expense of the underlying hedged transaction. The carrying value of derivative financial instruments is reported within current assets or other current liabilities.

We fair value certain embedded derivative and freestanding warrants. Changes in their fair value are recorded in the income statement and their carrying value is recorded within current assets or current liabilities.

(m) Revenue

Our revenues are derived from product revenue and contract revenue. Revenue is shown net of taxes, trade discounts, chargebacks and rebates.

Product Revenue — Product revenue includes: (i) the sale of products; (ii) royalties; (iii) the sales of product rights and related inventory (referred to as product disposals and product rationalizations); and (iv) product co-promotion, marketing and similar activities.

- i. The sale of products consists of the sale of pharmaceutical drugs and diagnostic products, primarily to wholesalers and physicians.
- ii. We receive a percentage of revenue on certain products marketed by third parties as royalties.
- iii. Revenue from the sale of product rights and related inventory consists of the proceeds from the disposal of products, inventory and intellectual property less the unamortized cost of the related intangible assets.
- iv.

Revenue from product co-promotion, marketing and similar activities consisted of the reimbursement of commercialization expenses from our risk-sharing arrangements with Pharma Marketing Ltd. (together with its subsidiary, "Pharma Marketing") and Autoimmune Diseases Research and Development Corp., Ltd. ("Autoimmune").

Revenue on the sale of products is recognized when title passes, net of applicable estimated discounts, sales returns, rebates and charge-backs. Other product revenues are recognized based on the terms of the applicable contract. 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. These amounts are included in other current liabilities (rebates) or deducted from trade receivables (other discounts).

Revenue is also recorded net of provision, made at the time of sale, for estimated cash discounts, rebates and charge-backs. We enter into contracts with certain 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 amounts paid to reimburse 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.

Contract Revenue — Contract revenue arises from contracts to perform R&D services on behalf of clients or technology licensing and business ventures. Contract revenue is recognized when earned and non-refundable, and when we have no future obligation with respect to the revenue, in accordance with the terms prescribed in the applicable contract. Contract research revenue consists of payments or milestones arising from R&D activities performed by us on behalf of third parties.

U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 104, 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 or joint development activities) by the seller after an asset disposal. We defer and amortize up-front license fees to income 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.

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Accounting for milestone payments 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 necessary 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, then we 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.

(n) Advertising expenses

We expense the costs of advertising as incurred. Advertising expenses were \$6.3 million in 2004 (2003: \$7.3 million; 2002: \$37.5 million).

(o) Research and development

R&D costs are charged to expense as incurred. Acquired in process research and development arising on business combinations is expensed on acquisition. Costs to acquire intellectual property, product rights and other similar intangible assets are capitalized and amortized on a straight-line basis over the estimated useful life of the asset or on the projected cash flow basis where it better reflects the product life cycle.

(p) Taxation

The provision for income taxes has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences of events that have been recognized for financial reporting or income tax reporting purposes. Provision for income tax represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax basis of our assets and liabilities, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. We do not record a provision for income tax on undistributed earnings of foreign subsidiaries that we do not expect to repatriate in the foreseeable future.

We establish liabilities for possible assessments by taxing authorities resulting from known tax exposures. Such amounts represent a reasonable provision for taxes ultimately expected to be paid, and may need to be adjusted over time as more information becomes known.

(q) Discontinued operations, sales of businesses, and assets and liabilities held for sale

In accordance with SFAS No. 144, the results and gains or losses arising from discontinued operations are aggregated and included within one line in the income statement, "Net loss from discontinued operations." A discontinued operation is a component of an entity whose operations and cash flows can be clearly distinguished and have been or will be eliminated from the ongoing operations of the entity and the entity will not have any significant continuing involvement in the operations of the component after its disposal, such as continuing involvement, including ongoing supply arrangements or formulation activities.

Sales of businesses that do not constitute discontinued operations as defined above, are recorded on the face of the income statement. The reported gain is equal to proceeds received net of the carrying values of the business assets and liabilities being disposed of, transaction costs and the allocation of goodwill based on the relative fair value of the business to its reporting unit.

We categorize assets and liabilities as held for sale when all of the following are met:

- Management, having the authority to approve the action, commits to a plan to sell the asset;
- The asset is available for immediate sale in its present condition, subject only to customary terms;

- An active program to locate a buyer and other necessary actions required to complete the plan to sell the asset have been initiated;
- The sale of the asset is probable, and transfer of the asset is expected to qualify for recognition as a completed sale, within one year;
- The asset is being actively marketed for sale at a price that is reasonable in relation to its current fair value; and
- Actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

(r) Accumulated other comprehensive income

Comprehensive income is comprised of our net income or loss and other comprehensive income/(loss) ("OCI"). OCI includes certain changes in stockholders' equity that are excluded from net income. Specifically, we include in OCI changes in the fair value of unrealized gains and losses on our available-for-sale securities and foreign currency translation adjustments. Comprehensive loss for the years ended December 31, 2004, 2003 and 2002 has been reflected in the Consolidated Statements of Stockholders' Equity and Other Comprehensive Income/(Loss).

(s) Foreign operations

Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing at subsequent balance sheet dates, and the resulting gains and losses are recognized in the profit and loss account and, where material, separately disclosed.

The functional currency of most of our subsidiaries is U.S. dollars. For those subsidiaries with non-U.S. dollars functional currency, their assets and liabilities are translated using year-end rates and income is translated at average rates. The cumulative effect of exchange differences arising on consolidation of the net investment in overseas subsidiaries and associates are recognized as other comprehensive income in the Consolidated Statement of Shareholders' Equity and Other Comprehensive Income/(Loss).

(t) Stock-based compensation

We account for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," ("SFAS No. 123"), as amended by SFAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosures." Accordingly, no expense has been recognized for options granted to employees where the option exercise price is equal to the fair value of the underlying shares at the date of grant. When the exercise price of the option is less than the fair value of the underlying shares at the date of grant, the intrinsic value is recorded as compensation expense based on the graded vesting method over the vesting periods of the applicable stock purchase rights and stock options, generally four years. The graded vesting method provides for vesting of portions of the overall awards at interim dates and results in greater expense recorded in earlier years than under the straight-line method.

SFAS No. 123 requires the use of option pricing models. The Black-Scholes option-pricing model requires the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Since our employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate, we do not believe that the existing

models necessarily provide a reliable single measure of the fair value of employee stock options.

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Had compensation expense been determined based on the fair value at the grant date for all awards, consistent with the provisions of SFAS No. 123, reported pro forma net loss and net loss per share would have been as follows (in millions, except per share data):

	2004	2003	2002
Net loss as reported	\$ (394.7)	\$ (506.1)	\$ (2,358.2)
Add: Intrinsic value method expense	1.6	1.1	0.1
Deduct: Fair value method expense	(49.4)	(75.2)	(127.5)
Pro-forma net loss	\$ (442.5)	\$ (580.2)	\$ (2,485.6)
Basic and diluted loss per Ordinary Share: <sup>(1)</sup>			
As reported	\$ (1.01)	\$ (1.42)	\$ (6.74)
Pro-forma	\$ (1.13)	\$ (1.63)	\$ (7.11)

(1) There is no difference, for the periods presented, in weighted average number of ordinary shares used for basic and diluted net loss per ordinary share as the effect of all dilutive ordinary shares outstanding for each period was anti-dilutive. The estimated weighted-average fair value of the individual options granted during the years ended December 31, 2004, 2003 and 2002 was \$9.93, \$3.50 and \$4.11, respectively, on the date of grant. The fair value of options granted was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2004	2003	2002
Risk-free interest rate	3.36%	1.02%	1.62%
Volatility	61.0%	99.3%	91.0%
Dividend yield	Nil	Nil	Nil
Expected life (years)	4.3	6.7	5.9

(u) Pensions and other employee benefit plans

We have two defined pension plans covering our employees based in Ireland. We account for pension benefit obligations and related costs in accordance with SFAS No. 87, "Employer's Accounting for Pensions." These plans are managed externally and the related pension costs and liabilities are assessed annually in accordance with the advice of a professionally qualified actuary. Two significant assumptions, the discount rate and the expected rate of return on plan assets, are important elements of expense and/or liability measurement. We evaluate these assumptions annually, with the assistance of an actuary. Other assumptions involve employee demographic factors such as retirement patterns, mortality, turnover and the rate of compensation increase. We use a December 31, 2004 measurement date. All plan assets and liabilities are reported as of that date. The cost or benefit of plan changes, which increase or decrease benefits for prior employee service is included in expense on a straight-line basis over the period the

employee is expected to receive the benefits.

In addition, we have a number of other defined contribution benefit plans, primarily for employees outside of Ireland. The cost of providing these plans is expensed as incurred.

In December 2003, the FASB issued SFAS No. 132 (Revised 2003), "Employers' Disclosures about Pensions and Other Postretirement Benefits," which revises employers' disclosures about pension plans and other postretirement benefit plans. All provisions of this statement are effective for the year ended December 31, 2004. See Note 24 for further information on our pension and other employee benefit plans.

#### (v) Contingencies

In accordance with SFAS No. 5, "Accounting for Contingencies" ("SFAS No. 5"), we assess the likelihood of any adverse outcomes to contingencies, including legal matters, as well as the potential range 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. See Note 26 for further information.

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### 3. Revenue

The composition of revenue for the years ended December 31, was as follows (in millions):

	2004	2003	2002
Product revenue	\$ 404.4	\$ 586.7	\$ 742.4
Contract revenue	77.3	98.9	350.7
Total revenue	\$ 481.7	\$ 685.6	\$ 1,093.1

Product revenue can be further analyzed as follows (in millions):

	2004	2003	2002
Retained products	\$ 305.4	\$ 274.2	\$ 230.7
Divested products <sup>(1)</sup>	65.0	278.5	441.1
Amortized revenue— Adalat/Avinza	34.0	34.0	7.8
Risk-sharing arrangements	—	—	62.8
Total product revenue	\$ 404.4	\$ 586.7	\$ 742.4

(1) Products described as "Divested Products" include products or businesses divested since the beginning of 2002. Contract revenue can be further analyzed as follows (in millions):

	2004	2003	2002
License fees	\$ 17.6	\$ 49.6	\$ 234.7
Risk-sharing arrangements	—	—	37.2
Research revenues/milestones	59.7	49.3	78.8
Total contract revenue	\$ 77.3	\$ 98.9	\$ 350.7

Included in license fee revenue is \$Nil, \$35.2 million and \$203.8 million for 2004, 2003 and 2002, respectively, related to license fees earned from business ventures. There were no remaining unamortized license fees from the business ventures at December 31, 2004.

#### 4. Earnings Per Share

Basic income/(loss) per share is computed by dividing the net income/(loss) for the period available to ordinary shareholders by the sum of the weighted average number of ordinary shares outstanding during the period. Diluted net income/(loss) per share is computed by dividing the net income/(loss) for the period by the weighted average number of ordinary shares outstanding and, when dilutive, adjusted for the effect of all dilutive potential ordinary shares, including stock options, warrants, and convertible debt securities on an as-if-converted basis.

The following table sets forth the computation for basic and diluted net income/(loss) per share:

	2004	2003	2002
<u>Basic and diluted net loss per ordinary share:</u>			
Basic and diluted net loss per share from continuing operations	\$ (1.06)	\$ (1.33)	\$ (6.20)
Basic and diluted net income/(loss) per share from discontinued operations	0.05	(0.09)	(0.54)
Basic and diluted net loss per ordinary share	\$ (1.01)	\$ (1.42)	\$ (6.74)

The weighted average number of ordinary shares outstanding at December 31, 2004 was 390.1 million (2003: 356.0 million; 2002: 349.7 million). The potential effect of anti-dilutive stock options, warrants and convertible debt securities, for the year ended December 31, 2004 was 75.5 million shares (2003: 70.2 million shares; 2002: 26.2 million shares).

#### 5. Restricted Cash

We had total restricted cash of \$192.7 million at December 31, 2004 (2003: \$33.1 million), of which \$124.3 million is held by EPIL III and was reserved for the repayment of EPIL III Notes of \$39.0 million due and repaid in full in March 2005.

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Following this debt repayment, the remaining cash in EPIL III can be used for general corporate purposes. Restricted cash at December 31, 2004 also includes \$40.0 million reserved in escrow for our estimate of the ultimate cost to



settle the shareholder class action lawsuit and \$28.4 million of pledged cash to secure certain letters of credit. The restricted cash at December 31, 2003 of \$33.1 million consisted of the cash held by EPIL III and pledged cash to secure certain letters of credit.

#### 6. Accounts Receivable, Net

Our accounts receivable at December 31 of each year end consisted of the following (in millions):

	2004	2003
Trade receivables	\$ 47.0	\$ 49.5
Less amounts provided for doubtful accounts	(5.5)	(11.6)
Trade receivables, net	\$ 41.5	\$ 37.9

#### 7. Marketable Investment Securities

The following information on current marketable investment securities is presented in accordance with the requirements of SFAS No. 115 at December 31, 2004 and 2003 as follows (in millions):

	Cost	Gross Unrealized Gains	Fair Value
At December 31, 2004			
Total trading securities	\$ —	\$ —	\$ —
Available for sale securities			
Equity securities	19.6	11.7	31.3
Debt securities	25.0	9.2	34.2
Total available for sale securities	44.6	20.9	65.5
Total marketable investment securities	\$ 44.6	\$ 20.9	\$ 65.5
At December 31, 2003			
Total trading securities	\$ 74.8	\$ 11.8	\$ 86.6
Available for sale securities			
Equity securities	76.9	96.3	173.2
Debt securities	75.4	14.2	89.6
Total available for sale securities	152.3	110.5	262.8
Total marketable investment securities	\$ 227.1	\$ 122.3	\$ 349.4

Unrealized gains on trading securities included in earnings for 2004, 2003 and 2002 totaled \$Nil, \$11.8 million and \$0.8 million, respectively. The unrealized losses on trading securities included in earnings for 2004, 2003 and 2002 were \$Nil, \$Nil and \$12.5 million, respectively.

The cash inflows arising from the sale and maturity of marketable investment securities were \$178.9 million, \$185.1 million and \$222.6 million in 2004, 2003 and 2002, respectively. The net realized gains arising from the sale and maturity of marketable investment securities were \$99.3 million, \$68.7 million and \$1.8 million in 2004, 2003 and 2002, respectively. The cash outflows arising from the purchase of marketable investment securities were \$Nil, \$2.1 million and \$83.7 million in 2004, 2003 and 2002, respectively.

We have accounted for certain freestanding warrants and embedded derivatives in accordance with SFAS No. 133. The income effect of derivative fair value movements was a loss of \$33.0 million, a gain of \$26.1 million and a loss of \$4.4 million in 2004, 2003, and 2002, respectively. Included in the 2004 impairment charge relating to investments held of \$71.8 million (2003: \$87.5 million; 2002: \$1,006.0 million) was \$Nil (2003: \$Nil; 2002: \$31.6 million) in relation to the impairment of SFAS No. 133 derivative instruments. These derivatives had a fair value of \$1.4 million and \$34.1 million at December 31, 2004 and 2003, respectively.

The impairment charge of \$71.8 million for 2004 includes all other-than-temporary impairments at December 31, 2004. There are no investments with unrealized losses at December 31, 2004.

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Non-current available-for-sale marketable securities, recorded at cost, were as follows at December 31 (in millions):

	2004	2003
Equity securities	\$ 20.8	\$ 45.6
Debt securities	18.2	132.9
Other	—	14.4
Total	\$ 39.0	\$ 192.9

The cash inflows arising from the sale of non-current available-for-sale securities were \$76.6 million, \$53.1 million and \$10.4 million in 2004, 2003 and 2002, respectively. The cash outflows arising from the purchase of non-current available-for-sale securities were \$1.4 million, \$11.8 million and \$117.1 million for 2004, 2003 and 2002, respectively.

#### 8. Inventory

Product inventories at December 31, 2004 and 2003 consisted of the following (in millions):

	2004	2003
Raw materials	\$ 6.8	\$ 17.1
Work-in-process	8.2	21.3
Finished goods	14.0	31.1
Total inventory	\$ 29.0	\$ 69.5

The decrease in inventories during 2004 primarily reflects the disposal of businesses and products.

#### 9. Prepaid and Other Current Assets

Prepaid and other current assets at December 31 consisted of the following (in millions):

	2004	2003 (restated)
Other receivables	\$ 27.6	\$ 34.6
Insurance deposit <sup>(1)</sup>	21.0	18.8
Prepayments	25.0	28.0
Fair value of derivatives <sup>(2)</sup>	5.0	42.8
Total prepaid and other current assets	\$ 78.6	\$ 124.2

(1) Amount represents insurance program deposit balance received in January 2005.

(2) The decrease in the fair value of derivatives during 2004 reflects the disposal of investments during the current year.

#### 10. Property, Plant and Equipment

	Land & Buildings	Plant & Equipment (in millions)	Total
Cost:			
At January 1, 2004	\$ 254.6	\$ 297.7	\$ 552.3
Additions	30.0	35.1	65.1
Disposals	(60.0)	(25.2)	(85.2)
At December 31, 2004	\$ 224.6	\$ 307.6	\$ 532.2
Accumulated depreciation:			
At January 1, 2004	\$ (39.2)	\$ (144.0)	\$ (183.2)
Charged in year	(5.9)	(33.2)	(39.1)
Disposals	14.3	22.0	36.3
At December 31, 2004	\$ (30.8)	\$ (155.2)	\$ (186.0)
Net book value: December 31, 2004	\$ 193.8	\$ 152.4	\$ 346.2
Net book value: December 31, 2003	\$ 215.4	\$ 153.7	\$ 369.1

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Property, plant and equipment disposals during 2004 primarily include the sale and leaseback of a building in San Diego, which is now accounted for as an operating lease.

The net book value of assets held under capital leases at December 31, 2004 amounted to \$60.1 million (2003: \$53.2 million) and related depreciation for the period amounted to \$12.8 million (2003: \$11.4 million; 2002: \$13.9 million).

#### 11. Goodwill and Other Intangible Assets

	Goodwill	Other Intangible Assets (in millions)	Total
Cost:			
At January 1, 2003	\$ 316.5	\$ 1,266.5	\$ 1,583.0

Additions		—		12.2		12.2
Disposals		(41.9)		(391.9)		(433.8)
At December 31, 2003	\$	274.6	\$	886.8	\$	1,161.4
Additions		—		26.7		26.7
Disposals		(6.6)		(104.1)		(110.7)
At December 31, 2004	\$	268.0	\$	809.4	\$	1,077.4
Accumulated amortization:						
At January 1, 2003	\$	—	\$	(258.9)	\$	(258.9)
Charged in year		—		(121.9)		(121.9)
Disposals		—		127.2		127.2
At December 31, 2003	\$	—	\$	(253.6)	\$	(253.6)
Charged in year		—		(84.5)		(84.5)
Disposals		—		41.5		41.5
At December 31, 2004	\$	—	\$	(296.6)	\$	(296.6)
Net book value: December 31, 2004	\$	268.0	\$	512.8	\$	780.8
Net book value: December 31, 2003	\$	274.6	\$	633.2	\$	907.8

Other intangible assets consist primarily of patents, licenses and intellectual property. At December 31, 2004, the main components of the carrying value of patents and licenses were \$220.0 million for Maxipime and Azactam, \$97.5 million for the Alzheimer's disease intellectual property, \$84.2 million for Prialt, \$61.7 million for Verelan and \$19.9 million for Tysabri.

Disposals of other intangible assets during 2004 primarily relate to the net intangible assets related to Zonegran (zonisamide) of \$42.0 million and net intangible assets related to Frova of \$22.2 million, both of which were sold during 2004.

At December 31, 2003, the main components of the carrying value of patents and licenses were \$248.6 million for Maxipime and Azactam, \$105.5 million for the Alzheimer's disease intellectual property, \$89.2 million for Prialt, \$68.8 million for Verelan, \$22.9 for Frova, and \$16.1 million for Tysabri.

Disposals of other intangible assets during 2003 primarily relate to the net intangible assets related to Sonata of \$156.2 million and net intangible assets related to Roxane of \$54.7 million, both of which were sold during 2003.

Amortization expense for the year ended December 31, 2004 amounted to \$84.5 million (2003: \$121.9 million; 2002: \$129.3 million) and is recorded as cost of sales, selling, general and administrative expenses and R&D expenses in the Consolidated Statements of Operations, as it relates to the respective function.

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As of December 31, 2004, our expected future annual amortization expense of other intangible assets was as follows (in millions):

Year ending December 31,		
2005	\$	101.8
2006		93.5

2007		93.5
2008		38.5
2009		23.4
Total	\$	350.7

## 12. Other Assets

Non-current other assets at December 31 consisted of the following (in millions):

	2004	2003
Deferred financing costs	\$ 42.6	\$ 21.1
Other	12.4	11.4
Total other assets	\$ 55.0	\$ 32.5

Deferred financing costs increased during 2004 due to the completion of our debt refinancing in November 2004. Please refer to Note 15 for additional information on our long-term and convertible debt.

## 13. Accrued and Other Current Liabilities

Accrued and other current liabilities at December 31 consisted of the following (in millions):

	2004	2003
Payroll and related taxes	\$ 58.6	\$ 67.7
Litigation accruals	63.4	12.0
Accrued interest	31.8	21.1
Clinical trial accruals	27.7	36.2
Restructuring and other accruals	18.0	38.7
Deferred rent	17.3	13.7
Other accruals	73.7	147.8
Total accrued and other current liabilities	\$ 290.5	\$ 337.2

### Restructuring and other accruals

In the early months of 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, the announcement of a profit warning and an investigation by the SEC. These disappointments ultimately led to a loss of confidence in Elan. To address these issues, we announced a recovery plan in July 2002 to restructure our business, assets and balance sheet in order to enable us to meet our financial commitments.

In February 2004, we announced the completion of our recovery plan. 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

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- 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.

For additional information related to the recovery plan and the associated restructuring and other charges, please refer to Note 20 to the Consolidated Financial Statements.

The following table summarizes activities related to the restructuring and other charges (in millions):

	Facilities	Severance	Pharma Marketing royalty rights	Other exit costs	Assets impairments	Total
Balance at December 31, 2002	\$ 19.7	\$ 17.3	\$ —	\$ —	\$ —	\$ 37.0
Restructuring and other charges <sup>(1)</sup>	12.7	34.5	297.6	34.8	71.6	451.2
Cash payments	(6.6)	(34.2)	(297.6)	(34.8)	—	(373.2)
Non-cash charges	(4.7)	—	—	—	(71.6)	(76.3)
Balance at December 31, 2003	\$ 21.1	\$ 17.6	\$ —	\$ —	\$ —	\$ 38.7
Restructuring and other charges	0.8	3.0	—	—	—	3.8
Cash payments	(4.7)	(19.3)	—	—	—	(24.0)
Non-cash charges	(0.5)	—	—	—	—	(0.5)
Balance at December 31, 2004	\$ 16.7	\$ 1.3	\$ —	\$ —	\$ —	\$ 18.0

(1)The total restructuring and other charges of \$451.2 million in 2003 includes \$58.7 related to the costs associated with exit disposal activity that involved discontinued operations, and such charges were included in the results of discontinued operations. The remaining charges of \$392.5 million are included in restructuring and other charges, net (see Note 20). Costs incurred related to the shareholder litigation and SEC investigation did not relate to the restructuring and other activities under the recovery plan and so have been excluded from the table above.

#### 14. EPIL II Guarantee Provision

We had guaranteed the debt of EPIL II, to the extent that the investments held by it were insufficient to repay the debt when it fell due in June 2004. At December 31, 2003, we had recorded a provision of \$344.5 million in respect of this guarantee. On June 28, 2004, the guaranteed 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 agreement. We recorded an expense of \$47.1

million in 2004 (2003: \$49.0 million; 2002: \$295.4 million) arising from the guarantee to EPIL II noteholders and the insufficiency of EPIL II's assets to repay its debt.

In June 2000, we sold a portfolio of equity and debt securities to EPIL II, a wholly-owned, unconsolidated subsidiary. EPIL II was not consolidated as a subsidiary prior to June 2004. It qualified as a special purpose entity within the meaning of SFAS No. 125, as grandfathered under SFAS No. 140, as we had effected a true legal sale of the investments and had not retained control over such assets. Accordingly, the transfer of investments to EPIL II was treated as a sale of the assets at fair value and the related loan notes were not included as a liability. We did not expense the related interest charge in the income statement. We recorded a gain of \$39.2 million arising from the disposal of investments to EPIL II in June 2000.

We held a retained interest in EPIL II through our ownership of the retained beneficial interest (100% of the common stock). The retained beneficial interest entitled us to any residual proceeds in EPIL II after repayment of the EPIL II Notes. Pursuant to the Stock Pledge Agreement, we had pledged the common stock in EPIL II to the noteholders of EPIL II. On December 31, 2003, the estimated fair value of our retained interest in EPIL II was \$Nil. The holders of the loan notes had control of key voting rights, such as the right to approve the appointment of directors of EPIL II and the right to approve amendments to the Memorandum of Association and By-Laws of EPIL II. The board of directors of EPIL II was independent and was comprised of a majority of independent directors and one director appointed by us. In accordance with the organizational documents, EPIL II could dispose of investments upon maturity of its loan notes.

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Upon the maturity of the loan notes due 2004, if there were more than sufficient investments to repay the loan notes, the organizational documents of EPIL II did not contain provisions concerning the selection of investments, or the amount of investments, to be disposed of. In this situation, any decision as to which assets to dispose of was made by the board of directors of EPIL II. When the loan notes of EPIL II were repaid, the Stock Pledge Agreement terminated and we were entitled to the residual proceeds, if any, through ownership of the common stock in EPIL II. We did not have a call option or similar unilateral legal right over the transferred investments. We had provided a direct guarantee to the holders of the loan notes of EPIL II for the repayment of the loan notes and the payment of any unpaid interest. In the event that EPIL II did not meet its obligations to pay amounts due to the noteholders, the noteholders could call upon our guarantee.

Our accounting policy was to allocate the previous carrying amount of the investments transferred, between the investments transferred and the retained interest based on their relative fair values on the date of transfer. The fair value of a retained interest, both for initial and subsequent measurement, was calculated as the fair value of the qualifying special purpose entity's assets less the fair value of its liabilities. For disclosure purposes, the fair value of the assets of EPIL II was estimated using established financial methodologies, including quoted market prices, where available, and takes into account the time value of money. The fair value of investments in private entities and non-traded securities of public entities is typically measured by valuation methodologies such as option-pricing models and valuations achieved in recent private placements by the investee. The key assumptions used in measuring the fair value of our retained interest in EPIL II was common stock prices for equity-based assets and the discount rate used for debt-based assets. The fair value of the liabilities of EPIL II was measured as the total amount outstanding under its loan notes, including accrued but unpaid interest (if any), and takes into account the time value of money. The fair value of the guarantee was measured as de minimis on the transfer date. The guarantee was subsequently accounted for, under U.S. GAAP, as a loss contingency in accordance with the requirements of SFAS No. 5. This required that we record a charge under the guarantee if it was probable that a payment would be made under the

guarantee to the EPIL II noteholders.

Our retained interest in EPIL II had a fair value of \$Nil on the transfer date. We were carrying the common stock of EPIL II at cost, as it did not qualify as a debt security or a debt-like security as defined in SFAS No. 115.

We provided services such as bookkeeping and administration, monitoring, administering compliance with applicable laws and regulation and custodian service to EPIL II. Such services were for the benefit of EPIL II. All compensation paid represents an arms-length price for those services. In 2004, we received a fee of \$0.4 million (2003: \$0.8 million; 2002: \$0.8 million) for providing these services to EPIL II.

#### 15. Long-Term and Convertible Debt

Long-term and convertible debt at December 31, 2004 and 2003 consisted of the following (in millions):

	Due		2004		2003
EPIL III Notes	2005	\$	—	\$	390.0
7.25% senior notes ("Athena Notes")	2008		650.0		650.0
6.5% convertible notes	2008		460.0		460.0
7.75% senior notes ("7.75% Notes")	2011		850.0		—
Senior floating rate notes ("Floating Rate Notes")	2011		300.0		—
Total long term and convertible debt		\$	2,260.0	\$	1,500.0

#### Athena Notes

In February 2001, Athena Neurosciences Finance, LLC ("Athena Finance"), an indirect wholly-owned subsidiary, issued \$650.0 million in aggregate principal amount of Athena Notes due February 2008 at a discount of \$2.5 million. The Athena Notes are senior, unsecured obligations of Athena Finance and are fully and unconditionally guaranteed on a senior unsecured basis by Elan Corporation, plc and certain of our subsidiaries. Issuance costs associated with the financing amounted to \$8.3 million. Interest is paid in cash semi-annually.

On January 14, 2002, we entered into an interest rate swap to convert our fixed rate interest obligations for \$100.0 million of the Athena Notes to variable rate interest obligations. The swap had a fair value gain of \$3.6 million at December 31, 2004 (2003: \$8.5 million). On November 22, 2004, we entered into an interest rate swap to convert an additional \$200.0 million of this debt to variable rate interest obligations. The swap had a fair value loss of \$0.9 million at December 31, 2004.

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#### 6.5% Convertible Notes

In November 2003, we completed the offering and sale of \$460.0 million in aggregate principal amount of 6.5% Convertible Notes issued by Elan Capital Corporation, an indirect wholly-owned subsidiary, and guaranteed by Elan Corporation, plc. The 6.5% Convertible Notes mature on November 10, 2008.



Holders of the 6.5% Convertible Notes have the right to convert the notes into fully-paid American Depository Shares ("ADSs") at a conversion price of \$7.42 at any time up to November 10, 2008 or seven trading days preceding the date of redemption if the notes are called for redemption.

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

#### 7.75% Notes

In November 2004, we completed the offering and sale of \$850.0 million in aggregate principal amount of 7.75% Notes due November 15, 2011 issued by Elan Finance plc. Elan Corporation, plc and certain of our subsidiaries have guaranteed the 7.75% Notes. At any time prior to November 15, 2008, we may redeem the 7.75% Notes, in whole, but not in part, at a price equal to 100% of their principal amount plus a make-whole premium plus accrued and unpaid interest. We may redeem the 7.75% Notes, in whole or in part, beginning on November 15, 2008 at an initial redemption price of 103.875% of their principal amount plus accrued and unpaid interest. In addition, at any time after February 17, 2006 and on or prior to November 15, 2007, we may redeem up to 35% of the 7.75% Notes using the proceeds of certain equity offerings at a redemption price of 107.75% of the principal.

#### Floating Rate Notes

In November 2004, we also completed the offering and sale of \$300.0 million in aggregate principal amount of Floating Rate Notes due November 15, 2011, also issued by Elan Finance plc. The Floating Rate Notes bear interest at a rate, adjusted quarterly, equal to the three-month London Interbank Offer Rate ("LIBOR") plus 4.0%, except the first interest payment, which bears interest at a rate equal to six-month LIBOR plus 4.0%. Elan Corporation, plc, and certain of our subsidiaries have guaranteed the Floating Rate Notes. At any time prior to November 15, 2006, we may redeem the Floating Rate Notes, in whole, but not in part, at a price equal to 100% of their principal amount plus a make-whole premium plus accrued and unpaid interest. We may redeem the Floating Rate Notes, in whole or in part, beginning on November 15, 2006 at an initial redemption price of 102% of their principal amount plus accrued and unpaid interest. In addition, at any time after February 17, 2006 and on or prior to November 15, 2007, we may redeem up to 35% of the Floating Rate Notes using the proceeds of certain equity offerings at a redemption price of 100% of the principal amount plus a premium equal to the interest rate per annum on the Floating Rate Notes, plus accrued and unpaid interest thereon.

#### EPIL III Notes

In March 2001, we transferred a portfolio of equity and debt securities to a special purpose entity, EPIL III, a wholly owned and consolidated subsidiary. EPIL III issued \$200.0 million in aggregate principal amount of Series C Guaranteed Notes in a private placement to a group of financial institutions. In addition, EPIL III issued \$160.0 million in aggregate principal amount of Series A Guaranteed Notes and \$190.0 million of Series B Guaranteed Notes, in exchange for all outstanding guaranteed notes issued in June 1999 by Elan Pharmaceutical Investments, Ltd ("EPIL"). We fully and unconditionally guaranteed the Series B Guaranteed Notes and Series C Guaranteed Notes on a subordinated basis. The Series A Guaranteed Notes bore interest at the rate of 8.43% per annum. The Series B Guaranteed Notes bore interest at the rate of 8.43% per annum through June 2002 and 7.72% per annum thereafter. The Series C Guaranteed Notes bear interest at the rate of 7.62% per annum.

In 2001, EPIL III paid cash of \$106.0 million to us and also exchanged the EPIL III Series A and Series B Guaranteed Notes for all outstanding EPIL guaranteed notes as consideration for the portfolio of investments transferred to it. Other than these payments and a payment of \$0.8 million (2003: \$0.8 million, 2002: \$0.8 million) for administration

services, there were no other cash flows between EPIL III and us in 2004, 2003 or 2002. The remaining investments and cash in

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EPIL III are held as security against the EPIL III Series B Guaranteed Notes and the Series C Guaranteed Notes. These assets were not available for distribution outside EPIL III prior to repayment of the EPIL III Notes. The investments and cash had a fair value of \$125.3 million (principally cash of \$124.3 million), and a carrying value of \$125.3 million, at December 31, 2004. EPIL III used the funds to repay the remaining EPIL III Notes of \$39.0 million in March 2005. Issuance costs associated with the EPIL III Notes amounted to \$6.1 million.

In June 2002, EPIL III disposed of securitized investments to Shelly Bay, an entity established by Elan, in order to repay the \$160.0 million in the aggregate principal amount of its Series A Guaranteed Notes which matured on June 29, 2002. Shelly Bay financed the entire purchase price of the investments through borrowings under a non-recourse bank loan facility which we guaranteed. Elan made a cash payment of \$141.6 million to satisfy its obligation under the guarantee.

In November 2004, through our wholly owned subsidiary, Elan International Services, Ltd. , we completed a cash tender offer to purchase \$351.0 million of the EPIL III Series B and C Guaranteed Notes.

The net interest expense related to all of the convertible notes and long-term debt for the years ended December 31, 2004, 2003 and 2002 is as follows (in millions):

	2004	2003 (restated)	2002 (restated)
Interest expense:			
Interest on Athena Notes	\$ 47.2	\$ 47.2	\$ 47.2
Interest on 6.5% Convertible Notes	29.9	4.2	—
Interest on 7.75% Notes	8.4	—	—
Interest on Floating Rate Notes	2.5	—	—
Interest on EPIL III Notes <sup>(1)</sup>	33.1	30.0	37.6
Financing charges	5.5	19.4	12.9
Foreign exchange loss	3.0	8.9	2.6
Interest on Liquid Yield Option Notes ("LYONs")	—	19.2	31.7
Other	1.2	(0.2)	5.4
Interest expense	\$ 130.8	\$ 128.7	\$ 137.4
Interest income:			
Bank interest	\$ (12.5)	\$ (11.0)	\$ (32.4)
Investment interest	(6.8)	(10.2)	(33.2)
Swap interest	(3.7)	(3.7)	(1.1)
Interest income	\$ (23.0)	\$ (24.9)	\$ (66.7)
Net interest expense	\$ 107.8	\$ 103.8	\$ 70.7

(1)Includes a consent and early tender fee of \$6.4 million in 2004 (2003: \$Nil; 2002: \$Nil)  
Covenants

The agreements governing some of our outstanding convertible and long-term 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 ratios, however, they 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 and may result in a default under our other indebtedness subject to cross acceleration provisions.

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## 16. Fair Value of Financial Instruments

Fair value is the amount at which a financial instrument could be exchanged in an arm's-length transaction between informed and willing parties, other than in a forced or liquidation sale. Cash and cash equivalents and marketable securities are held at fair value on the Consolidated Balance Sheets.

### Debt Instruments

The fair value of debt instruments was as follows (in millions):

	At December 31, 2004		At December 31, 2003	
	Carrying Value	Fair Value	Carrying Value	Fair Value
EPIL III Notes <sup>(1)</sup>	\$ 39.0	\$ 39.0	\$ 390.0	\$ 390.0
Athena Notes	650.0	679.3	650.0	600.4
6.5% Convertible Notes	460.0	1,754.9	460.0	594.1
7.75% Notes	850.0	909.5	—	—
Floating Rate Notes	300.0	317.3	—	—
Total convertible debt and guaranteed notes	\$ 2,299.0	\$ 3,700.0	\$ 1,500.0	\$ 1,584.5

(1)The fair value of the EPIL III Notes approximates the carrying value as EPIL III repaid the remaining guaranteed notes of \$39.0 million in March 2005. The EPIL III Notes are included within current liabilities in the Consolidated Balance Sheet.

See Note 15 for additional information.

The fair values of the debt instruments has decreased significantly with our voluntary suspension of Tysabri in February 2005 from \$3,700.0 million at December 31, 2004 to \$1,769.0 million at March 31, 2005 primarily due to the decrease in the option value of the 6.5% Convertible Notes.

## Derivative Instruments

The fair value of derivative instruments were as follows (in millions):

	At December 31, 2004		At December 31, 2003	
	Contract Amount	Fair Value	Contract Amount	Fair Value
Forward contracts:				
United States Dollar forward contracts	\$ 9.4	\$ (0.4)	\$ —	\$ —
Euro forward contracts	9.0	1.2	—	—
Swap contracts:				
Interest rate swap—January 2002	\$ 100.0	\$ 3.6	\$ 100.0	\$ 8.5
Interest rate swap—November 2004	200.0	(0.9)	—	—

## Forward contracts

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 United States Dollar forward contracts require us to sell Japanese Yen for United States Dollars on various dates through December 2005. The Euro forward contracts require us to sell United States Dollars for Euro on various dates through December 2005.

## Swaps

On January 14, 2002, we entered into an interest rate swap to convert our 7.25% fixed rate interest obligations on \$100.0 million of the Athena Notes to variable rate interest obligations. On November 22, 2004, we entered into an interest rate swap to convert an additional \$200.0 million of this debt to variable rate interest obligations. These swaps qualify as fair value hedges.

## 17. Deferred Revenue

Deferred revenue consists of a current portion of \$55.8 million and a non-current portion of \$54.6 million (2003: \$61.5 million, \$93.3 million, respectively). The principal component of total deferred revenue is the remaining unamortized

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revenue related to the licensing of rights to our generic form of Adalat CC with Watson Pharmaceutical, Inc. ("Watson") and the restructuring of our Avinza (morphine sulfate extended-release) license agreement with Ligand Pharmaceuticals, Inc. ("Ligand"). The generic Adalat CC transaction was completed in 2002. We received \$45.0 million in cash from Watson. The Avinza transaction was also completed in 2002. We received a cash payment of \$100.0 million from Ligand, in return for a reduction in the on-going royalty rate from the previous level of 30% of net sales of Avinza in the United States and Canada to approximately 10%. The remaining unamortized revenue on these products of \$69.2 million will be recognized as revenue through June 2007 (generic Adalat CC, \$22.5 million) and November 2006 (Avinza, \$46.7 million), reflecting our on-going involvement in the manufacture of these

products.

#### 18. Provision for Income Taxes

The following table sets forth the details of income taxes for the years ended December 31 (in millions):

	2004		2003		2002
Irish corporation tax—current	\$ 1.8	\$	9.7	\$	2.3
Foreign taxes—current	(2.3)		(32.5)		5.7
Income tax expense/(benefit) on continuing operations	\$ (0.5)	\$	(22.8)	\$	8.0
Tax expense/(benefit) on discontinued operations	\$ —	\$	0.8	\$	11.8
Tax expense/(benefit) reported in shareholders' equity related to:					
Exercise of stock options	\$ (2.7)	\$	—	\$	—

Current tax, including Irish corporation tax and foreign taxes, is provided on our taxable profits, using the tax rates and laws that have been enacted or substantially enacted by the balance sheet date. In each of the three years ended December 31, 2004, 2003 and 2002, substantially all of our income in Ireland was exempt from taxation by virtue of relief granted on income derived from patents or due to tax losses incurred. The total tax benefit of \$0.5 million and \$22.0 million for 2004 and 2003, respectively, reflect 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.

Reflecting the exempt nature of certain Irish income and the availability of tax losses in Ireland and foreign operations, there was no deferred tax expense for the above years.

Irish and overseas taxation have been provided at current rates on the profits earned for the periods covered by the Consolidated Financial Statements.

For the years ended December 31, a reconciliation of the expected tax expense/(benefit) on continuing operations (computed by applying the standard Irish tax rate to (losses)/profits before tax) to the actual tax expense/(benefit) is as follows (in millions):

	2004		2003		2002
Irish standard tax rate	12.5%		12.5%		16.0%
Taxes at the Irish standard rate	\$ (51.8)	\$	(62.2)	\$	(346.0)
Irish income at reduced rates	(10.4)		(6.9)		(18.4)
Foreign income at rates other than the Irish standard rate	(44.3)		(82.5)		(9.4)
Losses creating no tax benefit	105.8		127.3		378.2
Share of investments accounted for under the equity method (including elimination of revenue)	0.2		1.5		3.4
Other	—		—		0.2
Income tax expense/(benefit)	\$ (0.5)	\$	(22.8)	\$	8.0

For the years ended December 31, the distribution of income/(loss) from continuing operations before provision for income taxes by geographical area was as follows (in millions):

	2004	2003	2002
Loss from continuing operations before provision for income taxes:			
Ireland	\$ (126.9)	\$ (307.5)	\$ (925.0)
Foreign	(287.3)	(189.9)	(1,236.6)
Loss from continuing operations before provision for income taxes	\$ (414.2)	\$ (497.4)	\$ (2,161.6)

#### Deferred Taxation

The deferred taxation provision under U.S. GAAP is calculated in accordance with the requirements of SFAS No. 109, "Accounting for Income Taxes," ("SFAS No. 109").

The full potential amounts of deferred taxation and amounts accounted for in our balance sheet comprised the following deferred tax assets and liabilities at December 31 (in millions):

	2004	2003
Deferred taxation liabilities:		
Property, plant and equipment	\$ (88.0)	\$ (45.8)
Intangible asset on acquisition	(4.1)	(52.6)
Deferred interest	—	(2.9)
Total deferred taxation liabilities	\$ (92.1)	\$ (101.3)
Deferred taxation assets		
Net operating losses	\$ 354.8	\$ 232.3
Deferred interest	139.8	92.2
Capitalized items	87.8	128.6
Tax credits	77.1	83.9
Reserves/provisions	21.0	70.3
Fixed assets	0.7	—
Other	1.8	2.6
Total deferred taxation assets	\$ 683.0	\$ 609.9
Valuation allowance	\$ 590.9	\$ 508.6
Deferred tax asset/(liability)	\$ —	\$ —

We apply SFAS No. 109, which requires the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled and when net operating losses are expected to be utilized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance has

been established in respect of those deferred tax assets to the extent it is deemed more likely than not that the asset will not be realized in the future.

The valuation allowance recorded against the deferred tax assets as of December 31, 2004 was \$590.9 million. The net change in the valuation allowance for 2004 was an increase of \$82.3 million (2003: increase of \$77.0 million; 2002: increase of \$29.6 million).

We expect approximately \$137.1 million of the valuation allowance at December 31, 2004 to be applied directly to contributed capital under U.S. GAAP when deferred tax assets associated with certain stock option exercises are recognized. We have adjusted our net operating losses to reflect the amounts expected to be recognized on a probable basis. In 2004, we have credited \$2.7 million to shareholders' equity to reflect recognition of United States state tax and U.K. corporation tax benefits from the utilization of stock option deductions.

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At December 31, 2004 certain U.S. subsidiaries had net operating loss carryovers for federal income tax purposes of approximately \$503.9 million and for state income tax purposes of approximately \$219.8 million. The federal net operating losses will expire from 2009 to 2024. The state net operating losses expire from 2005 to 2023, with \$142.0 million of the state net operating losses expiring in 2013 to 2014 to the extent they are not utilized. In addition, at December 31, 2004, certain U.S. subsidiaries had federal research and orphan drug credit carryovers of \$58.0 million, which will expire from 2007 through 2022 and state credit carryovers of \$29.5 million, mostly research credits, of which \$29.3 million can be carried to subsequent tax years indefinitely, and \$0.2 million will expire from 2010 to 2011 to the extent they are not utilized. We may have had "changes in ownership" as described in the U.S. Internal Revenue Code Section 382. Consequently, utilization of federal and state net operating losses and credits may be subject to certain annual limitations.

At December 31, 2004 certain of our non-U.S. subsidiaries had net operating loss carryovers for income tax purposes of \$1,303.1 million. Approximately \$1,269.4 million of these losses arose in Ireland and can be carried forward indefinitely but are limited to the same trade/trades. The remaining loss carryovers have arisen in the U.K. and The Netherlands. These remaining loss carryovers can be carried forward indefinitely, subject to local rules.

No taxes have been provided for the unremitted and untaxed earnings of our overseas subsidiaries as these are considered permanently employed in the business of these companies. Cumulative unremitted earnings of overseas subsidiaries and related undertakings totaled approximately \$1,237.4 million at December 31, 2004. Unremitted earnings may be liable to overseas taxes or Irish taxation if they were to be distributed as dividends. It is impracticable to determine at this time the potential amount of additional tax due upon remittance of earnings.

#### 19. Leases

We lease certain of our facilities under noncancelable operating lease agreements that expire at various dates through 2016. The major components of our operating leases are as described below.

In August 1998, we entered into an agreement for the lease of four buildings located in South San Francisco, California. These buildings are utilized for R&D, administration and other corporate functions. The initial lease period expires in December 2012 with an option to renew for two additional five-year periods.

In May 2001, we entered into a lease agreement for our R&D facility located in King of Prussia, Pennsylvania. This lease agreement expires in April 2006 with an option to renew for an additional five-year period.

In January 2004, we entered into a lease agreement for our R&D, sales and administrative facility at Lusk Campus, San Diego, California. This lease expires in January 2007 with an option to renew for an additional five-year period.

In September 2004, we entered into a lease agreement for our new corporate headquarters located in the Treasury Building, Dublin, Ireland. This lease expires in July 2014, with an option to renew for two additional ten-year periods.

We recorded rental expense under operating leases of \$19.0 million in 2004 (2003: \$18.7 million; 2002: \$23.5 million), net of sublease income of \$0.8 million in 2004 (2003: \$0.5 million; 2002: \$0.1 million). As of December 31, 2004, our future minimum rental commitments for operating leases with non-cancelable terms in excess of one year are as follows (in millions):

Due in:		
2005	\$	18.4
2006		18.1
2007		12.7
2008		14.6
2009		19.5
Later years		66.8
Total	\$	150.1

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As of December 31, 2004, we had obligations under capital leases as follows (in millions):

2005	\$	6.9
2006		6.6
2007		3.1
2008 and thereafter		—
Total gross payments	\$	16.6
Less: finance charges included above	\$	(1.0)
Total net capital lease obligations	\$	15.6

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 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).

## 20. Restructuring and Other Charges, Net



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 litigation and the SEC investigation (see also Note 13).

Restructuring and other charges for the years ended December 31 consisted of (in millions):

	2004		2003		2002
(A) Shareholder litigation and SEC investigation	\$ 56.0	\$	10.7	\$	22.6
(B) Severance, relocation and exit costs	3.0		29.7		77.8
(C) Purchase of royalty rights	—		297.6		121.0
(D) EPIL II/III waiver fee	—		16.8		—
(E) Asset impairments	—		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	0.8		17.4		19.4
Total restructuring and other charges, net	\$ 59.8	\$	403.2	\$	500.7

(A) Shareholder litigation and SEC investigation

During 2004, we recorded \$56.0 million (2003: \$10.7 million; 2002: \$22.6 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 (\$15.0 million) and the related shareholder class action lawsuit (\$40.0 million).

We and certain of our former and current officers and directors were named as defendants in a putative class action filed in early 2002 alleging that our Consolidated Financial Statements were not prepared in accordance with generally accepted accounting principles, 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 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 settlement is subject to final court approval.

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We were also the subject of an investigation by the SEC's Division of Enforcement. 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 settlement, 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 and 2002 relates to legal expenses incurred on the SEC investigation and shareholder class action lawsuit.

For additional information on pending litigation, 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; 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 employee numbers.

(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/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 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 2004, we recorded \$Nil (2003: \$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. 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 forecasted profitability of these assets.

	2003	2002
	(in millions)	
Quadrant	\$ —	\$ 59.5
Delsys	—	45.7
Naprelan	—	34.2
Marketing technology	—	20.8
Other	32.6	105.9
Total asset impairments	\$ 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 of \$59.5 million, as under the recovery plan we decided to dispose of or close the Quadrant business. We sold this business to a company managed by former employees of the business in July 2003 for one pound Sterling.

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In September 2001, we acquired Delsys, for \$50.0 million. Delsys was formed in 1995 and was 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 \$34.2 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 no longer used.

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

#### (F) Gain on repurchase of LYONs

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 net gain of \$1.6 million after 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 net 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., Allergan, Inc. and Allergan Sales, LLC and shareholder derivative actions.

#### (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 401(k) plan between 1998 and 2001. The sale of these ADSs to the participants in the 401(k) plan should have been 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.

## 21. Discontinued Operations, Sales of Businesses, and Held for Sale Assets and Liabilities

## Discontinued Operations

A discontinued operation is a component of an entity whose operations and cash flows have been or will be eliminated from the ongoing operations of the entity, and with respect to which, the entity will not have any significant continuing involvement in the operations of the component after its disposal.

We have recorded the results and gains or losses on the divestment of our discontinued operations including Frova (frovatriptan succinate), Myobloc (botulinum toxin type B), the Pain Portfolio, Actiq (oral transmucosal fentanyl citrate), Abelcet (amphotericin B lipid complex) U.S./Canada, the dermatology portfolio of products, Athena Diagnostics, Elan Diagnostics, drug delivery businesses, Myambutol (ethambutol hydrochloride) and various other smaller operations within discontinued operations in the income statement, because we do not have a significant continuing involvement in the operations of these components.

For the years ended December 31, 2004, 2003 and 2002, the effect on the results of discontinued operations is set out below (in millions):

2004

	Revenue	Cost of sales	Selling, general and administrative expenses	Research and development expenses	(Gain)/loss on disposal of businesses	Other charges	Net interest and investment (gains)/losses	Provision for income taxes	Income/(loss) from discontinued operations
(A) Frova	\$ 15.0	\$ 11.4	\$ 2.7	\$ —	\$ (7.9)	\$ —	\$ —	\$ —	\$ 8.8
(B) Myobloc	7.6	1.4	1.4	3.4	(3.9)	—	—	—	5.3
Others	6.1	0.5	0.4	(0.1)	0.3	—	0.1	—	4.9
Total	\$ 28.7	\$ 13.3	\$ 4.5	\$ 3.3	\$ (11.5)	\$ —	\$ 0.1	\$ —	\$ 19.0

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2003

	Revenue	Cost of sales	Selling, general and administrative expenses	Research and development expenses	(Gain)/loss on disposal of businesses	Other charges	Net interest and investment (gains)/losses	Provision for income taxes	Income/(loss) from discontinued operations
(A) Frova	\$ 38.5	\$ 36.5	\$ 9.7	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (7.7)
(B) Myobloc	15.0	6.3	5.3	11.6	—	43.6	—	—	(51.8)
(C) Pain Portfolio	68.0	17.0	25.9	0.3	(36.7)	—	4.2	—	57.3

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(D) Actiq	10.5	—	—	—	—	—	—	—	—	10.5
Others	43.2	33.9	9.6	11.6	13.8	14.8	(1.5)	0.8		(39.8)
Total	\$ 175.2	\$ 93.7	\$ 50.5	\$ 23.5	\$ (22.9)	\$ 58.4	\$ 2.7	\$ 0.8		\$ (31.5)

2002

	Revenue	Cost of sales	Selling, general and administrative expenses	Research and development expenses	(Gain)/loss on disposal of businesses	Other charges	Net interest and investment (gains)/losses	Provision for income taxes	Income/(loss) from discontinued operations
(A) Frova	\$ 12.4	\$ 18.2	\$ 8.9	\$ —	\$ —	\$ 24.4	\$ —	\$ —	\$ (39.1)
(B) Myobloc	19.7	6.5	18.6	14.4	—	77.8	—	—	(97.6)
(C) Pain Portfolio	59.8	19.4	18.0	0.2	—	86.3	4.6	—	(68.7)
(D) Actiq	31.8	1.8	5.0	—	—	—	—	—	25.0
(E) Abelcet	77.4	27.1	32.7	—	(112.6)	1.8	—	—	128.4
(F) Dermatology	47.5	14.6	48.7	0.5	—	41.1	—	—	(57.4)
(G) Diagnostics	70.6	29.4	22.6	3.4	(65.3)	12.9	0.4	11.3	55.9
(H) Drug delivery	14.5	18.0	4.0	14.3	—	(4.1)	0.9	—	(18.6)
(I) Myambutol	1.3	0.7	2.5	—	—	78.0	—	—	(79.9)
Others	27.0	19.1	7.6	10.5	—	26.0	—	0.4	(36.6)
Total	\$ 362.0	\$ 154.8	\$ 168.6	\$ 43.3	\$ (177.9)	\$ 344.2	\$ 5.9	\$ 11.7	\$ (188.6)

(A) Frova

We licensed exclusive North American sales and distribution rights for Frova in October 1998 from Vernalis plc ("Vernalis"). Frova is a 5HT<sub>1B/1D</sub> agonist used as an anti-migraine therapy. In November 2001, the Food and Drug Administration ("FDA") approved Frova for the acute treatment of migraine. In 2002, the intangible assets related to Frova were written-down by \$24.4 million to reflect reduced projected revenue and profitability from this product. In 2004, we terminated the development and license agreements with Vernalis regarding Frova and Vernalis purchased our commercialization rights in North America for Frova resulting in a net gain of \$7.9 million.

(B) Myobloc

We developed Myobloc (Neurobloc in Europe). It is a sterile liquid formulation of a purified neurotoxin that acts at the neuromuscular junction to produce flaccid paralysis. Myobloc was approved by the FDA for the treatment of patients with cervical dystonia to reduce the severity of abnormal head position and neck pain. Myobloc was launched in the United States in December 2000 and Neurobloc was launched in the European Union in March 2001. The carrying value of Myobloc was written down by \$77.8 million in 2002 due to lower than expected revenue from this product for 2002 and changed expectations for this product. A further impairment charge of \$43.6 million was recorded in 2003. The product was sold to Solstice NeuroSciences LLC in July 2004 resulting in a gain of \$3.9 million.

(C) Pain Portfolio

We acquired the Pain Portfolio from Roxane Laboratories ("Roxane") in September 2001. These products included the rights to Roxicodone (oxycodone hydrochloride) tablets and oral solution, Oramorph SR (morphine sulfate sustained-release) tablets, Roxanol (morphine sulfate) and Duraclon (clonidine hydrochloride). The intangible assets related to the Pain Portfolio were written down by \$86.3 million during 2002 due to supply difficulties since its acquisition, leading to diminished selling support, as well as changed commercial expectations related to generic competition. The Pain Portfolio was sold to aaiPharma Inc. ("aaiPharma") in December 2003. The total consideration was \$101.8 million, comprising a cash payment of \$50.4 million and the assumption, by aaiPharma, of \$51.4 million of our product payment obligations to Roxane resulting in a gain of \$36.7 million.

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#### (D) Actiq

In October 2002, we sold our rights to Actiq in twelve territories, principally in Europe, to Anesta Corp. ("Anesta"), a subsidiary of Cephalon Inc. At the date of disposal, Actiq was marketed by Elan in the United Kingdom, Ireland and Germany. We received \$47.8 million in cash from Anesta. Included within 2003 discontinued operations' product revenue for Actiq is \$10.5 million (2002: \$31.8 million) related to the sale of this product.

#### (E) Abelcet

We acquired Abelcet with The Liposome Company, Inc. ("Liposome") in May 2000. Abelcet, which is an amphotericin B lipid complex, is used for the treatment of systemic fungal infections. These infections mainly occur in immuno-compromised patients such as those undergoing cancer chemotherapy. In November 2002, we sold our U.S., Canadian and Japanese rights to Abelcet, and certain related assets, to Enzon Pharmaceuticals ("Enzon"). We received a net cash payment of \$360.0 million from Enzon, representing the total consideration, after agreed price adjustments. The gain amounted to \$112.6 million. In February 2004, we sold our remaining marketing rights to Abelcet to Zeneus Pharma Ltd. ("Zeneus") (formerly Medeus Pharma Ltd.) as part of the sale of our European sales and marketing business.

#### (F) Dermatology

In June 2002, we elected not to exercise our purchase option to acquire certain dermatology products from GlaxoSmithKline, plc ("GSK"). This resulted in rights to all products reverting to GSK at the end of 2002. As a result of this decision, we wrote-down the related assets by \$41.1 million.

#### (G) Diagnostics

We recorded an impairment charge of \$12.9 million in 2002 related to Elan Diagnostics, Inc. ("Elan Diagnostics") due to changed expectations for this business. In December 2002, we together with the other stockholders of our subsidiary, Athena Diagnostics, Inc. ("Athena Diagnostics"), completed the sale of all of the outstanding stock of Athena Diagnostics to Behrman Capital and certain of its affiliated investment funds for \$81.8 million and a net gain of \$65.3 million. In April 2003, we completed the sale of the assets of Elan Diagnostics to Novitron International, Inc. and recorded a gain of \$0.3 million on disposal (included in "others" for 2003).

#### (H) Drug delivery

During the course of the recovery plan, we sold or closed a number of drug delivery businesses, including the sale of a transdermal technology business, and the closure of our medipad business and our research facility in Princeton. We recorded impairment charges \$4.1 million and \$11.3 million in 2002 and 2003, respectively, related to these businesses and gains on sales in 2003 of \$5.3 million.

#### (I) Myambutol

The intangible assets related to Myambutol were written down by \$78.0 million during 2002 due to the impact of generic competition on this product and reduced project revenue and profitability. Myambutol was sold to Stat-Trade, Inc. in April 2004, resulting in a loss of \$0.6 million on the sale (included in "others" for 2004 and 2003).

#### Sale of Businesses — Continuing Operations

During the course of the recovery plan and subsequent realignment of our operation as a biotech company, we sold a number of businesses (principally Zonegran, the primary care franchise and the European sales and marketing business), which are not included in discontinued operations because we have a significant continuing involvement in the operations of these businesses, for example, through ongoing supply arrangements or formulation activities.

For the years ended December 31, 2004 and 2003, details of the disposal of businesses are given below (in millions):

	Net Gain/(Loss) 2004	Net Gain/(Loss) 2003
Zonegran	\$ 42.9	\$ —
European business	(2.9)	—
Primary care franchise (Skelaxin™ metaxalone and Sonata™ zaleplon)	—	264.4
Other	4.2	3.4
Total gain on sale of businesses	\$ 44.2	\$ 267.8

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2004

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 Pharmaceutical Co., Ltd. related to the assignment of the Zonegran license agreements. The gain amounted to \$42.9 million. With respect to Zonegran, we may 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 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 European Union 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.

2003

In 2003, a net gain of \$264.4 million was recognized on the divestment of the primary care franchise to King Pharmaceuticals, Inc. ("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.

We did not dispose of any businesses in 2002.

#### Asset and Liabilities Held for Sale

In accordance with SFAS No. 144 and as a part of our recovery plan, at December 31, 2003, we recorded as held for sale the assets and liabilities related to our former European sales and marketing business, a San Diego office property and Elan Pharma S.A., a manufacturing and R&D business based in Switzerland. Each of these divestments were completed during the first quarter of 2004.

## 22. Share Capital

Share capital at December 31, 2004 and 2003 was:

Authorized Share Capital	No. of Ordinary Shares
Ordinary Shares (par value 5 Euro cent)	600,000,000
Executive Shares (par value 1.25 Euro)(the "Executive Shares")	1,000
"B" Executive Shares (par value 5 Euro cent)(the "B" Executive Shares")	25,000

	At December 31, 2004		At December 31, 2003	
	Number	\$000s	Number	\$000s
Issued and Fully Paid Share Capital				
Ordinary Shares	395,072,974	22,574	386,182,274	22,015
Executive Shares	1,000	2	1,000	2
"B" Executive Shares	21,375	2	21,375	2

In November 2003, we successfully completed a private offering of 35.0 million Ordinary Shares at a price of \$4.95 per share.

The Executive Shares do not confer on the holders thereof the right to receive notice of, attend or vote at any of our meetings, or the right to be paid a dividend out of our profits, except for such dividends as the directors may from time to time determine.



The "B" Executive Shares confer on the holders thereof the same voting rights as the holders of Ordinary Shares. The "B" Executive Shares do not confer on the holders thereof the right to be paid a dividend out of our profits except for such dividends as the directors may from time to time determine.

Shares issuable at December 31, 2004 of \$0.7 million relate to shares of Athena Neurosciences, Inc., ("Athena Neurosciences"), Sano Corporation ("Sano"), Neurex Corporation ("Neurex"), Liposome and Dura Pharmaceuticals, Inc. ("Dura") common stock remaining to be converted into Ordinary Shares pursuant to the acquisition of these companies.

In October 1998, we completed the acquisition of all of the assets and liabilities of NanoSystems LLC ("Nanosystems"). As part of the acquisition, we issued warrants with an estimated value of \$16.4 million, to acquire 1.5 million Ordinary Shares at an exercise price of \$45 per share. The warrants are included in shares issuable at December 31, 2004 and are exercisable until October 2006.

At the Annual General Meeting in May 1999, we were authorized to make market purchases of up to 15% of the issued share capital on that date. During the remainder of the year ended December 31, 1999, we purchased 621,500 Ordinary Shares of Elan at a cost of \$17.4 million and these are currently held in treasury stock. In 2000, we terminated our share purchase program.

### 23. Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income, net of \$Nil taxes, were as follows (in millions):

	2004		2003	
Net unrealized gains on available-for-sale securities	\$	20.9	\$	110.5
Currency translation adjustments		(12.8)		(12.0)
Accumulated other comprehensive income	\$	8.1	\$	98.5

### 24. Pension and Other Employee Benefit Plans

#### Pension

The pension costs of the major Irish retirement plans have been presented in the following tables in accordance with the requirements of SFAS No. 132 Employees' Disclosures about Pensions and Other Postretirement Benefits." We fund the pensions of certain employees through defined benefit plans. Two plans are operated for employees based in Ireland. In general, on retirement, eligible employees are entitled to a pension calculated at 1/60th of their final salary for each year of service, subject to a maximum of 40 years. These plans are managed externally and the related pension costs and liabilities are assessed in accordance with the advice of a professionally qualified actuary. The investments of the plans at December 31, 2004 consisted of units held in independently administered funds. The change in benefit obligation was (in millions):

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		2004		2003
Benefit obligation at January 1	\$	37.6	\$	27.4
Service cost		2.4		2.1
Interest cost		1.9		1.6
Plan participants' contributions		1.3		1.4
Actuarial gain/(loss)		2.6		(0.6)
Benefits paid		(0.2)		(0.3)
Foreign currency exchange rate changes		3.7		6.0
Benefit obligation at December 31	\$	49.3	\$	37.6

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The changes in plan assets at December 31 were (in millions):

		2004		2003
Fair value of plan assets at beginning of year	\$	34.5	\$	21.0
Actual return on plan assets		3.2		3.3
Employer contribution		2.6		3.9
Plan participants' contributions		1.3		1.4
Benefits paid		(0.2)		(0.3)
Foreign currency exchange rate changes		3.3		5.2
Fair value of plan assets at end of year	\$	44.7	\$	34.5
Funded status	\$	(4.7)	\$	(3.1)
Unrecognized net actuarial gain		15.6		13.1
Unamortized prior service cost		1.1		1.1
Prepaid benefit cost	\$	12.0	\$	11.1

The net periodic pension cost was comprised of the following (in millions):

		2004		2003		2002
Service cost	\$	2.4	\$	2.1	\$	1.8
Interest cost		1.9		1.6		1.2
Expected return on plan assets		(2.4)		(2.1)		(1.9)
Amortization of net loss		0.5		0.6		0.3
Amortization of prior service cost		0.1		0.1		0.1
Net periodic pension cost	\$	2.5	\$	2.3	\$	1.5

Weighted average assumptions used to determine net periodic pension cost and benefit obligation at December 31 were:

2004

2003

Discount rate	4.5%	5.2%
Expected return on plan assets	6.4%	6.9%
Rate of compensation increase	3.8%	4.0%

The expected long-term rate of return on assets of 6.4% was calculated based on the assumptions of the following returns for each asset class: Equities 7.25%; Property 6.25%; Government Bonds 4.25%; and Cash 2.0%.

The fixed interest yield at December 31, 2004 was 4.25%; hence the assumed return on bonds is 4.25%. Returns for the other asset classes are set by reference to the fixed interest yield plus a risk premium. For equities the risk premium is 3% and for property the premium is 2%.

The weighted average asset allocations at December 31 by asset category were:

	2004	2003
Equity	73.5%	74.5%
Bonds	14.6%	16.8%
Property	5.5%	6.9%
Cash / other	6.4%	1.8%
Total	100.0%	100.0%

Our pension plan assets are invested in two managed unit trusts. Our key objective is to achieve long-term capital growth by investing primarily in a range of Eurozone and international equities, bonds, property and cash.

The investment mix is biased towards equities, with a diversified domestic and international portfolio of shares listed and traded on recognized Exchanges.

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The long-term asset allocation ranges of the trusts are as follows:

Equities	60% – 80%
Bonds	10% – 40%
Property	0% – 10%
Cash	0% – 10%

The accumulated benefit obligation for all defined benefit pension plans was \$42.0 million at December 31, 2004 (2003: \$31.3 million).

At December 31, 2004, the expected future cash benefits per year to be paid in respect of the plans for the period of 2005-2009 are collectively less than \$1.0 million. The expected cash benefits to be paid in the period of 2010-2014 is approximately \$1.1 million.

The expected benefits to be paid are based on the same assumptions used to measure our benefit obligation at December 31, 2004 and include the estimated future employee service.

We contributed \$2.6 million to our pension plan in 2004. We recognized a \$9.8 million charge to Other Comprehensive Income in 2002 in respect of the shortfall between the unfunded accumulated benefit obligation less the unrecognized prior service cost and the prepaid benefit cost. This was reversed in 2003 as the shortfall no longer existed at December 31, 2003. There was no shortfall in the plans at December 31, 2004. We expect to contribute \$2.1 million to our pension plan in 2005.

In addition, we operate a number of defined contribution pension plans, primarily for employees outside of Ireland. The costs of these plans are charged to the income statement in the period they are incurred. The pension cost for these plans was \$10.3 million, \$9.2 million and \$8.8 million for 2004, 2003 and 2002, respectively.

#### Stock Options and Warrants

Stock options have been granted to directors, employees, consultants and certain other parties. Options are granted at the price equal to the market value at the date of grant and will expire on a date not later than ten years after their grant. Options generally vest between one and five years from the date of grant.

The following table summarizes the number of options outstanding and available to grant as of December 31:

	Outstanding		Available to Grant	
	2004	2003	2004	2003
1986/1989 Plans	—	44,400	—	—
1996 Plan	8,784,892	9,290,558	3,256,142	4,342,004
1998 Plan	4,246,395	4,841,957	—	—
1999 Plan	27,012,432	33,758,641	2,671,459	2,802,142
Segix Plan	319,670	376,501	—	—
Consultant Plan	425,000	425,000	—	—
Total	40,788,389	48,737,057	5,927,601	7,144,146

We also have granted options and warrants for acquisitions, a developing and license agreement and a service agreement. As a result of the acquisition of Athena Neurosciences on July 1, 1996, options and warrants granted by Athena Neurosciences prior to the acquisition date vested and were converted into options and warrants to acquire 6,346,424 Ordinary Shares. As a result of the acquisition of Neurex on August 14, 1998, options and warrants granted by Neurex were converted into a total of 3,011,702 options to acquire Ordinary Shares. As a result of the acquisition of Liposome on May 12, 2000, options and warrants granted by Liposome were converted into a total of 1,875,260 options to acquire Ordinary Shares. As a result of the acquisition of Dura on November 9, 2000, options and warrants granted by Dura vested and were converted into options and warrants to acquire 5,513,457 Ordinary Shares. The following table summarizes the number of acquisition related options outstanding as of December 31:

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	2004	2003
Athena Neurosciences	120,996	206,276

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Neurex	66,370	99,872
Liposome	125,147	149,971
Dura	63,171	107,213
Total	375,684	563,332

Arising from the acquisition by us of all the assets and liabilities of NanoSystems, we granted 750,000 warrants to purchase 1,500,000 Ordinary Shares. These warrants are exercisable at \$45.00 per share from February 1, 1999 to October 1, 2006 and were unexercised as of December 31, 2004 and 2003.

The stock options and warrants outstanding and exercisable are summarized as follows:

	Options		Warrants	
	Shares	WAEP*	Shares	WAEP*
Outstanding at December 31, 2001	40,913,911	\$ 34.06	6,121,622	\$ 39.89
Exercised	(544,124)	17.59	(7,432)	28.01
Granted	21,905,272	5.46	—	—
Expired	(9,253,816)	34.89	(1,045,246)	46.05
Outstanding at December 31, 2002	53,021,243	22.28	5,068,944	38.64
Exercised	(764,944)	2.39	—	—
Granted	5,956,098	4.47	—	—
Expired	(8,912,008)	24.54	(2,494,498)	32.51
Outstanding at December 31, 2003	49,300,389	20.03	2,574,446	39.20
Exercised	(8,879,018)	7.83	(12)	26.72
Granted	5,767,595	19.70	—	—
Expired	(5,024,893)	31.34	—	—
Outstanding at December 31, 2004	41,164,073	21.24	2,574,434	39.20
Exercisable at December 31, 2004	31,335,573	\$ 23.44	2,574,434	\$ 39.20

\*Weighted average exercise price

At December 31, 2004, the range of exercise prices and weighted average remaining contractual life of outstanding and exercisable options were as follows:

Number Outstanding	WAEP	Range	Weighted Average Remaining Contractual Life (years)	Number Exercisable	WAEP
13,588,154	\$ 2.96	\$ 1.93–\$10.00	7.9	9,519,637	\$ 2.69
10,747,844	\$ 17.06	\$ 10.01–\$25.00	6.6	6,596,362	\$ 16.59
11,016,661	\$ 31.53	\$ 25.01–\$40.00	4.8	9,764,661	\$ 32.25
5,811,414	\$ 52.20	\$ 40.01–\$58.60	6.2	5,454,913	\$ 52.18
41,164,073	\$ 21.24	\$ 1.93–\$58.60	6.5	31,335,573	\$ 23.44

Employee Equity Purchase Plans

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

employees based in the 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 IRC restrictions.

The board of directors approved the Irish Sharesave Option Scheme 2004 and U.K. Sharesave Option Plan 2004, effective January 1, 2005, for employees based in Ireland and the United Kingdom, respectively ("the Irish/U.K.

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Sharesave Plans"). In total, 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 Euro per month under the Irish Scheme or 250 pounds Sterling under the U.K. Plan and they may purchase shares anytime within six months after the end of the offering period.

As of December 31, 2004, 1,500,000 shares were reserved for future issuance under the U.S. Purchase Plan and Irish/U.K. Sharesave Plans.

#### Employee Savings and Retirement Plan 401(K)

We maintain a 401(k) retirement savings plan for our employees based in the United States. Participants in the 401(k) plan may contribute up to 20% of their annual compensation, limited by the maximum amount allowed by the Internal Revenue Code. We match 3% of each participating employee's annual compensation on a quarterly basis and may contribute discretionary matching up to another 3% of the employee's annual compensation on an annual basis. Our matching contributions are vested immediately. For the year ended December 31, 2004, we recorded \$5.1 million (2003: \$7.5 million; 2002: \$6.2 million), of expense in connection with the matching contributions under the 401(k) plan.

#### 25. Commitments and Contingencies

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

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 \$64.4 million at December 31, 2004 (2003: \$63.8 million).

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.

## 26. Litigation

We are involved in various legal and administrative proceedings, relating to securities matters, patent matters, antitrust matters and other matters. The most significant of these matters are described below.

As of December 31, 2004, we had accrued \$63.4 million for the resolution of legal matters, including \$55.0 million relating to the securities matters and SEC investigation described below. 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. With the exception of such securities matters/SEC investigation and the BioPort Corporation ("BioPort") litigation, we do not believe that it is feasible to predict or determine the outcomes of the pending actions, investigations and proceedings and any possible effect on our business or to reasonably estimate the amounts of minimum losses or potential range of losses, if any, with respect to the pending actions, investigations and proceedings.

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The costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings, settlements, judgments and claims, and changes in those matters (including the matters described below) and developments or assertions by or against us relating to intellectual property, could have a material adverse effect on our business, financial condition, results of operations and liquidity.

### Securities matters

Commencing in January 1999, several class actions were filed in the U.S. District Court for the Southern District of California against Dura, one of our subsidiaries, and various then current or former officers of Dura. The actions, which allege violations of the U.S. federal securities laws, were consolidated and sought damages on behalf of a class of shareholders who purchased Dura common stock during a defined period. In July 2000, the court issued an order granting the defendants' motion to dismiss the complaint without prejudice on the basis that it failed to state an actionable claim. In November 2001, the court granted Dura's motion to dismiss with prejudice and judgment was entered in Dura's favor. In December 2001, plaintiffs filed an appeal of the judgment with the Ninth Circuit Court of Appeals. Oral argument was held on February 4, 2003. On August 5, 2003, the Ninth Circuit issued its opinion, reversing the lower court's prior dismissal. A timely petition for rehearing en banc was filed, but was denied by the Ninth Circuit on September 29, 2003. Thereafter, we petitioned the U.S. Supreme Court for a writ of certiorari. On June 28, 2004, the U.S. Supreme Court granted certiorari. The matter was argued before the U.S. Supreme Court on January 12, 2005 and the parties are currently awaiting a final decision.

We and certain of our former and current officers and directors were named as defendants in a class action filed in early 2002 in the U.S. District Court for the Southern District of New York alleging claims under the U.S. federal securities laws. The complaint alleged, among other things, that our Consolidated Financial Statements were not

prepared in accordance with generally accepted accounting principles, 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 officers; and certain alleged related-party transactions. We settled this 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 which will be paid by our insurance carrier. On February 18, 2005, the court conducted a hearing on approval of the proposed settlement and took the matter under advisement. The parties are currently awaiting a final decision from the court.

We were also the subject of an investigation by the SEC's Division of Enforcement. We provisionally settled the investigation in October 2004. Under the settlement agreement, which received final approval in February 2005, 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.

During 2004, we reserved \$55.0 million, net of insurance coverage, with respect to our estimate of the ultimate cost to settle the shareholder class action and the SEC investigation.

We and some of our officers and directors have been named as defendants in putative class actions filed in the U.S. District Courts for the District of Massachusetts (on March 4 and 14, 2005), the Southern District of New York (on March 14, 2005) and the Superior Court of the State of California, County of San Diego (on March 23, 2005). The class action complaints allege claims under the U.S. federal securities laws and state laws and, in the actions filed in Massachusetts and New York, seek damages on behalf of a class of shareholders who purchased our stock prior to the announcement of the voluntary suspension of Tysabri. The action filed in California as a derivative action, purports to seek damages on our behalf. The complaints allege that we caused the release of materially false or misleading information regarding Tysabri. The complaints allege that class members were damaged when our stock price fell after we and Biogen Idec announced the voluntary suspension of the marketing and dosing of Tysabri in response to reports

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of serious adverse events involving clinical trial patients treated with 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.

In March 2005, we received a letter from the SEC stating that the SEC's Division of Enforcement is conducting an informal inquiry into actions and securities trading relating to us. The SEC's inquiry primarily relates to events surrounding the February 28, 2005 announcement of the decision to voluntarily suspend the marketing and clinical dosing of Tysabri.



Patent matters

In October 1998, we filed a patent infringement action in the U.S. District Court for the Southern District of Florida against Andrx Corporation ("Andrx") alleging that, by its submission of an Abbreviated New Drug Application ("ANDA") for a generic version of Naprelan™ (naproxen sodium controlled-release), which submission included a paragraph IV certification, Andrx infringed our U.S. Patent No. 5,637,320 (the "320 patent"). In March 2002, the court issued a decision finding the 320 patent invalid and dismissed the action. The court did not consider the issue of infringement. We subsequently appealed the decision to the U.S. Court of Appeals for the Federal Circuit ("CAFC"). On May 5, 2004, the CAFC reversed the district court's invalidation of our patent for its Naprelan product. The case has now been remanded to the district court for consideration of the remaining issues. On July 12, 2004, the U.S. District Court in Florida held a status conference in the case, during which the court indicated that it was prepared to issue a final decision in the case. The court asked the parties to file briefs updating the law on all outstanding issues. The additional briefing materials requested by the court have been filed and the parties are awaiting the court's final ruling; no additional hearings are expected at this time. It is currently unclear when the district court's ruling will be issued and we cannot predict with any certainty the likelihood of the ultimate outcome.

Eon Labs, Inc. ("EON") submitted to the FDA an ANDA for a generic equivalent of our 400 mg Skelaxin product. The application included a paragraph IV certification pertaining to U.S. patent No. 6,407,128 (the "128 patent"). Eon provided notice to Elan Pharmaceuticals, Inc. ("EPI") of its paragraph IV certification in November 2002, and we filed a patent infringement suit against Eon in the U.S. District Court for the Eastern District of New York on January 2, 2003. Eon filed its answer and counterclaim on January 23, 2003 and then filed an amended answer and counterclaim on February 19, 2003. We filed our reply to the counterclaim on March 7, 2003. Corepharma LLC ("Corepharma") also has submitted to the FDA an ANDA for a generic equivalent of our 400 mg Skelaxin product, including a paragraph IV certification pertaining to the 128 patent. Corepharma provided notice of its paragraph IV certification in January 2003, and we filed a patent infringement suit against Corepharma in the U.S. District Court for the District of New Jersey on March 7, 2003. In May 2003, we agreed to transfer the Corepharma litigation to the U.S. District Court for the Eastern District of New York for consolidation with the Eon litigation. The rights under the patents at issue in the Eon and Corepharma litigations were subsequently sold and transferred to King. Accordingly, we are cooperating in the prosecution of these matters and are working together to substitute King as a plaintiff to the two actions. Discovery in this matter is still ongoing and no trial date has been set. However, the parties will participate in an April 2005 court-ordered mediation aimed at resolving issues relating to both matters.

On December 17, 2004, King commenced a lawsuit in the U.S. District Court for the Eastern District of New York against Eon alleging patent infringement of the above-referenced 128 patent in connection with Eon's November 2004 amended ANDA submission to the FDA seeking the approval to engage in the manufacture, use or sale of an 800 mg generic equivalent of the Skelaxin product. On January 10, 2005, Eon answered King's complaint and counterclaimed against Elan Pharmaceuticals, Inc. Eon's counterclaims are similar to those asserted in the litigation described in the immediately preceding paragraph. Discovery relating to this matter has not yet commenced. Given the status of the proceedings and the fact that no discovery has taken place, we are unable to predict the likelihood of a successful outcome or any associated damages at this time. However, we believe that Eon's claims are without merit and intend to vigorously defend against the claims.

On November 3, 2004, Classen Immunotherapies, Inc. ("Classen") commenced a lawsuit against King, Elan Corporation, plc and EPI in the U.S. District Court for the District of Maryland alleging patent infringement of U.S. Patent No. 6,219, 674 (the "674 patent") and U.S. Patent No. 6,584,472 (the "472 patent"). Classen asserts, inter alia, that King and the Elan defendants purportedly infringed claims of the 674 and 472 patents in connection with their manufacture, development and distribution of our former Skelaxin product. We have answered Classen's complaint. King has filed a motion to dismiss Classen's claims as well as a motion to transfer the matter to the district court in Tennessee. To date,

no hearing has been set for King's motions and no discovery has taken place. Given the status of the proceedings and the fact that no discovery has taken place, we are unable to predict the likelihood of a successful outcome or any associated damages at this time. However, we believe that the Classen claims are without merit and intend to vigorously defend against the claims.

On June 17, 2004, Duke University ("Duke") and Orexigen Therapeutics, Inc. ("Orexigen") filed a lawsuit against Elan Corporation, plc, Elan Pharmaceuticals, Inc., Eisai Co., Ltd., Eisai, Inc. and Elan employee, Julianne E. Jennings (collectively, "the Elan and Eisai Defendants") involving a provisional patent application (the "Patent Application") filed with the U.S. Patent and Trademark Office that relates to the use of our former zonisamide product and the treatment of obesity. On April 27, 2004, we transferred all of our rights in the zonisamide product and the Patent Application to Eisai, Inc. pursuant to an asset purchase agreement. Duke and Orexigen assert, inter alia, that the Patent Application fails to identify certain Duke employees as inventors or acknowledge Duke's purported rights in the application. We filed a motion to dismiss the claims on August 13, 2004. To date, no hearing has been scheduled on the motion. Given the status of the proceedings and the fact that no discovery has taken place, we are unable to predict the likelihood of a successful outcome or any associated damages at this time. We believe that the Duke and Orexigen claims are without merit and intend to vigorously defend against the claims.

#### Antitrust matters

In March 2001, Andrx filed a complaint in the U.S. District Court for the Southern District of Florida alleging that we engaged in anti-competitive activities in an effort to prevent or delay the entry of a generic alternative to Naprelan. We filed a motion to dismiss the complaint and for judgment on the pleadings. In April 2003, the court granted our motion and dismissed Andrx's complaint with prejudice and without leave to amend. In June 2003, the court reaffirmed its April decision, denying Andrx's motion for reconsideration and for leave to amend its complaint. On July 14, 2003, Andrx filed a notice of appeal. A hearing on the appeal took place on June 29, 2004. The parties are currently awaiting a final decision from the appellate court.

Indirect purchasers of Naprelan have filed three putative class actions in the U.S. District Court for the Eastern District of Pennsylvania against us and Skye Pharma, Inc. In September 2002, the cases were consolidated and in October 2002, a consolidated amended class action complaint was filed. The consolidated complaint alleges that we violated the antitrust laws by engaging in sham patent litigation and entering into an unlawful settlement agreement in an effort to prevent or delay the entry of a generic alternative to Naprelan. The damages claimed are unspecified. We have not yet answered or otherwise responded to the amended complaint. Other than preliminary document production, the litigation has been stayed and the case placed on the court's suspense docket pending the outcome of further proceedings in the pending Andrx patent infringement litigation described above. On August 4, 2003 plaintiffs filed a motion to remove the litigation from the court's suspension docket. However, the court subsequently denied plaintiffs' motion and this matter remains on the court's suspension docket.

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

In 2002 and 2003, ten actions were filed in the U.S. District Courts (seven in the District of Columbia and three in the Southern District of New York) claiming that we (and others) have violated federal and state antitrust laws based on the licensing arrangement with Biovail relating to nifedipine. The complaints seek various forms of remedy, including

damages and injunctive relief. The actions have been brought by putative classes of direct purchasers, individual direct purchasers, and putative classes of indirect purchasers. On May 29, 2003, the Judicial Panel for Multidistrict Litigation coordinated and consolidated for pre-trial proceedings all pending cases in the U.S. District Court for the District of Columbia. Since consolidation of the matters, the Court has held several case management conferences to coordinate the early stages of the case. In accordance with one of the Court's preliminary orders, Plaintiffs filed amended complaints. We and co-defendant Biovail responded by filing an omnibus motion to dismiss in response to the amended complaints. Co-defendant Teva filed a joinder in certain parts of our motion. The Court completed a hearing on the motions May 7, 2004 and took the matter under submission. On September 1, 2004, the Court issued a Memorandum Opinion and Order granting in part and denying in part the motions to dismiss. The Court held that none of the claims for injunctive relief had any basis and, accordingly, the Court lacked jurisdiction over the indirect purchaser federal and state claims.

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Consequently, the Court granted the motion as it related to the putative class of indirect purchasers and dismissed that consolidated class complaint without prejudice. The Court also dismissed the claims for injunctive relief of the purported direct purchaser plaintiffs. The Court declined to dismiss the damage claims of the purported direct purchaser plaintiffs, ruling that it would be premature to do so without allowing discovery given the Court's obligation to accept as true all allegations when tested on a motion to dismiss. The parties in the litigation have begun preliminary discovery. It should be noted that counsel for the putative indirect purchaser class have also commenced an action asserting the same or similar claims under California state law in California state court. Per the California state court's request, the parties have developed a plan to coordinate discovery with the remaining federal cases. We believe that our conduct is lawful, but as these matters are in their early stages, we cannot predict the likelihood of any outcome.

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., Elan Corporation or others may have engaged in an effort to restrain trade by entering into an agreement that 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 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.

#### Other matters

On June 27, 2002, BioPort filed suit against us in the Superior Court of the State of California alleging breach of certain collaboration and supply agreements relating to the development, manufacture and supply of botulinum toxin. In addition to claims for breach of contract, BioPort asserted claims for intentional interference with contractual relations (as to the Company), unfair business practices and unjust enrichment. The complaint seeks a five percent royalty on net sales of Myobloc, payments allegedly owned under the collaboration agreement, a declaration that BioPort has an ownership interest in Myobloc, and other relief, including punitive damages. A trial date for this matter has been scheduled for July 15, 2005. In addition, the parties intend to conduct an April 2005 mediation conference aimed at resolving some or all of the issues before trial. Discovery in this matter is continuing.

On December 11, 2003, two of our subsidiaries, EPI and Neuralab, commenced AAA arbitration proceedings against Pfizer and Pharmacia and Upjohn Company ("Pharmacia") in connection with certain alleged breaches relating to an

Exclusive Mutual Beta Secretase Inhibitors Research, Development and Marketing Collaboration Agreement, dated July 28, 2000, originally between Pharmacia and Neuralab. As a result of these breaches and our subsequent termination of the collaboration agreement, we believe that we hold an exclusive worldwide license of, among other things, all of Pfizer and Pharmacia's interest in regulatory approvals, patents and know-how relating to the subject matter of the parties' collaboration. On December 23, 2003, Pfizer and Pharmacia asked the New York State Supreme Court to stay our arbitration proceedings and the court subsequently issued a stay order on January 14, 2004. We appealed the stay order to the New York Supreme Court Appellate Division. On August 26, 2004, the New York Court Appellate Division reversed the lower court's decision and remanded the matter back to the lower court for further proceedings relating to whether our arbitration proceedings should be stayed.

On September 13, 2004, we commenced an action against Pfizer and Pharmacia in the California Superior Court. The complaint in this action asserts essentially the same breach of contract claim asserted in the AAA arbitration demand and also alleges claims for common-law monopolization, unfair competition and improper disclosure of trade secrets. In conjunction with the filing of their California lawsuit, we withdrew our arbitration demand. On September 23, 2004, Pfizer and Pharmacia commenced a New York state action against us for injunctive relief, declaratory relief and breach of contract. Immediately upon filing this action, Pfizer and Pharmacia asked the New York Supreme Court to stay our prosecution of the above-referenced California lawsuit. The New York state court subsequently issued an order temporarily staying us from taking any action in the above-referenced California lawsuit. In addition, the Court scheduled a February 14, 2005 evidentiary hearing on the applicability of certain dispute resolution provisions contained in the parties' collaboration agreement. The court has advised the parties that, after it conducts this evidentiary hearing, the court intends to lift its temporary stay order and permit us to proceed with our California litigation. The parties are currently engaged in discovery relating to the above-referenced evidentiary hearing. However, the hearing was temporarily taken off calendar to allow the parties to conduct settlement discussions.

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## 27. Related Parties

### Antigenics

At December 31, 2003, we had invested a total of \$14.9 million in Antigenics, a biotechnology company whose chairman, Dr. Garo Armen, is also a director of Elan. At December 31, 2003, our shareholding represented approximately 3% of Antigenics' outstanding share capital. At December 31, 2003, this investment had a carrying value of \$11.0 million and a fair value of \$12.5 million. In February and March 2004, we disposed of all of our 1,098,937 common shares in Antigenics for \$11.4 million.

Following the appointment of Dr. Armen as chairman on July 9, 2002, we signed a memorandum of understanding with Antigenics in respect of costs incurred by either company in respect of work done for the other. The agreement provided that no profit margin should be charged on such costs. In 2004, the amount of such charges from Antigenics was approximately \$0.1 million (2003: \$0.2 million) and the amount of such charges to Antigenics was \$Nil (2003: \$0.2 million).

In addition, on February 28, 2003, a settlement was signed between Antigenics, Neuralab and EPI regarding a dispute relating to a supply agreement entered into on November 23, 1999 between Antigenics, then known as Aquila Biopharmaceuticals, Inc., Neuralab and EPI. Under the terms of the settlement, Elan paid Antigenics \$0.3 million and received an agreed amount of an adjuvant.

## Amarin/Mr. Thomas Lynch

Amarin Corporation plc ("Amarin") is a specialty pharmaceutical company focused on neurodegenerative and pain management. Thomas Lynch, a former employee and executive vice chairman, and John Groom, a director of Elan, serve on Amarin's board of directors. Mr. Lynch is non-executive chairman of Amarin.

## 2001 to 2003

In 2001, we entered into a distribution and option agreement with Amarin, whereby Amarin agreed to market and distribute Permax™ (pergolide mesylate) in the United States, and Amarin was granted an option to acquire rights to the product from us. We subsequently provided a loan of \$45.0 million to Amarin in 2001, the proceeds of which were used by Amarin to exercise its option to acquire Permax from us. Permax is used for the treatment of Parkinson's disease. The terms of the distribution and option agreement and the loan agreement were subsequently amended in 2001 and 2003.

During 2001, we also granted Amarin a purchase option to acquire Zelapar™ (selegiline). Zelapar is a fast melt formulation of selegiline for the treatment of Parkinson's disease.

## 2004

In February 2004, we further amended our contractual arrangements subject to the sale by Amarin of certain of its assets, including its rights to Zelapar and Permax, to Valeant Pharmaceuticals International ("Valeant"). On February 25, 2004, Amarin's sale of assets to Valeant closed and the amendments became effective. The amendments required, in full settlement of all previous liabilities owed by Amarin to us and as a deemed exercise of Amarin's option to acquire Zelapar, the payment by Amarin of \$17.2 million to us, which was paid in February 2004, and the issuance of a \$5.0 million five-year 8% loan note and issued warrants to purchase 500,000 ordinary shares in Amarin to Elan. Under the agreements, we were also entitled to receive a \$1.0 million milestone payment upon the successful completion of certain Zelapar safety studies. The milestone was received in December 2004. We are also entitled to receive from Valeant a revenue contingent milestone on Zelapar of \$10.0 million if annual sales of Zelapar exceed \$20.0 million, and royalties on future net sales by Valeant of 13% for Zelapar and 10% for Permax.

In February 2004, our share ownership in Amarin increased to approximately 28% on a fully diluted basis. Prior to September 30, 2004, we accounted for Amarin using the equity method based on our equity investment in Amarin. Amarin was a related party to us until this date.

On September 30, 2004, we sold all of our remaining investments in Amarin for \$6.5 million to Amarin Investment Holding Ltd., a company controlled by Mr. Thomas Lynch.

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The following table summarizes our investment in Amarin at December 31 (in millions):

	2004		2003
Loans and related interest	\$	—	\$ 18.1
Net equity investment		—	3.0

Total investment	\$	—	\$	21.1
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Net revenue earned from Amarin was \$3.0 million for 2004 (2003: \$0.3 million; 2002: \$4.8 million).

## 28. Development and Marketing Collaboration Agreement with Biogen Idec

In August 2000, we entered into a development and marketing collaboration agreement with Biogen Idec, successor to Biogen, Inc., to collaborate in the development and commercialization of Tysabri. Along with Biogen Idec, we are developing Tysabri for multiple sclerosis ("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 progressive multifocal leukoencephalopathy ("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.

## 29. Business Ventures

From 1996 to mid 2001, we pursued collaborations with biotechnology, drug delivery and pharmaceutical companies in order to leverage our drug delivery technologies and our proprietary neurological and oncology research, and to access complementary or synergistic R&D programs in our areas of expertise. We have historically referred to this program in a number of ways, including as a joint venture program, a business venture program, and a strategic licensing program. For the purposes of these Consolidated Financial Statements, this program will be referred to as the "business venture program". We have not entered into any new business ventures under the business venture program since mid-2001.

In 2002, as part of the recovery plan, we completed 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. The restructuring process and any terms agreed have been the result of negotiations with respective business venture parents. As such, the agreed terms arising from the restructuring process vary between different business venture relationships. Typically, as part of the termination of a business venture, the technologies contributed by the business venture parent and Elan are returned, the technology developed in the business venture is transferred to the business venture parent or Elan,

and we transfer our interest in the business venture to the business venture parent in exchange for a continuing interest in the product or technology previously in the business venture, such as a royalty. There were approximately 55 business ventures in place prior to July 2002. 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.

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As all business ventures have been terminated, restructured or are now inactive, the description of the business venture program below is described in the past tense.

The business venture program generally involved licensing drug delivery technologies and pharmaceutical R&D assets, to a newly formed subsidiary of an emerging biotechnology; drug delivery or pharmaceutical company and the establishment of a joint development collaboration.

The business venture program generally involved licensing drug delivery technologies and know-how, or pharmaceutical R&D assets, to a newly formed subsidiary ("the business venture") of an emerging biotechnology, drug delivery or pharmaceutical company ("the business venture parent") and the establishment of a joint development collaboration.

Contemporaneously with the licensing and collaborative transaction, we typically made an investment in the business venture. Investments in business ventures were in various forms. Prior to mid-1999, those investments were generally in the form of voting common stock. Subsequently, these investments were in the form of non-voting preferred stock convertible into common stock after a period of two years. We typically held an initial fully diluted equity interest of 19.9% in the business venture. We also typically made a contemporaneous investment in the business venture parent in the form of common equity and convertible/exchangeable preferred stock or convertible/exchangeable debt. The convertible/exchangeable securities in the business venture parent were generally convertible, at our option, into common equity of the business venture parent or exchangeable for up to 30.1% of the common equity in the business venture, potentially bringing our fully diluted equity interest in the business venture up to 50%. In many transactions, if we chose to exchange the convertible/exchangeable securities in the business venture parent into common equity of the business venture, then we would be required to pay the business venture parent an amount equal to 30.1% of the cumulative operating funding of the business venture to the date of exchange such that we and the business venture parent would have shared equally (on a cumulative basis) in such funding. We sold certain of our investments in the business ventures and the business venture parents to EPIL II in June 2000 and to EPIL III in March 2001. EPIL II and EPIL III were securitization entities and the investments were held by EPIL II and EPIL III as security for outstanding indebtedness issued by the entities.

The business venture generally conducted R&D activities using its technologies and proprietary know-how in an agreed research field. Our partner, the business venture parent, principally managed the business venture. The technologies and proprietary know-how of the business venture were in-licensed by the business venture from us and the business venture parent. On formation, a number of contracts were entered into to govern the in-licensing of intellectual property assets to the business venture from us and the business venture parent.

Development of products and technologies for pharmaceutical applications involves risk. The nature of pharmaceutical development, with stringent regulatory constraints and guidelines designed to protect the health and safety of patients and those working with the products, means that development activities are costly and time consuming. Our portfolio of business ventures allowed us to diversify the risks associated with product development.

Individual development programs within the business ventures had varying degrees of success and failure. We and the business venture parent would typically work together using commercially reasonable efforts and our combined technical, regulatory and clinical expertise to increase the likelihood of success of the business ventures. This could lead to changes in the direction of a development program, adding or substituting technologies or products and redirection of clinical programs as deemed necessary.

We and the business venture parent continually reviewed the progress of the R&D activities in the business venture. As part of this review, the parties could decide that it was not commercially or technically practical to continue to support the business venture.

The business ventures typically had the following operational structure. The board of directors of a business venture was generally comprised of a majority of directors from the business venture parent and one director nominated by us. For a quorum, the presence of our nominated director was required. The business plan required the approval of the board of directors of the business venture, including our nominated director. This approval was subject to the directors' fiduciary duty to the business venture. The contracts of establishment provided for subsequent reviews, either annually or more frequently, of the business plan and required the continuing approval by our nominated director. The business ventures also typically had a management committee or a R&D committee. These committees generally provided for equal representation by us and the business venture parent. The committees had responsibility for day-to-day activities of the business venture and for the implementation of the business plan. At their inception, the business ventures typically had no funds after payment of the initial fee to us. The operating funding of the business venture was provided by the

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business venture parent and Elan, subject to the approval of both parties. Funding was generally utilized to pay for R&D activities. Funding was typically provided in proportion to the respective fully-diluted ownership of the business venture by the business venture parent and us (typically 80.1% and 19.9%, respectively). We expensed the subsequent funding that we provided directly to the business venture. We expensed \$Nil, \$3.0 million, and \$23.9 million of subsequent business venture funding in 2004, 2003 and 2002, respectively. We also made additional investments in the business venture parent in the form of convertible debt recorded as an investment. We provided additional financing of \$Nil, \$7.1 million, and \$83.4 million to business venture parents in 2004, 2003 and 2002, respectively. All business ventures have been terminated, restructured or are now inactive and we do not expect to provide any additional financing to the business ventures and business venture parents.

The business ventures incurred R&D expenditures of approximately \$Nil, \$17.0 million and \$125.0 million in 2004, 2003 and 2002, respectively. While the business ventures and the business venture parents were generally responsible for ongoing R&D activities, they could request that we conduct R&D on their behalf. We received research revenue from the business ventures of \$Nil, \$3.7 million and \$13.4 million in 2004, 2003 and 2002, respectively. In addition, we recognized license fee revenue from the business ventures of \$Nil, \$35.2 million and \$203.8 million in 2004, 2003 and 2002, respectively. There were no remaining unamortized license fees at December 31, 2004 and 2003. We do not expect to receive any future research revenues from the business ventures.

Investments in the business ventures and the business venture parents were made at fair value. The fair value of investments was typically initially determined using established financial methodologies, including quoted market prices for quoted equity securities. Unquoted equity investments and non-traded securities of public entities were assessed using 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 flow models.

Subsequent to our investment in a business venture and business venture parent, the fair values of the investments have been typically determined periodically, by an independent financial institution using methodologies similar to those described above.

We recognized impairments to our investment portfolio, including investments held by EPIL III. This includes impairment charges relating to investments in business ventures and business venture parent companies of \$0.2 million, \$4.0 million and \$114.4 million in 2004, 2003 and 2002, respectively, and \$58.6 million, \$106.0 million and \$880.0 million in 2004, 2003 and 2002, respectively.

### 30. 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, we entered into a Program Agreement with Pharma Marketing. The Program Agreement, which substantially regulated the relationship, was a risk-sharing arrangement. 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 incurred by us in connection with the commercialization and development of 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 these payments.

We received no revenue from Pharma Marketing in 2004 or 2003. Revenue from Pharma Marketing was \$31.3 million in 2002, consisting of \$24.0 million for commercialization expenditures, which was recorded as product revenue, and \$7.3 million for development expenditures, which was 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

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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) 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 of 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 its subsidiary, 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.

In January 2003, Pharma Operating 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 we sell our interest in Sonata to a third party. On January 30, 2003, we settled 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 agreed to the terms of the additional collateral mechanism. On May 20, 2003, 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 its 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

amounts 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, we and Autoimmune 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 terminated all risk-sharing arrangement with Autoimmune and the royalty obligations to Autoimmune were terminated. The total consideration for the royalty rights was \$121.0 million, less our investment of \$38.5 million, resulted in a net cash cost of \$82.5 million. We expensed \$121.0 million for the acquisition of royalty rights from Autoimmune.

### 31. Segment Information

During 2003, our business was conducted through two business units, Core Elan and Elan Enterprises. With the completion of the recovery plan on February 12, 2004, we announced the end of operations for our Elan Enterprises business unit. In February 2004, we reorganized into two business units: Biopharmaceuticals and GS&O. In this reorganization, our Core Elan business, with the exception of its drug delivery business, 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 biopharmaceutical R&D activities and pharmaceutical commercial 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. GS&O focuses on product development and manufacturing to provide technology platforms that address the drug delivery challenges of the pharmaceutical industry. All prior period financial information has been reclassified to reflect the new basis of segmentation.

Revenue by region (by destination of customers)

	2004	2003 (in millions)	2002
Region:			
Ireland	\$ 17.2	\$ 24.3	\$ 33.0
United States	401.3	527.7	775.7
Rest of World	63.2	133.6	284.4
Total revenue	\$ 481.7	\$ 685.6	\$ 1,093.1

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## Distribution of operating loss by region

	2004	2003 (in millions)	2002
Ireland	\$ (56.5)	\$ (264.8)	\$ (492.4)
United States	(172.7)	(35.5)	(101.8)
Rest of World	(72.9)	(60.2)	(14.5)
Total operating loss	\$ (302.1)	\$ (360.5)	\$ (608.7)

## Total assets by region

	2004 (in millions)	2003
Ireland	\$ 827.7	\$ 906.1
United States	780.6	872.1
Bermuda	1,326.9	1,084.9
Rest of World	40.7	166.7
Total assets	\$ 2,975.9	\$ 3,029.8

## Property, plant and equipment by region

	2004 (in millions)	2003
Ireland	\$ 238.0	\$ 223.5
United States	105.6	143.5
Bermuda	0.1	0.1
Rest of World	2.5	2.0
Total property, plant and equipment	\$ 346.2	\$ 369.1

## Major customers

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The following three customers each contributed 10% or more of our operating revenue for 2004, 2003 and 2002:

	2004	2003	2002
McKesson Corporation	19%	18%	15%
AmerisourceBergen	19%	17%	16%
Cardinal Health	18%	22%	17%

No other customer accounted for more than 10% of our revenue in 2004, 2003 or 2002.

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Revenue analysis by segment

	Biopharmaceuticals			GS&O			Total		
	2004	2003	2002	2004	2003	2002	2004	2003	2002
	(US\$ in millions)								
Product revenue:									
Retained products									
Maxipime	117.5	109.1	79.2	—	—	—	117.5	109.1	79.2
Azactam	50.6	45.1	33.0	—	—	—	50.6	45.1	33.0
Tysabri	6.4	—	—	—	—	—	6.4	—	—
Contract manufacturing and royalties	15.3	12.4	9.4	115.6	107.6	109.1	130.9	120.0	118.5
Total retained products' revenue	189.8	166.6	121.6	115.6	107.6	109.1	305.4	274.2	230.7
Amortized revenue —									
Adalat/Avinza	—	—	—	34.0	34.0	7.8	34.0	34.0	7.8
Divested products									
European business	10.5	89.0	81.7	—	—	—	10.5	89.0	81.7
Zonegran	41.2	80.7	43.1	—	—	—	41.2	80.7	43.1
Skelaxin	—	60.2	145.4	—	—	—	—	60.2	145.4
Sonata	—	48.2	92.5	—	—	—	—	48.2	92.5
Zanaflex	7.7	(5.2)	56.8	—	—	—	7.7	(5.2)	56.8
Other	5.6	5.6	21.6	—	—	—	5.6	5.6	21.6
Total divested products revenue	65.0	278.5	441.1	—	—	—	65.0	278.5	441.1
Co-promotion fees	—	—	62.8	—	—	—	—	—	62.8
Total product revenue	254.8	445.1	625.5	149.6	141.6	116.9	404.4	586.7	742.4
Contract revenue:									
License fees	13.4	27.6	5.0	4.2	22.0	229.7	17.6	49.6	234.7
Risk-sharing arrangements	—	—	37.2	—	—	—	—	—	37.2
Research revenues/milestones	6.9	7.0	20.8	52.8	42.3	58.0	59.7	49.3	78.8

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Total contract revenue	20.3	34.6	63.0	57.0	64.3	287.7	77.3	98.9	350.7
Total revenue	\$ 275.1	\$ 479.7	\$ 688.5	\$ 206.6	\$ 205.9	\$ 404.6	\$ 481.7	\$ 685.6	\$1,093.1

Analysis by segment

	Biopharmaceuticals				GS&O				Total	
	2004	2003	2002	2004	2003	2002	2004	2003	2004	2003
Revenue	\$ 275.1	\$ 479.7	\$ 688.5	\$ 206.6	\$ 205.9	\$ 404.6	\$ 481.7	\$ 685.6	\$ 1,093.1	\$ 1,093.1
Gain (loss) on sale of businesses	\$ 41.2	\$ 271.2	\$ —	\$ 3.0	\$ (3.4)	\$ —	\$ 44.2	\$ 267.8	\$ —	\$ —
Depreciation and amortization (i)	\$ 78.8	\$ 90.3	\$ 89.8	\$ 42.4	\$ 43.2	\$ 45.8	\$ 121.2	\$ 133.5	\$ 133.5	\$ 133.5
Restructuring and other charges, net (ii)	\$ 0.2	\$ 343.7	\$ 319.1	\$ 1.3	\$ 13.9	\$ 127.0	\$ 1.5	\$ 357.6	\$ 446.1	\$ 446.1
Operating income/(loss) (iii)	\$ (253.2)	\$ (318.1)	\$ (582.8)	\$ 14.2	\$ 5.7	\$ 32.9	\$ (239.0)	\$ (312.4)	\$ (549.2)	\$ (549.2)
Capital expenditures (iv)	\$ 17.1	\$ 12.3	\$ 51.0	\$ 41.8	\$ 22.2	\$ 129.1	\$ 58.9	\$ 34.5	\$ 180.3	\$ 180.3

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(i) Reconciliation of depreciation & amortization (in millions):

	2004	2003	2002
Segmental depreciation and amortization	\$ 121.2	\$ 133.5	\$ 135.6
Corporate depreciation and amortization	1.2	2.4	2.7
	\$ 122.4	\$ 135.9	\$ 138.3

(ii) Reconciliation of restructuring and other charges (in millions):

	2004	2003	2002
Segmental other charges	\$ 1.5	\$ 357.6	\$ 446.1
Corporate other charges	58.3	45.6	54.6
Restructuring and other charges, net	\$ 59.8	\$ 403.2	\$ 500.7

Corporate other charges relate primarily to litigation provisions and costs for the SEC investigation and shareholder class action lawsuits in 2004, severance, relocation and exit costs and EPIL II/III waiver fee in 2003, and primarily severance, relocation and exit costs in 2002.

## (iii) Reconciliation of operating loss (in millions):

	2004	2003	2002
Segmental operating loss	\$ (239.0)	\$ (312.4)	\$ (549.9)
Corporate expense/(credit)	63.1	48.1	58.8
Operating loss (v)	\$ (302.1)	\$ (360.5)	\$ (608.7)

Segmental operating income/(loss) is shown after allocation of central administrative and other costs. Corporate expense/(credit) relates primarily to litigation provisions and costs for the SEC investigation and shareholder class action lawsuits in 2004, severance, relocation and exit costs and EPIL II/III waiver fee in 2003, and primarily severance, relocation and exit costs in 2002.

## (iv) Reconciliation of capital expenditures (in millions):

	2004	2003	2002
Segmental capital expenditures	\$ 58.9	\$ 34.5	\$ 180.1
Corporate capital expenditures	6.2	0.3	2.2
	\$ 65.1	\$ 34.8	\$ 182.3

## (v) Reconciliation of operating loss to net loss (in millions):

	2004	2003	2002
Operating loss	\$ (302.1)	\$ (360.5)	\$ (608.7)
Net interest and investment losses	(112.1)	(136.9)	(1,552.9)
Provision for income taxes	0.5	22.8	(8.0)
Net income/(loss) from discontinued operations	19.0	(31.5)	(188.6)
Net loss	\$ (394.7)	\$ (506.1)	\$ (2,358.2)

## Goodwill

	2004	2003
Biopharmaceuticals	\$ 218.3	\$ 224.9
GS&O	49.7	49.7
Total goodwill	\$ 268.0	\$ 274.6

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Total assets

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	2004	2003
Biopharmaceutical assets	\$ 1,024.9	\$ 1,352.2
GS&O assets	612.4	581.8
Corporate assets	1,338.6	1,095.8
Total assets	\$ 2,975.9	\$ 3,029.8

32. Supplemental Guarantor Information

As part of the offering and sale of the \$850.0 million in aggregate principal amount of 7.75% Notes due November 15, 2011 and the \$300.0 million Floating Rate Notes due November 15, 2011. Elan Corporation, plc and certain of our subsidiaries have guaranteed the 7.75% Notes and the Floating Rate Notes. Equivalent guarantees have also been given to the holders of the Athena Notes.

Presented below is consolidated information for Elan Finance plc, the issuer of the debt, Elan Corporation, plc, the parent guarantor of the debt, the guarantor subsidiaries of Elan Corporation, plc, listed below, and the non-guarantor subsidiaries of Elan Corporation, plc. All of the subsidiary guarantors are wholly owned subsidiaries of Elan Corporation, plc.

Elan Corporation, plc  
Consolidating Statements of Operations  
For the Year Ended December 31, 2004  
(in millions)

	Elan Finance, plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination Adjustment	Consolidated
Revenue	\$ —	\$ —	\$ 67.3	\$ 630.3	\$ 3.8	\$ (219.7)	\$ 481.7
Operating expenses:							
Cost of sales	—	—	8.3	188.9	1.7	(28.5)	170.4
Selling, general and administrative expenses	—	—	28.5	306.8	3.6	1.6	340.5
Research and development expenses	—	—	14.7	425.1	0.2	(182.7)	257.3
Gain on sale of businesses	—	—	—	14.1	—	(58.3)	(44.2)
Restructuring and other charges, net	—	—	72.1	(3.0)	0.1	(9.4)	59.8
Total operating expenses	—	—	123.6	931.9	5.6	(277.3)	783.8
Operating income/(loss)	—	—	(56.3)	(301.6)	(1.8)	57.6	(302.1)
Net interest (income)/expense and investment (gains)/losses	3.9	—	77.4	73.4	(33.0)	(9.6)	112.1
Net income/(loss) from continuing operations before provision for/(benefit from) income taxes	(3.9)	—	(133.7)	(375.0)	31.2	67.2	(414.2)
Provision for/(benefit from) income taxes	—	—	—	(2.2)	0.1	1.6	(0.5)
	(3.9)	—	(133.7)	(372.8)	31.1	65.6	(413.7)



Net income/(loss) from continuing operations								
Net income/(loss) from discontinued operations (net of tax)	—	—	—	19.1	(0.1)	—	19.0	
Net income/(loss)	\$ (3.9)	\$ —	\$ (133.7)	\$ (353.7)	\$ 31.0	\$ 65.6	\$ (394.7)	

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Elan Corporation, plc  
Consolidating Statements of Operations  
For the Year Ended December 31, 2003  
(in millions)

	Elan Finance, plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination Adjustment	Consolidated
Revenue	\$ —	\$ —	\$ 49.1	\$ 837.9	\$ 59.3	\$ (260.7)	\$ 685.6
Operating expenses:							
Cost of sales	—	—	8.7	331.7	31.8	(123.3)	248.9
Selling, general and administrative expenses	—	—	4.4	350.8	28.9	0.1	384.2
Research and development expenses	—	—	13.6	421.8	8.3	(166.1)	277.6
(Gain)/loss on sale of businesses	—	—	0.4	(261.9)	(2.2)	(4.1)	(267.8)
Restructuring and other charges, net	—	—	92.6	753.8	47.8	(491.0)	403.2
Total operating expenses	—	—	119.7	1,596.2	114.6	(784.4)	1,046.1
Operating income/(loss)	—	—	(70.6)	(758.3)	(55.3)	523.7	(360.5)
Net interest (income)/expense and investment (gains)/losses	—	—	99.0	(8.1)	(49.9)	95.9	136.9
Net income/(loss) from continuing operations before provision for/(benefit from) income taxes	—	—	(169.6)	(750.2)	(5.4)	427.8	(497.4)
Provision for/(benefit from) income taxes	—	—	—	(0.5)	—	(22.3)	(22.8)
Net income/(loss) from continuing operations	—	—	(169.6)	(749.7)	(5.4)	450.1	(474.6)
Net income/(loss) from discontinued operations (net of tax)	—	—	—	(66.7)	35.2	—	(31.5)

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Net income/(loss)           \$       —\$       —\$ (169.6) \$ (816.4) \$ 29.8 \$ 450.1 \$ (506.1)

Elan Corporation, plc  
Consolidating Statements of Operations  
For the Year Ended December 31, 2002  
(in millions)

	Elan Finance, plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination Adjustment	Consolidated	
Revenue	\$	—\$	—\$	114.2	\$ 1,668.3	\$ 24.9	\$ (714.3)	\$ 1,093.1
Operating expenses:								
Cost of sales		—	—	10.8	550.2	17.2	(272.6)	305.6
Selling, general and administrative expenses		—	—	28.0	497.4	19.6	(3.4)	541.6
Research and development expenses		—	—	38.5	517.3	4.9	(206.8)	353.9
Restructuring and other charges, net		—	—	5,794.2	301.6	(29.0)	(5,566.1)	500.7
Total operating expenses		—	—	5,871.5	1,866.5	12.7	(6,048.9)	1,701.8
Operating income/(loss)		—	—	(5,757.3)	(198.2)	12.2	5,334.6	(608.7)
Net interest (income)/expense and investment (gains)/losses		—	—	62.2	766.3	161.8	562.6	1,552.9
Net income/(loss) from continuing operations before provision for /(benefit from) income taxes		—	—	(5,819.5)	(964.5)	(149.6)	4,772.0	(2,161.6)
Provision for/(benefit from) income taxes		—	—	0.4	(0.1)	0.4	7.3	8.0
Net income/(loss) from continuing operations		—	—	(5,819.9)	(964.4)	(150.0)	4,764.7	(2,169.6)
Net income/(loss) from discontinued operations (net of tax)		—	—	—	(161.5)	(27.1)	—	(188.6)
Net income/(loss)	\$	—\$	—\$	(5,819.9)	\$ (1,125.9)	\$ (177.1)	\$ 4,764.7	\$ (2,358.2)

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In July 2002, we announced a recovery plan aimed at focusing our business and R&D activities and meeting our financial obligations. Elan Corporation, plc recorded a write-down to investments of \$5,593.4 million in its single entity financial statements as a consequence of restructuring its business, reflected in an impairment charge to investments in, and loans to, subsidiary undertakings.

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Elan Corporation, plc  
 Consolidating Balance Sheets  
 As of December 31, 2004  
 (in millions)

	Elan Finance, plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination Adjustment	Consolidated
<b>Assets</b>							
<b>Current Assets</b>							
Cash and cash equivalents	\$ 10.2	\$ —	\$ 38.6	\$ 1,293.5	\$ 5.9	\$ (0.6)	\$ 1,347.6
Restricted cash	—	—	40.0	—	124.3	—	164.3
Accounts receivable, net	—	—	8.9	32.6	—	—	41.5
Marketable investment securities	—	—	—	20.5	—	45.0	65.5
Inventory	—	—	—	29.0	—	—	29.0
Intercompany receivables	1,122.5	666.7	2,097.6	5,105.3	0.9	(8,993.0)	—
Prepaid and other current assets	—	—	1.3	101.0	12.8	(36.5)	78.6
Total current assets	1,132.7	666.7	2,186.4	6,581.9	143.9	(8,985.1)	1,726.5
Property, plant and equipment	—	—	—	344.9	1.3	—	346.2
Goodwill and other intangible assets	—	—	67.0	314.4	2.8	396.6	780.8
Marketable investment securities	—	—	—	108.5	6.9	(76.4)	39.0
Investments in subsidiaries	—	—	579.2	10,236.1	—	(10,815.3)	—
Restricted Cash	—	—	—	28.4	—	—	28.4
Other assets	26.3	2.9	1.4	27.3	—	(2.9)	55.0
Total assets	\$ 1,159.0	\$ 669.6	\$ 2,834.0	\$ 17,641.5	\$ 154.9	\$ (19,483.1)	\$ 2,975.9
<b>Liabilities and Shareholders' Equity</b>							
<b>Current Liabilities</b>							
Accounts payable	\$ —	\$ —	\$ 1.8	\$ 53.2	\$ —	\$ —	\$ 55.0
Accrued and other current liabilities	11.4	16.7	59.9	(233.3)	347.9	87.9	290.5
EPIL III notes	—	—	—	—	39.0	—	39.0
Deferred revenue	—	—	25.0	72.9	—	(42.1)	55.8
Intercompany payables	1.5	—	2,264.8	11,859.6	110.7	(14,236.6)	—
Total current liabilities	12.9	16.7	2,351.5	11,752.4	497.6	(14,190.8)	440.3
Long term and convertible debt	1,150.0	650.0	—	460.0	—	—	2,260.0
Deferred revenue	—	—	21.7	—	—	32.9	54.6
Other liabilities	—	2.9	13.3	62.2	—	(62.4)	16.0
Total liabilities	1,162.9	669.6	2,386.5	12,274.6	497.6	(14,220.3)	2,770.9
<b>Shareholders' Equity</b>							
Ordinary shares	—	—	22.6	290.1	1.9	(292.0)	22.6
Additional paid-in capital	—	—	4,796.4	7,013.7	110.4	(7,124.1)	4,796.4
Treasury stock	—	—	(17.4)	—	—	—	(17.4)

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Accumulated deficit	(3.9)	—	(4,354.1)	(1,954.1)	(455.3)	2,162.7	(4,604.7)
Accumulated other comprehensive income/(loss)	—	—	—	17.2	0.3	(9.4)	8.1
Shareholders' equity	(3.9)	—	447.5	5,366.9	(342.7)	(5,262.8)	205.0
Total liabilities and shareholders' equity	\$ 1,159.0	\$ 669.6	\$ 2,834.0	\$ 17,641.5	\$ 154.9	\$ (19,483.1)	\$ 2,975.9

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Elan Corporation, plc  
Consolidating Balance Sheets  
As of December 31, 2003  
(in millions)

	Elan Finance plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination Adjustment	Consolidated
<b>Assets</b>							
<b>Current Assets</b>							
Cash and cash equivalents	\$ —	\$ —	21.7	\$ 736.9	\$ 19.6	\$ —	\$ 778.2
Accounts receivable, net	—	—	4.3	47.4	25.3	(39.1)	37.9
Marketable investment securities	—	—	—	111.9	63.7	173.8	349.4
Inventory	—	—	—	84.8	8.9	(24.2)	69.5
Held for sale assets	—	—	—	—	—	135.2	135.2
Intercompany receivables	—	666.7	2,038.0	3,605.0	2.5	(6,312.2)	—
Prepaid and other current assets	—	—	1.7	79.0	1.9	41.6	124.2
Total current assets	—	666.7	2,065.7	4,665.0	121.9	(6,024.9)	1,494.4
Property, plant and equipment	—	—	14.4	354.5	15.3	(15.1)	369.1
Goodwill and other intangible assets	—	—	86.5	412.0	20.9	388.4	907.8
Marketable investment securities	—	—	—	328.4	36.4	(171.9)	192.9
Investments in subsidiaries	—	—	541.5	10,373.2	—	(10,914.7)	—
Restricted cash	—	—	—	33.1	—	—	33.1
Other assets	—	3.9	3.5	28.4	0.4	(3.7)	32.5
Total assets	\$ —	\$ 670.6	\$ 2,711.6	\$ 16,194.6	\$ 194.9	\$ (16,741.9)	\$ 3,029.8
<b>Liabilities and Shareholders' Equity</b>							
<b>Current Liabilities</b>							
Accounts payable	\$ —	\$ —	1.3	\$ 27.0	\$ 4.4	\$ (6.5)	\$ 26.2
	—	16.7	6.5	205.5	11.5	97.0	337.2

Accrued and other current liabilities								
EPIL II guarantee provision	—	—	344.5	—	—	—	—	344.5
Deferred revenue	—	—	25.0	18.1	—	18.4	—	61.5
Intercompany payables	—	—	1,764.8	9,690.4	22.4	(11,477.6)	—	—
Held for sale liabilities	—	—	—	—	—	27.9	—	27.9
Total current liabilities	—	16.7	2,142.1	9,941.0	38.3	(11,340.8)	—	797.3
Long term and convertible debt	—	650.0	—	460.0	390.0	—	—	1,500.0
Deferred revenue	—	—	46.7	—	—	46.6	—	93.3
Other liabilities	—	3.9	13.8	66.4	0.1	(62.9)	—	21.3
Total liabilities	—	670.6	2,202.6	10,467.4	428.4	(11,357.1)	—	2,411.9
Shareholders' Equity								
Ordinary shares	—	—	22.0	267.6	17.0	(284.6)	—	22.0
Additional paid-in capital	—	—	4,724.8	7,031.2	261.5	(7,292.7)	—	4,724.8
Treasury stock	—	—	(17.4)	—	—	—	—	(17.4)
Accumulated deficit	—	—	(4,220.4)	(1,600.4)	(486.3)	2,097.1	—	(4,210.0)
Accumulated other comprehensive income/(loss)	—	—	—	28.8	(25.7)	95.4	—	98.5
Shareholders' equity	—	—	509.0	5,727.2	(233.5)	(5,384.8)	—	617.9
Total liabilities and shareholders' equity	\$	—\$ 670.6	\$ 2,711.6	\$ 16,194.6	\$ 194.9	\$ (16,741.9)	\$	\$ 3,029.8

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Elan Corporation, plc  
Consolidating Statement of Cash Flows  
For the Year Ended December 31, 2004  
(in millions)

	Elan Finance, plc	Athena Finance	Parent Company	Guarantor Subsidiaries	Non- Guarantor Subsidiaries	Elimination	Consolidated
<b>Cash flows from operating activities:</b>							
Net income/(loss)	\$ (3.9)	\$ —	(133.7)	\$ (353.7)	\$ 31.0	\$ 65.6	\$ (394.7)
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:							