

ELAN CORP PLC
Form 20-F
February 28, 2007

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

(Mark One)

- o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR(g) OF THE SECURITIES EXCHANGE ACT OF 1934**
OR
- o ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended: December 31, 2006
OR
- o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
OR
- o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-13896

Elan Corporation, plc

(Exact name of Registrant as specified in its charter)

Ireland

*(Jurisdiction of incorporation
or organization)*

**Treasury Building, Lower Grand Canal Street,
Dublin 2, Ireland**

(Address of principal executive offices)

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

Title of Each Class

Name of Exchange on Which Registered

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

New York Stock Exchange

New York Stock Exchange

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

None

(Title of Class)

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

None

(Title of Class)

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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: 467,485,612 Ordinary Shares.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

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

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

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

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General

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

Our Consolidated Financial Statements contained in this Form 20-F have been prepared on the basis of accounting principles generally accepted in the United States (US GAAP). In addition to the Consolidated Financial Statements contained in this Form 20-F, we also prepare separate Consolidated Financial Statements, included in our Annual Report, in accordance with International Financial Reporting Standards (IFRS), which differ in certain significant respects from US GAAP. The Annual Report under IFRS is a separate document from this Form 20-F.

Unless otherwise indicated, our Consolidated Financial Statements and other financial data contained in this Form 20-F are presented in United States (US) 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 US 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 and potential products that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as anticipate, estimate, project, intend, plan, believe and other 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) the potential of *Tysabri*[®] (*natalizumab*), the incidence of serious adverse events associated with *Tysabri* (including cases of progressive multifocal leukoencephalopathy (PML)) and the potential for the successful development and commercialization of additional products; (2) the potential of *Prial*[™] (*ziconotide intrathecal infusion*) as an intrathecal treatment for severe pain; (3) our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements; (4) whether restrictive covenants in our debt obligations will adversely affect us; (5) competitive developments affecting our products, including the introduction of generic competition following the scheduled loss of patent protection or marketing exclusivity for our products (including, in particular, *Maxipime*[™] (*cefepime hydrochloride*), which loses its basic US patent protection in March 2007 and *Azactam*[™] (*aztreonam for injection, USP*), which lost its basic US patent protection in October 2005); (6) our ability to protect our patents and other intellectual property; (7) difficulties or delays in manufacturing (including, in particular, with respect to *Maxipime*); (8) trade buying patterns; (9) pricing pressures and uncertainties regarding healthcare reimbursement and reform; (10) the failure to comply with anti-kickback and false claims laws in the United States (including, in particular, with respect to past marketing practices with respect to our former *Zonegran*[™] product, which are being investigated by the US Department of Justice and the US Department of Health and Human Services. The resolution of the *Zonegran* matter could require us to pay substantial fines and to take other actions that could have a material adverse effect on us); (11) the success of our research and development (R&D) activities (including, in particular,

whether the Phase 2 clinical trials for AAB-001 and the Phase 1 clinical trials for ACC-001 are successful) and the speed with which regulatory authorizations and product launches may be achieved; (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 putative class action lawsuits initiated following the voluntary suspension of the commercialization and clinical dosing of *Tysabri* and the outcome of our other pending or future litigation; (17) the volatility of our stock price; and

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(18) some of our agreements that may discourage or prevent someone from acquiring us. We assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Part I**Item 1. Identity of Directors, Senior Management and Advisers.**

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

Item 3. Key Information.**A. Selected Financial Data**

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

Years Ended December 31,	2006	2005	2004	2003	2002
	(In millions, except per share data)				
Income Statement Data:					
Total revenue	\$ 560.4	\$ 490.3	\$ 481.7	\$ 685.6	\$ 1,093.1
Operating loss	\$ (166.4) ⁽¹⁾	\$ (198.5) ⁽²⁾	\$ (302.1) ⁽³⁾	\$ (360.5) ⁽⁴⁾	\$ (608.7) ⁽⁵⁾
Net loss from continuing operations	\$ (267.3)	\$ (384.2)	\$ (413.7)	\$ (474.6)	\$ (2,169.6)
Net income/(loss) from discontinued operations		0.6	19.0	(31.5)	(188.6)
Net loss	\$ (267.3) ⁽¹⁾	\$ (383.6) ⁽⁶⁾	\$ (394.7) ⁽³⁾	\$ (506.1) ⁽⁷⁾	\$ (2,358.2) ⁽⁸⁾
Basic loss per Ordinary Share ⁽⁹⁾ from continuing operations	\$ (0.62)	\$ (0.93)	\$ (1.06)	\$ (1.33)	\$ (6.20)
from discontinued operations			0.05	(0.09)	(0.54)
Total basic loss per Ordinary Share	\$ (0.62)	\$ (0.93)	\$ (1.01)	\$ (1.42)	\$ (6.74)
Diluted loss per Ordinary Share ⁽⁹⁾ from continuing operations	\$ (0.62)	\$ (0.93)	\$ (1.06)	\$ (1.33)	\$ (6.20)
from discontinued operations			0.05	(0.09)	(0.54)
Total diluted loss per Ordinary Share	\$ (0.62)	\$ (0.93)	\$ (1.01)	\$ (1.42)	\$ (6.74)

At December 31,	2006	2005	2004	2003	2002
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(In millions)

Balance Sheet Data:

Cash and cash equivalents	\$ 1,510.6	\$ 1,080.7	\$ 1,347.6	\$ 778.2	\$ 984.5
Restricted cash	\$ 23.2	\$ 24.9	\$ 192.7	\$ 33.1	\$ 29.4
Investment securities - current	\$ 11.2	\$ 10.0	\$ 65.5	\$ 349.4	\$ 450.6
Total assets	\$ 2,746.3	\$ 2,340.9	\$ 2,975.9	\$ 3,029.8	\$ 4,031.7
Debts	\$ 2,378.2	\$ 2,017.2	\$ 2,260.0	\$ 1,500.0	\$ 1,046.3
Total shareholders' equity	\$ 85.1	\$ 16.9	\$ 205.0	\$ 617.9	\$ 843.1
Weighted-average number of shares outstanding - Basic and diluted	433.3	413.5	390.1	356.0	349.7

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- (1) *After other net gains of \$20.3 million, primarily relating to an arbitration award of \$49.8 million, offset by acquired in-process research and development costs of \$22.0 million and severance, restructuring and other costs of \$7.5 million; and after a \$43.1 million net gain on sale of products and businesses.*
- (2) *After other net charges of \$4.4 million, primarily relating to net severance, restructuring and other costs of \$14.4 million, offset by a credit of \$10.0 million primarily associated with a litigation settlement; and after a \$103.4 million net gain on sale of businesses.*
- (3) *After other net charges of \$59.8 million, primarily relating to the settlement of the US 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.*
- (4) *After other net charges of \$403.2 million, primarily relating to asset impairments of \$32.6 million, severance, restructuring and other 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.*
- (5) *After other net charges of \$500.7 million, primarily relating to asset impairments of \$266.1 million, severance, restructuring and other 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.*
- (6) *After other net charges of \$4.4 million, primarily relating to net severance, restructuring and other costs of \$14.4 million, offset by a credit of \$10.0 million primarily associated with a litigation settlement; a \$103.4 million net gain on sale of businesses; and after a net charge of \$51.8 million on the retirement of debt.*
- (7) *After other net charges of \$403.2 million, primarily relating to asset impairments of \$32.6 million, severance, restructuring and other costs of \$29.7 million and the purchase of royalty rights of \$297.6 million, offset by a net gain of \$267.8 million on the sale of businesses and repurchase of debt; and after charges of \$136.5 million, primarily relating to investments and the guarantee issued to the noteholders of Elan Pharmaceutical Investments II, Ltd. (EPIL II).*
- (8) *After other net charges of \$500.7 million, primarily relating to asset impairments of \$266.1 million, severance, restructuring and other costs of \$77.8 million and the purchase of royalty rights of \$121.0 million, partially offset by a gain of \$37.7 million on the repurchase of debt; and after charges of \$1,443.0 million, primarily relating to investment impairments and the guarantee issued to the noteholders of EPIL II.*
- (9) *Earnings per share is based on the weighted-average number of outstanding Ordinary Shares and the effect of potential dilutive securities including options, warrants and convertible securities, unless anti-dilutive.*

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.

Our future success depends upon the successful commercialization of Tysabri and the successful development and commercialization of additional products. If Tysabri is not commercially successful, either because of the incidence of serious adverse events associated with Tysabri (including cases of PML) or for other reasons, and if we do not successfully develop and commercialize additional products, we will be materially and adversely affected.

While approximately half of our 2006 revenue was generated by our Elan Drug Technologies (EDT) business unit, we have only four marketed products and several potential products in the early stages of clinical development. Our future success depends upon the successful commercialization of *Tysabri* and the development and the successful commercialization of additional products.

Uncertainty created by the serious adverse events that have occurred or may occur, with respect to *Tysabri*, and the restrictive labeling and distribution system for *Tysabri* mandated by regulatory agencies, may significantly impair the commercial potential for *Tysabri*. If there are more serious adverse events in patients treated with *Tysabri* (including cases of PML), then we may be seriously and adversely affected.

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We commit substantial resources to our R&D activities, including collaborations with third parties such as Biogen Idec Inc. (Biogen Idec) with respect to *Tysabri*. We have committed significant resources to the development and the commercialization of *Tysabri* and to the other potential products in our development pipeline. These investments may not be successful.

In the pharmaceutical industry, the R&D process is lengthy, expensive 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 potential products in our R&D pipeline, including product candidates from our Alzheimer's disease research programs such as AAB-001, AZD-103/ELND-005 and ACC-001, 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 or have manufactured 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. 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, 2006, we had \$2,378.2 million of debt. At such date, we had cash and cash equivalents and restricted cash of \$1,533.8 million. Our substantial indebtedness could have important consequences to us. For example, it could:

Increase our vulnerability to general adverse economic and industry conditions;

Require us to dedicate a substantial portion of our cash flow from operations to payments on indebtedness, thereby reducing the availability of our cash flow to fund R&D, working capital, capital expenditures, acquisitions, investments and other general corporate purposes;

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

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

Limit our ability to borrow additional funds.

We estimate that we have sufficient cash, liquid resources and current assets and investments to meet our liquidity requirements for at least the next twelve months. Although we expect to continue to incur operating losses in 2007, 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 successfully commercialize *Tysabri* on a timely basis, then we could be required to obtain additional funds. If our estimates are incorrect or are not consistent with actual future developments and we are required to obtain additional funds, then we may not be able to obtain those funds on commercially reasonable terms, or at all, which would have a material adverse effect on our financial condition. In addition, if we are not able to generate sufficient liquidity from operations, we may be forced to curtail programs, sell assets or otherwise take steps to reduce expenses. Any of these steps may have a material adverse effect on our prospects.

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

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

Incur additional debt;

Create liens;

Enter into transactions with related parties;

Enter into some types of investment transactions;

Engage in some asset sales or sale and leaseback transactions;

Pay dividends or buy back our Ordinary Shares; 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 which are larger and have greater financial resources, technical staff, manufacturing,

R&D and marketing capabilities than Elan. We also compete with smaller research companies and generic drug manufacturers.

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

Our product *Azactam* lost its basic US patent protection in October 2005. We expect that *Azactam* will be subject to generic competition in 2007 and that our sales of *Azactam* will be materially and adversely affected by such generic competition. However, to date, no generic *Azactam* product has been approved.

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In addition, the US basic patent covering our product *Maxipime* for injection expires in March 2007. Two formulation US patents covering *Maxipime* expire in February 2008. *Maxipime* may become subject to generic competition following the expiration of the basic patent or after expiration of the formulation patents and that would materially and adversely affect our sales of *Maxipime*.

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.

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.

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

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

We do not manufacture *Tysabri*, *Prialt*, *Maxipime* or *Azactam*. Our dependence upon collaborators and third parties for the manufacture of our products may result in unforeseen delays or other problems beyond our control. For example, if our third-party manufacturers are not in compliance with current good manufacturing practices (cGMP) or other applicable regulatory requirements, then the supply of our products could be materially adversely affected. If we are unable to retain or obtain replacements for our third-party manufacturers or if we experience delays or difficulties with our third-party manufacturers in producing our products (as we did with *Maxipime* in 2006 and prior years), then sales of these products could be materially and adversely affected. In this event, we may be unable to enter into alternative manufacturing arrangements on commercially reasonable terms, if at all.

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

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

Our product revenue may vary periodically 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 period could cause sales of those products to be lower than expected in subsequent periods.

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

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

Recent reforms in Medicare added a prescription drug reimbursement benefit for all Medicare beneficiaries. Although we cannot predict the full effects on our business of this legislation, it is possible that the new benefit, which is being 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

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markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices.

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

In addition to the US 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 anti-kickback statutes and false claims statutes.

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

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

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

In January 2006, Elan received a subpoena from the US Department of Justice and the Department of Health and Human Services, Office of Inspector General asking for documents and materials primarily related to our marketing practices for Zonegran. In April 2004, we completed the sale of our interests in Zonegran in North America and Europe to Eisai Co. Ltd. (Eisai). We are cooperating with the government in its investigation. The resolution of this Zonegran matter could require Elan to pay substantial fines and to take other actions that could have a material adverse effect on Elan. In April 2006, Eisai delivered to Elan a notice making a contractual claim for indemnification in connection with a similar subpoena received by Eisai.

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

The pharmaceutical industry is subject to significant regulation by state, local, national and international governmental regulatory authorities. In the United States, the FDA regulates the design, development, pre-clinical and clinical testing, manufacturing, 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.

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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.

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 or lease, 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 US federal Medicaid rebate program, as well as several state rebate programs. Under the federal and state Medicaid rebate programs, we pay a rebate to each state

for our products that are reimbursed by those programs. The amount of the rebate for each unit of product is set by law based on reported pricing data. The rebate amount may also include a penalty if our prices increase faster than the rate of inflation.

As a manufacturer of single source, innovator and non-innovator multiple source products, rebate calculations vary among products and programs. The calculations are complex and, in some respects, subject to interpretation by

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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 US Department of Health and Human Services. The terms of our participation in the program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in an overage or shortfall in our rebate liability for past quarters (up to 12 past quarters), depending on the direction of the correction. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

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

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

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

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

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

Risks relating to product liability claims are inherent in the development, manufacturing and marketing of our products. Any person who is injured while using one of our products or products which we are responsible for, 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.

Excluding any self-insured arrangements we currently do not maintain product liability insurance for the first \$25.0 million of aggregate claims, but do maintain coverage for the next \$150.0 million with our insurers. Our insurance coverage may not be sufficient to cover fully all potential claims, nor can we guarantee the solvency of any of our insurers.

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 or terms.

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 US 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.

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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. The market price of our shares likely will continue to fluctuate due to a variety of factors, including:

Material public announcements by us;

Developments regarding *Tysabri*;

The timing of new product launches by others and us;

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

Regulatory issues affecting us;

Availability and level of third-party reimbursement;

Developments relating to patents and other intellectual property rights;

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

Political developments and proposed legislation affecting the pharmaceutical industry;

Economic and other external factors;

Hedge or arbitrage activities by holders of our securities;

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

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

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

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

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

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

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

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

Item 4. *Information on the Company.*

A. History and Development of Elan

Elan, an Irish public limited company, is a neuroscience-based biotechnology company headquartered in Dublin, Ireland. We were incorporated as a private limited company in Ireland in December 1969 and became a public limited company in January 1984. Our principal executive offices are located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland and our telephone number is 353-1-709-4000. Our principal R&D, manufacturing and marketing facilities are located in Ireland and the United States.

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

In the area of autoimmune diseases, we continue to research and develop novel therapies that may help patients who suffer from diseases where an immune reaction is mistakenly directed at cells, tissues and organs in different parts of the body. Currently there are few autoimmune diseases for which the disease can be reversed or cured; autoimmune diseases are, therefore, often chronic, requiring life-long care. The wide range of autoimmune diseases includes multiple sclerosis (MS), Crohn's disease (CD), ulcerative colitis and rheumatoid arthritis (RA).

In the area of neurodegenerative diseases, we continue to focus on Alzheimer's disease and Parkinson's disease. Our R&D efforts in Alzheimer's disease and Parkinson's disease span more than two decades. In the United States and throughout the world, Alzheimer's disease and related disorders represent a significant unmet medical need. While a number of approved treatment options exist for Alzheimer's disease and Parkinson's disease, available options do not address the underlying causes of the diseases nor their progression.

Our specialty business group encompasses our commercial activities related to meeting the needs of specialists treating severe bacterial infections in hospitals, and pain specialists addressing severe chronic pain. Our products are the antibacterial hospital products *Maxipime* and *Azactam*, and *Prialt*, a new class of treatment for severe chronic pain, which we launched in the United States in January 2005.

EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry. For more than 37 years, Elan has been applying its skills and knowledge to enhance the performance of dozens of drugs that have been marketed worldwide.

AUTOIMMUNE DISEASES

In autoimmune diseases, the immune system mistakenly targets the cells, tissues and organs of a person's body, generally causing inflammation. Inflammation is a response of body tissues to trauma, infection, chemical or physical injury, allergic reaction, or other factors. It is usually characterized by a collection of cells and molecules at a target site. Different autoimmune diseases affect the body in different ways. For example, in MS, the autoimmune reaction is directed against the brain. In CD, it is directed against the gastrointestinal tract; and in RA, it is directed against the joints. Autoimmune diseases are often chronic, affecting millions of people and requiring life-long care. Most autoimmune diseases cannot currently be reversed or cured.

Elan's therapeutic strategy for treating autoimmune diseases is to identify mechanisms common to autoimmune diseases, and develop novel therapeutics that stop the underlying causes of disease. Alpha 4 integrin is a protein expressed by immune cells that allows those cells to leave the blood stream and invade target tissue. Blocking alpha 4 integrin stops immune cells from entering tissues.

Tysabri

Tysabri is an alpha 4 integrin antagonist. *Tysabri* is designed to inhibit immune cells from leaving the bloodstream and to prevent these immune cells from migrating into chronically inflamed tissue where they may cause or maintain inflammation. *Tysabri* was developed and is now being commercialized by us in collaboration with Biogen Idec.

FDA Review of Tysabri for the Treatment of Multiple Sclerosis

In June 2006, the FDA approved the re-introduction of *Tysabri* for the treatment of relapsing forms of MS. Approval for the marketing of *Tysabri* in the European Union was also received in June 2006. The distribution of *Tysabri* in both the United States and European Union commenced in July 2006.

The FDA granted approval for the reintroduction of *Tysabri* based on the review of *Tysabri* clinical trial data, revised labeling with enhanced safety warnings, and a risk management plan called the *Tysabri* Outreach: Unified

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Commitment to Health (TOUCH Prescribing Program), which is designed to inform physicians and patients of the benefits and risks of *Tysabri* treatment and minimize potential risk of PML. Under the TOUCH Prescribing Program, only prescribers, infusion centers and pharmacies associated with infusion centers registered in the TOUCH Prescribing Program are able to prescribe, infuse or distribute *Tysabri*. Elan has contracted with a single distributor and twelve specialty pharmacies to distribute product in accordance with the requirements of the TOUCH Prescribing Program.

The reintroduction of *Tysabri* was the culmination of a 17-month process and encompassed the following events:

On February 28, 2005, we and Biogen Idec announced the voluntary suspension of the commercialization and dosing in clinical trials of *Tysabri*, based on two reports of PML. PML is an opportunistic viral infection of the brain that usually leads to death or severe disability.

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

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

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

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

In February 2006, we and Biogen Idec were informed by the FDA that it had removed the hold on clinical trial dosing of *Tysabri* in MS in the United States.

On March 8, 2006, the Peripheral and Central Nervous System Drug (PCNS) Advisory Committee voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS.

On March 29, 2006, we and Biogen Idec announced the re-initiation of *Tysabri* clinical trial dosing in MS. Specifically, it was announced that the first patients were enrolled and dosed in the *Tysabri* monotherapy safety extension study program in MS.

On April 28, 2006, we and Biogen Idec announced that the Committee for Medicinal Products for Human Use, the scientific committee of the EMA, issued a positive opinion recommending marketing authorization for *Tysabri* as a treatment for relapsing-remitting MS to delay the progression of disability and reduce the frequency of relapses.

On June 29, 2006, the EMA approved *Tysabri* for the treatment of relapsing-remitting forms of MS.

In both the United States and Europe, special provisions are in place to ensure patients are informed of the risks of therapy and to enhance collection of post-marketing safety data and utilization of *Tysabri* in MS.

Evaluating Tysabri in Crohn's Disease

In collaboration with Biogen Idec, we are evaluating *Tysabri* as a treatment for CD. In September 2004, we submitted a Marketing Authorization Application to the EMEA for the approval of *Tysabri* for the treatment of CD. Following approval of *Tysabri* as a treatment for MS in 2006, we have re-initiated discussion with the EMEA and expect European regulatory action regarding *Tysabri* in CD in 2007. A sBLA for *Tysabri* as a treatment for CD in the

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United States was filed with the FDA on December 15, 2006 and has been accepted for review. The filing was based on the results of three randomized, double-blind, placebo-controlled, multi-center trials of *Tysabri* assessing its safety and efficacy as both an induction and maintenance therapy.

Autoimmune Diseases Research & Development

Our ongoing research in autoimmune diseases is primarily based on cell trafficking and focuses on discovering disease-modifying approaches to treating a wide range of autoimmune diseases, including MS, CD and RA. *Tysabri* emerged from this research program. We remain focused on discovering disease-modifying approaches to treating a wide range of autoimmune diseases, including MS, CD and RA. In 2006, we expanded our research in autoimmune diseases to include novel anti-inflammatory approaches in addition to our core alpha 4 integrin programs.

Since first publishing the hypothesis concerning the therapeutic potential of blocking alpha 4 integrin in 1992, our scientists have been expanding and refining our understanding of how cells enter tissues. We now have a clear understanding of how cells enter the gut, brain, or joints, and cause the damage characteristic of MS, CD, and RA. Through the course of this work we have developed small molecules that can selectively block particular alpha 4 integrin interactions. The first drug candidate evolving from this effort is ELND-001, which is in Phase 1. Further work is ongoing for other molecules that target the alpha 4 integrin pathway.

In June 2006, we entered into a multi-product alliance with Archemix Corp. (Archemix) to discover, develop and commercialize aptamer therapeutics for autoimmune diseases. This program is in the discovery phase.

NEURODEGENERATIVE DISEASES

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

Alzheimer's disease is a degenerative brain disorder that primarily affects older persons. 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 likely cause death.

Parkinson's disease is a progressive degenerative neurologic movement disorder that destroys nerve cells in the part of the brain responsible for muscle control and movement. This creates problems walking, maintaining balance and coordination in patients diagnosed with the disease.

Our Scientific Approach to Alzheimer's Disease and Related Disorders

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

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

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Alzheimer's Research and Development

Our scientists are investigating three key therapeutic approaches that target the elimination and prevention of production or aggregation of beta amyloid. In collaboration with Wyeth, we are developing beta amyloid immunotherapies. Separately, we have research programs focused on small molecule inhibitors of beta secretase and gamma secretase, enzymes whose actions result in the over-production of beta amyloid in the brains of patients with Alzheimer's disease. In addition, in September 2006 we entered into a collaboration agreement with Transition Therapeutics, Inc. (Transition) to develop AZD-103 (also referred to as AZD-103/ELND-005), a small molecule therapeutic that acts by breaking down and preventing the aggregation of beta amyloid fibrils.

Research in Beta Amyloid Immunotherapy

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

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

Our scientists have developed a series of monoclonal antibodies and active immunization approaches that may have the ability to selectively clear a variety of beta amyloid species. These new approaches have the potential to deliver immunotherapies with potent and broad therapeutic activity. Our AAB-001, AAB-002 and ACC-001 programs have emerged from this work.

AAB-001

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

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

During the first half of 2005, we initiated two Phase 2 clinical trials with AAB-001. Both trials are randomized, double-blind, placebo-controlled, multiple ascending dose studies with four dose cohorts. One trial includes approximately 240 patients and the other includes approximately 30 patients, all with mild to moderate Alzheimer's disease. The patients are being followed for 18 months. Data from this clinical trial will be used to design the next phase of clinical trials. It will also determine the time point at which this program can progress into the next phase of clinical trials.

AAB-002

We anticipate a potential filing of an IND in 2007 for AAB-002, a follow-on antibody program, which is also in collaboration with Wyeth. This antibody has demonstrated unique attributes in our experimental animal models when compared to AAB-001.

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ACC-001

We, in collaboration with Wyeth, are also developing ACC-001, a novel beta amyloid-related active immunization approach. ACC-001 is in a Phase 1 clinical study designed to study safety and immunogenicity in patients with mild to moderate Alzheimer's disease. The ACC-001 approach is intended to induce a highly specific antibody response to beta amyloid. The goal is to clear beta amyloid while minimizing side effects such as inflammation of the central nervous system. Initiation of Phase 2 clinical trials has been targeted for 2007.

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. We have been at the forefront of research in this area, publishing extensively since 1989, and have developed and are pursuing advanced discovery programs focused on molecule inhibitors of beta and gamma secretases.

Beta Secretase

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

Gamma Secretase

Gamma secretase is an unusual multi-protein complex that is thought to play a significant role in the formation of beta amyloid. We have played a critical leadership role in the increased awareness of how gamma secretase may affect Alzheimer's disease pathology. Our finding, published in 2001, that functional gamma secretase inhibitors appear to reduce beta amyloid levels in the brain, was an important step in this area of Alzheimer's disease research. We continued to progress our gamma secretase discovery program in 2006.

AZD-103/ELND-005

In 2006, we entered into a collaboration with Transition to develop a small molecule approach to the treatment of mild to moderate Alzheimer's disease. The molecule is a beta-amyloid anti-aggregate. Based upon pre-clinical data, by blocking the aggregation of amyloid beta, clearance of amyloid occurs and plaque build up is prevented.

Daily oral treatment with this compound has been shown to prevent cognition decline in a transgenic mouse model of Alzheimer's disease, with reduced amyloid plaque load in the brain accompanied with an increased survival rate of these animals.

In 2006, three Phase 1 Single Ascending Dose studies were conducted by Transition showing that AZD-103/ELND-005 has a favorable pharmacokinetic profile and is safe and well tolerated. No significant

drug-related adverse events have been reported to date.

In 2007, we will conduct additional clinical and non-clinical studies to support the initiation of a Phase 2 trial, targeted for 2007. This Phase 2 study will be a randomized, double-blind, placebo-controlled, dose-ranging study in mild to moderate Alzheimer's disease patients.

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Parkinson's Research

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

Our early discovery efforts in Parkinson's disease are guided by our expertise and leadership in Alzheimer's disease research. We made significant scientific progress in 2006, identifying unusual modified forms of alpha-synuclein in human Parkinson's disease brain tissue. These unique forms have led us to a series of therapeutic targets that will be a focus of our small and large molecule drug discovery efforts over the next few years.

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

SPECIALTY BUSINESS GROUP

Our specialty business group encompasses our commercial activities related to meeting the needs of specialists treating severe bacterial infections in hospitals, and pain specialists addressing severe chronic pain. Our products are the antibacterial hospital products *Maxipime* and *Azactam*, and *Prialt*, a new class of therapy for patients suffering from severe chronic pain.

Prialt

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

Prialt is administered through appropriate programmable microinfusion pumps that can be implanted or external, and which release the drug into the fluid surrounding the spinal cord. *Prialt* is in a class of non-opioid analgesics known as N-type calcium channel blockers. It is a synthetic equivalent of a naturally occurring conopeptide found in a marine snail known as *Conus magus*. Research suggests that the novel mechanism of action of *Prialt* works by targeting and blocking N-type calcium channels on nerves that ordinarily transmit pain signals.

In January 2005, we launched *Prialt* in the United States. We believe *Prialt* represents an important therapeutic option addressing an unmet need, and that it has the potential for significant patient impact and market contribution in the area of severe chronic pain. Revenue from sales of *Prialt* totaled \$12.1 million for 2006 (2005: \$6.3 million). In March 2006, Elan completed the sale of the *Prialt* rights in Europe to Eisai, while retaining the product rights in the United States.

Hospital Business and Products

Severe bacterial infections remain a major medical concern. We market two products that treat severe bacterial infections, each designed to address medical needs within the hospital market.

Maxipime

We licensed the US marketing rights to *Maxipime* from Bristol-Myers Squibb Company (Bristol-Myers) in January 1999. *Maxipime* is a fourth-generation injectable cephalosporin antibiotic used to treat patients with serious and/or life-threatening infections. Pulmonologists, infectious disease specialists, emergency medicine specialists, surgeons, internal medicine physicians, hematologists and oncologists prescribe *Maxipime* for patients with severe infections requiring hospitalization, such as pneumonia, urinary tract infection and febrile neutropenia. Attributes of *Maxipime* are its broad spectrum of activity, including activity against many pathogens resistant to other antibiotics, ease of use and favorable pharmaco-economic profile. Revenue from sales of *Maxipime* totaled

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\$159.9 million for 2006 (2005: \$140.3 million). The basic US patent on *Maxipime* expires in March 2007. Two other US patents covering *Maxipime* formulations expire in February 2008.

Azactam

We licensed the US marketing rights to this injectable antibiotic from Bristol-Myers in January 1999. *Azactam* is a monobactam and is principally used by surgeons, infectious disease specialists and internal medicine physicians to treat pneumonia, post-surgical infections and septicemia. *Azactam* is often used in these infections for patients who have a known or suspected penicillin allergy. Revenue from sales of *Azactam* totaled \$77.9 million for 2006 (2005: \$57.7 million). The basic US patent on *Azactam* expired in October 2005. No generic *Azactam* product has been approved to date, however we expect that generic competition to *Azactam* will emerge in 2007.

Please refer to Item 5A. Operating Results for additional information concerning our revenue by category for 2006, 2005 and 2004.

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ELAN DRUG TECHNOLOGIES

For more than 37 years, we have been applying our skills and knowledge to enhance the performance of dozens of drugs that have been marketed in many countries worldwide. EDT focuses on product development, scale-up and manufacturing to address drug optimization challenges of the pharmaceutical industry. EDT offers the industry a suite of proprietary technology-driven solutions. EDT recorded total revenue of \$284.6 million in 2006 (2005: \$261.2 million).

Our *NanoCrystal*[™] technology continues to be one of the key platforms that differentiates EDT. Sales by third parties of products incorporating *NanoCrystal* technology continued to grow in 2006. During 2006, we signed a number of development agreements with third parties, including a license agreement with Abbott Pharmaceutical PR Ltd. (Abbott) to develop a single fixed-dose combination of TriCor[®] and Crestor[®] for high cholesterol patients.

Elan's Patented and Commercialized NanoCrystal Technology

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

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

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

Emend[®] oral tablet form of aprepitant, a poorly water-soluble compound;

Megace[®] ES concentrated oral suspension, with reduced dose and improved dissolution and bioavailability;

Rapamune[®] convenient oral tablet form eliminating reconstitution and refrigerated storage of original compound; and

TriCor new formulation of Abbott's fenofibrate, which can be taken without regard to food.

Manufacturing and Scale-up Activities

The combination of development and manufacturing capabilities on the same sites in EDT allows for streamlined scale-up and transfer to commercial scale manufacturing activities. EDT's principal manufacturing and development facilities are located in Athlone, Ireland and in King of Prussia, Pennsylvania and Gainesville, Georgia, in the United States. Our range of services includes formulation development, analytical development, clinical trial manufacturing and scale-up, including sterile fill and finish as well as product registration support. The Athlone campus comprises more than 460,000 square feet under roof, of which 218,000 square feet is dedicated to manufacturing.

ENVIRONMENT

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

principal properties.

Pharmaceutical Market

The US 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, place emphasis on requirements in the United States.

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Government Regulation

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

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

Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing and marketing of pharmaceutical products. For example, the Federal Food, Drug and Cosmetics Act, the Public Health Service Act, the Controlled Substances Act and other federal statutes and regulations impose requirements on the clinical and non-clinical testing, safety, effectiveness, manufacturing, labeling, storage, recordkeeping, reporting, advertising, marketing, import, export, distribution and approval of our products in the United States. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions. In addition, administrative remedies can involve requests to recall violative products, the refusal of the government to enter into supply contracts or the refusal to approve pending product approval applications for drugs, biological products, or medical devices, until manufacturing or other alleged deficiencies are brought into 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 US Centers for Disease Control and Prevention regulate select biologics and toxins. This includes registration and inspection of facilities involved in the transfer or receipt of select agents. Select agents are subject to specific regulations for packaging, 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.

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 US Federal Trade Commission (FTC) resolving the FTC's investigation of a licensing arrangement between us and Biovail Corporation (Biovail) relating to nifedipine, a generic version of the hypertension drug Adalat[™] CC. The settlement is reflected in a consent order which, by its terms, does not constitute an admission by us that any law had been violated, and does not provide for monetary fines or penalties.

We continue to satisfy all of the terms of the consent order.

In June 2001, we received a letter from the FTC stating that the FTC was conducting a non-public investigation to determine whether Brightstone Pharma, Inc. (Brightstone), Elan Corporation, plc or others may have engaged in an effort to restrain trade by entering into an agreement which may restrict the ability of Brightstone or others to market a bioequivalent or generic version of Naprelantm. 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

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have voluntarily provided documents and witness testimony in response to the subpoena and continue to cooperate with the FTC relating to this investigation. We do not believe that it is feasible to predict or determine the outcome of the investigation and any possible effect on our business, or to reasonably estimate the amounts or potential range of loss, if any, with respect to the resolution of the investigation.

In January 2006, Elan received a subpoena from the US Department of Justice and the Department of Health and Human Services, Office of Inspector General asking for documents and materials primarily related to our marketing practices for Zonegran. In April 2004, we completed the sale of our interests in Zonegran in North America and Europe to Eisai. We are cooperating with the government in its investigation. The resolution of this Zonegran matter could require Elan to pay substantial fines and to take other actions that could have a material adverse effect on Elan. In April 2006, Eisai delivered to Elan a notice making a contractual claim for indemnification in connection with a similar subpoena received by Eisai.

Product Approval

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

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

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

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

also subject to FDA approval and ongoing regulation.

In the United States, under the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act, the FDA receives fees for reviewing product applications and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For example, the NDA or BLA review fee alone can exceed \$0.5 million, although certain deferrals, waivers and

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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, 2006, we had manufacturing facilities in Ireland and the United States.

At December 31, 2006, we employed 543 people in our manufacturing and supply 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 US Drug Enforcement Administration for the manufacture, packaging and distribution of Schedule II controlled drugs.

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

In May 2001, Elan Holdings, Inc. (Elan Holdings), a wholly owned subsidiary of Elan, the late Donal J. Geaney, then chairman and chief executive officer of Elan, William C. Clark, then president, operations, and two then employees of Elan Holdings, Hal Herring and Cheryl Schuster, entered into a consent decree of permanent injunction with the US 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, Avinzatm once-daily, novel dual release morphine sulphate, RitalinLA[®] once-daily, pulsatile release of methylphenidate and Focalin XR[®]

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once daily dexamethylphenidate for treatment of Attention-Deficit Hyperactivity Disorder. The consent decree did not represent an admission by Elan Holdings of any of the allegations set forth in the decree. Under the terms of the consent decree, Elan Holdings is permanently enjoined from violating cGMP regulations. The consent decree was removed in 2006.

Patents and Intellectual Property Rights

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

These patents cover, for example:

Pharmaceutical active ingredients, products containing them and their uses;

Pharmaceutical formulations; and

Product manufacturing processes.

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

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

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

The fundamental US patent covering the use of *Prialt* to produce analgesia expires in 2011. A further US patent covering the stabilized formulation of *Prialt* expires in 2015. One of our patents covering *Prialt* may qualify for a US patent term extension of up to five years.

The basic US patent for *Maxipime* expires in March 2007. However, two US patents covering *Maxipime* formulations may provide patent protection until February 2008. The basic US patent for *Azactam* expired in October 2005. *Maxipime* and *Azactam* are expected to face generic competition, which is expected to have a substantial adverse effect on our revenues from, and gross margin for, these products.

The primary patents covering Elan's *NanoCrystal* technology expire in the United States in 2011 and in countries outside the United States in 2012. We also have numerous US and international patents and patent applications that

relate to our *NanoCrystal* drug optimization technology applicable to poorly water-soluble compounds.

In addition, we have a large patent estate resulting from our Alzheimer's disease research.

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

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Competition

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

Tysabri, a treatment for relapsing forms of MS, competes primarily with Avonex[®] marketed by our collaborator Biogen Idec; Betaseron[®] marketed by Berlex (an affiliate of Bayer Schering Pharma AG) in the United States and sold under the name Betaferon[®] by Bayer Schering Pharma in Europe; Rebif[®] marketed by Merck Serono and Pfizer in the United States and by Merck Serono in Europe; and Copaxone[®] marketed by Teva Neurosciences, Inc. (Teva) in the United States and co-promoted by Teva and Sanofi-Aventis in Europe. Many companies are working to develop new therapies or alternative formulations of products for MS, which if successfully developed would compete with *Tysabri*.

A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and, thereafter, it may be subject to further competition from generic products. Our product *Azactam* lost its basic US patent protection in October 2005. We expect that generic competition to *Azactam* will emerge in 2007 and will have a material and adverse effect on our sales of *Azactam*. The basic US patent for *Maxipime* expires in March 2007. However, two US patents covering *Maxipime* formulations may provide patent protection until February 2008. When a generic competitor for *Maxipime* enters the market, it will have a material and adverse effect on our sales of *Maxipime*.

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

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

Distribution

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

We often 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 are dependent on third-party manufacturers for 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.

Table of Contents***Employees***

On December 31, 2006, we had 1,734 employees worldwide, of whom 494 were engaged in R&D activities, 543 were engaged in manufacturing and supply activities, 328 were engaged in sales and marketing activities and the remainder worked in general and administrative areas.

C. Organizational Structure

At December 31, 2006, 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 Corp., Ltd.	Financial services company	100	Clarendon House 2 Church St Hamilton, Bermuda
Elan Drug Delivery, Inc.	R&D	100	3000 Horizon Drive King of Prussia, PA, United States
Elan Finance plc	Financial services company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Holdings, Inc.	Manufacture of pharmaceutical and medical device products	100	1300 Gould Drive Gainesville, GA, United States
Elan Holdings Ltd.	Holding company	100	Monksland, Athlone Co. Westmeath, Ireland
Elan International Services Ltd.	Financial services company	100	Clarendon House, 2 Church St Hamilton, Bermuda
Elan Management Ltd.	Provision of management services	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Pharma International Ltd.	R&D, manufacture, sale and distribution of pharmaceutical products and financial services	100	Monksland, Athlone Co. Westmeath, Ireland
Elan Pharmaceuticals, Inc.	R&D and sale of pharmaceutical products	100	800 Gateway Blvd South San Francisco, CA, United States
Monksland Holding BV	Financial services company	100	Amsteldijk 166 6th Floor

Neuralab Ltd.	Non-trading	100	1079 LH Amsterdam The Netherlands Clarendon House, 2 Church St Hamilton, Bermuda
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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 14 to the Consolidated Financial Statements, which discloses amounts invested in land and buildings and plant and equipment, Note 22 to the Consolidated Financial Statements, which discloses future minimum rental commitments, Note 27 to the Consolidated Financial Statements, which

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discloses capital commitments for the purchase of property, plant and equipment and Item 5 B. Liquidity and Capital Resources, which discloses our capital expenditures.

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

Location and Ownership Interest	Use	Size (Sq. Ft.)
Owned: Athlone, Ireland	R&D, manufacturing and administration	463,000
Owned: Gainesville, Georgia United States	R&D, manufacturing and administration	84,000
Leased: South San Francisco, California, United States	R&D and administration	213,000
Leased: King of Prussia, Pennsylvania, United States	R&D, manufacturing, sales and administration	113,000
Leased: San Diego, California, United States	Sales, marketing and administration	68,000
Leased: Stevenage, United Kingdom	Product development and administration	8,000
Leased: Dublin, Ireland	Corporate administration	20,000
Leased: New York City, New York, United States	Corporate administration	14,000

Item 4A. *Unresolved Staff Comments*

Not applicable.

Item 5. *Operating and Financial Review and Prospects*

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements, the accompanying notes thereto and other financial information, appearing in Item 18. Consolidated Financial Statements.

Our Consolidated Financial Statements contained in this Form 20-F have been prepared on the basis of US GAAP. In addition to the Consolidated Financial Statements contained in this Form 20-F, we also prepare separate Consolidated Financial Statements, included in our Annual Report, in accordance with IFRS, which differ in certain significant respects from US GAAP. The Annual Report under IFRS is a separate document from this Form 20-F.

This financial review primarily discusses:

Current operations;

Critical accounting policies;

Recently issued accounting pronouncements;

Post balance sheet events;

Results of operations for the year ended December 31, 2006 compared to 2005;

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

Segment analysis; 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 .

CURRENT OPERATIONS

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

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manufacturing to address drug optimization challenges of the pharmaceutical industry. For additional information on our current operations, please refer to Item 4B on pages 14 to 28.

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 and tangible fixed assets, revenue recognition, the accounting for contingencies, the fair value of share-based compensation 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, Tangible Fixed Assets and Impairment

We account for goodwill and identifiable intangible assets in accordance with the Financial Accounting Standards Board's (FASB) Statement No. 142, *Goodwill and Other Intangible Assets*, (SFAS 142). Pursuant to SFAS 142, goodwill and identifiable intangible assets with indefinite useful lives are no longer amortized, but instead are tested for impairment at least annually. Intangible assets with estimable useful lives are amortized on a straight-line basis over their respective estimated useful lives to their estimated residual values and reviewed for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

We review our goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. At December 31, 2006, we had no other intangible assets with indefinite lives.

The goodwill impairment test is performed at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment as defined by SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information*. We have two reporting units: Biopharmaceuticals and EDT. We compare the fair value of each reporting unit with its carrying value, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired. If the carrying amount of a reporting unit exceeds its fair value, the second step of the goodwill impairment test would be performed to measure the amount of impairment charge, if any. The second step compares the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill, and any excess of the carrying amount over the implied fair value is recognized as an impairment charge. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination is determined, by allocating the fair value of a reporting unit to individual assets and liabilities. The excess of the fair value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. The results of our goodwill impairment tests did not indicate any impairment in 2006.

There were no material impairment charges relating to intangible assets in either 2006, 2005 or 2004. For additional information on goodwill and other intangible assets, please refer to Note 15 to the Consolidated Financial Statements.

Total goodwill and other intangible assets amounted to \$575.9 million at December 31, 2006 (2005: \$665.5 million). If we were to use different estimates, particularly with respect to the likelihood of R&D success, the likelihood and date of commencement of generic competition or the impact of any reorganization or change of business focus, then a material impairment charge could arise. We believe that we have used reasonable estimates in assessing the carrying values of our intangible assets.

In January 2005, we launched *Prialt* in the United States. Revenues from sales of *Prialt* totaled \$12.1 million and \$6.3 million in 2006 and 2005, respectively. These revenues were lower than our initial forecast. Our estimates of the

fair value of this product, based on future net cash flows, are well in excess of the asset's carrying value of \$64.5 million at December 31, 2006. We believe that we have used reasonable estimates in assessing the carrying value of this intangible. Nevertheless, should our future revenues from this product fail to meet our expectations, the carrying value of this asset may become impaired.

We have invested significant resources in our manufacturing facilities in Ireland to provide us with the capability to manufacture products from our product development pipeline. To the extent that we are not successful

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in developing these pipeline products or do not acquire products to be manufactured at our facilities, the carrying value of these facilities may become impaired. At December 31, 2006, our best estimates of the likely success of development and commercialization of our pipeline products support the carrying value of our manufacturing facilities.

Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements in accordance with the SEC's Staff Accounting Bulletin No. 104, Revenue Recognition, (SAB 104), which requires the deferral and amortization of up-front fees when there is a significant continuing involvement (such as an ongoing product manufacturing contract) by the seller after an asset disposal. We 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 apply the proportional performance 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.

Share-based Compensation

On January 1, 2006, we adopted SFAS No. 123 (revised 2004), Share-Based Payment, (SFAS 123R) which requires the measurement and recognition of compensation expense for all share-based awards made to employees and directors based on estimated fair values. These awards include employee stock options, Restricted Stock Units (RSUs) and stock purchases related to our employee equity purchase plans. SFAS 123R supersedes our previous accounting under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, (APB 25) beginning January 1, 2006. In March 2005, the SEC issued SAB No. 107, Share-based Payment, (SAB 107) relating to SFAS 123R. We have applied the provisions of SAB 107 in our adoption of SFAS 123R.

We adopted SFAS 123R using the modified prospective transition method, which requires that share-based compensation expense be recorded for (a) any share-based awards granted through but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the pro-forma provisions of SFAS No. 123, Accounting for Stock-Based Compensation, (SFAS 123), and (b) any share-based awards granted or modified subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Our Consolidated Financial Statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, our Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R. The adoption of SFAS 123R has had a material effect on our reported financial results. Share-based compensation expense recognized under SFAS 123R for the year ended December 31, 2006 was \$47.1 million. See Note 26 to the Consolidated Financial Statements for additional information.

SFAS 123R requires companies to estimate the fair values of share-based awards on the date of grant using an option-pricing model. The value of awards expected to vest is recognized as an expense over the requisite service periods. Prior to the adoption of SFAS 123R, we accounted for share-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS 123. Under the intrinsic value method, no share-based compensation expense had been recognized in our Consolidated Statement of Operations, other than as related to modifications and compensatory employee equity purchase plans, because the exercise price

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of the stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

Estimating the fair value of share-based awards as of the date of grant using an option-pricing model, such as the binomial model, is affected by our stock price as well as assumptions regarding a number of complex variables. These variables include, but are not limited to, the expected stock price volatility over the term of the awards, risk-free interest rates, and actual and projected employee exercise behaviors. If factors change and/or we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R for future grants may differ significantly from what we have recorded in the Consolidated Financial Statements. However, we believe we have used reasonable assumptions to estimate the fair value of our share-based awards.

Contingencies Relating to Actual or Potential Administrative and Legal Proceedings

We are currently involved in legal and administrative proceedings, relating to securities matters, patent matters, antitrust matters and other matters, as described in Note 28 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 nor a minimum amount of loss is estimable, then appropriate disclosure is provided, but no amounts are accrued. As of December 31, 2006, we had accrued \$5.0 million, representing our estimates of liability and costs for the resolution of these matters. We developed estimates in consultation with outside counsel handling our defense in these matters using the 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 assessment of the science subject to the litigation, and the likelihood of settlement and 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 estimates, depending on the outcome of these matters.

Sales Discounts and Allowances

We recognize revenue on a gross revenue basis and make various deductions to arrive at net revenue as reported in the Consolidated Statements of Operations. These adjustments are referred to as sales discounts and allowances and are described in detail below. Sales discounts and allowances include charge-backs, managed health care and Medicaid rebates, cash discounts, sales returns and other adjustments. Estimating these sales discounts and allowances is complex and involves significant estimates and judgments, and we use information from both internal and external sources to generate reasonable and reliable estimates. We believe that we have used reasonable judgments in assessing our estimates, and this is borne out by our historical experience. At December 31, 2006, we had total provisions of \$16.5 million for sales discounts and allowances, of which approximately 65.6% and 27.6% related to *Maxipime* and *Azactam*, respectively. We have over eight years of experience in relation to *Maxipime* and *Azactam*. The sales discounts and allowances related to *Tysabri* are estimated based on historical data of a similar product and our experience to date with this product. We do not expect *Tysabri* sales returns to be material given the manner in which this product is prescribed and used.

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.

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

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

	Years Ended December 31,		
	2006	2005	2004
Gross revenue subject to discounts and allowances	\$ 311.3	\$ 273.2	\$ 291.7
Manufacturing revenue and royalties	234.8	207.1	130.9
Contract revenue	27.5	32.2	77.3
Amortized revenue Adalat/Avinza	30.7	34.0	34.0
Gross revenue	\$ 604.3	\$ 546.5	\$ 533.9
Sales discounts and allowances:			
Charge-backs	\$ (28.6)	\$ (22.8)	\$ (24.6)
Managed health care rebates and other contract discounts	(3.7)	(2.9)	(5.1)
Medicaid rebates	(1.2)	(1.6)	(8.2)
Cash discounts	(6.5)	(5.5)	(5.6)
Sales returns	(0.6)	(20.9)	(7.1)
Other adjustments	(3.3)	(2.5)	(1.6)
Total sales discounts and allowances	\$ (43.9)	\$ (56.2)	\$ (52.2)
Net revenue subject to discounts and allowances	267.4	217.0	239.5
Manufacturing revenue and royalties	234.8	207.1	130.9
Contract revenue	27.5	32.2	77.3
Amortized revenue Adalat/Avinza	30.7	34.0	34.0
Net revenue	\$ 560.4	\$ 490.3	\$ 481.7

Total sales discounts and allowances increased from 17.9% of gross revenue subject to discounts and allowances in 2004 to 20.6% in 2005, and decreased to 14.1% in 2006, as detailed in the rollforward below and as further explained in the following paragraphs.

Charge-backs decreased slightly as a percentage of gross revenue subject to discounts and allowances from 8.4% in 2004 to 8.3% in 2005, and increased to 9.2% in 2006. The managed health care and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances have declined from 1.7% and 2.8%, respectively, in 2004, to 1.1% and 0.6% in 2005, and to 1.2% and 0.4% in 2006, respectively. These changes are due primarily to changes in the product mix.

Cash discounts as a percentage of gross revenue subject to discounts and allowances remained fairly consistent at 1.9% in 2004, compared to 2.0% in 2005 and to 2.1% in 2006. In the United States, we offer cash discounts, generally at 2% of the sales price, as an incentive for prompt payment by our customers.

Sales returns as a percentage of gross revenue subject to discounts and allowances increased from 2.4% in 2004 to 7.6% in 2005, and decreased to 0.2% in 2006. The increase in 2005, compared to 2004 and 2006, was principally due to the voluntary suspension of *Tysabri* in February 2005, which increased the provision for returns in 2005, and changes in the product mix.

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

	Charge-Backs	Managed Health Care Rebates and Other Contract Discounts	Medicaid Rebates	Cash Discounts	Sales Returns	Other Adjustments	Total
Balance at December 31, 2004	\$ 8.9	\$ 2.1	\$ 1.7	\$ 0.4	\$ 8.6	\$ 0.4	\$ 22.1
Provision related to sales made in current period	22.8	2.9	1.6	5.5	22.4	2.5	57.7
Provision related to sales made in prior periods					(1.5)		(1.5)
Returns and payments	(24.9)	(3.3)	(1.9)	(5.0)	(22.8)	(2.4)	(60.3)
Divestments	(0.1)	(0.3)	(0.3)		(0.1)		(0.8)
Balance at December 31, 2005	6.7	1.4	1.1	0.9	6.6	0.5	17.2
Provision related to sales made in current period	28.6	3.7	1.2	6.5	2.3	3.3	45.6
Provision related to sales made in prior periods					(1.7)		(1.7)
Returns and payments	(28.6)	(3.5)	(1.4)	(6.3)	(2.0)	(2.8)	(44.6)
Balance at December 31, 2006	\$ 6.7	\$ 1.6	\$ 0.9	\$ 1.1	\$ 5.2	\$ 1.0	\$ 16.5

(a) Charge-backs

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

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, 2006, *Maxipime* and *Azactam* represented approximately 91.7% and 7.2%, respectively, of the total charge-backs accrual balance of \$6.7 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for *Maxipime* and *Azactam*, the accrual for charge-backs would increase/(decrease) by approximately \$2.7 million. We believe that our estimate of the levels of inventory for *Maxipime* and *Azactam* in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

(b) Managed health care rebates and other contract discounts

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

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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, 2006, *Maxipime* and *Azactam* represented approximately 67.7% and 29.2%, respectively, of the total managed health care rebates and other contract discounts accrual balance of \$1.6 million. If we were to increase/(decrease) our estimated level of inventory in the distribution channel by one month's worth of demand for *Maxipime* and *Azactam*, the accrual would increase/(decrease) by approximately \$0.3 million. We believe that our estimate of the levels of inventory for *Maxipime* and *Azactam* in the distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

(c) Medicaid rebates

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

(d) Cash discounts

In the United States, we offer cash discounts, generally at 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount of the discounts. We consider payment performance of each customer and adjust the accrual and revenue periodically throughout each year to reflect actual experience and future estimates.

(e) Sales returns

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

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

In the event of a product recall, product discontinuance or introduction of a generic product, we consider a number of factors, including the estimated level of inventory in the distribution channel that could potentially be returned, historical experience, estimates of the severity of generic product impact, estimates of continuing demand and our

return goods policy. We consider the reasons for, and impact of, such actions and adjust the sales returns accrual and revenue as appropriate.

Returns from newly introduced products are significantly more difficult for us to assess. We determine our estimate of the sales return accrual primarily based on the historical sales returns experience of similar products, such as those within the same or similar therapeutic category. We also consider the shelf life of new products and

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

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the shelf life of inventory in the distribution channel. At December 31, 2006, *Maxipime* and *Azactam* represented approximately 32.5% and 63.3%, respectively, of the total sales returns accrual balance of \$5.2 million. At December 31, 2006, we have estimated the gross revenue value of *Maxipime* and *Azactam* inventory in the distribution channel to be approximately \$22.5 million (2005: \$32.1 million) and \$10.0 million (2005: \$5.5 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 2008 (gross revenue value approximately \$1.5 million) and 2009 (gross revenue value approximately \$31.0 million). *Azactam* lost its patent exclusivity in October 2005; however, to date no generic *Azactam* product has been approved. We believe, based upon both the estimated shelf life and also our historical sales returns experience, that the vast majority of this inventory will be sold prior to its expiration date, and accordingly believe that our sales returns accrual is appropriate.

(f) Other adjustments

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

(g) Provisions related to sales made in prior periods

During 2006, we recorded \$1.7 million of adjustments to reduce the discounts and allowances related to sales made in prior periods, primarily due to the availability of additional information relating to our actual returns experience for *Maxipime* and *Azactam*.

(h) Divestments

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

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(i) Use of information from external sources

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

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

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

Our internal information.

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

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial and Financial Liabilities*, (SFAS 159), which is effective as of the beginning of fiscal years beginning after November 15, 2007. SFAS 159 provides companies with the option to measure specified financial instruments and warranty and insurance contracts at fair value on a contract-by-contract basis, with changes in fair value recognized in earnings each reporting period. We are currently evaluating the provisions of SFAS 159, however we do not expect that its adoption will have a material impact on our financial position or results of operations.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements*, (SFAS 157), which is effective for financial statements issued for fiscal years beginning after November 15, 2007. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. We do not expect that the adoption of SFAS 157 will have a material impact on our financial position or results from operations.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, (FIN 48), which is effective for fiscal years beginning after December 15, 2006. FIN 48 applies to all tax positions related to income taxes subject to Statement No. 109, *Accounting for Income Taxes*. Under FIN 48, a company would recognize the benefit from a tax position only if it is more-likely-than-not that the position would be sustained upon audit based solely on the technical merits of the tax position. FIN 48 clarifies how a company would measure the income tax benefits from the tax positions that are recognized, provides guidance as to the timing of the derecognition of previously recognized tax benefits and describes the methods for classifying and disclosing the liabilities within the financial statements for any unrecognized tax benefits. FIN 48 also addresses when a company should record interest and penalties related to tax positions and how the interest and penalties may be classified within the income statement

and presented in the balance sheet. We do not expect that the adoption of FIN 48 will have a material impact on our financial position or results from operations.

In September 2006, the FASB issued Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB No. 87, 88, 106 and 132R*, (SFAS 158). SFAS 158 requires that the funded status of defined benefit postretirement plans be recognized on the company's balance sheet, and changes in the funded status be reflected in comprehensive income, effective fiscal years ending after December 15, 2006. The standard also requires companies to measure the funded status of the plan as of the date of

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its fiscal year-end, effective for fiscal years ending after December 15, 2008. We adopted SFAS 158 as of December 31, 2006. See Note 26 to the Consolidated Financial Statements for additional details.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements*, (SAB 108) which provides interpretive guidance on how registrants should quantify financial statement misstatements. Under SAB 108 registrants are required to consider both a rollover method which focuses primarily on the income statement impact of misstatements and the iron curtain method which focuses primarily on the balance sheet impact of misstatements. The transition provisions of SAB 108 permit a registrant to adjust retained earnings for the cumulative effect of immaterial errors relating to prior years. We were required to adopt SAB 108 in our current fiscal year. There were no historical uncorrected differences that required correction upon adoption of SAB 108 and consequently there were no changes made to the opening retained earnings balance.

In May 2005, the FASB issued Statement No. 154, *Accounting Changes and Error Corrections*, (SFAS 154), which changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles required recognition via a cumulative effect adjustment within net income of the period of the change. SFAS 154 requires retrospective application to prior periods financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. However, SFAS 154 does not change the transition provisions of any existing accounting pronouncements. The provisions were effective for Elan beginning in the first quarter of fiscal year 2006.

POST BALANCE SHEET EVENTS

In December 2006, Elan issued an early redemption notice for the 7.25% senior notes (Athena Notes), which were due in February 2008. In January 2007, the remaining aggregate principal amount of \$613.2 million of the Athena Notes was redeemed and the related \$300.0 million of interest rate swaps were cancelled. As a result, Elan will record a net charge on debt retirement of approximately \$20 million in 2007. As of December 31, 2006, the \$613.2 million of aggregate principal amount for the Athena Notes were classified as current liabilities.

Table of Contents**A. OPERATING RESULTS***2006 Compared to 2005 (in millions, except share and per share amounts)*

	2006	2005	% Increase/ (Decrease)
Product revenue	\$ 532.9	\$ 458.1	16%
Contract revenue	27.5	32.2	(15)%
Total revenue	560.4	490.3	14%
Operating expenses:			
Cost of sales	211.2	196.1	8%
Selling, general and administrative expenses	363.1	358.4	1%
Research and development expenses	215.9	233.3	(7)%
Net gain on divestment of products and businesses	(43.1)	(103.4)	(58)%
Other net (gains)/charges	(20.3)	4.4	(561)%
Total operating expenses	726.8	688.8	6%
Operating loss	(166.4)	(198.5)	(16)%
Net interest and investment (gains) and losses:			
Net interest expense	111.5	125.7	(11)%
Net investment (gains)/losses	(1.6)	7.2	(122)%
Net charge on debt retirements		51.8	(100)%
Net interest and investment losses	109.9	184.7	(41)%
Loss from continuing operations before provision for/(benefit from) income taxes	(276.3)	(383.2)	(28)%
Provision for/(benefit from) income taxes	(9.0)	1.0	(1,000)%
Net loss from continuing operations	(267.3)	(384.2)	(30)%
Net income from discontinued operations (net of tax)		0.6	(100)%
Net loss	\$ (267.3)	\$ (383.6)	(30)%
Basic and diluted net loss per ordinary share:			
Net loss from continuing operations	\$ (0.62)	\$ (0.93)	(33)%
Net income from discontinued operations (net of tax)			
Net loss	\$ (0.62)	\$ (0.93)	(33)%

Table of Contents**Product Revenue**

Total product revenue increased 16% to \$532.9 million in 2006 from \$458.1 million in 2005. The increase was primarily due to the growth of revenue from marketed products and manufacturing revenue and royalties, partially offset by a decrease in amortized revenue. The components of product revenue are set out below (in millions):

	2006	2005	% Increase/ (Decrease)
(A) Marketed products			
Tysabri- US	\$ 28.2	\$ 11.0	156%
Tysabri- EU	(10.7)		
Maxipime	159.9	140.3	14%
Azactam	77.9	57.7	35%
Prialt	12.1	6.3	92%
Total revenue from marketed products	267.4	215.3	24%
(B) Manufacturing revenue and royalties	234.8	207.1	13%
(C) Amortized revenue Adalat/Avinza	30.7	34.0	(10)%
Revenue from divested products ⁽¹⁾		1.7	(100)%
Total product revenue	\$ 532.9	\$ 458.1	16%

(1) Products described as *Divested Products* include products or businesses divested since the beginning of 2004.

(A) Revenue from marketed products

Total revenue from marketed products increased 24% to \$267.4 million in 2006 from \$215.3 million in 2005. The increase reflects higher sales of *Tysabri*, *Maxipime*, *Azactam* and *Prialt*.

In June 2006, the FDA approved the re-introduction of *Tysabri* for the treatment of relapsing forms of MS. Approval for the marketing of *Tysabri* in the European Union was also received in June 2006 and, in October 2006, approval was received for the marketing of *Tysabri* in Canada. The distribution of *Tysabri* in both the United States and European Union commenced in July 2006. Global in-market net sales of *Tysabri* in 2006 were \$38.1 million, consisting of \$28.2 million in the United States and \$9.9 million in the European Union, compared to \$11.0 million in 2005.

Tysabri was developed and is now being marketed in collaboration with Biogen Idec. In general, subject to certain limitations imposed by the parties, we share with Biogen Idec most development and commercialization costs. Biogen Idec is responsible for manufacturing the product. In the United States, we purchase *Tysabri* from Biogen Idec and are responsible for distribution. Consequently, we record as revenue the net sales of *Tysabri* in the US market. We purchase product from Biogen Idec as required at a price which includes the cost of manufacturing, plus Biogen Idec's gross profit on *Tysabri* and this cost, together with royalties payable to other third parties, is included in cost of sales. During 2006, Elan recorded net sales of \$28.2 million (2005: \$11.0 million) in the US market.

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In the EU market, Biogen Idec is responsible for distribution and we record as revenue our share of the profit or loss on EU sales of *Tysabri*, plus our directly-incurred expenses on these sales. In 2006, Elan recorded negative revenue of \$10.7 million (2005: \$Nil), which was calculated as follows:

	2006
EU in-market sales by Biogen Idec	\$ 9.9
EU operating expenses incurred by Elan and Biogen Idec	(34.3)
EU operating loss incurred by Elan and Biogen Idec	(24.4)
Elan's 50% share of Tysabri EU collaboration operating loss	(12.2)
Elan's directly-incurred costs	1.5
Net Tysabri EU negative revenue	\$ (10.7)

Maxipime revenue increased 14% to \$159.9 million in 2006 from \$140.3 million in 2005. The increase primarily reflects growth in the demand for the product. The basic patent on *Maxipime* will expire in March 2007. Two other US patents covering *Maxipime* formulations expire in February 2008. We expect generic competition for the product, which is expected to adversely impact future revenues.

Azactam revenue increased 35% to \$77.9 million in 2006 from \$57.7 million in 2005 primarily due to increased demand. *Azactam* lost its patent exclusivity in October 2005 and its sales are expected to be adversely impacted by generic competition. However, to date, no generic *Azactam* product has been approved.

Prialt revenue increased to \$12.1 million in 2006 from \$6.3 million in 2005, which was primarily due to increased demand. *Prialt* was launched in the US market in the first quarter of 2005. In March 2006, we completed the sale of the European rights to *Prialt* to Eisai, while retaining the product rights in the United States. We had not made any commercial sales of *Prialt* in Europe prior to this divestment.

(B) Manufacturing revenue and royalties

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

	2006	2005	% Increase/ (Decrease)
Tricor	\$ 52.1	\$ 45.4	15%
Skelaxin™	36.5	17.9	104%
Verelan™	36.3	34.7	5%
Focalin/Ritalin	22.5	17.8	26%
Diltiazem	19.5	18.6	5%
Other	67.9	72.7	(7)%

Total	\$ 234.8	\$ 207.1	13%
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Manufacturing revenue and royalties from our EDT business comprises revenue earned from products we manufacture for third parties and royalties we earn principally on sales by third parties of products that incorporate our technologies.

Manufacturing revenue and royalties increased 13% to \$234.8 million in 2006 from \$207.1 million in 2005. The increase was primarily due to increased royalties on sales by third parties, primarily Tricor and Skelaxin, and increased manufacturing activity. In January 2006, our royalty on Skelaxin changed from 5% on all net sales of the product by King Pharmaceuticals, Inc. (King) in 2005, to 10% on net sales in excess of \$50.0 million in each calendar year going forward. Except as noted above, no other single product accounted for more than 10% of our manufacturing revenue and royalties in either 2006 or 2005. In 2006, 40% of these revenues consisted of royalties received on products that we do not manufacture, compared to 34% in 2005.

Table of Contents***(C) Amortized revenue Adalat/Avinza***

Amortized revenue of \$30.7 million in 2006 (2005: \$34.0 million) 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) (\$21.7 million). Both of these transactions occurred in 2002. The remaining \$4.5 million of unamortized deferred revenue relating to Adalat CC will be recognized as revenue during 2007. The deferred revenue relating to Avinza was fully amortized by December 31, 2006.

Contract Revenue

	2006	2005	% Increase/ (Decrease)
	(In millions)		
Amortized fees	\$ 12.7	\$ 16.4	(23)%
Research revenues/milestones	14.8	15.8	(6)%
Total contract revenue	\$ 27.5	\$ 32.2	(15)%

Contract revenue consists of research revenue and milestones arising from R&D activities we perform on behalf of third parties. The decrease in contract revenue was primarily due to the timing of milestone receipts and a reduction in R&D activities for third parties.

Cost of Sales

Cost of sales was \$211.2 million in 2006 (including share-based compensation of \$4.2 million), compared to \$196.1 million in 2005 (including share-based compensation of \$Nil). The cost of sales as a percentage of product revenue was 40% for 2006 and 43% for 2005, resulting in a gross profit margin of 60% in 2006 and 57% in 2005. The improvement in gross profit margin was primarily due to the change in the mix of product sales and the inclusion in 2005 of costs related to the voluntary suspension of *Tysabri* in the United States.

Selling, General and Administrative Expenses (SG&A)

SG&A expenses were \$363.1 million in 2006, compared to \$358.4 million in 2005, and included \$75.0 million (2005: \$84.7 million) in relation to *Tysabri*. The increase in total SG&A expenses reflects the expensing of share-based compensation of \$28.8 million in 2006 (2005: \$Nil), offset by decreased expenses in relation to *Tysabri* and also due to ongoing financial discipline. The decrease in SG&A expenses related to *Tysabri* reflects the impact of the temporary suspension of *Tysabri* in 2005, the re-launch of *Tysabri* in the United States in 2006, and the launch of *Tysabri* in the European Union in 2006, partially offset by the expensing of shared-based compensation of \$2.5 million (2005: \$Nil).

Research and Development Expenses

R&D expenses were \$215.9 million in 2006, compared to \$233.3 million in 2005, and included \$31.6 million (2005: \$66.9 million) in relation to *Tysabri*. This reduction of 7% reflects the completion of the safety evaluation related to

Tysabri in 2005, offset by increased spending relating to the progression of key Alzheimer's programs, particularly AAB-001, the initiation of new collaborations in the areas of autoimmune diseases and neurodegeneration with Archemix and Transition, and by the cost of expensing share-based compensation of \$14.1 million in 2006 (2005: \$Nil).

Table of Contents***Net Gain on Divestment of Products and Businesses***

	2006	2005
	(In millions)	
Prialt European rights	\$ (43.3)	\$
Zonegran		(85.6)
European business	0.2	(17.1)
Other		(0.7)
Total	\$ (43.1)	\$ (103.4)

In March 2006, we sold the *Prialt* European rights to Eisai. We received \$50.0 million at closing and are entitled to receive an additional \$10.0 million on the earlier of two years from closing or launches of *Prialt* in key European markets. We recorded a gain of \$43.3 million on this sale. We may also receive an additional \$40.0 million contingent on *Prialt* achieving revenue related milestones in Europe. As of December 31, 2006, we have received \$4.0 million of the \$10.0 million related to the launches of *Prialt* in key European markets.

In April 2004, we sold our interests in Zonegran in North America and Europe to Eisai for initial net consideration of \$113.5 million at closing. We were also entitled to receive additional consideration of up to \$110.0 million from Eisai if no generic Zonegran was approved by certain dates up through January 1, 2006. We received \$85.0 million of this contingent consideration prior to the approval of generic Zonegran in December 2005. Consequently, the total net proceeds received from the sale of Zonegran amounted to \$198.5 million and resulted in a cumulative net gain of \$128.5 million, of which \$85.6 million was recognized in 2005 and \$42.9 million in 2004.

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

Other Net (Gains)/Charges

The principal items classified as other charges/(gains) include acquired in-process research and development, severance, restructuring and other costs, legal settlements and awards, and losses incurred from certain litigation or regulatory actions. These items have been treated consistently from period to period. We believe that disclosure of significant other charges/(gains) is meaningful because it provides additional information in relation to these material items.

	2006	2005
	(In millions)	
(A) Acquired in-process research and development costs	\$ 22.0	\$
(B) Legal settlements and awards	(49.8)	(7.4)
(C) Severance, restructuring and other costs, net	7.5	11.8

Total other net (gains)/charges	\$ (20.3)	\$ 4.4
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(A) Acquired in-process research and development costs

In July 2006, Elan and Archemix entered into a multi-year, multi-product alliance focused on the discovery, development and commercialization of aptamer therapeutics to treat autoimmune diseases. As a result of the alliance, Elan paid Archemix an upfront payment of \$7.0 million. In addition, in September 2006, Elan and Transition announced an exclusive, worldwide collaboration agreement for the joint development and commercialization of AZD-103, for the treatment of Alzheimer's disease. Elan incurred a charge related to the license fee of \$15.0 million, of which \$7.5 million was paid to Transition in the fourth quarter of 2006 and the

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remaining balance is due to be paid in 2007. For additional information, please refer to Item 4B. Business Overview, which describes our R&D programs in detail.

(B) Legal settlements and awards

In December 2006, we were awarded \$49.8 million following the conclusion of binding arbitration proceedings which were initiated against King with respect to an agreement to reformulate Sonata[®]. This award was recognized as a gain in 2006 and was received in January 2007.

During 2005, we recorded a net gain of \$7.4 million related primarily to the Pfizer litigation settlement in which we received a payment of \$7.0 million. The settlement arose from a claim concerning intellectual property rights and the development of target compounds arising from a collaboration with Pfizer.

(C) Severance, restructuring and other costs

During 2006, we incurred net severance, restructuring and other costs of \$7.5 million (2005: \$11.8 million) arising from the realignment of our resources to meet our current business structure. The restructuring and severance charges in 2006 were primarily related to the consolidation of our Biopharmaceuticals R&D activities into our South San Francisco facility. These charges arose from termination of certain operating leases, reduction and relocation of employees, and they include the reversal of a \$9.4 million charge for future lease payments on an unutilized facility in South San Francisco. As a part of the restructuring of our Biopharmaceutical R&D activities, this facility has now been brought back into use.

Net Interest Expense

Net interest expense was \$111.5 million in 2006, compared to \$125.7 million in 2005. The decrease of 11% primarily reflects the decrease in interest expense associated with the early retirement of \$36.8 million of the Athena Notes due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of 6.5% Convertible Notes in the second quarter of 2005 and increased income associated with higher cash balances and interest rates, partially offset by interest expense related to the 8.875% senior notes due in 2013 (8.875% Notes) and senior floating rate notes due in 2013 (Floating Rate Notes due 2013), both of which were issued in November 2006.

Net Investment (Gains)/Losses

Net investment gains were \$1.6 million in 2006, compared to a loss of \$7.2 million in 2005. The net investment gains were primarily comprised of gains on the sale and maturity of investment securities of \$8.3 million (2005: \$17.5 million) and impairment of investments of \$7.3 million (2005: \$24.0 million). In 2006, we raised \$14.1 million (2005: \$62.7 million) in net cash proceeds from the disposal of investment securities. The \$8.3 million in gains on the sale and maturity of investment securities in 2006 includes gains on sale of securities of Salu, Inc. of \$3.0 million, Nobex Corporation of \$2.5 million and Women First Healthcare, Inc. of \$1.0 million. The \$17.5 million of gains on the sale and maturity of investment securities in 2005 included a gain on the sale of securities of Allergy Therapeutics plc of \$10.0 million, Iomai Corporation of \$3.2 million and Emisphere Technologies, Inc. of \$1.8 million.

During 2006, investment impairment charges of \$7.3 million (2005: \$24.0 million) reflect other-than-temporary impairments to the value of a number of investments, primarily in emerging pharmaceutical and biotechnology companies.

Net Charge on Debt Retirements

In June 2005, we incurred a net charge of \$51.8 million associated with the early retirement of \$36.8 million of the Athena Notes due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of the 6.5% Convertible Notes due in 2008. For additional information, please refer to Note 18 to the Consolidated Financial Statements.

Table of Contents***Provision for/(Benefit from) Income Taxes***

We had a net tax benefit of \$9.0 million for 2006, compared to a net tax provision of \$1.0 million for 2005. The overall tax benefit for 2006 was \$11.0 million. Of this amount, \$2.0 million has been credited to shareholders' equity to reflect utilization of stock option deductions. The remaining \$9.0 million benefit is allocated to ordinary activities. The tax benefit reflected the availability of tax losses, tax at standard rates in the jurisdictions in which we operate, income derived from Irish patents and foreign withholding tax. Our Irish patent derived income was exempt from tax pursuant to Irish legislation, which exempts from Irish tax income derived from qualifying patents. Currently, there is no termination date in effect for such exemption. For additional information regarding tax, please refer to Note 21 to the Consolidated Financial Statements.

2005 Compared to 2004 (in millions, except share and per share amounts)

	2005	2004	% Increase/ (Decrease)
Product revenue	\$ 458.1	\$ 404.4	13%
Contract revenue	32.2	77.3	(58)%
Total revenue	490.3	481.7	2%
Operating expenses:			
Cost of sales	196.1	173.6	13%
Selling, general and administrative expenses	358.4	337.3	6%
Research and development expenses	233.3	257.3	(9)%
Net gain on sale of products and businesses	(103.4)	(44.2)	134%
Other net (gains)/charges	4.4	59.8	(93)%
Total operating expenses	688.8	783.8	(12)%
Operating loss	(198.5)	(302.1)	(34)%
Net interest and investment (gains) and losses:			
Net interest expense	125.7	109.0	15%
Net investment (gains)/losses	7.2	(42.8)	117%
Net charge on debt retirements	51.8		
Charge arising from guarantee to EPIL II noteholders		47.1	(100)%
Net interest and investment losses	184.7	113.3	63%
Loss from continuing operations before provision for/(benefit from) income taxes	(383.2)	(415.4)	(8)%
Provision for/(benefit from) income taxes	1.0	(1.7)	159%
Net loss from continuing operations	(384.2)	(413.7)	(7)%
Net income from discontinued operations (net of tax)	0.6	19.0	(97)%

Net loss	\$ (383.6)	\$ (394.7)	(3)%
Basic and diluted net loss per ordinary share:			
Net loss from continuing operations	\$ (0.93)	\$ (1.06)	(12)%
Net income from discontinued operations (net of tax)		0.05	(100)%
Net loss	\$ (0.93)	\$ (1.01)	(8)%

Product Revenue

The increase of 13% in total product revenue in 2005 was primarily due to the growth of product revenue from our core business. Product revenue from our core business increased 34% from 2004 and more than compensated

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for the loss of revenue from products divested during 2004. The components of product revenue are set out below (in millions):

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

(1) Products described as *Divested Products* include products or businesses divested since the beginning of 2004.

(2) Sold to Zeneus in February 2004.

(3) Sold to Eisai in April 2004.

(A) Revenue from marketed products

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

Maxipime revenue increased from \$117.5 million in 2004 to \$140.3 million in 2005. The 19% increase reflects growth in demand, a price increase of 8% taken at the end of 2004, and improved supply conditions. We experienced third

party supply shortages and disruptions with *Maxipime* during 2005. This led to a significant decline in inventories held by our wholesale customers and hospitals and, consequently, affected our ability to meet demand. The supply situation improved beginning in the third quarter of 2005.

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

The FDA granted accelerated approval of *Tysabri* in late November 2004 for the treatment of patients in the United States with all forms of relapsing remitting MS. Revenue from *Tysabri* amounted to \$11.0 million in 2005 and \$6.4 million in 2004. The commercialization and clinical dosing of *Tysabri* was voluntarily suspended in February 2005. On March 7-8, 2006, the PCNS Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS. In June 2006, the FDA approved the re-introduction of *Tysabri* for the treatment of relapsing forms of MS. Approval for the marketing of *Tysabri* in the European Union was also received in June 2006, and in October 2006, approval was received for the

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marketing of *Tysabri* in Canada. The distribution of *Tysabri* in both the United States and European Union commenced in July 2006.

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

(B) Manufacturing revenue and royalties

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

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

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

(C) Amortized revenue - Adalat/Avinza

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

(D) Divested products

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

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

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

Table of Contents***Contract Revenue***

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

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

Cost of Sales

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

Selling, General and Administrative Expenses

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

Research and Development Expenses

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

Net Gain on Sale of Businesses

	2005	2004
	(In millions)	
Zonegran	\$ (85.6)	\$ (42.9)
European business	(17.1)	2.9

Other	(0.7)	(4.2)
Total	\$ (103.4)	\$ (44.2)

In April 2004, we sold our interests in Zonegran in North America and Europe to Eisai for initial net consideration of \$113.5 million at closing. We were also entitled to receive additional consideration of up to \$110.0 million from Eisai if no generic Zonegran was approved by certain dates up through January 1, 2006. We received \$85.0 million of this contingent consideration prior to the approval of generic Zonegran in December 2005. Consequently, the total net proceeds received from the sale of Zonegran amounted to \$198.5 million and resulted in a cumulative net gain of \$128.5 million, of which \$85.6 million was recognized in 2005 and \$42.9 million in 2004.

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

Table of Contents***Other Net (Gains)/Charges***

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

	2005	2004
	(In millions)	
(A) Pfizer litigation settlement, shareholder litigation, and SEC investigation	\$ (7.4)	\$ 56.0
(B) Severance, restructuring and other costs	11.8	3.8
Total other net charges	\$ 4.4	\$ 59.8

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

During 2005, we recorded a net gain of \$7.4 million related primarily to the Pfizer litigation settlement in which we received a payment of \$7.0 million. The settlement arose from a claim concerning intellectual property rights and the development of target compounds arising from a collaboration with Pfizer.

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

We were also the subject of an investigation by the SEC's Division of Enforcement regarding matters similar to those alleged in the class action. We provisionally settled the investigation in October 2004 and the SEC formally approved the settlement in February 2005. Under the settlement agreement reached with the SEC, we neither admitted nor denied the allegations contained in the SEC's civil complaint, which included allegations of violations of certain provisions of the federal securities laws. The settlement contains a final judgment restraining and enjoining us from future violations of these provisions. In addition, under the final judgment, we paid a civil penalty of \$15.0 million. In connection with the settlement, we were not required to restate or adjust any of our historical financial results or information.

For additional information on litigation which we are involved in, please refer to Note 28 to the Consolidated Financial Statements.

(B) Severance, restructuring and other costs

During 2005, we incurred severance, restructuring and other costs of \$11.8 million arising from the realignment of our resources to meet our current business structure. These expenses arose from termination of certain operating leases and a reduction in employee headcount.

During 2004, we incurred severance, restructuring and other costs arising from the implementation of our recovery plan of \$3.8 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 headcount.

Table of Contents***Net Interest Expense***

Net interest expense was \$125.7 million in 2005, compared to \$109.0 million in 2004. The increase of 15% primarily reflects the interest costs associated with the issuance of \$850.0 million of 7.75% senior fixed rate notes (7.75% Notes) and \$300.0 million of senior floating rate notes due in 2011 (Floating Rate Notes due 2011) in November 2004, partially offset by the impact of the repayment of the Elan Pharmaceutical Investments III Ltd. (EPIL III) Series B and C guaranteed notes (collectively, EPIL III Notes) in November 2004, the early retirement of \$36.8 million of the Athena Notes due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of 6.5% Convertible Notes due in 2008 in the second quarter of 2005, and increased interest income associated with higher cash balances and interest rates.

Net Investment (Gains)/Losses

Net investment losses were \$7.2 million in 2005, compared to net investment gains of \$42.8 in 2004. The net investment losses in 2005 comprised primarily of gains on sale and maturity of investment securities of \$17.5 million (2004: \$106.2) and impairment of investments of \$24.0 million (2004: \$72.4 million). In 2005, we raised \$62.7 million (2004: \$255.5 million) in net cash proceeds from the disposal of investment securities. The \$17.5 million in gains on the sale and maturity of investment securities in 2005 includes gains on the sale of securities of Allergy Therapeutics plc of \$10.0 million, Iomai Corporation of \$3.2 million and Emisphere Technologies, Inc. of \$1.8 million. The \$106.2 million in gains on the sale and maturity of investment securities in 2004 included a gain on the sale of securities of Warner Chilcott plc of \$43.6 million, DOV Pharmaceutical, Inc. of \$22.6 million, Curis, Inc. of \$15.3 million and Atrix Laboratories of \$13.1 million.

During 2005, investment impairment charges of \$24.0 million (2004: \$72.4 million) reflect other-than-temporary impairments to the value of a number of investments, primarily in privately-held biotech companies.

Net Charge on Debt Retirements

In June 2005, we incurred a net charge of \$51.8 million (2004: \$Nil) associated with the early retirement of \$36.8 million of the Athena Notes due in 2008 and the early conversion of \$206.0 million in aggregate principal amount of the 6.5% Convertible Notes due in 2008.

Charge Arising from Guarantee to EPIL II Noteholders

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

Provision for/(Benefit from) Income Taxes

We had a net tax provision of \$1.0 million for 2005, compared to a net tax benefit of \$1.7 million for 2004. The overall tax provision for 2005 was \$0.4 million. Of this amount, \$0.6 million has been credited to shareholders' equity to reflect utilization of stock option deductions. The remaining \$1.0 million provision is allocated to ordinary

activities. The tax provision reflected tax at standard rates in the jurisdictions in which we operate, income derived from Irish patents, foreign withholding tax and the availability of tax losses. Our Irish patent derived income was exempt from tax pursuant to Irish legislation, which exempts from Irish tax income derived from qualifying patents. Currently, there is no termination date in effect for such exemption. For additional information regarding income taxes, please refer to Note 21 to the Consolidated Financial Statements.

Table of Contents**Net Income/(Loss) from Discontinued Operations**

Net income from discontinued operations was \$0.6 million in 2005, compared to a net income from discontinued operations of \$19.0 million in 2004. The net income from discontinued operations includes a net gain on sale of businesses of \$0.5 million (2004: \$11.5 million). During the course of the completed recovery plan, we sold a number of products and businesses, including Athena Diagnostics, Elan Diagnostics, a portfolio of pain products (the Pain Portfolio), Actiq™, the dermatology portfolio of products, Abelcet™ US/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 Consolidated Statement of Operations.

SEGMENT ANALYSIS

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

Analysis by Segment

	Biopharmaceuticals			2006	EDT		2006	Total	
	2006	2005	2004		2005	2004		2005	2004
	(In millions)			(In millions)		(In millions)			
Revenue	\$ 275.8	\$ 229.1	\$ 259.8	\$ 284.6	\$ 261.2	\$ 221.9	\$ 560.4	\$ 490.3	\$ 481.7
Segmental operating income/(loss)	\$ (235.6)	\$ (245.4)	\$ (282.6)	\$ 69.1	\$ 47.6	\$ 43.6	\$ (166.5)	\$ (197.8)	\$ (239.0)
Corporate expense/(credit)							(0.1)	0.7	63.1
Operating loss							\$ (166.4)	\$ (198.5)	\$ (302.1)

Biopharmaceuticals revenue increased 20% to \$275.8 million in 2006 from \$229.1 million in 2005 and 6% from \$259.8 million in 2004. The increase is primarily due to the increase in revenue from increased sales of *Maxipime*, *Azactam* and *Tysabri*, offset by decreases in revenue from divested products. Biopharmaceuticals operating loss decreased 4% to \$235.6 million in 2006 from \$245.4 million in 2005 and 17% from \$282.6 million in 2004. The decrease in the operating loss was principally due to the increase in revenues, offset by a decrease in the gain on sale of products and businesses. Biopharmaceuticals net gain on sale of products and businesses decreased to \$43.1 million in 2006 (primarily related to the gain on sale of European rights to *Prialt*) from \$103.1 million in 2005 (primarily related to the gains on the sale of *Zonegran* and our European business). Biopharmaceuticals other net charges increased to \$26.3 million in 2006 from \$5.6 million in 2005, primarily due to acquired in-process research and development costs incurred in 2006.

EDT revenue increased 9% to \$284.6 million in 2006 from \$261.2 million in 2005 and increased 28% from \$221.9 million in 2004. The increase was due to increased manufacturing revenue and royalties, offset by decreased contract revenue. EDT operating income increased to \$69.1 million in 2006 from \$47.6 million in 2005 and from \$43.6 million in 2004. The increase was primarily due to the increase in revenues and also due to a net other gain of

\$47.2 million in 2006, which was primarily related to an arbitration award in our favor and against King in 2006.

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

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

	2006	2005	Increase/ (Decrease)
Cash and cash equivalents	\$ 1,510.6	\$ 1,080.7	40%
Restricted cash	23.2	24.9	(7)%
Investment securities (current)	11.2	10.0	12%
Shareholders' equity	85.1	16.9	404%

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, 2006 consisted of cash and cash equivalents of \$1,510.6 million, which excludes restricted cash of \$23.2 million, and current investment securities of \$11.2 million.

At December 31, 2006, our shareholders' equity was \$85.1 million, compared to \$16.9 million at December 31, 2005. The increase is due primarily to the conversion of convertible debt and proceeds from employee stock issuances, offset by the net loss incurred during the year.

Cash Flows Summary

	2006	2005	2004
		(In millions)	
Net cash used in operating activities	\$ (238.7)	\$ (283.5)	\$ (347.9)
Net cash provided by investing activities	34.7	120.9	474.2
Net cash provided by/(used in) financing activities	629.3	(99.7)	441.5
Effect of exchange rate changes on cash	4.6	(4.6)	1.6
Net increase/(decrease) in cash and cash equivalents	429.9	(266.9)	569.4
Cash and cash equivalents at beginning of year	1,080.7	1,347.6	778.2
Cash and cash equivalents at end of year	\$ 1,510.6	\$ 1,080.7	\$ 1,347.6

The results of our cash flow activities for 2006 and 2005 are described below.

2006

Net cash used in operating activities was \$238.7 million in 2006. 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 receivables and prepaid and other assets of \$79.2 million (principally \$49.8 million arbitration award entered in our favor and against King in December 2006, which was paid by King in January 2007), the increase in inventory of \$7.1 million, and the net increase of \$15.2 million in accounts payable and accrued and other liabilities.

Net cash provided by investing activities was \$34.7 million in 2006. The major component of cash generated from investing activities includes net proceeds of \$14.1 million from the sale and maturity of investment securities and \$54.2 million from the sale of the European rights to *Prialt* (net of transaction costs), partially offset by \$31.5 million for capital expenditures. As of December 31, 2006, we did not have any significant commitments to purchase property, plant and equipment, except for committed additional capital expenditures of \$5.6 million.