

ELAN CORP PLC  
Form 20-F  
February 26, 2009

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

(Mark One)

- o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
OR**
- p ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended: December 31, 2008  
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)*

**William Daniel, Secretary**

**Elan Corporation, plc**

**Treasury Building, Lower Grand Canal Street**

**Dublin 2, Ireland**

**011-353-1-709-4000**

**liam.daniel@elan.com**

*(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact person)*

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

<b>Title of Each Class</b>	<b>Name of Exchange on Which Registered</b>
American Depositary Shares (ADSs), representing Ordinary Shares, Par value 0.05 each (Ordinary Shares) Ordinary Shares	New York Stock Exchange  New York Stock Exchange

**Securities registered or to be registered pursuant to Section 12(g) of the Act:**  
**None**

*(Title of Class)*

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

*(Title of Class)*

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 471,413,777 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 of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes  No

Indicate by check mark 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 basis of accounting the registrant has used to prepare the financial statements included in this filing: U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If "Other" has been checked in response to the previous question, 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 (U.S. 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 as adopted by the European Union (IFRS), which differ in certain significant respects from U.S. 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 dollars (\$). We prepare our Consolidated Financial Statements on the basis of a calendar fiscal year beginning on January 1 and ending on December 31. References to a fiscal year in this Form 20-F shall be references to the fiscal year ending on December 31 of that year. In this Form 20-F, financial results and operating statistics are, unless otherwise indicated, stated on the basis of such fiscal years.

### **Forward-Looking Statements**

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

This Form 20-F contains forward-looking statements about our financial condition, results of operations and estimates, business prospects and products 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, 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*<sup>®</sup> (*natalizumab*) and the incidence of serious adverse events associated with *Tysabri* (including cases of progressive multifocal leukoencephalopathy (PML)); (2) the success of our research and development (R&D) activities (including, in particular, whether the Phase 3 clinical trials for bapineuzumab (AAB-001) are successful) and the speed with which regulatory authorizations and product launches may be achieved; (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 we will be able to enter into or consummate a definitive transaction as the result of our evaluation of strategic alternatives and whether we will be able to enhance shareholder value through that process or any resulting transaction; (5) whether the proposed acquisition of Wyeth by Pfizer Inc. will affect our collaboration with Wyeth; (6) whether restrictive covenants in our debt obligations will adversely affect us; (7) competitive developments affecting our products, including the introduction of generic competition following the loss of patent protection or marketing exclusivity for our products (including, in particular, *Maxipime*<sup>®</sup> (*cefepime hydrochloride*), which lost its basic U.S. patent protection in March 2007 and now faces generic competition, *Azactam*<sup>®</sup> (*aztreonam for injection, USP*), which lost its basic U.S. patent protection in October 2005, and several of the products from which we derive manufacturing or royalty revenues, which are under patent challenge by potential generic competitors); (8) our ability to protect our patents and other intellectual property; (9) difficulties or delays in manufacturing our products (we are

dependent on third parties for the manufacture of our products); (10) trade buying patterns; (11) pricing pressures and uncertainties regarding healthcare reimbursement and reform; (12) 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<sup>®</sup> product, which are being investigated by the U.S. Department of Justice and the U.S. 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); (13) extensive government regulation; (14) risks from potential environmental liabilities; (15) failure to comply with our reporting and payment obligations under Medicaid or other government programs; (16) exposure to product liability risks; (17) an adverse effect that could result from the putative class action lawsuits initiated following the release of the data from the Phase 2 clinical trial for bapineuzumab and the outcome of our other pending or future litigation; (18) the volatility of our stock price; (19) some of our agreements that may discourage or prevent someone from acquiring us; and (20) global, as well as local, political, economic and market conditions, including interest rate and currency exchange rate fluctuations. We assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law.

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

Not applicable.

**Item 2. Offer Statistics and Expected Timetable.**

Not applicable.

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

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

<b>Years Ended December 31,</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In millions, except per share data)</b>				
<b>Income Statement Data:</b>					
Total revenue	\$ 1,000.2	\$ 759.4	\$ 560.4	\$ 490.3	\$ 481.7
Operating loss	\$ (143.5) <sup>(1)</sup>	\$ (265.3) <sup>(2)</sup>	\$ (166.4) <sup>(3)</sup>	\$ (198.5) <sup>(4)</sup>	\$ (302.1) <sup>(5)</sup>
Net loss from continuing operations	\$ (71.0)	\$ (405.0)	\$ (267.3)	\$ (384.2)	\$ (413.7)
Net income from discontinued operations				0.6	19.0
Net loss	\$ (71.0) <sup>(6)</sup>	\$ (405.0) <sup>(7)</sup>	\$ (267.3) <sup>(3)</sup>	\$ (383.6) <sup>(8)</sup>	\$ (394.7) <sup>(5)</sup>
Basic and diluted loss per Ordinary Share: <sup>(9)</sup>					
Net loss from continuing operations	\$ (0.15)	\$ (0.86)	\$ (0.62)	\$ (0.93)	\$ (1.06)
Net income from discontinued operations (net of tax)					0.05
Total basic and diluted loss per Ordinary Share	\$ (0.15)	\$ (0.86)	\$ (0.62)	\$ (0.93)	\$ (1.01)
<b>At December 31,</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In millions)</b>				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 375.3	\$ 423.5	\$ 1,510.6	\$ 1,080.7	\$ 1,347.6
Restricted cash – current and non-current	\$ 35.2	\$ 29.6	\$ 23.2	\$ 24.9	\$ 192.7



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Investment securities	current	\$ 30.5	\$ 277.6	\$ 13.2	\$ 11.4	\$ 65.5
Total assets		\$ 1,867.6	\$ 1,780.8	\$ 2,746.3	\$ 2,341.0	\$ 2,975.9
Debt		\$ 1,765.0	\$ 1,765.0	\$ 2,378.2	\$ 2,017.2	\$ 2,260.0
Total shareholders	equity/(deficit)	\$ (232.2)	\$ (234.7)	\$ 85.1	\$ 16.9	\$ 205.0
Weighted-average number of shares	outstanding	473.5	468.3	433.3	413.5	390.1
	basic and diluted					

- (1) *After other net charges of \$34.2 million, primarily relating to severance, restructuring and other costs of \$22.0 million, the write-off of deferred transaction costs of \$7.5 million and a legal settlement of \$4.7 million.*
- (2) *After other net charges of \$84.6 million, primarily relating to a \$52.2 million impairment of the Maxipime and Azactam intangible assets and net severance and restructuring costs of \$32.4 million.*
- (3) *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.*
- (4) *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.*

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- (5) *After other net charges of \$59.8 million, primarily relating to the settlement of the U.S. 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.*
- (6) *After other net charges of \$34.2 million, primarily relating to severance, restructuring and other costs of \$22.0 million, the write-off of deferred transaction costs of \$7.5 million, a legal settlement of \$4.7 million and a tax credit of \$236.6 million, which resulted from the release of a deferred tax asset valuation allowance.*
- (7) *After other net charges of \$84.6 million, primarily relating to a \$52.2 million impairment of the Maxipime and Azactam intangible assets and net severance and restructuring costs of \$32.4 million; and after an \$18.8 million net charge on debt retirement.*
- (8) *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.*
- (9) *Basic and diluted net loss per ordinary share is based on the weighted-average number of outstanding Ordinary Shares and the effect of potential dilutive securities including stock options, Restricted Stock Units, warrants and convertible debt 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 continued 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, or if our Phase 3 clinical trials for bapineuzumab are not successful and we do not successfully develop and commercialize additional products, we will be materially and adversely affected.***

While approximately 30% of our 2008 revenue was generated by our Elan Drug Technologies (EDT) business unit, we have only four marketed products and several potential products in clinical development. Our future success depends upon the continued successful commercialization of *Tysabri*, which accounts for 56% of our total revenue for 2008, and the development and the successful commercialization of additional products, including bapineuzumab.

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.

We commit substantial resources to our R&D activities, including collaborations with third parties such as Biogen Idec Inc. with respect to *Tysabri*, and Wyeth and Transition Therapeutics, Inc. (Transition), with respect to parts of our Alzheimer's disease (AD) programs. We have committed significant resources to the development and the commercialization of *Tysabri* and to the other potential products in our development pipeline (in particular, bapineuzumab). These investments may not be successful.

The proposed acquisition of Wyeth by Pfizer may cause Wyeth to lose its focus on our collaboration. Should Pfizer acquire Wyeth, Pfizer may devote less attention and resources to our collaboration than Wyeth would have devoted, or, as part of the acquisition or afterwards, Wyeth or Pfizer may divest Wyeth's interest in our collaboration. Any of these outcomes could adversely affect our collaboration.

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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 bapineuzumab, ELND005 and ACC-001, will experience difficulties, delays or failures. If our Phase 3 clinical trials for bapineuzumab are not successfully completed, we will be materially and adversely affected.

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 continue to successfully commercialize *Tysabri* and develop and commercialize other products (such as bapineuzumab) would materially adversely affect us.

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

At December 31, 2008, we had \$1,765.0 million of debt due in November 2011 (\$1,150.0 million) and November 2013 (\$615.0 million). At such date, we had cash and cash equivalents, current restricted cash and current investments of \$426.0 million. Our substantial indebtedness could have important consequences to us. For example, it does or

could:

Increase our vulnerability to general adverse economic and industry conditions;

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

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

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

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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 12 months. Although we expect to continue to incur operating losses in 2009, 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. Even if our future operating performance does meet our expectations, including continuing to successfully commercialize *Tysabri*, we will need to obtain additional funds to meet our longer term liquidity requirements. We may not be able to obtain those funds on commercially reasonable terms, or at all, which would force us to curtail programs, sell assets or otherwise take steps to reduce expenses or cease operations. Any of these steps may have a material adverse effect on our prospects.

***Our failure to consummate a strategic transaction on favorable terms may adversely impact our value and prospects.***

On January 13, 2009, we announced that our board of directors had engaged an investment bank to conduct, in conjunction with executive management and other external advisors, a review of our strategic alternatives. The purpose of the engagement is to secure access to financial resources and commercial infrastructure that would enable us to accelerate the development and commercialization of our pipeline and product portfolio, while enhancing the ability of our shareholders to participate in the resulting longer term value creation. The range of alternatives that is being assessed includes a minority investment, strategic alliance, merger or sale. We are committed to completing this review of potential alternatives as promptly as practicable; however, there can be no assurances that any particular alternative will be pursued or that any transaction will occur, or, even if a transaction does occur, that it will be on terms favorable to us.

***The current economic and financial crisis may have a material adverse effect on our results.***

Many of the world's largest economies and financial institutions currently face extreme financial difficulty, including a decline in asset prices, liquidity problems and limited availability of credit. It is uncertain how long this crisis will last, but many countries are concerned that their economies have entered or may enter a deep and prolonged recession. Such difficult economic times may have a material adverse effect on our revenues, results of operations, financial condition and ability to raise capital. The current economic and financial crisis appears to be affecting all of the major markets in which we operate. As a result, there is a risk that consumers may cut back on prescription drugs to help cope with hard economic times.

The financial crisis has resulted, and may continue to result in losses and, in a lower return on our investments and a lower value on some of our assets. The financial crisis could also negatively impact the cost of financing or our ability to obtain finance on favorable terms, or at all. The impact of the current financial crisis on our future access to various types of capital, and the cost of that capital, is not currently predictable.

At the same time, significant changes and volatility in the consumer environment, the equity and credit markets, and in the competitive landscape make it increasingly difficult for us to predict our future. As a result, any guidance or outlook we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future results at the time we give such guidance, under current market conditions there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

***Restrictive covenants in our debt instruments restrict or prohibit our ability to engage in or enter into a variety of transactions and 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;

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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 U.S. patent protection in October 2005. To date, no generic *Azactam* product has been approved.

In addition, the U.S. basic patent covering our product *Maxipime* expired in March 2007. *Maxipime* became subject to generic competition following the expiration of the basic patent, and that has materially and adversely affected our sales of *Maxipime*.

Generic competitors have challenged existing patent protection for several of the products from which we earn manufacturing or royalty revenue. If these challenges are successful, our manufacturing and royalty revenue will be materially and adversely affected.

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 competitive products, including generic versions of our products, has had and will have a material and adverse affect on our revenues 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. If we fail to maintain our competitive position, then our revenues and results of operations may be materially and adversely affected.

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***If we are unable to secure or enforce patent rights, trade secrets or other intellectual property, then our revenues and potential revenues may be materially reduced.***

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 in which we are involved have been and will continue to be protracted and expensive and could be 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 has been and may be instituted 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 or their products. The outcome of any such litigation could adversely affect the validity and scope of our patents or other intellectual property rights, hinder, delay or prevent the marketing and sale of our products and cost us substantial sums of money.

***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 and adversely affected.***

We do not manufacture *Tysabri*, *Prialt*<sup>®</sup> (*ziconotide*), *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 and 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 and adversely affect the supply of our products.

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***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. Our ability to commercialize products successfully depends, in part, upon the extent to which healthcare 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 healthcare 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 and adversely affected.

The new administration and Congress in the United States have made significant healthcare reform a priority. Any fundamental healthcare reform may change the manner by which drugs and biologics are developed, marketed and purchased. In addition, managed care organizations, HMOs, preferred provider organizations, institutions and other government agencies continue to seek price discounts. Further, 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 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 healthcare system. This price regulation leads to inconsistent prices and some third-party trade in our products from markets with lower prices. Such trade-exploiting price differences between countries could undermine our sales in markets with higher prices.

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

In addition to the U.S. 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 healthcare 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 healthcare 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

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false claim paid. In recent years, many pharmaceutical and other healthcare 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, other pharmaceutical companies have settled charges under the federal False Claims Act, and related state laws, 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.

In January 2006, Elan received a subpoena from the U.S. Department of Justice and the Department of Health and Human Services, Office of Inspector General, asking for documents and materials primarily related to our marketing practices for Zonegran. In April 2004, we completed the sale of our interests in Zonegran in North America and Europe to Eisai Co. Ltd. We are cooperating with the government in its investigation. The resolution of this 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.

Because of the breadth of such federal and state laws and the narrowness of the safe harbors, it is possible that more 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 liquidity and our operations.

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

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

We must obtain and maintain approval for our products from regulatory authorities before such products may be sold in a particular jurisdiction. The submission of an application to a regulatory authority with respect to a product does not guarantee that approval to market the product will be granted. Each authority generally imposes its own requirements and may delay or refuse to grant approval, even though a product has been approved in another country. In our principal markets, including the United States, the approval process for a new product is complex, lengthy, expensive and subject to unanticipated delays. We cannot be sure when or whether approvals from regulatory authorities will be received or that the terms of any approval will not impose significant limitations that could negatively impact the potential profitability of the approved product. Even after a product is approved, it may be subject to regulatory action based on newly discovered facts about the safety and efficacy of the product, on any activities that regulatory authorities consider to be improper or as a result of changes in regulatory policy. Regulatory action may have a material adverse effect on the marketing of a product, require changes in the product's labeling or even lead to the withdrawal of the regulatory marketing approval of the product.

All facilities and manufacturing techniques used for the manufacture of products and devices for clinical use or for sale in the United States must be operated in conformity with cGMPs, the FDA's regulations governing the production of pharmaceutical products. There are comparable regulations in other countries. Any finding by the FDA or other regulatory authority that we are not in substantial compliance with cGMP regulations or that we or our employees have engaged in activities in violation of these regulations could interfere with the continued manufacture and distribution of the affected products, up to the entire output of such products, and, in some cases, might also require the recall of previously distributed products. Any such finding by the FDA or other regulatory agency

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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 result in substantial fines and other penalties and could cut off our supply of products.

***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 material reimbursements, penalties, sanctions and fines.***

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

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

U.S. federal law requires that any company that participates in the federal Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service's 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.

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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 material civil, administrative and criminal penalties.

***We are subject to continuing potential product liability risks, which could cost us material amounts of money.***

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 that 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 with our insurers for the next \$200.0 million. 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 result in a substantial judgment against us.***

We and some of our officers and directors have been named as defendants in putative class actions filed in 2008. The class action complaints allege claims under the U.S. federal securities laws. The complaints allege that we caused the release of materially false or misleading information regarding bapineuzumab. The complaints seek damages and other relief that the courts may deem just and proper. We believe that the claims in the lawsuits are without merit and intend to defend against them vigorously.

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

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

The market prices for our shares and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. 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*;

Developments regarding any strategic alternatives;

Results of clinical trials with respect to our products under development (in particular bapineuzumab) and those of our competitors;

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;

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Availability and level of third-party reimbursement;

Developments relating to patents and other intellectual property rights;

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 our 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 our 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

If we or Wyeth undergo a change of control, our collaboration agreement with Wyeth permits an acquirer to assume the role of the acquired party in most circumstances; however, 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 the Company**

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

**B. Business Overview**

**Advancing Neuroscience, Growing the Business**

In 2008, we continued to fulfill our mission of making significant scientific advancements in neuroscience while continuing overall growth of the business.

Our operations are organized into two business units: Biopharmaceuticals, which engages in research, development and commercial activities primarily in neuroscience, autoimmune and severe chronic pain, and Elan Drug Technologies (EDT), which focuses on the specialty pharmaceutical industry, including specialized drug delivery and manufacturing.

We made significant research and development progress, particularly in the clinical advancement of our Alzheimer's disease programs. Our Alzheimer's platform is marked by three distinct approaches to modify the beta amyloid cascade, a complex process thought to underlie Alzheimer's disease.

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Our deep scientific expertise is also evident in our work in Parkinson's disease, where our scientists continue to build on their work based on modified forms of alpha-synuclein found in human Parkinson's disease brain tissue, and with parkin, a brain protein linked to the disease.

We continued to grow the value of *Tysabri* as an important therapeutic approach to multiple indications. *Tysabri* is an approved therapy for relapsing forms of multiple sclerosis (MS) in the United States and for relapsing-remitting MS in the European Union. *Tysabri* sales grew significantly in 2008, reflecting strong patient demand across global markets.

*Tysabri* is also approved in the United States for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD), with evidence of inflammation, who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor alpha (TNF-alpha).

The medical and scientific opportunity represented by Elan's biopharmaceutical pipeline remains significant.

Our EDT business is the oldest, independent drug delivery firm in the industry. As a leader in the business, we have contributed to over \$15 billion of in-market sales for our clients over our history. An established, profitable specialty pharmaceutical business unit of Elan, EDT has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed worldwide. Today, products enabled by EDT technologies are used by millions of patients each day.

## **Strategic Alternatives**

On January 13, 2009, we announced that our board of directors had engaged an investment bank to conduct, in conjunction with executive management and other external advisors, a review of our strategic alternatives. The purpose of the engagement is to secure access to financial resources and commercial infrastructure that would enable us to accelerate the development and commercialization of our extensive pipeline and product portfolio while enhancing the ability of our shareholders to participate in the resulting longer term value creation. The range of alternatives that will be assessed could include a minority investment, strategic alliance, merger or sale.

We are committed to completing this review as promptly as practicable; however, there can be no assurances that any particular alternative will be pursued or that any transaction will occur, or, if a transaction does occur, that it will be on terms favorable to us.

## ***ALZHEIMER'S DISEASE***

### **Important Clinical Progress: Elan's Alzheimer's Programs**

Our scientists have been leaders in Alzheimer's disease research for more than two decades, and insights from their work are an important part of the foundation on which virtually all of today's Alzheimer's research and development is based. Throughout the industry and around the world, we are known and respected for our Alzheimer's disease platform and our commitment to creating new therapeutic opportunities for patients desperately in need of them.

### ***Our Scientific Approach***

Our scientific approach to Alzheimer's disease is centered upon landmark basic research that revealed that a toxic protein called beta amyloid (or abeta 1-42, or A $\beta$ ) accumulates in the brains of people with Alzheimer's disease. The process by which this protein is generated, aggregates and is ultimately deposited in the brain as plaques is often referred to as the amyloid cascade. The formation of beta amyloid plaques is a hallmark pathology of Alzheimer's

disease.

A growing body of scientific evidence, discovered by researchers at Elan and other organizations, indicates that modulating the amyloid cascade may result in the successful treatment of Alzheimer's disease patients, by attacking the underlying disease process.

Beta amyloid forms when a small part of a larger protein called the amyloid precursor protein (APP) separates from the larger protein. This separation happens when enzymes called secretases clip (or cleave) APP. It is

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becoming increasingly clear that once beta amyloid is produced, it exists in multiple physical forms (or species) with distinct functional activities. It is believed that the toxic effects of some of these forms are likely responsible for the complex cognitive, functional and behavioral deficits characteristic of Alzheimer's disease.

### ***Three Approaches to Disrupting the Beta Amyloid Cascade***

Our scientists and clinicians are pursuing separate therapeutic approaches to disrupting three distinct aspects of the beta amyloid cascade:

Clearing existing beta amyloid from the brain (beta amyloid immunotherapies) in collaboration with Wyeth

Preventing aggregation of beta amyloid in the brain (ELND005) in collaboration with Transition

Preventing production of beta amyloid in the brain (secretase inhibitors)

### ***Beta Amyloid Immunotherapies***

Beta amyloid immunotherapy pioneered by our scientists involves the potential treatment of Alzheimer's disease by inducing or enhancing the body's immune response in order to clear toxic species of beta amyloid from the brain. In almost a decade of collaboration with Wyeth, our scientists have been developing a series of therapeutic monoclonal antibodies (mABs) and active vaccination approaches that may have the ability to reduce or clear beta amyloid from the brain. These new approaches have the potential to alter the underlying cause of the disease by reducing a key pathway associated with it.

#### ***Bapineuzumab (AAB-001)***

Bapineuzumab is an experimental humanized monoclonal antibody delivered intravenously that is being studied as a potential treatment for mild to moderate Alzheimer's disease. Bapineuzumab is thought to bind to and clear beta amyloid peptide in the brain. It is designed to provide antibodies to beta amyloid directly to the patient, rather than requiring patients to produce their own immune responses.

Bapineuzumab has received fast-track designation from the FDA, which means that it may receive expedited approval in certain circumstances, in recognition of its potential to address the significant unmet needs of patients with Alzheimer's disease.

In May 2007, Elan and Wyeth announced the decision to initiate a Phase 3 clinical program for bapineuzumab. The Phase 3 program encompasses studies in North America and the rest of world (ROW). In December 2007, we announced that the first patient had been dosed in the studies taking place in North America. ROW studies, conducted by Wyeth, began enrolling patients in June 2008.

The Phase 3 program includes four randomized, double-blinded, placebo controlled studies across two subpopulations that are intended to enroll approximately 4,000 patients with mild to moderate AD at approximately 350 sites. The treatment duration for each patient will be 18 months with patients planned to be distributed between North America and ROW. The studies stratify patients by ApoE4 genotype and all studies have co-primary efficacy end points—one cognitive and one functional. In addition, this trial program will also include sophisticated imaging and biomarker sub-studies to attempt to further elucidate the clinical profile of bapineuzumab.

The decision to move to Phase 3 was based on the seriousness of Alzheimer's disease and what Elan and Wyeth have learned from their immunotherapy programs, including a scheduled interim look at data from the then-ongoing Phase



2 clinical trial.

The main Phase 2 study (#201), which has been completed, enrolled 234 patients with mild to moderate Alzheimer's disease. A second study (#202) enrolled approximately 30 patients and includes a beta amyloid imaging component. This study is expected to be completed in the first half of 2009.

Patients in the main Phase 2 study could qualify to enter an extension study, which is ongoing.

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The #201 and #202 Phase 2 studies were randomized, double-blind, placebo-controlled, multiple ascending dose studies with four dose cohorts. Both studies enrolled patients with mild to moderate Alzheimer's disease, with an 18-month treatment duration.

### ***Results from the Bapineuzumab Phase 2 Clinical Trial Presented at the International Conference on Alzheimer's Disease (ICAD)***

On July 29, 2008, detailed results from the company's 18-month Phase 2 study of bapineuzumab in patients with mild to moderate Alzheimer's disease were presented at ICAD in Chicago, Illinois. As previously announced as part of the preliminary findings, in the study, bapineuzumab appeared to have an acceptable safety profile and clinical activity in treating Alzheimer's disease. Potential efficacy signals were seen at a range of doses without a clear dose response. The study did not attain statistical significance on the pre-specified efficacy endpoints in the overall study population.

We believe that the safety and efficacy findings from this Phase 2 trial of bapineuzumab in patients with mild to moderate Alzheimer's disease support the design of the ongoing global Phase 3 program.

### ***ACC-001 (Active Immunotherapeutic Conjugate) vaccine***

ACC-001, currently being evaluated in a Phase 2 clinical study, is a novel beta amyloid immunoconjugate that leverages the innovative conjugate technology developed by Wyeth and widely used in other vaccine products. ACC-001 has also been granted fast track designation by the FDA.

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.

### ***Additional Studies: Bapineuzumab and Active Immunotherapeutic Conjugate***

In addition to the intravenous formulation of bapineuzumab, a subcutaneous formulation of this antibody is in Phase 2 clinical trials. There are a number of back-up compounds to both bapineuzumab and ACC-001 in the preclinical phase of development.

### ***AN-1792, a prototype active vaccine***

The first drug development candidate to be evaluated in clinical trials under the collaboration with Wyeth, AN-1792 (an immunoconjugate vaccine), was discontinued in 2002 when a subset of patients (6%) developed a type of brain inflammation. We believe the AN-1792 program played a major role in advancing the understanding of the relationship between beta amyloid and Alzheimer's disease, and has contributed to a growing body of scientific evidence pointing to the promise of immunotherapy as a potential treatment for Alzheimer's disease.

Long-term follow-up data presented in 2007 evaluated participants from the AN-1792 Phase 2 clinical trial and found that 4.5 years after dosing had stopped, patients who had responded to treatment by generating anti-A $\beta$  antibodies continued to show significantly slower decline, compared to placebo patients, on two key measures of patient function: the Disability Assessment for Dementia and the Dependence Scale.

### ***ELND005, an A $\beta$ aggregation inhibitor***

In 2006, Elan entered into an exclusive, worldwide collaboration with Transition for the joint development and commercialization of a novel therapeutic agent for Alzheimer's disease.

The small molecule, ELND005, is a beta amyloid anti-aggregation agent that has been granted fast track designation by the FDA. Preclinical data suggest that ELND005 may act through the unique mechanism of preventing and reversing the fibrilization of beta amyloid (the aggregation of beta amyloid into clumps of insoluble oligomers), thus enhancing clearance of amyloid and preventing plaque deposition. 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 and increased survival rate of these animals.

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In 2007, it was announced that multiple Phase 1 clinical studies had been completed, which assessed the safety, tolerability and pharmacokinetic profile of this compound. In these studies, ELND005 was found to be safe and well-tolerated at all doses and dosing regimens examined. No severe or serious adverse events were observed. ELND005 was also shown to be orally bioavailable, cross the blood-brain barrier and achieve levels in the brain and cerebral spinal fluid shown to be effective in animal models of Alzheimer's disease.

In December 2007, Elan and Transition announced that the first patient had been dosed in a Phase 2 clinical study. This 18-month, randomized, double-blind, placebo-controlled, dose-ranging study will evaluate the safety and efficacy of ELND005 in approximately 340 patients with mild to moderate Alzheimer's disease.

In October 2008, Elan and Transition announced that the patient enrollment target for this study had been achieved with 353 patients enrolled.

### ***Secretase Inhibitors***

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.

### ***Gamma Secretase***

Gamma secretase is an unusual multi-protein complex that is required to produce beta amyloid. We have played a critical leadership role characterizing how gamma secretase may affect Alzheimer's disease pathology. Our finding that functional gamma secretase inhibitors appear to reduce beta amyloid levels in the brain, published in the *Journal of Neurochemistry* in 2001, was an important step in this area of Alzheimer's disease research. We continue to progress our gamma secretase discovery program with unique molecules that affect the activity of gamma secretase in a substrate-specific manner.

In November 2008, we announced that the development program for ELND006, a small molecule gamma secretase inhibitor, had commenced with dosing in a Phase 1 clinical study, and other back-ups are in preclinical development.

In addition to our internal programs, we retain certain rights to Eli Lilly's LY450139 compound, which arose from collaborative research between us and Lilly that began in 1988 and ended in 1998. In 2008, Lilly initiated Phase 3 trials for LY450139 for mild to moderate Alzheimer's disease.

### ***Beta Secretase***

Beta secretase, sometimes called BACE (for Beta-site of APP Cleaving Enzyme), is believed to initiate the first step in the formation of beta amyloid, the precursor to plaque development in the brain. 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. Our ongoing drug discovery efforts in this area focus on inhibiting beta secretase and its role in the progression of Alzheimer's disease pathology.

## ***PARKINSON'S DISEASE***

### **Specialized Scientific Expertise: Our Work in Parkinson's Disease**

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 were guided by our expertise and leadership in Alzheimer's disease research. Our scientists have made significant scientific progress to date in identifying unusual modified

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forms of alpha-synuclein in human Parkinson's disease brain tissue. These unique forms have led us to a series of therapeutic targets that are the focus of our drug discovery efforts.

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.

### ***About Parkinson's Disease***

Parkinson's disease is a progressive degenerative neurologic movement disorder that destroys nerve cells in the part of the brain responsible for muscle control and movement. This creates problems walking and maintaining balance and coordination in patients diagnosed with the disease. It is estimated that 1.0 to 1.5 million Americans currently have Parkinson's disease, with tens of thousands of new cases diagnosed each year. The condition usually develops after the age of 65, but an estimated 15% of sufferers are diagnosed before the age of 50.

### ***MULTIPLE SCLEROSIS***

#### ***Tysabri for the Treatment of Multiple Sclerosis***

In June 2006, the FDA approved the reintroduction of *Tysabri* as a monotherapy to treat 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.

In the United States, Europe and the ROW, provisions are in place to ensure patients are informed of the risks associated with *Tysabri* therapy, including PML, and to enhance collection of post-marketing data on the safety and utilization of *Tysabri* for MS. PML is an opportunistic viral infection of the brain that can lead to death or severe disability.

For 2008, *Tysabri* global in-market net sales increased by 137% to \$813.0 million from \$342.9 million for 2007. Our recorded sales of *Tysabri* for 2008 increased 140% to \$557.1 million, over the \$231.7 million for 2007.

The significant growth in *Tysabri* sales reflects strong patient demand across global markets. *Tysabri* is currently approved in more than 40 countries, including the United States, the European Union, Switzerland, Canada, Australia and New Zealand.

*Tysabri* is a treatment approved for relapsing forms of multiple sclerosis (MS) in the United States and relapsing-remitting MS in the European Union. According to data that have been published in the *New England Journal of Medicine*, after two years, *Tysabri* treatment led to a 68% relative reduction in the annualized relapse rate, compared to placebo, and reduced the relative risk of disability progression by 42% to 54%.

Elan and Biogen Idec presented additional *Tysabri* data at the World Congress on Treatment and Research in MS in Montreal on September 19, 2008, including a post-hoc analysis of data from the *Tysabri* MS clinical trials. This analysis provided the first evidence that *Tysabri* is associated with a significant improvement in functional outcome, rather than only slowing or preventing progression of disability, in those living with relapsing MS.

As of the end of December 2008, approximately 37,600 patients were on therapy worldwide, including approximately 20,200 commercial patients in the United States and approximately 16,900 commercial patients in the ROW.

Cumulatively, in the post-marketing setting approximately 48,300 patients have been treated with *Tysabri* as of the end of December 2008. Of those patients, approximately 20,000 have received at least one year of *Tysabri* therapy, approximately 10,700 patients have received at least 18 months of *Tysabri* therapy, and 4,300 patients have received at least 24 months of *Tysabri* therapy. In the post-marketing setting, five cases of PML have occurred in *Tysabri*-treated MS patients.

The safety data to date continues to support a favorable benefit-risk profile for *Tysabri*. Complete information about *Tysabri* for the treatment of MS, including important safety information, is available at <http://www.tysabri.com>. The contents of this website are not incorporated by reference into this Form 20-F.

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*CROHN S DISEASE AND OTHER AUTOIMMUNE DISEASES*

*Tysabri for the Treatment of Crohn s Disease*

We evaluated *Tysabri* as a treatment for CD in collaboration with Biogen Idec. The safety and efficacy of *Tysabri* as both an induction and maintenance therapy were evaluated in 11 clinical studies, including three pivotal, randomized, double-blind, placebo-controlled, multi-center trials.

In January 2008, we were notified by the European Commission that it had denied marketing authorization of *Tysabri* as a treatment of Crohn s disease.

On January 14, 2008, the FDA approved the supplemental Biologics License Application (sBLA) for *Tysabri*, for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn s disease (CD), with evidence of inflammation, who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. We launched *Tysabri* for the treatment of Crohn s disease in the United States in the first quarter of 2008.

Complete information about *Tysabri* for the treatment of Crohn s disease, including important safety information, is available at <http://www.tysabri.com>. The contents of this website are not incorporated by reference into this Form 20-F.

*SEVERE CHRONIC PAIN*

*Prialt for the Treatment of Severe Chronic Pain*

For 2008, revenue from the sales of *Prialt* increased by 34% to \$16.5 million from \$12.3 million for 2007, primarily due to higher demand for the product.

*Prialt* is the only approved non-opioid, intrathecal (IT) analgesic and represents an important therapeutic option for interventional pain specialists. *Prialt* has had an impact in a broad range of chronic pain syndromes, especially in the area of severe neuropathic pain.

*Prialt* has been evaluated as an IT infusion in more than 1,200 patients participating in chronic pain trials. The longest treatment duration to date is more than eight years. This combined number of patients represents the largest IT analgesic safety database ever compiled for any IT treatment. *Prialt* is used in a variety of severe chronic pain patients, including patients with failed back surgery, complex regional pain syndrome, cancer, AIDS and other non-malignant causes.

*Prialt* is administered through appropriate programmable microinfusion pumps that can be implanted or external and that 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.

*AZACTAM AND MAXIPIME*

We distribute two products that treat severe bacterial infections, which remain a major medical concern. *Azactam* and *Maxipime* are designed to address medical needs within the hospital environment.



*Azactam*

We licensed the U.S. marketing rights to this injectable antibiotic from Bristol-Myers Squibb Company (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.

For 2008, revenue from *Azactam* increased 12% to \$96.9 million, compared to \$86.3 million for 2007. The increase for the period reflects a combination of increased demand and price. *Azactam* lost its patent exclusivity in

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October 2005 and its future sales are expected to be negatively impacted by generic competition. However, no generic form of *Azactam* has been approved to date.

### ***Maxipime***

We licensed the U.S. marketing rights to *Maxipime* from Bristol-Myers in January 1999. *Maxipime* is a fourth-generation injectable cephalosporin antibiotic used to treat patients with serious and/or life-threatening infections.

For 2008, revenue from *Maxipime* decreased 78% to \$27.1 million from \$122.5 million for 2007, principally due to generic competition. The first generic cefepime hydrochloride was launched in June 2007, and additional generic forms of *Maxipime* have since been launched.

### **Unique Scientific Opportunity**

Our biopharmaceutical pipeline includes a range of unique medical and scientific opportunities across a number of indications and formulations, particularly in our small molecule integrin platform. We believe this reflects considerable potential value for external licensing and/or partnering opportunities, beyond our core focus in neuroscience.

### ***Alpha 4 Integrin***

Our therapeutic strategy for treating autoimmune and other diseases is to identify mechanisms common to these 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 bloodstream and invade target tissues. Blocking alpha 4 integrin stops immune cells from entering tissues.

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. Through this deep understanding, we have developed small molecules that can selectively block particular alpha 4 integrin interactions.

We have advanced a number of compounds in this area. ELND002 is currently being studied for MS and oncology, and ELND004 is currently being studied for ulcerative colitis and Crohn's disease.

### ***Tysabri***

*Tysabri* is an alpha 4 integrin antagonist 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.

We, in collaboration with Biogen Idec, continue to explore additional indications for *Tysabri*, including oncology. An Investigational New Drug (IND) application was filed for *Tysabri* for multiple myeloma in 2007 and a Phase 1/Phase 2 proof of concept study was initiated in 2008.

### ***Pervasive Patient Relevance***

Our progress, goals and achievements are underscored by a deep commitment to creating, sustaining and growing the unique patient relevance of our therapies, science and relationships. In addition to the advancement of our products and clinical studies, this fundamental focus on patients is also evidenced by our collaborative research ventures, our patient assistance programs, our intellectual property estate enabling the advancement of innovation, and the

widespread, patient-facing outreach of our employees in the communities in which we work and live.

Moving forward, we remain steadfastly committed to pursuing the strategic opportunities that have the best potential to deliver significant benefit to millions of patients around the world.

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***Alzheimer's Drug Discovery Foundation (ADDF)***

ADDF, a biomedical venture philanthropy, is the only public charity solely dedicated to rapidly accelerating the discovery and development of drugs to prevent, treat and cure Alzheimer's disease and cognitive aging. On April 16, ADDF and Elan announced the winners of their third annual research award program, Novel Approaches to Drug Discovery for Alzheimer's Disease. Four international scientists received a total of \$530,000 in grant funding.

***The Parkinson's Institute and Clinical Center***

In addition to our internal programs for Parkinson's disease, we collaborate with world-class experts to expand the body of scientific knowledge around this disease. Our researchers have worked with scientists from the Parkinson's Institute and Clinical Center and have made significant progress in developing a new animal model, which could enable us to evaluate new treatment approaches.

***The Michael J. Fox Foundation for Parkinson's Research***

Since 2007, our efforts with the Michael J. Fox Foundation for Parkinson's Research have included a grant program, Novel Approaches to Drug Discovery, designed to identify and fund promising projects, to help them advance more quickly from the lab to the clinic.

With a strong focus on the development of disease-modifying therapies for Parkinson's disease, Novel Approaches to Drug Discovery provides funding for projects of up to one year's duration. Ideal proposals focus on efforts to develop promising biological targets into novel disease-modifying therapeutic strategies. Novel Approaches holds unique potential to provide awardees from both academic and biotech institutions with a clear opportunity for follow-on funding and collaboration for further development. We have an option for a right of first negotiation for any promising approaches or materials that arise out of this program.

***The Alzheimer's Association***

The Alzheimer's Association is the leading voluntary U.S. health organization in Alzheimer's care, support and research, with a mission to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Our multi-faceted relationship with the Alzheimer's Association includes participating in the Alzheimer's Association Research Roundtable, a consortium of scientific thought-leaders working to facilitate the development and implementation of new treatments for Alzheimer's disease.

***National Pain Foundation***

***The American Pain Society***

Severe chronic pain is a condition that requires a community of support and education. We have ongoing patient education initiatives with the National Pain Foundation and the American Pain Society, and we are proud to support their efforts to provide reliable information and services to patients and healthcare providers.

***Tysabri Financial Assistance Program***

Our collaborator on *Tysabri*, Biogen Idec, provides *Tysabri* patients a wide range of support services and programs to optimize access to *Tysabri* in the United States. Biogen Idec partners patients with a Financial Assistance Counselor to develop the best financial solution for accessing *Tysabri* therapy, helping to ensure that no patient is denied treatment based solely on financial reasons. Financial assistance programs encompass a number of options; are

tailored to address the various needs of patients, including those uninsured, privately insured, or insured through Medicare; and include a co-pay assistance program with a low monthly cap, subject to annual enrollment and income limit qualifications.

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**Our Patent Estate: Empowering Innovation**

Our commitment to a robust intellectual property (IP) discipline helps ensure that the scientific and technological innovations achieved by our products have the best chance to reach patients in a manner that is fair and driven both by patient need and competitive value. As an example, the U.S. Patent and Trademark Office recently issued a Notice of Allowance to our collaborator, Transition Therapeutics, for a patent for ELND005 covering a method of treating Alzheimer's disease. The patent should be issued during the first half of 2009 and will expire in the year 2025 or later due to any patent term extensions.

Our major patent-protected technology platforms cover immunotherapy, alpha 4 integrin, secretase inhibitors and the specialty pharma/drug delivery business, collectively representing thousands of patent filings worldwide.

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*ELAN DRUG TECHNOLOGIES*

Our EDT business is the oldest, independent drug delivery firm in the industry. As a leader in the business, we have contributed to over \$15 billion of in-market sales for our clients over our history. An established, profitable specialty pharmaceutical business unit of Elan, EDT has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed worldwide. Today, products enabled by EDT technologies are used by millions of patients each day.

EDT focuses on helping clients bring products to market through product optimization, new product generation and product rescue. As experts in life-cycle management we have successfully brought over 30 drugs to market for clients in over 90 countries worldwide. We provide a broad range of creative drug optimization approaches, including formulation development, scale-up and manufacturing. Commercialized technologies include those for poorly water-soluble compounds as well as technology platforms for customized oral release. Since 2001, our technologies have been incorporated and subsequently commercialized in 10 products in the United States, making us the most productive drug delivery company in the industry.

EDT generated \$301.6 million in revenue and an operating profit of \$85.8 million in 2008. EDT generates revenue from two sources: royalties and manufacturing fees from licensed products, and contract revenues relating to R&D services, license fees and milestones.

Typically, EDT receives royalties in the single-digit range as well as manufacturing fees based on cost-plus arrangements where appropriate. More recently, EDT has brought product concepts to a later stage of development before out-licensing and as a result has been able to retain an increasing proportion of revenue. There are currently 23 products marketed by EDT licensees, with 10 of these having been launched since 2001. EDT has a broad pipeline, with 15 products in clinical development, including three filed, four in Phase 3, three in Phase 2 and five in Phase 1. These marketed and pipeline products and EDT's technologies are protected by an extensive intellectual property portfolio.

***EDT's Business Strategy***

Throughout our nearly 40-year history, we have invested in the development of innovative technologies, particularly in Oral Controlled Release (OCR) platform technologies and technologies for poorly water-soluble compounds. We are focused on profitably growing as a specialty drug delivery business, underpinned by our product development capabilities and drug delivery technologies.



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In the near to medium term, we will drive growth through our existing approved licensed products and pipeline of 15 products in clinical development. In addition, we seek to generate new pipeline opportunities by entering into further licensing arrangements with pharmaceutical companies as well as identifying and developing proprietary products as we evolve our specialty pharmaceutical business model. As a leading provider of drug delivery technologies, we will continue to invest in the development and application of novel drug delivery technologies.

Our strategy, based on our comprehensive product development and proprietary technology platforms, involves two complementary elements:

Working with pharmaceutical companies to develop products through the application of our technologies to their pipeline and marketed products; and

Selectively developing product candidates based on our proprietary technologies (Proprietary Product Candidates or PPCs) where we originate the product concept and ultimately develop the product to a later stage of development prior to out-licensing or making a decision to continue internal development.

Our drug delivery technologies are key to our future business. Today, we have more than 1,700 patent and patent applications around our key technology and product areas.

***Marketed Products***

Twenty-three (23) products incorporating EDT technologies are currently marketed by EDT licensees, and EDT receives royalties and, in some cases, manufacturing fees on these, including:

<b>Licensee</b>	<b>Product</b>	<b>Indication</b>
Abbott Laboratories	TriCor® 145	Cholesterol
Merck & Co., Inc.	Emend®	Nausea post chemo
Novartis AG	Focalin XR®/Ritalin LA®	ADHD <sup>(1)</sup>
Wyeth	Rapamune®	Anti-rejection
Victory Pharma	Naprelan®	NSAID <sup>(2)</sup> Pain
King Pharmaceuticals, Inc.	Avinza®	Chronic pain
Par Pharmaceutical Co., Inc.	Megace® ES	Cachexia
Acorda Therapeutics, Inc.	Zanaflex®	Muscle spasticity

<sup>(1)</sup> *Attention Deficit Hyperactivity Disorder*

<sup>(2)</sup> *Non-Steroidal Anti-Inflammatory Drug*

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***EDT PRODUCT PIPELINE***

EDT's current pipeline spans a range of therapeutic classes, routes of administration and licensee profiles, as outlined below. In addition, EDT has a large number of projects at the preclinical or formulation development stage.

***Validated Platform of Technologies – Oral Controlled Release and NanoCrystal® Technology***

Elan has a unique platform of validated technologies to offer our clients – including oral controlled release, delayed release, and pulsatile release delivery systems as well as technology solutions for poorly water-soluble compounds. We have a complete range of capabilities from formulation development through to commercial-scale manufacture in modern facilities. Our technologies are supported by a robust patent estate of over 1,700 patents/patent applications.

***Proven Innovation for Poorly Water-soluble Compounds – NanoCrystal Technology***

EDT's proprietary *NanoCrystal* technology is a drug optimization technology applicable to many poorly water-soluble compounds. It is an enabling technology for evaluating new chemical entities exhibiting poor water-solubility and a tool for optimizing the performance of established drugs. *NanoCrystal* technology involves reducing drugs to particles in the nanometer size. By reducing particle size, the exposed surface area of the drug is increased and then stabilized to maintain particle size. A drug in *NanoCrystal* 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.

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Our *NanoCrystal* technology is a drug enablement and optimization technology applicable to poorly water-soluble compounds.

**Proven** Four products have been launched to date, achieving over \$1.5 billion annual in-market sales.

**Patent Protected** Over 1,000 patents/patent applications around the *NanoCrystal* technology in the United States and the ROW.

**Simple, Easy and Effective** Optimized and simplified from over 15 years of development behind the technology. It is applicable to all dosage forms and has been manufactured at commercial scale since 2001.

*By reducing particle size, the drug's exposed surface area is increased and is then stabilized to maintain the reduced particle size. The result is a stable drug formulation that exhibits an increased dissolution rate.*

The potential benefits of applying the *NanoCrystal* technology for existing and new products include:

Enhancing oral bioavailability;

Increased therapeutic effectiveness;

Reducing/eliminating fed/fasted variability;

Optimizing delivery; and

Increased absorption.

EDT's *NanoCrystal* technology has now been incorporated into four commercialized products, with more than 30 other compounds at various stages of development.

### *Oral Controlled Release Technology Platform*

OCR technologies provide significant benefits in developing innovative products that provide meaningful clinical benefits to patients. EDT has developed a range of OCR technologies, which it applies to help overcome many of the technical difficulties that have been encountered in developing oral controlled release products. Oral controlled release products are often difficult to formulate, develop and manufacture. As a result, significant experience, expertise and know-how are required to successfully develop such products.

EDT's OCR technologies are focused on using advanced drug delivery technology and its manufacturing expertise to formulate, develop and manufacture controlled release, oral dosage form pharmaceutical products that improve the release characteristics and efficacy of active drug agents, and also provide improved patient convenience and compliance. The drug delivery technologies employed, coupled with its manufacturing expertise, enable EDT to cost effectively develop value-added products and to enhance product positioning.

EDT's suite of OCR technologies has been incorporated into many commercialized products. EDT's OCR technology platform allows a range of release profiles and dosage forms to be engineered. Customized release profiles for oral dosage forms such as extended release, delayed release and pulsatile release have all been successfully developed and commercialized.



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A unique platform of validated technologies to offer our clients:

**Validated and Commercialized** 17 products currently on the market in over 90 countries.

**Multiple OCR Technologies** Customized release profiles for oral dosage forms such as extended release, delayed release and pulsatile release have all been developed and commercialized.

**Patent Protected** Over 450 issued/filed patents in the United States and the ROW.

**Fully Scalable** Optimized from almost 40 years of development. In-house manufacturing capabilities in the United States and Europe.

**SODAS® (Spheroidal Oral Drug Absorption System) is one of Elan's OCR platform technologies.** *Based on the production of controlled release beads, the SODAS technology is characterized by its inherent flexibility, enabling the production of customized dosage forms that respond directly to individual drug candidate needs.*

### ***Manufacturing, Development and Scale-up Expertise***

EDT has a long and established history in the manufacture and development of pharmaceutical dosage forms for pharmaceutical markets worldwide, with multiple products successfully launched in more than 90 countries in North America, Asia and Europe. EDT is uniquely prepared to assist companies with their pharmaceutical manufacturing, scale-up and development requirements. EDT's main production facilities are located in Athlone, Ireland, and Gainesville, Georgia. We have manufactured finished solid oral pharmaceutical products for clients for well over 30 years.

#### ***Range of Manufacturing Services***

In addition to formulation development, EDT provides a range of contract manufacturing services to include analytical development, clinical trial manufacturing, scale-up, product registration support and supply chain management for client products.

EDT offers our clients an extensive range of drug optimization and development services including formulation development, analytical development, clinical trial manufacturing and scale-up and product registration support. We provide full CMC (Chemistry, Manufacturing and Controls section), support for the optimized product, including handling responses to the relevant regulatory agencies. Our extensive experience in handling the CMC sections for clients provides our clients with valuable assistance in dealing with regulatory agencies and also determining an appropriate regulatory strategy for their products. The co-habitation of development and manufacturing capabilities on the same site allows for streamlined scale-up and transfer to commercial scale manufacturing activities.

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### *Services We Offer to Clients:*

A broad range of creative drug optimization approaches including formulation development, scale-up and manufacturing.

Our *NanoCrystal* technology offers superior results for poorly water-soluble compounds that can be incorporated into common dosage forms. This technology has been applied in four products contributing to over \$1.5 billion annual in-market sales for our clients.

Range of customized oral drug technologies such as extended release, delayed release and pulsatile release have all been developed and commercialized.

Suite of more than 1,700 patents/pending patents protecting our technology-based solutions.

FDA/European Medicines Agency approved manufacturing and packaging capabilities in the United States and Europe for solid oral dosage forms with annual capacity of 3 billion units.

Other services include analytical development, clinical trial manufacturing, product registration support and supply chain management for client products.

***Athlone, Ireland, Facility*** Located on a 40-acre site with over 200,000 sq ft of dedicated GMP grade facilities, Elan Drug Technologies has a proven manufacturing track-record 30 products optimized and manufactured for over 90 countries worldwide. The facility has a capacity of 3 billion unit doses per annum.

### ***ENVIRONMENT***

The U.S. market is our most important market. Refer to Note 30 to the Consolidated Financial Statements for an analysis of revenue by geographic region. For this reason, the factors discussed below, such as Government Regulation and Product Approval, place emphasis on requirements in the United States.

### ***Government Regulation***

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

Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing and marketing of pharmaceutical products. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications for drugs, biological products or medical devices until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions.

In addition, the U.S. Centers for Disease Control and Prevention regulate select biologics and toxins. 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.

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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 and the mechanism of price regulation varies. In the United States, while there are limited indirect federal government price controls over private sector purchases of drugs, it is not possible to predict future regulatory action on the pricing of pharmaceutical products.

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

In January 2006, we received a subpoena from the U.S. Department of Justice and the Department of Health and Human Services, Office of Inspector General, asking for documents and materials primarily related to our marketing practices for Zonegran. 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***

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

The clinical trial process can take three to 10 years or more to complete, and there can be no assurance that the data collected 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 Biologics License Application (BLA). In certain cases, an Abbreviated New Drug Application (ANDA) can be filed in lieu of filing an NDA.

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.

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.

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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.

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.

### ***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.

At December 31, 2008, we employed 601 people in our manufacturing and supply activities, over half of these in Athlone, Ireland. This facility is our primary location for the manufacture of oral solid dosage products, including instant, controlled release and oral nano particulate products. Additional dosage capabilities may be added as required to support future product introductions. Our facility in Gainesville, Georgia, United States, provides additional oral controlled release dosage product manufacturing capability and is registered with the U.S. Drug Enforcement Administration for the manufacture, packaging and distribution of Schedule II controlled drugs.

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.

### ***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.

*Tysabri* is covered by a number of issued patents and pending patent applications in the United States and many other countries. We have a basic U.S. patent, which expires in 2017, for *Tysabri* covering the humanized antibody and its use to treat MS. Additional U.S. patents and patent applications of Elan and/or our collaborator Biogen Idec that 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 the product and methods of manufacturing the product generally expire between 2014 and 2020, and may be subject to additional patent protection until 2020 in the nature of Supplementary Protection Certificates. International patents and patent applications covering methods of treatment using *Tysabri* would generally expire between 2012 to 2020.

In addition to our *Tysabri* collaboration with Biogen Idec, we have entered into licenses covering intellectual property related to *Tysabri*. We 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.

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The fundamental U.S. patent covering the use of *Prialt* to produce analgesia expires in 2016. A further U.S. patent covering the stabilized formulation of *Prialt* expires in 2015.

The basic U.S. patent for *Maxipime* expired in March 2007. An ANDA for a generic version of cefepime hydrochloride was approved by the FDA on June 18, 2007, and marketing of the generic product began immediately thereafter. Following this introduction of generic cefepime to the market, our revenues from, and gross margin for, *Maxipime* were materially and adversely affected.

The basic U.S. patent for *Azactam* expired in October 2005. *Azactam* will likely face generic competition, which is expected to have a substantial adverse effect on our revenues from, and gross margin for, this product.

The primary patents covering Elan's *NanoCrystal* technology expire in the United States in 2011 and in some countries outside the United States in 2012. We also have numerous U.S. 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 robust patent estate resulting from our Alzheimer's disease research.

## ***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 we have. We also compete with smaller research companies and generic drug manufacturers.

*Tysabri*, a treatment for relapsing forms of MS, competes primarily with Avonex<sup>®</sup> marketed by our collaborator Biogen Idec, Betaseron<sup>®</sup> marketed by Berlex (an affiliate of Bayer Schering Pharma AG) in the United States and sold under the name Betaferon<sup>®</sup> by Bayer Schering Pharma in Europe, Rebif<sup>®</sup> marketed by Merck Serono and Pfizer Inc. in the United States and by Merck Serono in Europe, and Copaxone<sup>®</sup> marketed by Teva Neurosciences, Inc. 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 that if successfully developed would compete with *Tysabri*.

A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and, thereafter, it may be subject to further competition from generic products. Our product *Azactam* lost its basic U.S. patent protection in October 2005, and the basic U.S. patent for *Maxipime* expired in March 2007.

Generic competitors have challenged existing patent protection for some of the products from which we earn manufacturing or royalty revenue. If these challenges are successful, our manufacturing and royalty revenue will be materially and adversely affected.

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 competitive products, including generic versions of our products, has had and may have a material adverse effect on our revenues 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 and adversely affected.

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***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.

***Employees***

On December 31, 2008, we had 1,687 employees worldwide, of whom 656 were engaged in R&D activities, 601 were engaged in manufacturing and supply activities, 123 were engaged in sales and marketing activities and the remainder worked in general and administrative areas.

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

At December 31, 2008, we had the following principal subsidiary undertakings:

<b>Company</b>	<b>Nature of Business</b>	<b>Group Share %</b>	<b>Registered Office &amp; Country of Incorporation</b>
Athena Neurosciences, Inc.	Holding company	100	800 Gateway Blvd., South San Francisco, CA, USA
Elan Drug Delivery, Inc.	R&D	100	3000 Horizon Drive, King of Prussia, PA, USA
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, USA
Elan Holdings Ltd.	Holding company	100	Monksland, Athlone, Co. Westmeath, Ireland
Elan International Insurance Ltd.	Captive insurance company	100	Clarendon House, 2 Church Street, Hamilton, Bermuda
Elan International Services Ltd.	Financial services company	100	Clarendon House, 2 Church Street, 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, USA

**D. Property, Plant and Equipment**

We consider that our properties are in good operating condition and that our machinery and equipment have 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, refer to Note 14 to the Consolidated Financial Statements, which discloses amounts invested in land and buildings and plant and equipment; Note 21 to the Consolidated Financial Statements, which discloses future minimum rental commitments; Note 26 to the Consolidated Financial Statements, which discloses capital commitments for the purchase of property, plant and equipment; and Item 5.B. Liquidity and Capital

Resources, which discloses our capital expenditures.



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

<b>Location and Ownership Interest</b>	<b>Use</b>	<b>Size (Sq. Ft.)</b>
Owned: Athlone, Ireland	R&D, manufacturing and administration	463,000
Owned: Gainesville, GA, USA	R&D, manufacturing and administration	89,000
Leased: South San Francisco, CA, USA	R&D, sales and administration	262,000 <sup>(1)(2)</sup>
Leased: King of Prussia, PA, USA	R&D, manufacturing, sales and administration	113,000
Leased: Dublin, Ireland	Corporate administration	41,000 <sup>(3)</sup>
Leased: New York City, NY, USA	Corporate administration	14,000 <sup>(4)</sup>

- <sup>(1)</sup> *In June and December 2007, we entered into lease agreements for two additional buildings in South San Francisco, which are currently under construction. The square footage for the first building will be approximately 108,000 square feet and for the second building approximately 84,000 square feet, which are not included in the 262,000 square feet noted above. The lease term for the first building is expected to commence in March 2009 and the second building in the first quarter of 2010. The buildings will be utilized for our R&D, sales and administrative functions.*
- <sup>(2)</sup> *Approximately 43,000 square feet of the 262,000 square feet currently occupied are related to short-term leases that will be vacated by August 2009.*
- <sup>(3)</sup> *In April 2008, we entered into a lease agreement for additional space for our corporate headquarters in the Treasury Building, Dublin, Ireland. The square footage for the additional space is approximately 21,000 square feet and will be utilized for our corporate administrative functions and our international development group.*
- <sup>(4)</sup> *On December 12, 2008, we announced the planned closure of the New York office to occur in the first half of 2009. For additional information, refer to Note 5 to the Consolidated Financial Statements.*

**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 U.S. 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 U.S. 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, 2008 compared to 2007 and 2006, including segment analysis; and

Liquidity and capital resources.

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

**Table of Contents***CURRENT OPERATIONS*

Our business is organized into two business units: Biopharmaceuticals and EDT. Biopharmaceuticals engages in research, development and commercial activities primarily in Alzheimer's disease, Parkinson's disease, multiple sclerosis, Crohn's disease, severe chronic pain and infectious diseases. EDT is an established, profitable specialty pharmaceutical business unit of Elan. For nearly 40 years, EDT has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed worldwide. For additional information on our current operations, refer to Item 4.B. Business Overview.

*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, estimating sales rebates and discounts, the fair value of share-based compensation, and the accounting for contingencies and income taxes, 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*

Total goodwill and other intangible assets amounted to \$553.9 million at December 31, 2008 (2007: \$457.6 million). 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 not amortized, but instead are tested for impairment at least annually. At December 31, 2008, we had no other intangible assets with indefinite lives.

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, as with other long-lived assets such as tangible fixed assets, are reviewed for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset be tested for possible impairment, we compare undiscounted cash flows expected to be generated by an asset to the carrying value of the asset. If the carrying value of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. We determine fair value using the income approach based on the present value of expected cash flows. Our cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. 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. The results of certain impairment tests on intangible assets with estimable useful lives are discussed below.

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. The goodwill impairment test is a two-step test and 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, which are at the operating-segment level. Under the first step, 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 and step two does not need to be performed. 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

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implied fair value of goodwill. In evaluating goodwill for impairment, we determine the fair values of the reporting units using the income approach, based on the present value of expected cash flows. We completed the annual goodwill impairment test on September 30 of each year and the result of our tests did not indicate any impairment in 2008, 2007 or 2006.

In performing our annual goodwill impairment test, we noted that the combined fair value of our reporting units based on the income approach exceeded our market capitalization at the test date. In turn, given our shareholders' deficit position, both the fair value of our reporting units and our market capitalization exceeded the combined carrying values of the reporting units by a substantial margin, at the impairment test date and as of December 31, 2008.

In June 2007, we recorded an impairment charge of \$52.2 million, within other net charges in the Consolidated Income Statement, relating to the *Maxipime* and *Azactam* intangible assets. As a direct result of the approval of a first generic formulation of cefepime hydrochloride in June 2007 and the anticipated approval for a generic form of *Azactam*, we revised the projected future cumulative undiscounted cash flows. The revised projected cumulative undiscounted cash flows were lower than the intangible assets' carrying value, thus indicating the intangible assets were not recoverable. Consequently, the impairment charge was calculated as the excess of the carrying value over the discounted net present value. In conjunction with the impairment charge, we revised the estimated useful lives of the intangibles by nine months from September 2008 to December 2007. Accordingly, the remaining net intangible assets carrying value was amortized, on a straight-line basis, through December 31, 2007. There were no material impairment charges relating to intangible assets in either 2008 or 2006. For additional information on goodwill and other intangible assets, refer to Note 15 to the Consolidated Financial Statements.

In January 2005, we launched *Prialt* in the United States. Revenues from sales of *Prialt* totaled \$16.5 million, \$12.3 million and \$12.1 million in 2008, 2007 and 2006, respectively. These revenues were lower than our initial forecast. Our estimates of the recoverable amount of this product, based on future net cash flows, are in excess of the asset's carrying value of \$51.6 million at December 31, 2008. 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 and for our clients. To the extent that we are not successful 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, 2008, 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

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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.

***Sales Discounts and Allowances***

We recognize revenue on a gross revenue basis (except for *Tysabri* revenue outside of the United States) 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, 2008, we had total provisions of \$19.2 million for sales discounts and allowances, of which approximately 52.0%, 28.5% and 16.0% related to *Tysabri*, *Azactam* and *Maxipime*, respectively. We have almost three years of experience for *Tysabri* and more than 10 years of experience in relation to *Azactam* and *Maxipime*.

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 that would compensate a wholesaler for the costs of holding inventory above normal inventory levels, thereby encouraging wholesalers to hold excess inventory.

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

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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 5.A. Operating Results, and in Note 3 to the Consolidated Financial Statements.

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In millions)</b>		
Gross revenue subject to discounts and allowances	\$ 627.7	\$ 508.3	\$ 322.0
Net <i>Tysabri</i> ROW revenue	135.5	14.3	(10.7)
Manufacturing revenue and royalties	282.6	271.3	234.8
Contract revenue	20.0	30.8	27.5
Amortized revenue Adalat/Avinza		4.5	30.7
<b>Gross revenue</b>	<b>\$ 1,065.8</b>	<b>\$ 829.2</b>	<b>\$ 604.3</b>
Sales discounts and allowances:			
Charge-backs	\$ (34.7)	\$ (41.6)	\$ (28.6)
Managed health care rebates and other contract discounts	(1.3)	(2.9)	(3.7)
Medicaid rebates	(5.4)	(3.5)	(1.2)
Cash discounts	(13.7)	(11.5)	(6.5)
Sales returns	(0.1)	(4.3)	(0.6)
Other adjustments	(10.4)	(6.0)	(3.3)
<b>Total sales discounts and allowances</b>	<b>\$ (65.6)</b>	<b>\$ (69.8)</b>	<b>\$ (43.9)</b>
Net revenue subject to discounts and allowances	562.1	438.5	278.1
Net <i>Tysabri</i> ROW revenue	135.5	14.3	(10.7)
Manufacturing revenue and royalties	282.6	271.3	234.8
Contract revenue	20.0	30.8	27.5
Amortized revenue Adalat/Avinza		4.5	30.7
<b>Net revenue</b>	<b>\$ 1,000.2</b>	<b>\$ 759.4</b>	<b>\$ 560.4</b>

Total sales discounts and allowances were 10.5% of gross revenue subject to discounts and allowances in 2008, 13.7% in 2007 and 13.6% in 2006, as detailed in the rollforward below and as further explained in the following paragraphs.

Charge-backs as a percentage of gross revenue subject to discounts and allowances were 5.5% in 2008, 8.2% in 2007 and 8.9% in 2006. The managed health care rebates and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances were 0.2% and 0.9%, respectively, in 2008; 0.6% and 0.7%, respectively, in 2007; and 1.1% and 0.4%, respectively, in 2006. These changes are due primarily to changes in the product mix, as a consequence of increasing revenues from *Tysabri*, which has a lower level of charge-backs associated with it than for our other principal products.

Cash discounts as a percentage of gross revenue subject to discounts and allowances remained fairly consistent at 2.2% in 2008, compared to 2.3% in 2007 and 2.0% 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 were Nil in 2008, 0.8% in 2007 and 0.2% in 2006, and in 2008, the sale returns were impacted by the provision adjustments related to sales made in prior periods.

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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):

	<b>Charge-Backs</b>	<b>Managed Health Care Rebates and Other Contract Discounts</b>	<b>Medicaid Rebates</b>	<b>Cash Discounts</b>	<b>Sales Returns</b>	<b>Other Adjustments</b>	<b>Total</b>
Balance at December 31, 2006	\$ 6.7	\$ 1.6	\$ 0.9	\$ 1.1	\$ 5.2	\$ 1.0	\$ 16.5
Provision related to sales made in current period	41.6	2.9	3.5	11.5	3.9	6.0	69.4
Provision related to sales made in prior periods					0.4		0.4
Returns and payments	(42.9)	(3.6)	(1.4)	(11.6)	(1.9)	(6.0)	(67.4)
Balance at December 31, 2007	5.4	0.9	3.0	1.0	7.6	1.0	18.9
Provision related to sales made in current period	34.7	1.3	5.4	13.7	2.8	10.4	68.3
Provision related to sales made in prior periods					(2.7)		(2.7)
Returns and payments	(37.6)	(1.8)	(2.4)	(12.8)	(1.1)	(9.6)	(65.3)
Balance at December 31, 2008	\$ 2.5	\$ 0.4	\$ 6.0	\$ 1.9	\$ 6.6	\$ 1.8	\$ 19.2

*(a) Charge-backs*

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

December 31, 2008, *Tysabri*, *Azactam* and *Maxipime* represented approximately 30.6%, 4.8% and 61.5%, respectively, of the total charge-backs accrual balance of \$2.5 million. If we were to increase our estimated level of inventory in the wholesale distribution channel by one month's worth of demand for *Tysabri*, *Azactam* and *Maxipime*, the accrual for charge-backs would increase by approximately \$1.8 million. We believe that our estimate of the levels of inventory for *Tysabri*, *Azactam* and *Maxipime* in the wholesale 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 healthcare rebates and other contract discounts*

We offer rebates and discounts to managed healthcare organizations in the United States. We account for managed healthcare 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 healthcare 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.

*(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 12 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.

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, 2008, *Tysabri*, *Azactam* and *Maxipime* represented approximately 24.2%, 58.0% and 14.1%, respectively, of the total sales returns accrual balance of \$6.6 million. We believe, based upon both the estimated shelf life and also our historical sales returns experience, that the vast majority of this inventory will be sold prior to the expiration dates, and accordingly believe that our sales returns accrual is appropriate.

*(f) Other adjustments*

In addition to the sales discounts and allowances described above, we make other sales adjustments primarily related to estimated obligations for credits to be granted to wholesalers under wholesaler service agreements we have entered into with many of our pharmaceutical wholesale distributors in the United States. Under these agreements, the wholesale distributors have agreed, in return for certain fees, to comply with various contractually

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defined inventory management practices and to perform certain activities such as providing weekly information with respect to inventory levels of product on hand and the amount of out-movement of product. As a result, we, along with our wholesale distributors, are able to manage product flow and inventory levels in a way that more closely follows trends in prescriptions. 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 and other relevant factors, and adjust the accruals and revenue periodically throughout each year to reflect actual experience.

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

During 2008, we recorded \$2.7 million of adjustments to decrease the sales returns 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) Use of information from external sources*

We use information from external sources to identify prescription trends and patient demand, including inventory pipeline data from three major drug wholesalers in the United States. The inventory information received from these 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 also 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. 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.

***Share-Based Compensation***

We account for share-based compensation in accordance with 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 grant date fair values. These awards include employee stock options, RSUs and stock purchases related to our employee equity purchase plans. Share-based compensation expense recognized under SFAS 123R for the years ended December 31, 2008, 2007 and 2006 was \$47.2 million, \$45.1 million and \$47.1 million, respectively. For additional information, refer to Note 25 to the Consolidated Financial Statements.

SFAS 123R requires companies to estimate the fair values of share-based awards on the date of grant and, in particular, using an option-pricing model for stock options. The value of awards expected to vest is recognized as an expense over the requisite service periods. 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 share price as well as assumptions regarding a number of complex variables. These variables include, but are not limited to, the expected share 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, some of which are described in Note 27 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

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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, 2008, we had accrued \$5.9 million (2007: \$1.7 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.

***Income Taxes***

We account for income tax expense based on income before taxes using the asset and liability method. Deferred tax assets (DTAs) and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. DTAs are recognized for the expected future tax consequences, for all deductible temporary differences and operating loss and tax credit carryforwards. A valuation allowance is required for DTAs if, based on available evidence, it is more likely than not that all or some of the asset will not be realized due to the inability to generate sufficient future taxable income. Because of cumulative losses, we had maintained a valuation allowance against substantially all of our net DTAs at December 31, 2007. However, as a result of the U.S. business generating cumulative earnings in recent years and projected U.S. profitability arising from the continued growth of the Biopharmaceuticals business in the United States, we now believe there is evidence to support the generation of sufficient future taxable income to conclude that most U.S. DTAs are more likely than not to be realized in future years. Accordingly, \$236.6 million of the U.S. valuation allowance was released during 2008.

Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past and future levels of R&D spending, likelihood of settlement, and changes in overall levels of income before taxes. Our assumptions, judgments and estimates relative to the recognition of the DTAs take into account projections of the amount and category of future taxable income, such as income from operations or capital gains income. Actual operating results and the underlying amount and category of income in future years could render our current assumptions of recoverability of net DTAs inaccurate.

***RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS***

In November 2007, the FASB's EITF reached consensus on Issue 07-01, *Accounting for Collaborative Arrangements*, (EITF 07-01), which is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. We do not expect that the adoption of EITF 07-01 will have a material impact on our



financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, (SFAS 141R), which is effective for financial statements issued for fiscal years beginning after December 15, 2008, with early adoption not permitted. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements at full fair value the identifiable assets acquired, the liabilities assumed, any

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noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. We do not expect that the adoption of SFAS 141R will have a material impact on our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51*, (SFAS 160), which is effective for financial statements issued for fiscal years beginning after December 15, 2008, with early adoption not permitted. SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes to a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. We do not expect that the adoption of SFAS 160 will have a material impact on our financial position or results of operations.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*, (SFAS 161), which is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption permitted. SFAS 161 requires disclosure of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. We do not expect that the adoption of SFAS 161 will have a material impact on our financial position or results of operations.

In April 2008, the FASB issued FASB Staff Position (FSP) SFAS 142-3, *Determination of the Useful Life of Intangible Assets*, (FSP SFAS 142-3), which is effective for financial statements issued for fiscal years beginning after December 15, 2008, with early adoption permitted. FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. We do not expect that the adoption of FSP SFAS 142-3 will have a material impact on our financial position or results of operations.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, (SFAS 162), which is effective for financial statements issued for fiscal years beginning after November 15, 2008. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy).

In May 2008, the FASB issued FSP Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*, (FSP APB 14-1), which is effective for financial statements issued for fiscal years beginning after December 15, 2008 on a retroactive basis. FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's non-convertible debt borrowing rate. We are currently evaluating the potential impact, if any, of the adoption of FSP-APB 14-1 on our financial position or results of operations.

## ***POST BALANCE SHEET EVENTS***

On February 25, 2009, we announced a postponement of our biologics manufacturing activities, a strategic redesign and realignment of the research and development organization within our Biopharmaceuticals business, and a reduction in related support activities. These adjustments will result in a reduction in our global workforce of approximately 230 positions, or 14% of our total workforce. We expect to reassess the opportunity to invest in a

biologics manufacturing facility and restart our related fill-finish activities after we have had the opportunity to evaluate the data from the Phase 3 trials of bapineuzumab in Alzheimer's disease.

**Table of Contents****A. RESULTS OF OPERATIONS***2008 Compared to 2007 and 2006 (in millions, except share and per share amounts)*

	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>% Increase/(Decrease)</b>	
				<b>2008/2007</b>	<b>2007/2006</b>
Product revenue	\$ 980.2	\$ 728.6	\$ 532.9	35%	37%
Contract revenue	20.0	30.8	27.5	(35)%	12%
Total revenue	1,000.2	759.4	560.4	32%	36%
Cost of sales	493.4	337.9	210.3	46%	61%
Gross margin	506.8	421.5	350.1	20%	20%
Operating expenses:					
Selling, general and administrative expenses	292.7	339.3	360.3	(14)%	(6)%
Research and development expenses	323.4	262.9	219.6	23%	20%
Net gain on divestment of products and businesses			(43.1)		(100)%
Other net charges/(gains)	34.2	84.6	(20.3)	(60)%	517%
Total operating expenses	650.3	686.8	516.5	(5)%	33%
Operating loss	(143.5)	(265.3)	(166.4)	(46)%	59%
Net interest and investment (gains) and losses:					
Net interest expense	132.0	113.1	111.5	17%	1%
Net investment (gains)/losses	21.8	0.9	(1.6)	2,322%	(156)%
Net charge on debt retirement		18.8		(100)%	
Net interest and investment losses	153.8	132.8	109.9	16%	21%
Loss before income taxes	(297.3)	(398.1)	(276.3)	(25)%	44%
Provision for/(benefit from) income taxes	(226.3)	6.9	(9.0)	(3,380)%	177%
Net loss	\$ (71.0)	\$ (405.0)	\$ (267.3)	(82)%	52%
Basic and diluted net loss per Ordinary Share:					
Net loss	\$ (0.15)	\$ (0.86)	\$ (0.62)	(83)%	39%

**Total Revenue**

Total revenue was \$1.0 billion in 2008, \$759.4 million in 2007 and \$560.4 million in 2006. Total revenue from our Biopharmaceuticals business increased 51% in 2008 and 67% in 2007, while revenue from our EDT business increased 2% in 2008 and 5% in 2007. Total revenue is further analyzed between revenue from the Biopharmaceuticals and EDT business units.

	2008	2007 (In millions)	2006	% Increase	
				2008/2007	2007/2006
Revenue from the Biopharmaceuticals business	\$ 698.6	\$ 463.9	\$ 278.3	51%	67%
Revenue from the EDT business	301.6	295.5	282.1	2%	5%
Total revenue	\$ 1,000.2	\$ 759.4	\$ 560.4	32%	36%

***Revenue from the Biopharmaceuticals business***

Total revenue from our Biopharmaceuticals business increased 51% to \$698.6 million from \$463.9 million in 2007. The increase was primarily due to the strong growth of *Tysabri*, which more than compensated for reduced sales of *Maxipime*, which has been adversely impacted by the introduction of generic competition in 2007. In 2007,

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revenue from our Biopharmaceuticals business increased 67% to \$463.9 million from \$278.3 million in 2006. The increase primarily reflects higher sales of *Tysabri* and *Azactam*, partially offset by the decline in sales of *Maxipime*.

	2008	2007	2006	% Increase/(Decrease)	
	(In millions)			2008/2007	2007/2006
Product revenue:					
<i>Tysabri</i> - U.S.	\$ 421.6	\$ 217.4	\$ 28.2	94%	671%
<i>Tysabri</i> - ROW	135.5	14.3	(10.7)	848%	234%
Total <i>Tysabri</i>	557.1	231.7	17.5	140%	1,224%
<i>Azactam</i>	96.9	86.3	77.9	12%	11%
<i>Maxipime</i>	27.1	122.5	159.9	(78)%	(23)%
<i>Prialt</i>	16.5	12.3	12.1	34%	2%
Royalties	1.0	1.8	2.4	(44)%	(25)%
Total product revenue	698.6	454.6	269.8	54%	68%
Contract revenue		9.3	8.5	(100)%	9%
Total revenue from Biopharmaceuticals business	\$ 698.6	\$ 463.9	\$ 278.3	51%	67%

***Tysabri***

Global in-market net sales of *Tysabri* can be analyzed as follows (in millions):

	2008	2007	2006	% Increase	
				2008/2007	2007/2006
United States	\$ 421.6	\$ 217.4	\$ 28.2	94%	671%
ROW	391.4	125.5	9.9	212%	1,168%
Total <i>Tysabri</i> in-market net sales	\$ 813.0	\$ 342.9	\$ 38.1	137%	800%

*Tysabri* in-market net sales were \$813.0 million in 2008, \$342.9 million in 2007 and \$38.1 million in 2006. The increases in 2008 and 2007 reflect strong patient demand across global markets. At the end of December 2008, approximately 37,600 patients were on therapy worldwide, including approximately 20,200 commercial patients in the United States and approximately 16,900 commercial patients in the ROW, representing an increase of 78% over the approximately 21,100 patients who were on therapy at the end of December 2007.

*Tysabri* was developed and is being marketed in collaboration with Biogen Idec. In general, subject to certain limitations imposed by the parties, we share with Biogen Idec most of the development and commercialization costs for *Tysabri*. 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

U.S. market. We purchase product from Biogen Idec at a price that includes the cost of manufacturing, plus Biogen Idec's gross margin on *Tysabri*, and this cost, together with royalties payable to other third parties, is included in cost of sales.

Outside of the United States, Biogen Idec is responsible for distribution and we record as revenue our share of the profit or loss on these sales of *Tysabri*, plus our directly incurred expenses on these sales.

As a result of the strong growth in *Tysabri* sales, in July 2008, we made an optional payment of \$75.0 million to Biogen Idec in order to maintain an approximate 50% share of *Tysabri* for annual global in-market net sales of *Tysabri* that are in excess of \$700.0 million. In addition, we exercised our option to pay a further \$50.0 million milestone to Biogen Idec in order to maintain our percentage share of *Tysabri* at approximately 50% for annual global in-market net sales of *Tysabri* that are in excess of \$1.1 billion. This \$50.0 million payment was made in January 2009 and was included in intangible assets and accrued other liabilities on our Consolidated Balance Sheet at December 31, 2008. The intangible assets have been and will be amortized on a straight-line basis over

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approximately 11 years. There are no further milestone payments required for us to retain our approximate 50% profit share.

*Tysabri-U.S.*

In the U.S. market, we recorded net sales of \$421.6 million (2007: \$217.4 million; 2006: \$28.2 million). Almost all of these sales are in relation to the MS indication.

As of the end of December 2008, approximately 20,200 patients were on commercial therapy, which represents an increase of 57% since the end of December 2007.

On January 14, 2008, the FDA approved the sBLA for *Tysabri* for the treatment of patients with CD, and *Tysabri* was launched in this indication at the end of the first quarter of 2008. On December 12, 2008, we announced a realignment of our commercial activities in *Tysabri* for CD, shifting our efforts from a traditional sales model to a model based on clinical support and education.

*Tysabri-ROW*

As previously mentioned, in the ROW market, Biogen Idec is responsible for distribution and we record as revenue our share of the profit or loss on ROW sales of *Tysabri*, plus our directly incurred expenses on these sales. In 2008, we recorded ROW revenue of \$135.5 million (2007: \$14.3 million; 2006: negative revenue of \$10.7 million), which was calculated as follows (in millions):

	2008	2007	2006	% Increase/(Decrease)	
				2008/2007	2007/2006
ROW in-market sales by Biogen Idec	\$ 391.4	\$ 125.5	\$ 9.9	212%	1,168%
ROW operating expenses incurred by Elan and Biogen Idec	(236.9)	(138.1)	(34.3)	72%	303%
ROW operating profit/(loss) generated/(incurred) by Elan and Biogen Idec	154.5	(12.6)	(24.4)	1,326%	48%
Elan's 50% share of <i>Tysabri</i> ROW collaboration operating profit/(loss)	77.3	(6.3)	(12.2)	1,327%	48%
Elan's directly incurred costs	58.2	20.6	1.5	183%	1,273%
Net <i>Tysabri</i> ROW revenue	\$ 135.5	\$ 14.3	\$ (10.7)	848%	234%

As of the end of December 2008, approximately 16,900 patients, principally in the European Union, were on commercial *Tysabri* therapy, an increase of 125% compared to approximately 7,500 patients at the end of December 2007.

*Other Biopharmaceuticals products*



*Azactam* revenue increased 12% to \$96.9 million in 2008 from our 2007 sales level and increased 11% to \$86.3 million in 2007 from our 2006 sales level, mainly reflecting increased pricing. *Azactam* lost its patent exclusivity in October 2005, and its future sales are expected to be negatively impacted by generic competition, although to date no generic form of *Azactam* has been approved.

*Maxipime* revenue decreased 78% to \$27.1 million in 2008 from our 2007 sales level and decreased 23% to \$122.5 million in 2007 from our 2006 sales level. The decreases in 2008 and 2007 were principally due to the introduction of generic competition. In June 2007, the first generic formulation of cefepime hydrochloride was approved by the FDA. Generic cefepime hydrochloride was launched shortly thereafter, and additional generic forms of *Maxipime* have since been launched. We expect generic competition to continue to materially and adversely affect our revenues from, and gross margin for, *Maxipime*.

*Prialt* revenue increased 34% to \$16.5 million in 2008 from our 2007 sales level and increased 2% to \$12.3 million in 2007 from our 2006 sales level. The increases in both 2008 and 2007 were primarily due to higher

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demand for the product. *Prialt* was launched in the U.S. 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 the divestment.

**Revenue from the EDT business**

Revenue from the EDT business increased 2% to \$301.6 million in 2008 and increased 5% to \$295.5 million in 2007 from \$282.1 million in 2006.

	2008	2007	2006	% Increase/(Decrease)	
	(In millions)			2008/2007	2007/2006
Product revenue:					
Manufacturing revenue and royalties:					
TriCor 145	\$ 67.7	\$ 62.5	\$ 52.1	8%	20%
Skelaxin®	39.7	39.3	36.5	1%	8%
Focalin XR/Ritalin LA	33.5	28.4	22.5	18%	26%
Verelan®	24.6	28.5	36.3	(14)%	(21)%
Diltiazem®	13.7	18.7	19.5	(27)%	(4)%
Zanaflex	12.8	13.1	4.9	(2)%	167%
Other	89.6	79.0	60.6	13%	30%
Total manufacturing revenue and royalties	281.6	269.5	232.4	4%	16%
Amortized revenue Adalat/Avinza		4.5	30.7	(100)%	(85)%
Total product revenue	281.6	274.0	263.1	3%	4%
Contract revenue:					
Amortized fees	2.4	4.3	4.2	(44)%	2%
Research revenue and milestones	17.6	17.2	14.8	2%	16%
Total contract revenue	20.0	21.5	19.0	(7)%	13%
Total revenue from the EDT business	\$ 301.6	\$ 295.5	\$ 282.1	2%	5%

Manufacturing revenue and royalties comprise revenue earned from products we manufacture for clients and royalties earned principally on sales by clients of products that incorporate our technologies.

Manufacturing revenue and royalties increased 4% to \$281.6 million in 2008 from our 2007 sales level and increased 16% to \$269.5 million in 2007 from our 2006 sales level. The increases in 2008 and 2007 primarily reflect continued growth across a number of products in our EDT portfolio and increased manufacturing activity.

Except as noted above, no other single product accounted for more than 10% of our manufacturing revenue and royalties in 2008, 2007 or 2006. In 2008, 47% of these revenues consisted of royalties received on products that we do not manufacture, compared to also 47% in 2007 and 44% in 2006.

Potential generic competitors have challenged the existing patent protection for several of the products from which we earn manufacturing revenue and royalties. We and our clients defend our intellectual property rights vigorously. However, if these challenges are successful, our manufacturing revenue and royalties will be materially and adversely affected.

In June 2008, a jury ruled in the U.S. District Court for the District of Delaware that Abraxis BioScience, Inc. had infringed a patent owned by us in relation to the application of our *NanoCrystal* technology to Abraxane. The jury awarded us \$55 million, applying a royalty rate of 6% to sales of Abraxane from January 2005 through June 13, 2008 (the date of the verdict). Abraxis has announced its intention to appeal the ruling. Consequently, pending final resolution of this matter, no settlement amount has been recognized in our financial statements as of and for the year ended December 31, 2008.

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Our EDT business continued to make positive progress on its development pipeline with its clients during 2008, including:

Jazz Pharmaceuticals Inc. received FDA approval in February and launched LUVOX CR<sup>®</sup> (fluvoxamine maleate) Extended-Release Capsules for the treatment of social anxiety disorder and obsessive compulsive disorder in adults in the United States. LUVOX CR is manufactured by us and incorporates our proprietary SODAS technology designed to minimize peak-to-trough plasma level fluctuations over a 24-hour period.

Acorda Therapeutics, Inc. successfully completed its Phase 3 clinical development program to assess Fampridine SR's safety and efficacy in improving the walking ability of people with MS. An NDA for Fampridine SR was submitted to the FDA on January 30, 2009. Fampridine SR incorporates our proprietary MXDAS<sup>®</sup> (Matrix Drug Absorption System) technology and is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP) and will be manufactured by us if it is approved.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. announced in August 2008 that the FDA issued a complete response letter for paliperidone palmitate for the treatment of schizophrenia requesting additional data before it will approve the NDA. No additional studies were requested. In early February 2009, Johnson & Johnson submitted its response to the FDA complete response letter. Paliperidone palmitate, an investigational once-monthly atypical antipsychotic intramuscular injection for treating schizophrenia and preventing recurrence of its symptoms, incorporates our proprietary *NanoCrystal* technology.

During the year, we completed an evaluation of the strategic options for a more formal separation of the EDT business. Given the dislocation and uncertainty in the financial and credit markets, we have decided to retain the EDT business for the foreseeable future.

*Amortized revenue Adalat/Avinza*

Amortized revenue was \$4.5 million in 2007 and \$30.7 million in 2006. The amortized revenue recorded in 2007 was related to the licensing to Watson Pharmaceuticals, Inc. in 2002 of rights to our generic form of Adalat CC (2006: \$9.0 million). The deferred revenue relating to Adalat CC was fully amortized by June 30, 2007. In 2006, we also recorded \$21.7 million of amortized revenue relating to the restructuring of our Avinza license agreement with Ligand Pharmaceuticals, Inc. in 2002. The deferred revenue relating to Avinza was fully amortized by December 2006.

*Contract revenue*

Contract revenue was \$20.0 million in 2008, \$21.5 million in 2007 and \$19.0 million in 2006. Contract revenue consists of research revenue and milestones arising from R&D activities we perform on behalf of third parties or technology licensing. The fluctuations between years in contract revenue were primarily due to the level of external R&D projects and the timing of when the milestones are earned.

*Cost of Sales*

Cost of sales was \$493.4 million in 2008, compared to \$337.9 million in 2007 and \$210.3 million in 2006. The fluctuations in the gross profit margin of 51% in 2008, 56% in 2007 and 62% in 2006 principally reflect the change in the mix of product sales, including the impact of increasing sales of *Tysabri* (which has a lower reported gross margin than our other products) and decreasing sales of *Maxipime*. The gross margin increased by 20% in 2008 (\$506.8 million), compared to 2007 (\$421.5 million), and by 20% in 2007, compared to 2006 (\$350.1 million), with increased gross margin earned from higher sales of *Tysabri* more than replacing loss of gross margin due to reduced sales of *Maxipime* following the introduction of generic competition in June 2007. The *Tysabri* gross profit margin of

42% in 2008 (2007: 32%; 2006: 19%) is impacted by the profit sharing and operational arrangements in place with Biogen Idec and reflects our gross margin on sales of the product in the United States of 37% in 2008 (2007: 36%; 2006: 34%), and our reported gross margin on ROW sales of 58% (2007: (33)%; 2006: (112)%). The ROW gross margin reflects our share of the profit or loss on ROW sales plus our directly incurred expenses on these sales,

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offset by the inclusion in cost of sales of royalties payable by us on sales of *Tysabri* outside of the United States. These royalties are payable by us but reimbursed by the collaboration.

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

SG&A expense was \$292.7 million in 2008, \$339.3 million in 2007 and \$360.3 million in 2006. The decrease of 14% in total SG&A expense in 2008, compared to 2007, principally reflects reduced sales and marketing costs resulting from the restructuring of our commercial infrastructure related to the approval of a generic form of *Maxipime* in June 2007 and the anticipated approval of a generic form of *Azactam*, along with reduced amortization expense following the impairment of our *Maxipime* and *Azactam* intangible assets. The SG&A expense related to the *Tysabri* ROW sales are reflected in the *Tysabri* ROW revenue as previously described.

The decrease of 6% in total SG&A expense in 2007, compared to 2006, reflected principally the restructuring of our commercial infrastructure as described above and the decrease in share-based compensation expense related to SG&A from \$28.8 million in 2006 to \$23.9 million in 2007.

***Research and Development Expenses***

R&D expenses were \$323.4 million in 2008, \$262.9 million in 2007 and \$219.6 million in 2006. The increases of 23% and 20% in 2008 and 2007, respectively, were primarily due to increased expenses associated with the progression of our Alzheimer's disease programs, including the advancement of bapineuzumab into Phase 3 clinical trials and the advancement of ELND005 into Phase 2 clinical trials.

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

There were no product or business divestments in 2008 or 2007.

In March 2006, we sold the *Prialt* European rights to Eisai and received \$50.0 million at closing and were entitled to receive an additional \$10.0 million on the earlier of two years from closing or launches of *Prialt* in key European markets. As of December 31, 2008, we had received the \$10.0 million related to the launches of *Prialt* in key European markets. We may also receive an additional \$40.0 million contingent on *Prialt* achieving revenue-related milestones in Europe. We recorded a gain of \$43.3 million on this sale in 2006.

***Other Net Charges/(Gains)***

The principal items classified as other charges/(gains) include severance, restructuring and other costs, the write-off of deferred transaction costs, legal settlements and awards, the impairment of our *Maxipime* and *Azactam* intangible assets, and acquired in-process research and development costs. 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 analyzing certain items.

	2008	2007	2006
	(In millions)		
(a) Severance, restructuring and other costs	\$ 22.0	\$ 32.4	\$ 7.5
(b) Write-off of deferred transaction costs	7.5		
(c) Legal settlements and awards	4.7		(49.8)
(d) <i>Maxipime</i> and <i>Azactam</i> asset impairment		52.2	

(e) Acquired in-process research and development costs				22.0
Total other net charges/(gains)	\$ 34.2	\$ 84.6	\$ (20.3)	

*(a) Severance, restructuring and other costs*

During 2008, we incurred severance, restructuring and other costs of \$22.0 million related primarily to the realignment of our commercial activities in *Tysabri* for CD and the announced closure of our offices in New York and Tokyo, which is to occur in the first half of 2009.

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During 2007, we incurred severance, restructuring and other costs of \$32.4 million arising principally from the restructuring of our commercial infrastructure and consolidation of our U.S. West Coast locations, which resulted in the closure of the San Diego facility and the expansion of our operations in South San Francisco. The restructuring of our commercial infrastructure was primarily a result of the approval of a generic form of *Maxipime* and the anticipated approval of a generic form of *Azactam*.

During 2006, the net severance, restructuring and other costs of \$7.5 million were related to the realignment of our resources to meet our business structure at that time. 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 of headcount and relocation of employees, and they also included 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 Biopharmaceuticals R&D activities, this facility was brought back into use.

### *(b) Write-off of deferred transaction costs*

During 2008, we wrote off \$7.5 million of deferred transaction costs related to the completed evaluation of the strategic options associated with the potential separation of our EDT business. Due to the dislocation and uncertainty in the financial and credit markets, we have decided to retain the EDT business for the foreseeable future.

### *(c) Legal settlements and awards*

The legal settlement of \$4.7 million, net of insurance coverage, in 2008 relates to several shareholder class action lawsuits, commencing in 1999 against Dura Pharmaceuticals, Inc., one of our subsidiaries, and various then-current or former officers of Dura. The actions, which alleged violations of the U.S. federal securities laws, were consolidated and sought damages on behalf of a class of shareholders who purchased Dura common stock during a defined period. The settlement has been reached in principle and without admission of fault by Dura. The settlement is subject to finalization by the parties and to approval by the court.

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

### *(d) Maxipime and Azactam asset impairment*

The *Maxipime* and *Azactam* asset impairment charge of \$52.2 million was related to the launch of a generic formulation of *Maxipime* in June 2007 and the anticipated approval of a generic form of *Azactam*. As a direct result, we revised the projected future cumulative undiscounted cash flows. The revised projected cumulative undiscounted cash flows were lower than the intangible assets carrying value thus indicating the intangible assets were not recoverable. Consequently, the impairment charge was calculated as the excess of the carrying value over the discounted net present value. The remaining net intangible assets carrying value was amortized, on a straight-line basis, through December 31, 2007.

### *(e) Acquired in-process research and development costs*

In July 2006, Elan and Archemix Corp. 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



ELND005 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 2006 and the rest in 2007. For additional information, refer to Item 4.B. Business Overview, which describes our R&D programs in detail.

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

Net interest expense was \$132.0 million in 2008, \$113.1 million in 2007 and \$111.5 million in 2006. The increase of 17% in 2008 as compared to 2007 was primarily due to decreased interest income as a result of lower cash balances and reduced interest rates, partially offset by lower debt interest expense as a result of lower interest rates associated with the Floating Rate Notes due 2011 and 2013.

The increase of 1% in 2007 as compared to 2006 primarily reflects less interest income earned as a result of lower cash balances.

***Net Investment (Gains)/Losses***

Net investment losses were \$21.8 million in 2008, compared to a loss of \$0.9 million in 2007 and a gain of \$1.6 million in 2006. The net investment losses in 2008 were primarily comprised of impairment charges of \$20.2 million (2007: \$6.1 million; 2006: \$7.3 million) and \$1.0 million in net realized losses on the sale of investment securities (2007: \$6.6 million net gain; 2006: \$8.3 million net gain).

At both December 31, 2008, and December 31, 2007, all of our liquid investments were invested in bank deposits and funds. In December 2007, due to the dislocations in the capital markets, one of these funds was closed. As a result, at December 31, 2007, the carrying value of our investment in this fund of \$274.8 million was no longer included in cash and cash equivalents and was presented as an investment. In conjunction with the closure of the fund, a charge of \$3.8 million (comprised of an impairment charge of \$3.6 million and a realized loss of \$0.2 million) was incurred and netted against a portion of the interest income earned from the fund in 2007. An additional charge of \$12.3 million (comprised of an impairment charge of \$10.9 million, net of interest income of \$2.2 million earned from the fund in 2008, and realized losses of \$1.4 million) was incurred in 2008.

In 2008, we recorded a net impairment charge of \$10.9 million (2007: \$Nil; 2006: \$Nil) related to the fund described above and a further impairment charge of \$6.0 million (2007: \$5.0 million; 2006: \$Nil) related to an investment in auction rate securities (ARS). The remaining impairment charges of \$3.3 million (2007: \$1.1 million; 2006: \$7.3 million) were related to various investments in emerging pharmaceutical and biotechnology companies.

At December 31, 2008, we had, at face value, \$11.4 million (2007: \$11.4 million) of principal invested in ARS, held at a carrying value of \$0.4 million (2007: \$6.3 million), which represents interests in collateralized debt obligations with long-term maturities through 2043 supported by U.S. residential mortgages, including sub-prime mortgages. The ARS, which historically had a liquid market and had their interest rates reset monthly through dutch auctions, have continued to fail at auction since September 2007 as a result of the ongoing dislocations experienced in the capital markets. In addition, the ARS, which had AAA/Aaa credit ratings at the time of purchase, were downgraded to CCC-/B1\*- ratings in 2008. At December 31, 2008, the estimated fair value of the ARS was \$0.4 million (2007: \$6.3 million). While interest continues to be paid by the issuers of the ARS, due to the significant and prolonged decline in the fair value of the ARS below their carrying value, we concluded that these securities experienced an other-than-temporary decline in fair value and recorded an impairment charge of \$6.0 million in 2008 (2007: \$5.0 million). Given that the ARS are illiquid, until there is a successful auction for them, the timing of which is presently unknown, the net carrying value has been classified as long-term investments in our Consolidated Balance Sheets at December 31, 2008 and 2007.

The framework used for measuring the fair value of our investment securities, including the ARS, is described in Note 19 to the Consolidated Financial Statements.

In 2008, we raised \$236.1 million in net cash proceeds from the disposal of investment securities, principally relating to the liquidation of the investment in the fund described above. The \$1.0 million in net losses on the sale of investment securities includes losses of \$1.4 million associated with the disposal of this fund.

In 2007, we raised \$31.3 million in net cash proceeds from the disposal of investment securities. The \$6.6 million in gains on the sale of investment securities in 2007 includes gains on sale of securities of Adnexus Therapeutics, Inc. of \$3.0 million and Women's First Healthcare, Inc. of \$1.3 million.

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In 2006, we raised \$14.1 million in net cash proceeds from the disposal of investment securities. The \$8.3 million in gains on the sale 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's First Healthcare, Inc. of \$1.0 million.

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

We had a net tax benefit of \$226.3 million for 2008, compared to a net tax provision of \$6.9 million in 2007 and a net tax benefit of \$9.0 million for 2006.

The overall net benefit from income tax for 2008 was \$228.7 million (2007: \$5.1 million provision; 2006: \$11.0 million benefit). Of this amount, \$2.4 million (2007: \$1.8 million; 2006: \$2.0 million) has been credited to shareholders' deficit to reflect utilization of stock option deductions. The remaining \$226.3 million benefit (2007: \$6.9 million provision; 2006: \$9.0 million benefit) is allocated to ordinary activities. The tax benefit reflected the release of the valuation allowance against the DTAs of our U.S. entities (U.S. valuation allowance), 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. From January 1, 2008, the amount of income that can qualify for the patent exemption will be capped at \$5 million per year. This cap will not have a material effect on our tax position. For additional information regarding tax, refer to Note 20 to the Consolidated Financial Statements.

The net benefit from income tax of \$226.3 million in 2008 includes the recognition of a net DTA of \$236.6 million. The deferred tax assets or liabilities are determined based on the differences between the GAAP basis financial statements and tax basis of assets and liabilities using the tax rates projected to be in effect for the periods in which the differences are to be utilized. DTAs are recognized for all deductible temporary differences and operating loss and tax credit carryforwards. A valuation allowance is required for DTAs if, based on available evidence, it is more likely than not that all or some of the asset will not be realized due to the inability to generate sufficient future taxable income. Because of cumulative losses, we had maintained a valuation allowance against substantially all of our net DTAs at December 31, 2007. However, as a result of the U.S. business generating cumulative earnings in recent years and projected U.S. profitability arising from the continued growth of the Biopharmaceutical business in the United States, we now believe there is evidence to support the generation of sufficient future taxable income to conclude that most U.S. DTAs are more likely than not to be realized in future years. Accordingly, \$236.6 million of the U.S. valuation allowance was released during 2008.

***SEGMENT ANALYSIS***

Our business is organized into two business units: Biopharmaceuticals and EDT. Biopharmaceuticals engages in research, development and commercial activities primarily in Alzheimer's disease, Parkinson's disease, MS, CD, severe chronic pain and infectious diseases. EDT is an established, profitable specialty pharmaceutical business unit of Elan. For additional information on our current operations, refer to Item 4.B. Business Overview.

**Table of Contents****Analysis of Results of Operations by Segment****BIOPHARMACEUTICALS (in millions)**

	2008	2007	2006	% Increase/(Decrease)	
				2008/2007	2007/2006
Product revenue	\$ 698.6	\$ 454.6	\$ 269.8	54%	68%
Contract revenue		9.3	8.5	(100)%	9%
Total revenue	698.6	463.9	278.3	51%	67%
Cost of sales	369.7	223.7	87.0	65%	157%
Gross margin	328.9	240.2	191.3	37%	26%
Operating expenses:					
Selling, general and administrative expenses	248.2	294.8	320.9	(16)%	(8)%
Research and development expenses	275.8	214.5	172.2	29%	25%
Net gain on divestment of products and businesses			(43.1)		(100)%
Other net charges	34.2	81.0	26.3	(58)%	208%
Total operating expenses	558.2	590.3	476.3	(5)%	24%
Operating loss	\$ (229.3)	\$ (350.1)	\$ (285.0)	(35)%	23%

**Total Revenue**

Refer to page 46 for additional discussion on revenue from our Biopharmaceuticals business.

**Cost of Sales**

Cost of sales was \$369.7 million in 2008, compared to \$223.7 million in 2007 and \$87.0 million in 2006. The gross profit margin was 47% in 2008, 52% in 2007 and 69% in 2006. The decreases in the gross profit margin in 2008 and 2007 were principally due to the change in the mix of product sales, including the impact of *Tysabri* and *Maxipime* as described previously.

**Selling, General and Administrative Expenses**

SG&A expense was \$248.2 million in 2008, \$294.8 million in 2007 and \$320.9 million in 2006. The decrease of 16% in total SG&A expense in 2008, compared to 2007, principally reflects reduced sales and marketing costs resulting from the restructuring of our commercial infrastructure related to the approval of a generic form of *Maxipime* in June 2007 and the anticipated approval of a generic form of *Azactam*, along with reduced amortization expense following the impairment of our *Maxipime* and *Azactam* intangible assets. The decrease also benefited from a reduction of employee compensation and benefits in 2008, compared to the 2007 levels.

The decrease of 8% in total SG&A expense in 2007, compared to 2006, was principally due to reduced sales and marketing costs and amortization expense related to *Maxipime* and *Azactam* as described above. The increase in SG&A expense related to *Tysabri* in 2007 reflects the relaunch of *Tysabri* in the United States in 2006.

***Research and Development Expenses***

R&D expenses were \$275.8 million in 2008, \$214.5 million in 2007 and \$172.2 million in 2006. The increase of 29% and 25% in 2008 and 2007, respectively, were primarily due to increased expenses associated with the progression of our Alzheimer's disease programs, including the advancement of bapineuzumab into Phase 3 clinical trials and the advancement of ELND005 into Phase 2 clinical trials. The increase in R&D expenses in 2008 was partially offset by our decision to reduce employee compensation and benefits during 2008, compared to 2007 levels.

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

There were no product or business divestments in 2008 or 2007. In 2006, the net gain of \$43.1 million on divestment of products and businesses was principally related to the sale of the *Prialt* European rights to Eisai. Refer to page 51 for additional discussion on the net gain on divestment of products and business for 2006.

***Other Net Charges***

	2008	2007	2006
	(In millions)		
Severance, restructuring and other costs	\$ 22.0	\$ 28.8	\$ 4.3
Deferred transaction costs	7.5		
Legal settlements	4.7		
<i>Maxipime</i> and <i>Azactam</i> asset impairment		52.2	
Acquired in-process research and development costs			22.0
Total other net charges	\$ 34.2	\$ 81.0	\$ 26.3

Refer to page 51 for additional discussion on other net charges from our Biopharmaceuticals business.

***ELAN DRUG TECHNOLOGIES (in millions)***

	2008	2007	2006	%	
				Increase/(Decrease)	
				2008/2007	2007/2006
Product revenue	\$ 281.6	\$ 274.0	\$ 263.1	3%	4%
Contract revenue	20.0	21.5	19.0	(7)%	13%
Total revenue	301.6	295.5	282.1	2%	5%
Cost of sales	123.7	114.2	123.3	8%	(7)%
Gross margin	177.9	181.3	158.8	(2)%	14%
Operating expenses:					
Selling, general and administrative expenses	44.5	44.5	39.4		13%
Research and development expenses	47.6	48.4	47.4	(2)%	2%
Other net charges/(gains)		3.6	(46.6)	(100)%	(108)%
Total operating expenses	92.1	96.5	40.2	(5)%	140%
Operating income	\$ 85.8	\$ 84.8	\$ 118.6	1%	(28)%

***Total Revenue***

Refer to page 49 for additional discussion on revenue from our EDT business.

***Cost of Sales***

Cost of sales was \$123.7 million in 2008, compared to \$114.2 million in 2007 and \$123.3 million in 2006. The gross profit margin was 59% in 2008, 61% in 2007 and 56% in 2006. The fluctuation in the gross profit margin in 2008, as compared to 2007 and 2006, was principally a result of changes in product mix and reduced amortized fees. In 2008, our royalties were 47% of total manufacturing revenue and royalties (2007: also 47%; 2006: 44%).

***Selling, General and Administrative Expenses***

SG&A expense was \$44.5 million in 2008, \$44.5 million in 2007 and \$39.4 million in 2006. The levels of spend were consistent in 2008 and 2007. The increase of 13% in 2007 from 2006 primarily reflects higher legal costs related to the protection of our intellectual property, which was partially offset by lower amortization charges as some of our EDT intangible assets were fully amortized in 2006.



**Table of Contents*****Research and Development Expenses***

R&D expenses were largely flat over the three years at \$47.6 million in 2008, \$48.4 million in 2007 and \$47.4 million in 2006.

***Other Net Charges/(Gains)***

	<b>2007</b>	<b>2006</b>
	<b>(In millions)</b>	
Severance, restructuring and other costs	\$ 3.6	\$ 3.2
Gain on arbitration award		(49.8)
Total other net charges/(gains)	\$ 3.6	\$ (46.6)

During 2007 and 2006, we incurred severance, restructuring and other costs of \$3.6 million and \$3.2 million, respectively, arising from the realignment of our resources to meet our business structure at that time.

In December 2006, we were awarded \$49.8 million following the conclusion of binding arbitration proceedings that 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.

**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):

	<b>2008</b>	<b>2007</b>	<b>Increase/ (Decrease)</b>
Cash and cash equivalents	\$ 375.3	\$ 423.5	(11)%
Restricted cash current	20.2	20.1	
Investment securities current	30.5	277.6	(89)%
Shareholders deficit	(232.2)	(234.7)	(1)%

We have historically financed our operating and capital resource requirements through cash flows from operations, sales of investment securities and borrowings. We consider all highly liquid deposits with an original maturity of three months or less to be cash equivalents. Our primary sources of funds as of December 31, 2008 consisted of cash and cash equivalents of \$375.3 million, which excludes current restricted cash of \$20.2 million, and current investment securities of \$30.5 million. Cash and cash equivalents primarily consist of bank deposits and holdings in U.S. Treasuries funds.

At December 31, 2008, our shareholders deficit was \$232.2 million, compared to \$234.7 million at December 31, 2007. The decrease is primarily due to adjustments to additional paid-in-capital relating to stock issued and share-based compensation expense, offset by the net loss incurred during the year. The net loss at December 31, 2008

included the recognition of a net DTA of \$236.6 million as of December 31, 2008. Our debt covenants do not require us to maintain or adhere to any specific financial ratios. Consequently, the shareholders' deficit has no impact on our ability to comply with our debt covenants.

We believe that we have sufficient current cash, liquid resources, realizable assets and investments to meet our liquidity requirements for at least the next 12 months. Longer term liquidity requirements and debt repayments will need to be met out of available cash resources, future operating cash flows, financial and other asset realizations and future financing. However, events, including a material deterioration in our operating performance as a result of our inability to sell significant amounts of *Tysabri*, material adverse legal judgments, fines, penalties or settlements arising from litigation or governmental investigations, failure to successfully develop and receive marketing approval for products under development (in particular, bapineuzumab) or the occurrence of other circumstances or events described under Item 3.D. Risk Factors, could materially and adversely affect our ability to meet our longer term liquidity requirements.

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

We continually evaluate our liquidity requirements, capital needs and availability of resources in view of, among other things, alternative uses of capital, debt service requirements, the cost of debt and equity capital and estimated future operating cash flow. We may raise additional capital; restructure or refinance outstanding debt; repurchase material amounts of outstanding debt (including the 7.75% Notes and the Floating Rate Notes due 2011 and the 8.875% Notes and the Floating Rate Notes due 2013); consider the sale of interests in subsidiaries, investment securities or other assets or the rationalization of products; or take a combination of such steps or other steps to increase or manage our liquidity and capital resources. Any such actions or steps, including any repurchase of outstanding debt, could be material. In the normal course of business, we may investigate, evaluate, discuss and engage in future company or product acquisitions, capital expenditures, investments and other business opportunities. In the event of any future acquisitions, capital expenditures, investments or other business opportunities, we may consider using available cash or raising additional capital, including the issuance of additional debt.

On January 13, 2009, we announced that the board of directors had engaged an investment bank to conduct, in conjunction with executive management and other external advisors, a review of our strategic alternatives. The purpose of the engagement is to secure access to financial resources and commercial infrastructure that would enable us to accelerate the development and commercialization of our extensive pipeline and product portfolio while maximizing the ability of our shareholders to participate in the resulting longer term value creation. The range of alternatives that will be assessed could include a minority investment, strategic alliance, or a merger or sale. We are committed to completing the review of potential alternatives as promptly as practicable. However, there can be no assurances that any particular alternative will be pursued or that any transaction will occur, or on what terms.

*Cash Flows Summary*

	<b>2008</b>	<b>2007</b> <b>(In millions)</b>	<b>2006</b>
Net cash used in operating activities	\$ (194.3)	\$ (167.5)	\$ (241.5)
Net cash provided by/(used in) investing activities	94.5	(318.1)	37.5
Net cash provided by/(used in) financing activities	51.5	(599.7)	629.3
Effect of exchange rate changes on cash	0.1	(1.8)	4.6
Net decrease in cash and cash equivalents	(48.2)	(1,087.1)	429.9
Cash and cash equivalents at beginning of year	423.5	1,510.6	1,080.7
Cash and cash equivalents at end of year	\$ 375.3	\$ 423.5	\$ 1,510.6

*Operating Activities*

The components of net cash used in operating activities at December 31 were as follows:

<b>2008</b>	<b>2007</b>	<b>2006</b>
-------------	-------------	-------------

**(In millions)**

Net interest and tax	\$ (135.2)	\$ (114.7)	\$ (101.6)
Other net (charges)/gains	(31.5)	(29.5)	21.4
Other operating activities	4.2	(30.4)	(91.1)
Working capital (increase)/decrease	(31.8)	7.1	(70.2)
Net cash used in operating activities	\$ (194.3)	\$ (167.5)	\$ (241.5)

Net cash used in operating activities was \$194.3 million in 2008 (2007: \$167.5 million; 2006: \$241.5 million).

Net interest and tax are discussed further on page 53 for net interest expense and on page 54 for income taxes. The interest and tax expenses within net cash used in operating activities exclude net non-cash gains of

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\$229.5 million in 2008 (2007: charges of \$5.3 million; 2006: charges of \$0.8 million), comprised of net non-cash interest expenses of \$5.0 million in 2008 (2007: \$4.8 million; 2006: \$2.2 million) and a net non-cash tax benefit of \$234.5 million (2007: charge of \$0.5 million; 2006: benefit of \$1.4 million).

The other net charges of \$31.5 million in 2008 (2007: \$29.5 million; 2006: other net gains of \$21.4 million) were principally related to the other net charges/(gains) described on pages 51 to 52, adjusted to exclude non-cash other charges of \$2.7 million in 2008 (2007: \$55.1 million; 2006: \$1.1 million).

The improvement in net cash flow from other operating activities from a \$30.4 million outflow in 2007 to an inflow of \$4.2 million in 2008 is primarily due to improved operating performance driven by a 32% increase in revenue while combined SG&A and R&D expenses increased by only 2%, reflecting the significant operating leverage associated with *Tysabri*, where product revenue increased 140% to \$557.1 million for 2008 from \$231.7 million for 2007.

The improvement in net cash flow from operating activities from a \$91.1 million outflow in 2006 to a \$30.4 million outflow in 2007 was principally driven by the 36% increase in revenues.

The working capital increase in 2008 of \$31.8 million was primarily driven by *Tysabri* sales. The working capital decrease in 2007 of \$7.1 million was primarily driven by a decrease in prepaid and other assets of \$60.3 million (principally related to the \$49.8 million arbitration award, which was paid by King in January 2007), offset by the increase in *Tysabri* sales. The working capital increase of \$70.2 million 2006 was primarily driven by an increase of \$56.4 million in prepaid and other assets (mainly due to the \$49.8 million King arbitration award noted above) and an increase in *Tysabri* sales.

*Investing Activities*

Net cash provided by investing activities was \$94.5 million in 2008. The primary components of cash provided by investing activities were proceeds of \$236.1 million from the sale of investment securities, principally relating to the liquidation of an investment in a fund that had been reclassified from cash equivalents to investments in December 2007 due to dislocations in the capital markets, and capital expenditure of \$137.9 million. Included within capital expenditures was a \$75.0 million optional payment made to Biogen Idec in order to maintain an approximate 50% share of *Tysabri* for annual global in-market net sales of *Tysabri* that are in excess of \$700.0 million.

Net cash used in investing activities was \$318.1 million in 2007. The primary component of cash used in investing activities was a transfer of \$305.9 million relating to the fund that was reclassified from cash equivalents to investments in December 2007. Net cash provided by investing activities was \$37.5 million in 2006. The major components of cash generated from investing activities were net proceeds of \$14.1 million from the sale of investment securities and \$54.2 million from the sale of the European rights to *Prialta* (net of transaction costs), partially offset by \$34.0 million for capital expenditures.

*Financing Activities*

Net cash provided by financing activities totaled \$51.5 million in 2008, primarily reflecting the net proceeds from employee stock issuances of \$50.0 million. Net cash used in financing activities totaled \$599.7 million in 2007, primarily reflecting the repayment of loans and capital lease obligations of \$629.6 million (principally the redemption of the \$613.2 million of the Athena Notes), partially offset by \$28.2 million of net proceeds from employee stock issuances. Net cash provided by financing activities totaled \$629.3 million in 2006, primarily reflecting the net proceeds of \$602.8 million from the issuances of \$465.0 million of the 8.875% Notes and \$150.0 million of the Floating Rate Notes due 2013, and \$29.8 million of net proceeds from employee stock issuances, offset by \$5.7 million related to the repayment of loans and capital lease obligations.



**Table of Contents*****Debt Facilities***

At December 31, 2008, we had outstanding debt of \$1,765.0 million, which consisted of the following (in millions):

7.75% Notes due 2011	\$ 850.0
Floating Rate Notes due 2011	300.0
8.875% Notes due 2013	465.0
Floating Rate Notes due 2013	150.0
 Total	 \$ 1,765.0

Our substantial indebtedness could have important consequences to us. For example, it does or could:

Increase our vulnerability to general adverse economic and industry conditions;

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

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

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

Limit our ability to borrow additional funds.

During 2008, as of December 31, 2008, and, as of the date of filing of this Form 20-F, we were not in violation of any of our debt covenants. Our debt covenants do not require us to maintain or adhere to any specific financial ratios. Consequently, the shareholders' deficit of \$232.2 million at December 31, 2008 has no impact on our ability to comply with our debt covenants. For additional information regarding our outstanding debt, refer to Note 18 to the Consolidated Financial Statements.

***Commitments and Contingencies***

For information regarding commitments and contingencies, refer to Notes 26 and 27 to the Consolidated Financial Statements.

***Capital Expenditures***

We believe that our current and planned manufacturing, research, product development and corporate facilities will adequately meet our current and projected needs. In June and December 2007, we entered into lease agreements for two additional buildings in South San Francisco, which are currently under construction. The lease term for the first building is expected to commence in March 2009, and the second building in the first quarter of 2010. The buildings will be utilized for our R&D, sales and administrative functions. We may invest a significant amount of our cash and resources into building a biologics manufacturing facility for bapineuzumab. We will use our resources to make capital expenditures as necessary from time to time and also to make investments in the purchase or licensing of products and technologies and in marketing and other alliances with third parties to support our long-term strategic

objectives.

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

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

**D. Trend Information**

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



**Table of Contents****E. Off-Balance Sheet Arrangements**

As of December 31, 2008, we have no unconsolidated special purpose financing or partnership entities or other off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, that are material to investors.

**F. Tabular Disclosure of Contractual Obligations**

The following table sets out, at December 31, 2008, our main contractual obligations due by period for debt principal and interest repayments and capital and operating leases. These represent the major contractual, future payments that may be made by Elan. The table does not include items such as expected capital expenditures on plant and equipment or future investments in financial assets. As of December 31, 2008, the directors had authorized capital expenditures, which had been contracted for, of \$31.4 million (2007: \$12.7 million), primarily related to the leasehold improvements for two new buildings that are under construction and located in South San Francisco. As of December 31, 2008, the directors had authorized capital expenditures, which had not been contracted for, of \$43.1 million (2007: \$1.8 million).

	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More Than 5 Years</b>
			<b>(In millions)</b>		
7.75% Notes due 2011	\$ 850.0	\$	\$ 850.0	\$	\$
Floating Rate Notes due 2011	300.0		300.0		
8.875% Notes due 2013	465.0			465.0	
Floating Rate Notes due 2013	150.0			150.0	
Total debt principal obligations	1,765.0		1,150.0	615.0	
Debt interest payments <sup>(1)</sup>	480.8	131.7	253.5	95.6	
Operating lease obligations	269.3	19.2 <sup>(2)</sup>	58.1 <sup>(2)</sup>	48.8	143.2
Total contractual obligations	\$ 2,515.1	\$ 150.9	\$ 1,461.6	\$ 759.4	\$ 143.2

<sup>(1)</sup> *The Floating Rate Notes due 2011 and Floating Rate Notes due 2013 bear interest at a rate, adjusted quarterly, equal to three-month London Interbank Offer Rate (LIBOR) plus 4.0%. and 4.125%, respectively. To calculate our interest payment obligation, we used the LIBOR at December 31, 2008.*

<sup>(2)</sup> *Net of estimated incentives for tenant leasehold improvements of \$7.2 million, \$3.7 million and \$1.9 million in 2009, 2010 and 2011, respectively.*

At December 31, 2008, we had liabilities related to unrecognized tax benefits of \$10.8 million. It is not possible to accurately assess the timing of or the amount of any settlement in relation to these liabilities.

At December 31, 2008, we had commitments to invest \$5.1 million (2007: \$1.8 million) in healthcare managed funds.

As a result of the strong growth in *Tysabri* sales, in July 2008, we made an optional payment of \$75.0 million to Biogen Idec in order to maintain an approximate 50% share of *Tysabri* for annual global in-market net sales of *Tysabri* that are in excess of \$700.0 million. In addition, we exercised our option to pay a further \$50.0 million milestone to Biogen Idec in order to maintain our percentage share of *Tysabri* at approximately 50% for annual global in-market net sales of *Tysabri* that are in excess of \$1.1 billion. This \$50.0 million payment was made in January 2009 and was included in intangible assets and accrued other liabilities on our Consolidated Balance Sheet at December 31, 2008. The intangible assets have been and will be amortized on a straight-line basis over approximately 11 years. There are no further milestone payments required for us to retain our approximate 50% profit share.

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

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

For information regarding the fair value of our debt, refer to Note 19 to the Consolidated Financial Statements.

Our debt ratings as of December 31, 2008 were as follows:

	<b>Standard &amp; Poor's</b>	<b>Moody's Investors Service</b>
7.75% Notes	B	B3
Floating Rate Notes due 2011	B	B3
8.875% Notes	B	B3
Floating Rate Notes due 2013	B	B3

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

*Kyran McLaughlin (64)*

*Non-Executive Chairman, Member of the Nominating and Governance Committee*

Mr. McLaughlin was appointed a director of Elan in January 1998 and was appointed chairman of Elan in January 2005. He is deputy chairman at Davy Stockbrokers, Ireland's largest stockbroker firm. He is also a director of Ryanair Holdings, plc and is a director of a number of private companies.

*Floyd Bloom, MD (72)*

*Non-Executive Director, Member of the Science and Technology Committee*

Dr. Bloom was appointed a director of Elan in July 2007. He is the retired chairman of the Scripps Research Department of Neuropharmacology and was the previous editor-in-chief of *Science*. He also served as president of the American Association for the Advancement of Science (2002-2003) and was chairman of its board of directors (2003-2004). A professor at Scripps Research since 1983, Dr. Bloom serves as chairman of the Department of Neuropharmacology (1989-2000; 2002 to present). A member of the National Academy of Science since 1977, Dr. Bloom is the recipient of numerous prizes for his contributions to science, including the Janssen Award in the Basic Sciences and the Pasarow Award in Neuropsychiatry. He is also a member of the Royal Swedish Academy of Sciences and a member of the Institute of Medicine.

*Shane Cooke (46)*

*Executive Director, Chief Financial Officer and Head of Elan Drug Technologies*

Mr. Cooke was appointed head of Elan Drug Technologies in May 2007. He was appointed a director of Elan in May 2005 and joined the company as executive vice president and chief financial officer in July 2001. Prior to joining Elan, Mr. Cooke was chief executive of Pembroke Capital Limited, an aviation leasing company, and prior to that held a number of senior positions in finance in the banking and aviation industries. Mr. Cooke is a chartered

accountant and a graduate of University College Dublin.

*Lars Ekman, MD, PhD (59)*

*Non-Executive Director, Chairman of the Science and Technology Committee*

Dr. Ekman was appointed a director of Elan in May 2005. He transitioned from his role as Elan's president of research and development in December 2007 to serve solely as a director. He joined Elan as executive vice president and president, global R&D, in 2001. Prior to joining Elan, he was executive vice president, R&D, at Schwarz Pharma AG since 1997. From 1984 to 1997, Dr. Ekman was employed in a variety of senior scientific and clinical functions at Pharmacia (now Pfizer). Dr. Ekman is a board certified surgeon with a PhD in experimental biology and has held several clinical and academic positions in both the United States and Europe. He obtained his PhD and MD from the University of Gothenburg, Sweden. He is a director of Amarin Corporation, plc., ARYx Therapeutics, Inc., Cebix Incorporated and InterMune, Inc.

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*Jonas Frick (51)*

*Non-Executive Director, Member of the Commercial Committee*

Mr. Frick was appointed a director of Elan in September 2007. He is the former chief executive officer of Scandinavian Life Science Ventures. He was chief executive officer and president of Medivir AB and served in senior executive positions in Pharmacia's international businesses in the central nervous system and autoimmune areas across Italy, Sweden and Japan. He is a founding member of the Swedish Biotechnology Industry Organization.

*Ann Maynard Gray (63)*

*Non-Executive Director, Member of the Nominating and Governance Committee*

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

*Gary Kennedy (51)*

*Non-Executive Director, Chairman of the Audit Committee*

Mr. Kennedy was appointed a director of Elan in May 2005. From May 1997 to December 2005, he was group director, finance & enterprise technology, at Allied Irish Banks, plc (AIB) and a member of the main board of AIB and was also on the board of M&T, AIB's associate in the United States. Prior to that, Mr. Kennedy was group vice president at Nortel Networks Europe after starting his management career at Deloitte & Touche. He served on the board of the Industrial Development Authority of Ireland for 10 years until he retired in December 2005. He is a director of Greencore Group plc, the NUI Galway Development Board, and a number of private companies. Mr. Kennedy is a chartered accountant.

*Patrick Kennedy (39)*

*Non-Executive Director, Chairman of the Leadership, Development and Compensation Committee*

Mr. Kennedy was appointed a director of Elan in May 2008. He is chief executive of Paddy Power plc, an international betting and gaming group listed on both the London and Irish Stock Exchanges. Mr. Kennedy was previously chief financial officer of Greencore Group plc and prior to that worked with McKinsey & Company and KPMG. Mr. Kennedy is a graduate of University College Dublin and a Fellow of the Institute of Chartered Accountants in Ireland.

*Giles Kerr (49)*

*Non-Executive Director, Member of the Audit Committee*

Mr. Kerr was appointed a director of Elan in September 2007. He is currently the director of finance with the University of Oxford, England, and a Fellow of Keble College. He is also a director and chairman of the Audit Committee of Victrex plc and a director of BTG plc, Isis Innovation Ltd. and a number of private companies. Previously, he was the group finance director and chief financial officer of Amersham plc, and prior to that, he was a partner with Arthur Andersen in the United Kingdom.

*G. Kelly Martin (49)*

*Executive Director, CEO*

Mr. Martin was appointed a director of Elan in February 2003 following his appointment as president and chief executive officer. He was formerly president of the International Private Client Group and a member of the executive

management and operating committee of Merrill Lynch & Co., Inc. He spent over 20 years at Merrill Lynch in a broad array of operating and executive responsibilities on a global basis.

*Kieran McGowan (65)*

*Non-Executive Director, Lead Independent Director, Chairman of the Nominating and Governance Committee*

Mr. McGowan was appointed a director of Elan in December 1998. From 1990 until his retirement in December 1998, he was chief executive of the Industrial Development Authority of Ireland. He is chairman of CRH, plc. He is also a director of United Drug, plc, and of a number of private companies.

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*Donal O Connor (58)*

*Non-Executive Director, Member of the Audit Committee*

Mr. O Connor was appointed a director of Elan in May 2008. He was senior partner of PricewaterhouseCoopers in Ireland from 1995 until 2007 and was a member of the PricewaterhouseCoopers Global Board and is a former Chairman of the Eurofirms Board. He is chairman of Anglo Irish Bank, plc and a director of Readymix, plc and the Administrator of Icarom plc. He is a graduate of University College Dublin and a Fellow of the Institute of Chartered Accountants in Ireland.

*William Rohn (65)*

*Non-Executive Director, Chairman of the Commercial Committee*

Mr. Rohn was appointed a director of Elan in May 2006. He is currently a director of Cebix, Inc., Cerus Corp. and Metabasis Therapeutics, Inc. Previously, he was chief operating officer of Biogen Idec until January 2005 and prior thereto president and chief operating officer of Idec Pharmaceutical Corporation from 1993.

*Dennis J. Selkoe, MD (65)*

*Non-Executive Director, Member of the Leadership, Development and Compensation Committee, Member of the Science and Technology Committee*

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

*Jeffrey Shames (53)*

*Non-Executive Director, Member of the Leadership, Development and Compensation Committee*

Mr. Shames was appointed a director of Elan in July 2007. He is the retired chairman and chief executive officer of MFS Investment Management. Mr. Shames is currently an executive in residence at the Massachusetts Institute of Technology (MIT) and has served on both the visiting committee and the Dean's Advisory Board of the Sloan School at MIT. He is the chairman of the Board of Trustees of Berklee College of Music; a member of the Board of Trustees of City Year (a youth service organization); co-founder and member of the Board of Hurricane Voices, a not-for profit breast cancer foundation; and trustee of the XPrize Foundation.

***Senior Management***

*Nigel Clerkin (35)*

*Senior Vice President, Finance and Group Controller*

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

*Richard T. Collier (55)*

*Executive Vice President and General Counsel*

Mr. Collier joined Elan as executive vice president and general counsel in November 2004. Prior to joining Elan, Mr. Collier was senior counsel at Morgan, Lewis & Bockius LLP. Prior to joining Morgan Lewis, he was senior vice

president and general counsel at Pharmacia, after serving in that position at Pharmacia & Upjohn. Prior to his experience at Pharmacia, Mr. Collier spent 11 years at Rhone-Poulenc Rorer, Inc. Previously, he was in private practice after having served with the U.S. Federal Trade Commission and U.S. Department of Justice. Mr. Collier is a graduate of Temple University and earned his Juris Doctor at Temple University.

*William F. Daniel (56)*

*Executive Vice President and Company Secretary*

Mr. Daniel was appointed a director of Elan in February 2003 and served until July 2007. He has served as the company secretary since December 2001, having joined Elan in March 1994 as group financial controller. In July



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1996, he was appointed group vice president, finance, group controller and principal accounting officer. From 1990 to 1992, Mr. Daniel was financial director of Xtravision, plc. Mr. Daniel is a chartered accountant and a graduate of University College Dublin.

*Kathleen Martorano (47)*

*Executive Vice President, Strategic Human Resources*

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

*Carlos V. Paya, MD, PhD (50)*

*President*

Dr. Paya joined Elan as president in November 2008. Dr. Paya joined Elan from Eli Lilly & Company, where he was vice president, Lilly Research Laboratories, and global leader of the Diabetes and Endocrine Platform, responsible for the company's franchise (insulin products). He had been an executive with Lilly since 2001, gaining a wide range of leadership experience in different therapeutic areas and business strategy. Prior to his career at Lilly, Dr. Paya had a 16-year relationship with the Mayo Clinic in Rochester, Minnesota, which began with his acceptance into the Mayo Graduate School of Medicine in 1984 and concluded with a six-year tenure as professor of medicine, Immunology and Pathology, and vice dean of the Clinical Investigation Program. Dr. Paya's other responsibilities and positions at or associated with the Mayo Clinic included two years as associate professor and senior associate consulting staff, Infectious Diseases and Internal Medicine, Pathology and Laboratory Medicine, and Immunology; and four years as a research scientist at Institute Pasteur, Paris, and as chief, Infectious Diseases Unit, Hospital 12 Octubre, Madrid, Spain.

**B. Compensation**

***Executive Officers and Directors Remuneration***

For the year ended December 31, 2008, all directors and officers as a group (21 persons) received total compensation of \$6.7 million.

We reimburse directors and officers for their actual business-related expenses. For the year ended December 31, 2008, an aggregate of \$0.3 million was accrued to provide pension, retirement and other similar benefits for directors and officers. We also maintain certain health and medical benefit plans for our employees in which our executive directors and officers participate.

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

**Table of Contents****Directors Remuneration**

	Year Ended December 31					
	2008 Salary/Fees	2008 Annual Bonus	2008 Pension	2008 Benefit in Kind	2008 Total	2007 Total
Executive Directors:						
G. Kelly Martin	\$ 806,154	\$ (1)	\$ 6,570	\$ 17,772	\$ 830,496	\$ 1,959,690(2)
Shane Cooke	624,078	414,000	73,485	12,652	1,124,215	1,315,922
Total	1,430,232	414,000	80,055	30,424	1,954,711	3,275,612
Non-Executive Directors:						
Kyran McLaughlin	300,000				300,000	300,000
Floyd Bloom, MD	67,500				67,500	31,481
Laurence G. Crowley(3)	32,378				32,378	75,908
Lars Ekman, MD, PhD	75,000				75,000	3,632,102(4)
Jonas Frick	66,458				66,458	16,462
Ann Maynard Gray	67,500				67,500	67,500
Gary Kennedy	80,000				80,000	73,711
Patrick Kennedy(5)	37,332				37,332	
Giles Kerr	68,750				68,750	16,462
Kieran McGowan	76,250				76,250	88,356
Donal O Connóir(6)	38,093				38,093	
William R. Rohn	69,783				69,783	67,500
Dennis J. Selkoe, MD	135,217(6)				135,217	137,500
Jeffrey Shames	70,000				70,000	34,606
Total	\$ 2,614,493	\$ 414,000	\$ 80,055	\$ 30,424	\$ 3,138,972	\$ 7,817,200

(1) In January 2009, after the LDCC determined the Company's bonus and equity pools for 2008, Mr. Martin requested that the board should not grant him either a cash bonus or equity in respect of the Company's performance for 2008. Notwithstanding the board's very positive assessment of Mr. Martin's performance for the year, it agreed to this request. As a result the approved bonus and equity pools were allocated only to other employees of the Company.

(2) On February 14, 2008, Mr. Martin waived his 2007 performance cash bonus, which would have been paid in 2008, in exchange for the grant of a stock option exercisable for 73,874 Ordinary Shares with an exercise price of \$25.01 per share. The stock option was granted with a fair value of \$1,040,000. Mr. Martin also received an annual stock option grant exercisable for 255,716 Ordinary Shares on the same date. The options will vest at a rate of 25% per year for four years and will expire 10 years from the date of grant.

(3) Retired as director on May 22, 2008.

(4)

*Incorporates a severance payment of \$2,500,000 and a cash payment made in respect of RSUs forfeited. See Item 7.B. Related Party Transactions for additional information.*

*(5) Appointed as directors on May 22, 2008.*

*(6) Includes fees of \$50,000 in 2008 and \$50,000 in 2007 under a consultancy agreement. See Item 7.B. Related Party Transactions for additional information.*

***Payments to a former director***

On July 1, 2003, we entered into a pension agreement with Mr. John Groom, a former director of Elan Corporation, plc, whereby we paid him a pension of \$200,000 per annum, monthly in arrears, until May 16, 2008 in respect of his former senior executive roles. Mr. Groom received total pension payments of \$75,556 in 2008.

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**C. Board Practices**

***The Board***

The roles of the chairman and CEO are separated. The chairman of the board is responsible for the leadership and management of the board. Our CEO is responsible for the operation of the business of the Company. Other significant commitments of the chairman are set out in Item 6.A. Directors and Senior Management. These commitments did not change during 2008.

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

Directors are provided with extensive induction materials on appointment and meet with key executives with a particular focus on ensuring non-executive directors are fully informed on issues of relevance to Elan and its operations. All directors are encouraged to update and refresh their skills and knowledge, for example, through attending courses on technical areas or external briefings for non-executive directors.

All directors have access to the advice and services of the company secretary. The company secretary supports the chairman in ensuring the board functions effectively and fulfills its role. He is secretary to the Audit Committee, Leadership Development and Compensation Committee (LDCC), Nominating and Governance Committee, Science and Technology Committee and the Commercial Committee and ensures compliance with applicable rules and regulations, as well as providing advice on a range of issues to commercial colleagues.

The board has reserved certain matters to its exclusive jurisdiction, thereby maintaining control of the Company and its future direction. All directors are appointed by the board, as nominated by its Nominating and Governance Committee, and subsequently elected by shareholders. Procedures are in place whereby directors and committees, in furtherance of their duties, may take independent professional advice, if necessary, at our expense. The board held eight scheduled meetings in 2008.

Our guidelines require that the board will conduct a self-evaluation at least annually to determine whether it and its committees are functioning effectively. An evaluation of the performance of the board, the board committees and individual directors was conducted during the year by the lead independent director through meetings with each member of the board. The results were presented to the nominating and governance committee and to the board. The board concluded that it and its committees had operated satisfactorily during the past year.

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

For additional information, see Items 7.B. Related Party Transactions and 10.B. Memorandum and Articles of Association.

***Independence of Directors***

Under our guidelines, at minimum, two-thirds of the board are required to be independent. At year-end, the board included 12 independent, non-executive directors who constitute in excess of two-thirds of the board. In addition to the provisions of the Combined Code, we adopted a definition of independence based on the rules of the New York Stock Exchange (NYSE), the exchange on which the majority of our shares are traded. For a director to be considered independent, the board must affirmatively determine that he or she has no material relationship with the Company.

The specific criteria that affect independence are set out in the Company's corporate governance guidelines and include former employment with the Company, former employment with the Company's independent auditors, receipt of compensation other than directors' fees, material business relationships and interlocking directorships.

In December 2008, the board considered the independence of each non-executive director and considers that all the non-executive directors, with the exception of Dr. Ekman who had retired as a full-time executive of the Company on December 31, 2007, were independent in character and judgment and there are no relationships or circumstances that are likely to affect their independent judgment.

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In reaching this conclusion, the board gave due consideration to participation by board members in our equity compensation plans. The board also considered the positions of Mr. McLaughlin, Chairman, Mr. McGowan and Dr. Selkoe, who have served as non-executive directors for in excess of nine years. Additionally, Dr. Selkoe has an ongoing consultancy agreement with the Company, which is set out in detail in Item 7.B. Related Party Transactions. It is the board's view that each of these non-executive directors discharges his duties in a thoroughly independent manner and constructively and appropriately challenges the executive directors and the board. For this reason, the board considers that they are independent.

### ***Audit Committee***

The Audit Committee, composed entirely of independent non-executive directors, helps the board in its general oversight of the Company's accounting and financial reporting practices, internal controls and audit functions, and is directly responsible for the appointment, compensation and oversight of the work of our independent auditors. The members of the committee are Mr. Gary Kennedy, Chairman, Mr. Kerr and Mr. O'Connor (appointed September 10, 2008). Mr. Crowley and Mr. Shames resigned from the Audit Committee on May 22, 2008 and January 29, 2009, respectively. Mr. Gary Kennedy qualifies as an audit committee financial expert. The Audit Committee held eight meetings in 2008. For additional information on the Audit Committee, refer to Item 16.A. Audit Committee Financial Expert and Item 16.C. Report of the Audit Committee.

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

The LDCC, composed entirely of independent non-executive directors, reviews our compensation philosophy and policies with respect to executive compensation, fringe benefits and other compensation matters. The committee determines the compensation of the chief executive officer and other executive directors and reviews the compensation of the other members of the executive management. The members of the committee are Mr. Patrick Kennedy, Chairman (appointed as a member September 10, 2008 and then as chairman on January 29, 2009), Dr. Selkoe and Mr. Shames (appointed January 29, 2009). Mr. Crowley resigned from the committee on May 22, 2008; Mr. Rohn replaced Dr. Selkoe as chairman on September 10, 2008 and acted in that role until his resignation from the committee on January 29, 2009. The committee held four meetings in 2008. Further information about the work of the LDCC is set out in the Report of the Leadership Development and Compensation Committee on page 70.

### ***Nominating and Governance Committee***

The Nominating and Governance Committee, composed entirely of independent non-executive directors, reviews on an ongoing basis the membership of the board of directors and of the board committees and the performance of the directors. It recommends new appointments to fill any vacancy that is anticipated or arises on the board of directors. The committee reviews and recommends changes in the functions of the various committees of the board. The guidelines and the charter of the committee set out the manner in which the performance evaluation of the board, its committees and the directors is to be performed and by whom. The members of the committee are Mr. McGowan, Chairman, Ms. Maynard Gray and Mr. McLaughlin. The committee held four meetings in 2008.

### ***Science and Technology Committee***

The Science and Technology Committee advises the board in its oversight of matters pertaining to our research and technology strategy and provides a perspective on those activities to the board. It does so by reviewing the discovery approaches within our internal research effort and external innovation network and by reviewing internal and external technology capabilities against long-term trends and advancements. The members of the committee are Dr. Ekman, Chairman, Dr. Bloom and Dr. Selkoe. Mr. Frick resigned from the committee on January 29, 2009. The committee held two meetings in 2008.



**Table of Contents****Commercial Committee**

The Commercial Committee was established in January 2009 and advises the board in its oversight of matters relating to our commercial business, including the structure and operation of our key commercial collaboration arrangements. The members of the committee are Mr. Rohn, Chairman, and Mr. Frick.

**Board and Board Committee Meetings**

The following table shows the number of scheduled board and board committee meetings held and attended by each director and secretary during the year . In addition to regular board and board committee meetings, there are a number of other meetings to deal with specific matters. If directors are unable to attend a board or board committee meeting because of a prior unavoidable engagement, they are provided with all the documentation and information relevant to that meeting and are encouraged to discuss issues arising in that meeting with the chairman or CEO.

	<b>Board</b>	<b>Audit Committee</b>	<b>LDCC</b>	<b>Nominating &amp; Governance Committee</b>	<b>Science &amp; Technology Committee</b>
<b>Directors</b>					
Kyran McLaughlin	8/8			4/4	
Floyd Bloom, MD	7/8				2/2
Shane Cooke	8/8				
Laurence G. Crowley <sup>(1)</sup>	3/4	5/5	1/1		
Lars Ekman, MD, PhD	7/8				2/2
Jonas Frick	7/8				1/2
Ann Maynard Gray	8/8			4/4	
Gary Kennedy	7/8	8/8			
Patrick Kennedy <sup>(2)</sup>	4/4		3/3		
Giles Kerr	7/8	7/8			
G. Kelly Martin	8/8				
Kieran McGowan	7/8			4/4	
Donal O'Connors <sup>(3)</sup>	4/4	1/1			
William R. Rohn	8/8		4/4		
Dennis J. Selkoe, MD	7/8		4/4		2/2
Jeffrey Shames	8/8	5/8			
<b>Secretary</b>					
William F. Daniel	8/8	8/8	4/4	4/4	2/2

<sup>(1)</sup> Retired as director on May 22, 2008.

<sup>(2)</sup> Appointed as director on May 22, 2008, and as member of the LDCC on September 10, 2008.

<sup>(3)</sup> Appointed as director on May 22, 2008, and as a member of the Audit Committee on September 10, 2008.

**Relations with Shareholders**



We communicate regularly with our shareholders throughout the year, specifically following the release of quarterly and annual results, and after major developments. Our Annual General Meetings, quarterly conference calls and presentations at healthcare investor conferences are webcast and are available on our website ([www.elan.com](http://www.elan.com)). The board periodically receives presentations on investor perceptions.

The principal forum for discussion with shareholders is the Annual General Meeting and shareholder participation is encouraged. Formal notification, together with an explanation of each proposed resolution, is sent to shareholders at least 21 calendar days in advance of the Annual General Meeting. At the meeting, the CEO provides a summary of the period's events after which the board and senior management are available to answer questions from shareholders. All directors normally attend the Annual General Meeting and shareholders are invited to ask questions during the meeting and to meet with directors after the formal proceedings have ended.

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In accordance with the Combined Code recommendations, the Company counts all proxy votes. On each resolution that is voted on with a show of hands, the Company indicates the level of proxies lodged, the number of votes for and against each resolution and the number of votes withheld.

### ***Going Concern***

The directors, having made inquiries, including consideration of the factors discussed in Item 5.B. Liquidity and Capital Resources, believe that the Company has adequate resources to continue in operational existence for at least the next 12 months and that it is appropriate to continue to adopt the going concern basis in preparing our Consolidated Financial Statements.

### ***Internal Control***

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

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

A formalized risk reporting system, with significant business risks addressed at each board meeting;

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

A comprehensive system for reporting financial results to the board, including a budgeting system with an annual budget approved by the board;

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

To support our system of internal control, we have separate Corporate Compliance, Internal Audit and Internal Control Departments. Each of these departments reports periodically to the Audit Committee. The Internal Control function is primarily responsible for the Company's compliance with Section 404 of the Sarbanes-Oxley Act 2002.

The directors reviewed our system of internal control and also examined the full range of risks affecting us and the appropriateness of the internal control structures to manage and monitor these risks. This process involved a confirmation that appropriate systems of internal control were in place throughout the financial year and up to the date of signing of these financial statements. It also involved an assessment of the ongoing process for the identification, management and control of the individual risks and of the role of the various risk management functions and the extent to which areas of significant challenges facing us are understood and are being addressed. No material unaddressed issues emerged from this assessment.

Refer to Item 15. Controls and Procedures, for management's annual report on internal control over financial reporting.

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

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

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

### *Remuneration Policy*

Our policy on executive directors' remuneration is to set remuneration levels that are appropriate for our senior executives having regard to their substantial responsibilities, their individual performance and our performance as a whole. The committee sets remuneration levels after reviewing remuneration packages of executives in the pharmaceutical and biotech industries. The committee takes external advice from independent benefit consultants and considers Section B of the Code of Best Practice of The Combined Code as issued by the London and Irish Stock Exchanges. The typical elements of the remuneration package for executive directors include basic salary and benefits, annual cash incentive bonus, pensions and participation in equity award plans. The committee grants equity awards to encourage identification with shareholders' interests.

The Nominating and Governance Committee, with the advice of independent compensation consultants, makes recommendations to the board of directors in respect of non-executive director compensation. Non-executive directors are compensated with fee payments and equity awards (with additional payments where directors are members of board committees) and are reimbursed for travel expenses to and from board meetings.

### *Executive Directors' Basic Salary*

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

### *Annual Cash Incentive Bonus*

We operate a cash bonus plan to which all employees, including executive directors, are eligible to participate if and when we achieve our strategic and operating goals. Bonuses are not pensionable. The cash bonus plan operates on a calendar year basis. We measure our performance against a broad series of financial, operational and scientific objectives and measurements and set annual metrics relating to them. A bonus target, expressed as a percentage of basic salary, is set for all employees. Payment will be made based on a combination of individual, team, group and company performance. In January 2009, after the LDCC determined the Company's bonus and equity pools for 2008, Mr. Martin requested that the board should not grant him either a cash bonus or equity in respect of the Company's performance for 2008. Notwithstanding the board's very positive assessment of Mr. Martin's performance for the year, it agreed to this request. As a result the approved bonus and equity pools were allocated only to other employees of the Company.

### *Long Term Incentive Plan*

On May 25, 2006, our shareholders approved the Elan Corporation, plc 2006 Long Term Incentive Plan (2006 LTIP). It is our policy, in common with other companies operating in the pharmaceutical and biotech industries, to award share options and RSUs to management and employees, taking into account the best interests of the Company. The equity awards generally vest between one and four years and do not contain any performance conditions other than service. In May 2008, our shareholders approved an amendment to the 2006 LTIP, which provides for an additional 18,000,000 shares to be reserved for issuance under the 2006 LTIP.

### *Employee Equity Purchase Plans*

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

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The board of directors, pursuant to the EEPP, subsequently established the Irish Sharesave Option Scheme 2004 and U.K. Sharesave Option Plan 2004, effective January 1, 2005, for employees based in Ireland and the United Kingdom, respectively (the Sharesave Plans). The Sharesave Plans allow eligible employees to purchase Ordinary Shares at no lower than 85% of the fair market value at the start of a 36-month saving period. No options are currently outstanding under the Sharesave Plans.

In May 2006, our shareholders approved an increase of 1,500,000 shares in the number of shares available to employees to purchase in accordance with the terms of the EEPP. In total, 3,000,000 shares have been reserved for issuance under the Sharesave Plans and U.S. Purchase Plan combined. In 2008, 313,954 (2007: 272,931) shares were issued under the U.S. Purchase Plan and 29,946 shares were issued under the Sharesave Plans (2007: Nil). As of December 31, 2008, 1,377,603 shares (2007: 1,721,053 shares) were reserved for future issuance under the EEPP.

*Approved Profit Sharing Scheme*

We also operate a profit sharing scheme, as approved by the Irish Revenue Commissioners, which permits employees and executive directors who meet the criteria laid down in the scheme to allocate a portion of their annual bonus to purchase shares. Participants may elect to take their bonus in cash subject to normal income tax deductions or may elect to have the bonus amount (subject to limits as prescribed by law) paid to the independent trustees of the scheme who use the funds to acquire shares. In addition, participants may voluntarily apply a certain percentage (subject to limits as prescribed by law) of their gross basic salary towards the purchase of shares in a similar manner. The shares must be held by the trustees for a minimum of two years after which participants may dispose of the shares but will be subject to normal income taxes until the shares have been held for a minimum of three years.

**D. Employees**

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

**E. Share Ownership***Directors and Secretary's Ordinary Shares*

The beneficial interests of those persons who were directors and the secretary of Elan Corporation, plc at December 31, 2008, including their spouses and children under 18 years of age, were as follows:

	<b>Ordinary Shares; Par Value 5 Cents Each</b>	
	<b>2008<sup>(2)</sup></b>	<b>2007<sup>(2)</sup></b>
<b>Directors</b>		
Kyran McLaughlin	190,000	190,000
Floyd Bloom, MD		
Shane Cooke	190,769	183,144
Lars Ekman, MD, PhD	90,387	33,496
Jonas Frick	2,000	
Ann Maynard Gray	3,500	3,500
Gary Kennedy	7,650	2,800
Patrick Kennedy <sup>(1)</sup>	2,500	
Giles Kerr		

G. Kelly Martin	203,150	183,150
Kieran McGowan	1,200	1,200
Donal O. Connolly <sup>(1)</sup>	18,900	
William Rohn	23,000	13,000
Dennis J. Selkoe, MD	163,175	163,175
Jeffrey Shames		
<b>Secretary</b>		
William F. Daniel	58,155	53,108

*(1) Appointed as directors on May 22, 2008.*

*(2) Individually less than one percent of total Ordinary Shares outstanding.*

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<b>Date of Grant</b>	<b>At December 31, 2007</b>	<b>Exercise Price</b>	<b>Granted 2008</b>	<b>Exercised or Vested/ Cancelled 2008</b>	<b>Market Price at Exercise Date</b>	<b>At December 31, 2008</b>	<b>Earliest Vest Date<sup>(1)</sup></b>
March 2, 2001	5,000	\$ 54.85			\$	5,000	March 2, 2002
March 10, 2004	40,000	16.27				40,000	March 10, 2005
March 10, 2005	7,500	7.47				7,500	January 1, 2006
February 1, 2006	10,000	15.90				10,000	February 1, 2008
February 21, 2007	10,000	13.95				10,000	February 21, 2009
February 14, 2008		RSU	10,000			10,000	
	<b>72,500</b>		<b>10,000</b>			<b>82,500</b>	
September 6, 2007	20,000	\$ 20.37			\$	20,000	September 6, 2008
February 14, 2008		RSU	10,000			10,000	
	<b>20,000</b>		<b>10,000</b>			<b>30,000</b>	
March 10, 2005	60,000	\$ 7.47			\$	60,000	January 1, 2006
May 25, 2005	150,000	7.21				150,000	January 1, 2006
February 1, 2006	63,899	15.90				63,899	January 1, 2007
February 1, 2006	9,435	RSU		3,145		6,290	February 1, 2007
February 21, 2007	115,620	13.95				115,620	February 21, 2008
February 21, 2007	17,921	RSU		4,480		13,441	February 21, 2008
February 14, 2008		25.01	39,068			39,068	February 14, 2009
February 14, 2008		RSU	21,991			21,991	February 14, 2009
	<b>416,875</b>		<b>61,059</b>	<b>7,625</b>		<b>470,309</b>	
March 2, 2001	5,000	\$ 54.85		5,000	\$		March 2, 2002
March 10, 2004	40,000	16.27				40,000	March 10, 2005
March 10, 2005	7,500	7.47				7,500	January 1, 2006
February 1, 2006	10,000	15.90				10,000	February 1, 2008
February 21, 2007	10,000	13.95				10,000	February 21, 2009
February 14, 2008		RSU	10,000	10,000			
	<b>72,500</b>		<b>10,000</b>	<b>15,000</b>		<b>67,500</b>	
December 7, 2000	125,000	\$ 53.25			\$	125,000	December 7, 2002
March 1, 2002	40,000	14.07				40,000	January 1, 2003
August 20, 2002	215,000	2.11		125,000	23.20		February 20, 2003



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				90,000	19.09				
April 2, 2003	15,000	2.79		15,000	19.11			January 1, 2004	D
March 10, 2004	40,000	16.27				40,000		January 1, 2005	D
March 10, 2005	60,000	7.47		20,000	19.07	40,000		January 1, 2006	D
February 1, 2006	127,799	15.90				127,799		January 1, 2007	D
February 21, 2007	106,371	13.95				106,371		February 21, 2008	D
February 21, 2007	16,487	RSU		16,487				February 21, 2008	
February 14, 2008		RSU	10,000			10,000			
	<b>745,657</b>		<b>10,000</b>	<b>266,487</b>		<b>489,170</b>			
September 13, 2007	20,000	\$ 19.51			\$	20,000		September 13, 2008	S
February 14, 2008		RSU	10,000			10,000			
	<b>20,000</b>		<b>10,000</b>			<b>30,000</b>			
March 2, 2001	5,000	\$ 54.85			\$	5,000		February 1, 2003	
March 10, 2004	40,000	16.27				40,000		March 10, 2005	
March 10, 2005	7,500	7.47				7,500		January 1, 2006	
February 1, 2006	10,000	15.90				10,000		February 1, 2008	
February 21, 2007	10,000	13.95				10,000		February 21, 2009	
February 14, 2008		RSU	10,000			10,000			
	<b>72,500</b>		<b>10,000</b>			<b>82,500</b>			
May 26, 2005	15,000	\$ 8.05			\$	15,000		May 26, 2007	
February 1, 2006	10,000	15.90				10,000		February 1, 2008	
February 21, 2007	10,000	13.95				10,000		February 21, 2009	
February 14, 2008		RSU	10,000			10,000			
	<b>35,000</b>		<b>10,000</b>			<b>45,000</b>			
May 22, 2008		\$ 25.09	20,000		\$	20,000		May 22, 2009	
			<b>20,000</b>			<b>20,000</b>			
September 13, 2007	20,000	\$ 19.51			\$	20,000		September 13, 2008	S
February 14, 2008		RSU	10,000			10,000			
	<b>20,000</b>		<b>10,000</b>			<b>30,000</b>			

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