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

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:

**Title of Each Class** 

Name of Exchange on Which Registered

American Depositary Shares (ADSs), representing Ordinary Shares, Par value 0.05 each (Ordinary Shares) Ordinary Shares New York Stock Exchange

New York Stock Exchange

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

(Title of Class)

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

(Title of Class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report: 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 b No o

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 o No b

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 b No o

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 b Accelerated filer o Non-accelerated filer o

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

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 o 
Item 18 o

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 o No b

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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. 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® (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® (cefepime hydrochloride), which lost its basic U.S. patent protection in March 2007 and now faces generic competition, Azactam® (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® 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.

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## Part I

## Item 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

## Item 2. Offer Statistics and Expected Timetable.

Not applicable.

## Item 3. Key Information.

#### A. Selected Financial Data

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

Years Ended December 31,		2008	(	2007 (In millions,	2006 cept per sha	re (	2005 e data)		2004		
Income Statement Data: Total revenue Operating loss Net loss from continuing operations Net income from discontinued operations		1,000.2 (143.5) <sup>(1)</sup> (71.0)	\$ \$ \$	759.4 (265.3) <sup>(2)</sup> (405.0)	\$ \$ \$	560.4 (166.4) <sup>(3)</sup> (267.3)	\$ \$ \$	490.3 (198.5) <sup>(4)</sup> (384.2) 0.6	\$ \$ \$	481.7 (302.1) <sup>(5)</sup> (413.7) 19.0	
Net loss Basic and diluted loss per Ordinary Share: <sup>(9)</sup>	\$	$(71.0)^{(6)}$	\$	(405.0) <sup>(7)</sup>	\$	$(267.3)^{(3)}$	\$	(383.6)(8)	\$	(394.7) <sup>(5)</sup>	
Net loss from continuing operations Net income from discontinued operations (net of tax)		(0.15)	\$	(0.86)	\$	(0.62)	\$	(0.93)	\$	(1.06) 0.05	
Total basic and diluted loss per Ordinary Share		(0.15)	\$ (0.86)		\$ (0.62)		\$	(0.93)	\$	(1.01)	
At December 31,		2008		2007		2006 (In millions		2005 s)		2004	
Balance Sheet Data: Cash and cash equivalents Restricted cash current and non-curre	ent	\$ 375 \$ 35		\$ 423.: \$ 29.0		\$ 1,510.6 \$ 23.2		\$ 1,080.7 \$ 24.9		\$ 1,347.6 \$ 192.7	

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 basic and diluted	473.5	468.3	433.3	413.5	390.1

- (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 bapineuezumab.

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 AB) 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 companies 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-Aß 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:

Licensee	Product	Indication			
Abbott Laboratories	TriCor® 145	Cholesterol			
Merck & Co., Inc.	Emend <sup>®</sup>	Nausea post chemo			
Novartis AG	Focalin XR®/Ritalin LA®	$ADHD^{(1)}$			
Wyeth	Rapamune <sup>®</sup>	Anti-rejection			
Victory Pharma	Naprelan <sup>®</sup>	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

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<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 Scaleable** 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® marketed by our collaborator Biogen Idec, Betaseron® marketed by Berlex (an affiliate of Bayer Schering Pharma AG) in the United States and sold under the name Betaferon® by Bayer Schering Pharma in Europe, Rebif® marketed by Merck Serono and Pfizer Inc. in the United States and by Merck Serono in Europe, and Copaxone® 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.

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### C. Organizational Structure

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

Company	Nature of Business	Group Share %	Registered Office & Country of Incorporation
Athena Neurosciences, Inc.	Holding company	100	800 Gateway Blvd., South San Francisco,
Elan Drug Delivery, Inc.	R&D	100	CA, USA 3000 Horizon Drive, King of Prussia, PA,
Elan Finance plc	Financial services company	100	USA 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>	Use	Size (Sq. Ft.)
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(1)(2)
Leased: King of Prussia, PA, USA	R&D, manufacturing, sales and administration	113,000
Leased: Dublin, Ireland	Corporate administration	41,000(3)
Leased: New York City, NY, USA	Corporate administration	$14,000_{(4)}$

- (1) 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.
- (2) 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.
- (3) 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.

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### **CURRENT OPERATIONS**

Our business is organized into two business units: Biopharmaceuticals and EDT. Biopharmaceuticals engages in research, development and commercial activities 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.

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

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):

Managed

		harge- Backs	H R C	lealth Care ebates and Other ontract		dicaid ebates		Cash scounts		ales turns	_	Other estments	7	<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 Provision related to sales	7	41.6	7	2.9	7	3.5	7	11.5	,	3.9	7	6.0	7	69.4
made in prior periods Returns and payments		(42.9)		(3.6)		(1.4)		(11.6)		0.4 (1.9)		(6.0)		0.4 (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 Provision related to sales		34.7		1.3		5.4		13.7		2.8		10.4		68.3
made in prior periods Returns and payments		(37.6)		(1.8)		(2.4)		(12.8)		(2.7) (1.1)		(9.6)		(2.7) (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.

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## A. RESULTS OF OPERATIONS

2008 Compared to 2007 and 2006 (in millions, except share and per share amounts)

	2008 200'		2007	2006		% Increase/ 2008/2007	(Decrease) 2007/2006	
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 Operating expenses:	506.8		421.5		350.1	20%	20%	
Selling, general and administrative expenses	292.7		339.3		360.3	(14)%	(6)%	
Research and development expenses  Net gain on divestment of products and	323.4		262.9		219.6	23%	20%	
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.

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							% In	crease	
	2008		2007 (In millions)		2006		2008/2007	2007/2006	
Revenue from the Biopharmaceuticals business	\$		\$	463.9	\$	278.3	51%	67%	
Revenue from the EDT business  Total revenue	Φ	301.6	\$	295.5	\$	282.1	2% 32%	5% 36%	
Total revenue	Ф	1,000.2	Ф	759.4	Ф	560.4	32%	3	

# 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*.

				<b>%</b>			
				Increase/	(Decrease)		
	2008	2007 (In millions)	2006	2008/2007	2007/2006		
Product revenue:							
Tysabri- U.S.	\$ 421.6	\$ 217.4	\$ 28.2	94%	671%		
Tysabri- ROW	135.5	14.3	(10.7)	848%	234%		
Total <i>Tysabri</i>	557.1	231.7	17.5	140%	1,224%		
Azactam	96.9	86.3	77.9	12%	11%		
Maxipime	27.1	122.5	159.9	(78)%	(23)%		
Prialt	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):

				% In	icrease
	2008	2007	2006	2008/2007	2007/2006
United States ROW	\$ 421.6 391.4	\$ 217.4 125.5	\$ 28.2 9.9	94% 212%	671% 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):

							%				
							Increase/	(Decrease)			
	2008		2007		2006		2008/2007	2007/2006			
ROW in-market sales by Biogen Idec ROW operating expenses incurred by Elan and	\$	391.4	\$	125.5	\$	9.9	212%	1,168%			
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 Tysabri 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.

							%			
							Increase/	(Decrease)		
	2	2008	2	2007	2	2006	2008/2007	2007/2006		
			(In n	nillions)						
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 <sup>®</sup>		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 Contract revenue:		281.6		274.0		263.1	3%	4%		
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® (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® (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 (In millions)	2006
<ul><li>(a) Severance, restructuring and other costs</li><li>(b) Write-off of deferred transaction costs</li></ul>	\$ 22.0 7.5	\$ 32.4	\$ 7.5
(c) Legal settlements and awards	4.7		(49.8)
(d) Maxipime and Azactam 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.

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### 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.

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# 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.

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## 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 (In millions)	2006
Severance, restructuring and other costs	\$ 22.0	\$ 28.8	\$ 4.3
Deferred transaction costs	7.5		
Legal settlements	4.7		
Maxipime and Azactam 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)

							<b>%</b>					
							Incr	ease/(	Decrease)			
	200	8	2	007	2	2006	2008/20	07	2007/2006			
Product revenue	\$ 28	1.6	\$	274.0	\$	263.1		3%	4%			
Contract revenue	2	0.0		21.5		19.0	(	7)%	13%			
Total revenue	30	1.6	:	295.5		282.1		2%	5%			
Cost of sales	12	3.7		114.2		123.3		8%	(7)%			
Gross margin	17	7.9		181.3		158.8	(2	2)%	14%			
Operating expenses:												
Selling, general and administrative expenses	4	4.5		44.5		39.4			13%			
Research and development expenses	4	7.6		48.4		47.4	(:	2)%	2%			
Other net charges/(gains)				3.6		(46.6)	(10	0)%	(108)%			
Total operating expenses	9	2.1		96.5		40.2	(.	5)%	140%			
Operating income	\$ 8	5.8	\$	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.

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### 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)

	2007 (In m	2006 illions)
Severance, restructuring and other costs Gain on arbitration award	\$ 3.6	\$ 3.2 (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):

	2008	2007	Increase/ (Decrease)	
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

	2	2008	(In	2007 millions)	2006
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:

2008	2007	2006

# (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)
	* (10.1 <b>5</b> )		
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 *Prialt* (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.

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#### **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.

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#### 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).

	Te	otal	7	Less Than Year	(In	1-3 Years millions)	3-5 ears	7	More Fhan Years
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(2)		58.1(2)	48.8		143.2
Total contractual obligations	\$ 2,	515.1	\$	150.9	\$	1,461.6	\$ 759.4	\$	143.2

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.

<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.

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:

	Standard & Poor s	Moody s Investors Service
7.75% Notes	В	В3
Floating Rate Notes due 2011	В	В3
8.875% Notes	В	В3
Floating Rate Notes due 2013	В	В3

### 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.

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# 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 <sup>(3)</sup>	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 <sup>(5)</sup>	37,332				37,332				
Giles Kerr	68,750				68,750	16,462			
Kieran McGowan	76,250				76,250	88,356			
Donal O Conno (5)	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			

(4)

<sup>(1)</sup> 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.

<sup>&</sup>lt;sup>(2)</sup> 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.

<sup>(3)</sup> Retired as director on May 22, 2008.

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.

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#### 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.

			Nominating &	Science &
	Audit		Governance	Technology
Boar	d Committee	LDCC	Committee	Committee
Directors				
Kyran McLaughlin 8/	8		4/4	
Floyd Bloom, MD 7/	8			2/2
Shane Cooke 8/	8			
Laurence G. Crowley <sup>(1)</sup>	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			
Patrick Kennedy <sup>(2)</sup> 4/	4	3/3		
Giles Kerr 7/	7/8			
G. Kelly Martin 8/	8			
Kieran McGowan 7/	8		4/4	
Donal O Conno <sup>2</sup> 4/	4 1/1			
William R. Rohn 8/	8	4/4		
Dennis J. Selkoe, MD	8	4/4		2/2
Jeffrey Shames 8/	5/8			
Secretary				
William F. Daniel 88	8/8	4/4	4/4	2/2

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

#### Relations with Shareholders

<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.

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). 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:

	Par Va	Ordinary Shares; Par Value 5 Cents Each		
	$2008^{(2)}$	$2007^{(2)}$		
Directors				
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				

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

<sup>(1)</sup> Appointed as directors on May 22, 2008.

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<sup>(2)</sup> Individually less than one percent of total Ordinary Shares outstanding.

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# Directors and Secretary s Options and Restricted Stock Units

				Exercised	Market		
	At December 31	, Exercise	Granted	or Vested/ Cancelled	Price at Exercise D	At December 31,	Earliest Vest
<b>Date of Grant</b>	2007	Price	2008	2008	Date	2008	Date <sup>(1)</sup>
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	·
	72,500		10,000			82,500	
September 6, 2007	20,000	\$ 20.37			\$	20,000	September 6, 2008
February 14, 2008		RSU	10,000			10,000	
	20,000		10,000			30,000	
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
	416,875		61,059	7,625		470,309	
March 2, 2001	5,000	\$ 54.85		5,000	\$		March 2, 2002
March 10, 2004		16.27		2,000	Ψ	40,000	March 10, 2005
March 10, 2005		7.47				7,500	January 1, 2006
February 1, 2006	,	15.90				10,000	February 1, 2008
February 21, 2007		13.95				10,000	February 21, 2009
February 14, 2008		RSU	10,000	10,000		10,000	1 columny 21, 2007
	72,500		10,000	15,000		67,500	
December 7, 2000	125,000	\$ 53.25			\$	125,000	December 7, 2002
March 1, 2002		14.07			Ψ	40,000	January 1, 2003
August 20, 2002		2.11		125,000	23.20	10,000	February 20, 2003

			19.09	90,000				
I	January 1, 2004	40.000	19.11	15,000		2.79	15,000	April 2, 2003
1	January 1, 2005	40,000	10.07	20.000		16.27	40,000	March 10, 2004
1	January 1, 2006	40,000	19.07	20,000		7.47	60,000	March 10, 2005
I I	January 1, 2007 February 21, 2008	127,799 106,371				15.90 13.95	127,799 106,371	February 1, 2006 February 21, 2007
1	February 21, 2008	100,571		16,487		RSU	16,487	February 21, 2007
	1 Columny 21, 2006	10,000		10,467	10,000	RSU	10,407	February 14, 2008
		10,000			10,000	RSC		1 cordary 14, 2000
		489,170		266,487	10,000		745,657	
S	September 13, 2008	20,000	\$			\$ 19.51	20,000	September 13, 2007
	-	10,000			10,000	RSU		February 14, 2008
		30,000			10,000		20,000	
	February 1, 2003	5,000	\$			\$ 54.85	5,000	March 2, 2001
	March 10, 2005	40,000	Ψ			16.27	40,000	March 10, 2004
	January 1, 2006	7,500				7.47	7,500	March 10, 2005
	February 1, 2008	10,000				15.90	10,000	February 1, 2006
	February 21, 2009	10,000				13.95	10,000	February 21, 2007
	•	10,000			10,000	RSU		February 14, 2008
		82,500			10,000		72,500	
	May 26, 2007	15,000	\$			\$ 8.05	15,000	May 26, 2005
	February 1, 2008	10,000	Ψ			15.90	10,000	February 1, 2006
	February 21, 2009	10,000				13.95	10,000	February 21, 2007
		10,000			10,000	RSU	,	February 14, 2008
		45,000			10,000		35,000	
		• • • • • •	•		••••	<b>4.27</b> 00		
	May 22, 2009	20,000	\$		20,000	\$ 25.09		May 22, 2008
		20,000			20,000			
S	September 13, 2008	20,000	\$			\$ 19.51	20,000	September 13, 2007
	-	10,000			10,000	RSU		February 14, 2008
		30,000			10,000		20,000	
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				Exercised	Market		
Date of Grant	At December 31, 2007	Exercise Price	Granted 2008	or Vested/ Cancelled 2008	Price at Exercise Date	At December 31, 2008	Earliest Vest Date <sup>(1)</sup>
Fahmany 6, 2002	1 000 000	¢ 205		22,000	¢ 26.12	044 000	Dagambar 21, 2002
February 6, 2003	1,000,000	\$ 3.85		23,000 33,000	\$ 26.13 34.56	944,000	December 31, 2003
November 13, 2003	1,000,000	5.28				1,000,000	December 31, 2003
March 10, 2004	60,000	16.27				60,000	January 1, 2005
March 10, 2005	280,000	7.47				280,000	January 1, 2006
December 7, 2005	750,000	12.03				750,000	December 31, 2006
February 21, 2007	494,855	13.95				494,855	February 21, 2008
February 14, 2008	,	25.01	329,590			329,590	February 14, 2009
	3,584,855		329,590	56,000		3,858,445	
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	10,000	RSU	10,000			10,000	1001001 21, 2007
	72,500		10,000			82,500	
May 22, 2008		\$ 25.09	20,000		\$	20,000	May 22, 2009
			20,000			20,000	
May 25, 2006	20,000	\$ 18.13			\$	20,000	May 25, 2007
February 21, 2007	10,000	13.95			Ψ	10,000	February 21, 2009
February 14, 2008	10,000	RSU	10,000			10,000	1 001 001 1
	30,000		10,000			40,000	
March 2, 2001	5,000	\$ 54.85			\$	5,000	March 2, 2002
March 10, 2004	40,000	16.27			Ψ	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
-	10,000		10.000				1 coluary 21, 2009
February 14, 2008		RSU	10,000			10,000	
	72,500		10,000			82,500	
September 6, 2007	20,000	\$ 20.37			\$	20,000	September 6, 2008
February 14, 2008	-,	RSU	10,000			10,000	1

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	20,000		10,000		30,000	
December 4, 1998	40,000	\$ 32.69		40,000	\$	December 4, 2001
November 8, 1999	40,000	24.00			40,000	November 8, 2001
February 24, 2000	35,000	37.19			35,000	January 1, 2002
March 2, 2001	25,000	54.85			25,000	January 1, 2002
March 1, 2002	30,000	14.07			30,000	January 1, 2003
August 20, 2002	30,000	2.11			30,000	February 20, 2003
May 1, 2003	6,000	3.84			6,000	January 1, 2004
March 10, 2004	30,000	16.27			30,000	January 1, 2005
December 23, 2004	705	22.29		705		February 1, 2008
March 10, 2005	50,000	7.47			50,000	January 1, 2006
February 1, 2006	47,925	15.90			47,925	January 1, 2007
February 1, 2006	7,076	RSU		2,359	4,717	February 1, 2007
February 21, 2007	69,372	13.95			69,372	February 21, 2008
February 21, 2007	10,753	RSU		2,688	8,065	February 21, 2008
February 14, 2008		25.01	17,758		17,758	February 14, 2009
February 14, 2008		RSU	9,996		9,996	February 14, 2009
	421,831		27,754	45,752	403,833	

Options outstanding at December 31, 2008 are exercisable at various dates between January 2009 and May 2018. During the year ended December 31, 2008, the closing market price ranged from \$5.36 to \$36.82 per ADS. The closing market price at February 23, 2009, on the NYSE, of our ADSs was \$6.19.

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<sup>(1)</sup> RSUs granted to non-executive directors on February 14, 2008 will become vested if, after having served for a minimum of three years, the non-executive director resigns or is removed from the board of directors for any reason other than cause, or on the tenth anniversary of the grant date.

<sup>(2)</sup> Retired as director on May 22, 2008.

<sup>(3)</sup> Appointed as directors on May 22, 2008.

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The following changes in directors and secretary s interests occurred between December 31, 2008 and February 23, 2009:

			ercise Price	No. of Options	No. of RSUs
Directors				•	
Kyran McLaughlin	February 11, 2009				11,250
Floyd Bloom, MD	February 11, 2009				7,500
Shane Cooke	February 11, 2009	\$	7.75	97,780	23,271
Lars Ekman, MD, PhD	February 11, 2009				7,500
Jonas Frick	February 11, 2009				7,500
Ann Maynard Gray	February 11, 2009				7,500
Gary Kennedy	February 11, 2009				7,500
Patrick Kennedy	February 11, 2009				7,500
Giles Kerr	February 11, 2009				7,500
G. Kelly Martin	February 11, 2009				
Kieran McGowan	February 11, 2009				7,500
Donal O Connor	February 11, 2009				7,500
William R. Rohn	February 11, 2009				7,500
Dennis J. Selkoe, MD	February 11, 2009				7,500
Jeffrey Shames	February 11, 2009				7,500
Secretary					
William F. Daniel	February 11, 2009	\$	7.75	77,643	18,479
			RSUs	Options	ADRs
	Date		Vested	Exercised	Sold
Shane Cooke	February 11, 20	09	3,145		
Shane Cooke	February 14, 20	09	5,497	,	
Shane Cooke	February 21, 20	09	4,480	)	
William F. Daniel	February 11, 20	09	2,358	}	
William F. Daniel	February 14, 20	09	2,499	1	
William F. Daniel	February 21, 20	09	2,688		

### Executive Directors Pension Arrangements

Pensions for executive directors are calculated on basic salary only (no incentive or benefit elements are included).

From July 2001 to December 2004, Mr. Cooke participated in a defined benefit pension plan, which is designed to provide eligible employees based in Ireland two-thirds of their basic salary at retirement at age 60 for full service. The total accumulated accrued annual benefit for Mr. Cooke at December 31, 2008 was 14,666 (2007: 13,393). Mr. Cooke now participates in a small self-administered pension fund to which we contribute.

Mr. Martin participates in a defined contribution plan (401(k) plan) for U.S.-based employees. Non-executive directors do not receive pensions.

For additional information on pension benefits for our employees, refer to Note 24 to the Consolidated Financial Statements.

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#### Item 7. Major Shareholders and Related Party Transactions.

### A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of Ordinary Shares or American Depository Shares at February 23, 2009 by major shareholders and all of our directors and officers as a group (either directly or by virtue of ownership of our ADSs):

Name of Owner or Identity of Group	No. of Shares	Date of Disclosure <sup>(1)</sup>	Percent of Class <sup>(2)</sup>
Fidelity Management and Research Company	71,209,248	February 3, 2009	14.80%
T. Rowe Price	34,936,222	December 31, 2008	7.26%
Wellington Management	34,754,314	December 31, 2008	7.22%
Westfield Capital Management	17,783,174	December 31, 2008	3.70%
All directors and officers as a group (19 persons)	6,468,855		1.34%

- (1) Since the date of disclosure, the interest of any person listed above in our Ordinary Shares may have increased or decreased. No requirement to notify us of any change would have arisen unless the holding moved up or down through a whole number percentage level.
- (2) Based on 475.7 million Ordinary Shares outstanding on February 23, 2009 and 5.4 million Ordinary Shares issuable upon the exercise of currently exercisable options held by directors and officers as a group as of February 23, 2009.
- (3) Includes 5.4 million Ordinary Shares issuable upon exercise of currently exercisable options held by directors and officers as a group as of February 23, 2009.

Except for these interests, we have not been notified at February 23, 2009 of any interest of 3% or more of our issued share capital. Neither Fidelity Management and Research Company, T. Rowe Price, Wellington Management nor Westfield Capital Management Co. LLC has voting rights different from other shareholders.

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

A total of 475,746,237 Ordinary Shares of Elan were issued and outstanding at February 23, 2009, of which 3,663 Ordinary Shares were held by holders of record in the United States, excluding shares held in the form of American Depository Receipts (ADRs). 391,809,352 Ordinary Shares were represented by our ADSs, evidenced by ADRs, issued by The Bank of New York, as depositary, pursuant to a deposit agreement. At February 23, 2009, the number of holders of record of Ordinary Shares was 8,536, which includes 11 holders of record in the United States, and the number of registered holders of ADRs was 3,495. Because certain of these Ordinary Shares and ADRs were held by brokers or other nominees, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

# **B.** Related Party Transactions

There were no significant transactions with related parties during the year ended December 31, 2008 other than as outlined in Note 28 to the Consolidated Financial Statements.

#### Transactions with Directors

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

Mr. Martin

On January 7, 2003, we and Elan Pharmaceuticals, Inc. (EPI) entered into an agreement with Mr. G. Kelly Martin such that Mr. Martin was appointed president and chief executive officer effective February 3, 2003.

Effective December 7, 2005, we and EPI entered into a new employment agreement with Mr. Martin, under which Mr. Martin continues to serve as our chief executive officer with an initial base annual salary of \$798,000. Mr. Martin is eligible to participate in our annual bonus plan, performance-based stock awards and merit award plans. Under the new agreement, Mr. Martin was granted an option to purchase 750,000 Ordinary Shares with an exercise price per share of \$12.03, vesting in three equal annual installments (the

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2005 Options). Mr. Martin s employment agreement was amended on December 19, 2008 to comply with the requirements of Section 409A of the IRC.

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

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

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

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

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

No other executive director has an employment contract extending beyond 12 months.

#### Dr. Ekman

Effective December 31, 2007, Dr. Lars Ekman resigned from his operational role as president of research and development and has continued to serve as a member of the board of directors of Elan.

Under the agreement reached with Dr. Ekman, we agreed by reference to Dr. Ekman s contractual entitlements and in accordance with our severance plan to (a) make a lump-sum payment of \$2,500,000; (b) make milestone payments to Dr. Ekman, subject to a maximum amount of \$1,000,000, if we achieve certain milestones in respect of our Alzheimer s disease program; (c) accelerate the vesting of, and grant a two-year exercise period, in respect of certain of his equity awards, with a cash payment being made in respect of one grant of RSUs (which did not permit accelerated vesting); and (d) continue to make annual pension payments in the amount of \$60,000 per annum, provide the cost of continued health coverage and provide career transition services to Dr. Ekman for a period of up to two years. A total severance charge of \$3.6 million was expensed in 2007 for Dr. Ekman, excluding potential future success milestone payments related to our Alzheimer s disease program. To date, none of the milestones has been triggered, and they remain in effect at December 31, 2008.

Dr. Selkoe

On July 1, 2006, EPI entered into a consultancy agreement with Dr. Dennis Selkoe whereby Dr. Selkoe agreed to provide consultant services with respect to the treatment and/or prevention of neurodegenerative and autoimmune diseases. We will pay Dr. Selkoe a fee of \$12,500 per quarter. The agreement is effective for three years unless terminated by either party upon 30 days written notice and supersedes all prior consulting agreements between Dr. Selkoe and Elan. Prior thereto, Dr. Selkoe was party to various consultancy agreements with EPI and Athena. Under the various consultancy agreements, Dr. Selkoe received \$50,000 in 2008, 2007 and 2006.

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#### Arrangements with Former Directors

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 payments of \$75,556 in 2008 and \$200,000 in 2007 and 2006.

#### External Appointments and Retention of Fees

Executive directors may accept external appointments as non-executive directors of other companies and retain any related fees paid to them.

#### C. Interest of Experts and Counsel

Not applicable.

### Item 8. Financial Information.

# A. Consolidated Statements and Other Financial Information

See item 18.

#### **B.** Significant Changes

None.

#### Item 9. The Offer and Listing.

# A. Offer and Listing Details

See item 9C.

#### B. Plan of Distribution

Not applicable.

# C. Markets

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

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

		0.05 Ordinary Shares		American Depository Shares <sup>(1)</sup>		
	High	Low	High	Low		
	(	)	(\$	)		
Year ended December 31						
2004	23.80	5.40	30.09	7.06		
2005	22.25	2.42	29.00	3.24		
2006	14.90	10.27	19.21	12.50		
2007	16.89	9.04	24.52	11.98		
2008	23.47	4.02	36.82	5.36		
Calendar Year						
2007						
Quarter 1	11.20	9.04	14.82	11.98		
Quarter 2	16.24	9.90	22.05	13.36		
Quarter 3	16.24	12.30	22.56	17.20		
Quarter 4	16.89	14.71	24.52	21.28		
2008						
Quarter 1	17.95	12.10	26.70	18.40		
Quarter 2	23.00	13.35	35.55	20.75		
Quarter 3	23.47	7.03	36.82	9.93		
Quarter 4	8.27	4.02	11.12	5.36		
Month Ended						
August 2008	10.22	7.08	14.25	9.93		
September 2008	9.15	7.23	12.99	10.03		
October 2008	8.27	4.92	11.12	6.54		
November 2008	6.12	4.22	7.40	5.36		
December 2008	5.70	4.02	7.31	5.63		
January 2009	6.36	4.53	8.70	6.78		

<sup>(1)</sup> An ADS represents one Ordinary Share, par value 0.05.

# D. Selling Shareholders

Not applicable.

#### E. Dilution

Not applicable.

# F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

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#### B. Memorandum and Articles of Association

#### **Objects**

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

#### Directors

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

The names of the directors are shown in Item 6.A. Directors and Senior Management. Mr. Patrick Kennedy and Mr. O Connor were appointed as directors on May 22, 2008. They will seek election at the forthcoming Annual General Meeting (AGM). Mr. Crowley retired as a director on May 22, 2008. Under the terms of our Articles of Association, directors serve for a term of three years expiring at the AGM in the third year following their appointment at an AGM or as the case may be, their re-appointment at the AGM. Additionally, in line with the provisions of the Combined Code, non-executive directors who have served on the board for in excess of nine years are subject to annual re-election by shareholders. Directors are not required to retire at any set age and may, if recommended by the board of directors, offer themselves for re-election at any AGM where they are deemed to have retired by rotation.

# Meetings

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

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

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

#### Liquidation Rights

In the event of the Company being wound up, the liquidator may, with the authority of a special resolution, divide among the holders of Ordinary Shares the whole or any part of the net assets of the Company (after the return of

capital on the non-voting Executive shares), and may set such value as is deemed fair upon each kind of property to be so divided and determine how such division will be carried out.

# Actions Necessary to Change the Rights of Shareholders

The rights attaching to the different classes of shares may be varied by special resolution passed at a class meeting of that class of shareholders. The additional issuance of further shares ranking *pari passu* with, or

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subordinate to, an existing class shall not, unless specified by the Articles or the conditions of issue of that class of shares, be deemed to be a variation of the special rights attaching to that class of shares.

#### Limitations on the Right to Own Shares

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

# Other Provisions of the Memorandum and Articles of Association

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

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

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

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

We incorporate by reference all other information concerning our Memorandum and Articles of Association from the section entitled Description of Ordinary Shares in the Registration Statement on Form 8-A/A3 (SEC File No. 001-13896) we filed with the SEC on December 6, 2004 and our Memorandum and Articles of Association filed as Exhibit 4.1 of our Registration Statement on Form S-8 (SEC File No. 333-135185) filed with the SEC on June 21, 2006.

#### C. Material Contracts

#### Indentures

Indentures governing the 7.75% Notes, 8.875% Notes, the Floating Rate Notes due 2011 and the Floating Rate Notes due 2013 contain covenants that restrict or prohibit our ability to engage in or enter into a variety of transactions. These restrictions and prohibitions could have a material and adverse effect on us. 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. For additional information with respect to the restrictive covenants contained in our indentures, refer to Note 18 to the Consolidated Financial Statements.

# Development and Marketing Collaboration Agreement with Biogen Idec

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

In November 2004, *Tysabri* received regulatory approval in the United States for the treatment of relapsing forms of MS. In February 2005, Elan and Biogen Idec voluntarily suspended the commercialization and dosing in clinical trials of *Tysabri*. This decision was based on reports of two serious adverse events, one of which was fatal, in patients treated with *Tysabri* in combination with Avonex in clinical trials. These events involved two cases of PML, a rare and potentially fatal, demyelinating disease of the central nervous system. Both patients received more than two years

of *Tysabri* therapy in combination with Avonex. In March 2005, the companies announced that their ongoing safety evaluation of *Tysabri* led to a previously diagnosed case of malignant astrocytoma being reassessed as PML, in a patient in an open label CD clinical trial. The patient had received eight doses of *Tysabri* over an 18-month period. The patient died in December 2003.

A comprehensive safety evaluation was performed of more than 3,000 *Tysabri* patients in collaboration with leading experts in PML and neurology. The results of the safety evaluation performed in 2005 yielded no new confirmed cases of PML beyond the three previously reported.

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

In June 2006, the FDA approved the reintroduction of *Tysabri* for the treatment of relapsing forms of MS. Approval for the marketing of *Tysabri* in the European Union was also received in June 2006 and has subsequently been received in a number of other countries. The distribution of *Tysabri* in both the United States and the ROW commenced in July 2006. Global in-market net sales of *Tysabri* in 2008 were \$813.0 million (2007: \$342.9 million; 2006: \$38.1 million), consisting of \$421.6 million (2007: \$217.4 million; 2006: \$28.2 million) in the United States and \$391.4 million (2007: \$125.5 million; 2006: \$9.9 million) in the ROW.

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

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 revenue of \$135.5 million (2007: \$14.3 million; 2006: negative \$10.7 million).

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 our 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.

# Wyeth Collaboration Agreement

In March 2000, we entered into a research, development and commercialization collaboration agreement with Wyeth, successor to American Home Products, Inc., to collaborate in the research, development and commercialization of beta amyloid immunotherapies, including bapineuzumab, and ACC-001 for the treatment and prevention of some neurodegenerative conditions in humans.

In May 2007, Elan and Wyeth announced their decision to initiate a Phase 3 clinical program for bapineuzumab. The Phase 3 program encompasses studies in North America and the ROW. In December 2007, we announced that the first patient had been dosed in the studies taking place in North America. ROW studies began enrolling patients during the second half of 2008. We are responsible for conducting the studies in North America, while Wyeth is responsible for conducting the studies in the ROW.

The Phase 3 program includes four randomized, double-blinded, placebo controlled studies across two subpopulations, which are designed to total approximately 4,000 patients with mild to moderate AD at approximately 350 sites. The treatment duration for each patient is 18 months with patients intended to be equally distributed between North America and the ROW. The studies stratify patients by ApoE4 genotype, and all studies have co-primary efficacy end points—one cognitive and one functional.

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Under our collaboration with Wyeth, in general, subject to certain limitations imposed by the parties, we share most of the research, development and commercialization costs. We are responsible for the manufacture and supply of products, while Wyeth is responsible for distribution. We continue to discuss with Wyeth a joint commercialization plan. We are eligible to earn milestone payments from Wyeth for such events as first regulatory approval filings and product approvals and achieving a certain sales level.

#### **Transition Therapeutics**

In September 2006, we 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. In December 2007, the first patient was 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. The patient enrollment target for this study was achieved in October 2008.

Under our collaboration with Transition, we shall make a \$25.0 million milestone payment to Transition after the initiation of the first Phase 3 clinical trial for ELND005.

See Item 4.B. Business Overview for additional information regarding our collaboration activities and related clinical trials.

#### **D.** Exchange Controls

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

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

#### E. Taxation

The following is a general description of Irish taxation inclusive of certain Irish tax consequences to U.S. Holders (as defined below) of the purchase, ownership and disposition of ADSs or Ordinary Shares. As used herein, references to

the Ordinary Shares include ADSs representing such Ordinary Shares, unless the tax treatment of the ADSs and Ordinary Shares has been specifically differentiated. This description is for general information purposes only and does not purport to be a comprehensive description of all the Irish tax considerations that may be relevant in a U.S. Holder s decision to purchase, hold or dispose of our Ordinary Shares. It is based on the various Irish Taxation Acts, all as in effect on February 23, 2009 and all of which are subject to change (possibly

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on a retroactive basis). The Irish tax treatment of a U.S. Holder of Ordinary Shares may vary depending upon such holder s particular situation, and holders or prospective purchasers of Ordinary Shares are advised to consult their own tax advisors as to the Irish or other tax consequences of the purchase, ownership and disposition of Ordinary Shares.

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

#### Taxation of Corporate Income

We are a public limited company incorporated and resident for tax purposes in Ireland. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. The Taxes Consolidation Act, 1997 provides that a company that is resident in Ireland and is not resident elsewhere shall be entitled to have certain income from a qualifying patent disregarded for tax purposes. The legislation does not provide a termination date for this relief, although with effect from January 1, 2008, the amount of this income that is disregarded for tax purposes is capped at 5 million per year per group. A qualifying patent means a patent in relation to which the research, planning, processing, experimenting, testing, devising, designing, developing or similar activities leading to the invention that is the subject of the patent were carried out in an European Economic Area state. Income from a qualifying patent means any royalty or other sum paid in respect of the use of the invention to which the qualifying patent relates, including any sum paid for the grant of a license to exercise rights under such patent, where that royalty or other sum is paid, for the purpose of activities that would be regarded under Irish law as the manufacture of goods (to the extent that the payment does not exceed an arms-length rate), or by a person who is not connected with us. Accordingly, our income from such qualifying patents is disregarded for tax purposes in Ireland. Any Irish manufacturing income of Elan and its subsidiaries is taxable at the rate of 10% in Ireland until December 31, 2010. Any trading income that does not qualify for the patent exemption or the 10% rate of tax is taxable at the Irish corporation tax rate of 12.5% in respect of trading income for the years 2003 and thereafter. Non-trading income is taxable at 25%.

#### Taxation of Capital Gains and Dividends

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

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

Holders of our ADSs will be exempt from withholding tax if they are beneficially entitled to the dividend and their address on the register of depositary shares maintained by the depositary is in the United States, provided that the

depositary has been authorized by the Irish Revenue Commissioners as a qualifying intermediary and provided the appropriate declaration is made by the holders of the ADSs. Where such withholding is made, it will satisfy the liability to Irish tax of the shareholder except in certain circumstances where an individual shareholder may have an additional liability. A charge to Irish social security taxes and other levies can arise for individuals. However, under

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the Social Welfare Agreement between Ireland and the United States, an individual who is liable for U.S. social security contributions can normally claim exemption from these taxes and levies.

#### Irish Capital Acquisitions Tax

A gift or inheritance of Ordinary Shares will be and, in the case of our warrants or American Depository Warrant Shares (ADWSs) representing such warrants, may be, within the charge to Irish capital acquisitions tax, notwithstanding that the person from whom the gift or inheritance is received is domiciled or resident outside Ireland. Capital acquisitions tax is charged at the rate of 22% above a tax-free threshold. This tax-free threshold is determined by the relationship between the donor and the successor or donee. It is also affected by the amount of the current benefit and previous benefits taken since December 5, 1991 from persons within the same capital acquisitions tax relationship category. Gifts and inheritances between spouses are not subject to capital acquisitions tax.

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

#### Irish Stamp Duty

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

#### F. Dividends and Paying Agents

Not applicable.

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

Not applicable.

#### H. Documents on Display

The Company is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act). In accordance with these requirements, the Company files Annual Reports on Form 20-F with, and furnishes Reports of Foreign Issuer on Form 6-K to, the SEC. These materials, including our Annual Report on Form 20-F for the fiscal year ended December 31, 2008 and the exhibits thereto, may be inspected and copied at the SEC s Public Reference Room at 100 F Street, NE, Room 1580, Washington D.C. 20549. Copies of the materials may

be obtained from the Public Reference Room of the SEC at 100 F Street, NE, Room 1580, Washington, D.C., at prescribed rates. The public may obtain information on the operation of the SEC s Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. As a foreign private issuer, all documents that were filed or submitted after November 4, 2002 on the SEC s EDGAR system are available for retrieval on the website maintained by the SEC at http://www.sec.gov. These filings and submissions are also available from commercial document retrieval services.

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Copies of our Memorandum and Articles of Association may be obtained at no cost by writing or telephoning the Company at our principal executive offices. Our Memorandum and Articles of Association are filed with the SEC as Exhibit 4.1 of our Registration Statement on Form S-8 (SEC File No. 333-135185) filed with the SEC on June 21, 2006. You may also inspect or obtain a copy of our Memorandum and Articles of Association using the procedures prescribed above.

#### I. Subsidiary Information

Not applicable.

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

Market risk is the risk of loss from adverse changes in market prices, interest rates and foreign exchange rates. Our future earnings and cash flows are dependent upon prevailing market rates. Accordingly, we manage our market risk by matching projected cash inflows from operating, investing and financing activities with projected cash outflows for debt service, capital expenditures and other cash requirements. The majority of our outstanding debt has fixed interest rates, which minimizes the risk of fluctuating interest rates. Our exposure to market risk includes interest rate fluctuations in connection with our variable rate borrowings and our ability to incur more debt, thereby increasing our debt service obligations, which could adversely affect our cash flows.

# Inflation Risk

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

#### Exchange Rate Risk

We are a multinational business operating in a number of countries and the U.S. dollar is the primary currency in which we conduct business. The U.S. dollar is used for planning and budgetary purposes and is the functional currency for financial reporting. We do, however, have revenues, costs, assets and liabilities denominated in currencies other than U.S. dollars. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are recognized in the income statement. Consequently, we enter into forward contracts to manage our non-U.S. dollar foreign exchange risks and reduce exposures to market fluctuations in foreign exchange rates, where appropriate. We do not enter into derivative financial instruments for trading or speculative purposes.

The principal foreign currency risk to which we are exposed relates movements in the exchange rate of the U.S. dollar against the Euro. The main exposures are net costs in Euro arising from a manufacturing and research presence in Ireland and the sourcing of raw materials in European markets, and revenue received in Euro arising from sales of *Tysabri* in the European Union. Our exchange rate risk is partially mitigated by these counteracting exposures.

We had entered into a number of Euro forward foreign exchange contracts at various rates of exchange that required us to sell U.S. dollars for Euro on various dates. These forward contracts expired on various dates throughout 2007. There were no forward contracts outstanding at December 31, 2008.

During 2008, average exchange rates were \$1.47 = 1.00. We sell U.S. dollars to buy Euro for costs incurred in Euro.

#### Interest Rate Risk on Debt

Our debt is at fixed rates, except for the \$300.0 million of Floating Rate Notes due 2011 and \$150.0 million of Floating Rate Notes due 2013 issued in November 2004 and November 2006, respectively. Interest rate changes affect the amount of interest on our variable rate debt.

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The table below summarizes the market risks associated with our fixed and variable rate debt outstanding at December 31, 2008 (in millions):

	2011	2012	2013	Total
Fixed rate debt <sup>(1)</sup> Average interest rate	\$ 850. 7.7	.0 \$ 25%	\$ 465.0 8.875%	\$ 1,315.0 8.15%
Variable rate debt <sup>(2)(3)</sup> Average interest rate	\$ 300. 7.1	0 \$ 3%	\$ 150.0 7.44%	\$ 450.0 7.23%
Total	\$ 1,150	.0 \$	\$ 615.0	\$ 1,765.0
Weighted-average interest rate	7.5	9%	8.52%	7.91%

- (1) Represents 74.5% of all outstanding debt.
- (2) Represents 25.5% of all outstanding debt.
- (3) Variable interest rates are based on average LIBOR rates in 2008.

If market rates of interest on our variable rate debt increased by 10%, then the increase in interest expense on the variable rate debt would be \$1.4 million annually. As of December 31, 2008, the fair value of our debt was \$962.8 million. For additional information on the fair values of debt instruments, refer to Note 19 to the Consolidated Financial Statements.

#### Interest Rate Risk on Investments

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

The interest rate risk profile of our investments at December 31, 2008 was as follows (in millions):

		No			
	Fixed	Floating	Interest	Total	
Cash and cash equivalents	\$	\$ 375.3	\$	\$ 375.3	
Restricted cash current	\$	\$ 20.2	\$	\$ 20.2	
Restricted cash non-current	\$	\$ 15.0	\$	\$ 15.0	
Investment securities current	\$	\$ 27.7	\$ 2.8	\$ 30.5	
Investment securities non-current	\$	\$ 0.4	\$ 7.7	\$ 8.1	

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

#### Credit Risk

Our treasury function transacts business with counterparties that are considered to be low investment risks. Credit limits are established commensurate with the credit rating of the financial institution that business is being transacted with. The maximum exposure to credit risk is represented by the carrying amount of each financial asset, including derivative financial instruments, in the balance sheet.

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

Our principal sovereign risk relates to investments in U.S. Treasuries funds; however, we consider this risk to be remote.

At the balance sheet date, we have a significant concentration of credit risk given that our main customers or collaborator, AmerisourceBergen, Fournier Pharma Corp. and Biogen Idec account for 64% of our gross accounts receivable balance at December 31, 2008. However, we do not believe our credit risk in relation with these three customers is significant, as they each have an investment grade credit rating.

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#### Equity Price and Commodity Risks

We do not have any material equity price or commodity risks.

Item 12. Description of Securities Other than Equity Securities.

Not applicable.

#### Part II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

None.

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

None.

Item 15. Controls and Procedures.

#### Disclosure Controls and Procedures

We conducted an evaluation as of December 31, 2008 under the supervision and with the participation of management, including our CEO and CFO, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on the evaluation conducted, our management, including our CEO and CFO, concluded that at December 31, 2008 such disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

#### Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with U.S. GAAP. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal controls over financial reporting, based on the criteria set forth in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation conducted, our management, including our CEO and CFO, concluded that as of December 31, 2008, internal control over financial reporting was effective.

Our independent registered public accounting firm, KPMG, has issued an auditor s report on the Company s internal control over financial reporting as of December 31, 2008, which is included under Item 15 in this Annual Report on Form 20-F.

# Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders Elan Corporation, plc:

We have audited Elan Corporation, plc s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Elan Corporation, plc s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting, appearing under Item 15 in this Annual Report on Form 20-F. Our responsibility is to express an opinion on Elan Corporation, plc s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Elan Corporation, plc maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Elan Corporation, plc and subsidiaries, as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders—equity/(deficit) and other comprehensive income/(loss) and cash flows for each of the years in the three-year period ended December 31, 2008, and the related financial statement schedule, and our report dated February 26, 2009 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG

#### Item 16. Reserved.

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

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

### Item 16B. Code of Ethics.

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

#### Item 16C. Principal Accountant Fees and Services.

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

	2008	2007
Auditors remuneration: Audit fees <sup>(1)</sup> Audit-related fees <sup>(2)</sup>	\$ 2.9 2.8	\$ 3.0 0.5
Total audit and audit-related fees Tax fees <sup>(3)</sup> All other fees	\$ 5.7 1.8	\$ 3.5 0.9
Total auditors remuneration	\$ 7.5	\$ 4.4

- (1) Audit services include audit of our Consolidated Financial Statements, as well as work that generally only the independent auditor can reasonably be expected to provide, including comfort letters, statutory audits, and discussions surrounding the proper application of financial accounting or reporting standards.
- (2) Audit-related services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.
- (3) Tax fees consist of fees for professional services for tax compliance, tax advice and tax planning. This category includes fees related to the preparation and review of tax returns.

#### **Report of the Audit Committee**

The current members of the Audit Committee (the Committee) are Mr. Gary Kennedy, Chairman, Mr. Giles Kerr and Mr. Donal O Connor. They are all non-executive directors of the Company. The board considers each member to be

independent under the Combined Code and under the criteria of the NYSE corporate governance listing standards concerning the composition of audit committees. In March 2008, the Company submitted the required annual written affirmation to the NYSE confirming its full compliance with those standards.

The board is satisfied that at least one member of the Committee has recent and relevant financial experience. The Committee has determined that Mr. Kennedy is an Audit Committee financial expert for the purposes of the Sarbanes-Oxley Act of 2002.

The core responsibilities of the Committee include reviewing and reporting to the board on:

Matters relating to the periodic financial reporting prepared by the Company;

The independent auditors qualifications and independence;

The performance of the internal auditor and the corporate compliance functions;

Compliance with legal and regulatory requirements including the operation of the Company s Securities Trading Policy and Code of Conduct;

The Company s overall framework for internal control over financial reporting and other internal controls and processes; and

The Company s overall framework for risk management.

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The Committee oversees the maintenance and review of the Company s Code of Conduct. It has established procedures for the receipt and handling of complaints concerning accounting or audit matters.

It appoints and agrees on the compensation for the independent external auditors subject, in each case, to the approval of the Company's shareholders at general meeting. The Committee maintains policies and procedures for the pre-approval of all audit services and permitted non-audit services undertaken by the independent external auditor. The principal purpose of these policies and procedures is to ensure that the independence of the independent external auditor is not impaired. The policies and procedures cover three categories of work: audit services, audit-related services and non-audit services. The pre-approval procedures permit certain audit, audit-related and non-audit services to be performed by the independent external auditor during the year subject to fee limits agreed with the Audit Committee in advance. Authority to approve, between Committee meetings, work in excess of the pre-agreed fee limits is delegated to members of the Committee if required. Regular reports to the full Committee are also provided for and, in practice, are a standing agenda item at Committee meetings.

The Committee held a number of private meetings without management present with both the Company s head of internal audit and with the engagement partner from the Company s independent external auditors. The purpose of these meetings was to facilitate free and open discussions between the Committee members and those individuals separate from the main sessions of the Committee, which were attended by the chief financial officer, the group controller and the Company s general counsel.

At each regularly scheduled board meeting, the chairman of the Committee reported to the board on the principal matters covered at the preceding Committee meetings. The minutes of all Committee meetings were also circulated to all board members.

The Committee met on eight occasions in 2008. The Committee is scheduled to meet 10 times in 2009.

During 2008, the business considered and discussed by the Committee included the matters referred to below.

The Company s financial reports and financial guidance were reviewed and various accounting matters and policies were considered.

Reports were received from the independent external auditors concerning its audit strategy and planning and the results of its audit of the financial statements and from management, the internal audit function and independent external auditor on the effectiveness of the company s system of internal controls and, in particular, its internal control over financial reporting.

The Committee reviewed the operations of the Company s code of conduct, the employee helpline and email system. No material issues were reported through this route during the year. No waivers to the Code of Conduct were made in 2008.

The Committee reviewed the progress on the implementation of a comprehensive enterprise-wide risk management process in the Company.

Matters concerning the internal audit function, corporate compliance function and financial functions were reviewed. The Company s continuing work to comply with the applicable provisions of the Sarbanes-Oxley Act of 2002 was monitored by the Committee.

The Committee charter and the operation of the Committee were reviewed during 2008. No changes were recommended.

The amount of audit and non-audit fees of the independent auditor was monitored throughout 2008. The Committee was satisfied throughout the year that the objectivity and independence of the independent external auditor were not in any way impaired by either the nature of the non-audit work undertaken, the level of non-audit fees charged for such work or any other facts or circumstances.

On behalf of the Audit Committee,

Gary Kennedy
Chairman of the Audit Committee and
Non-Executive Director

February 26, 2009

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

Not applicable.

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

Not applicable.

# Item 16G. Corporate Governance.

We are required to disclose any significant ways in which our corporate governance practices differ from those required to be followed by domestic companies under NYSE listing standards.

Under Section 303A of the NYSE Listed Company Manual, we may, in general, follow Irish corporate governance practices in lieu of most of the NYSE corporate governance requirements. However, we are required to comply with NYSE Sections 303A.06, 303A.11, 303A.12(b) and 303A.12(c).

The following table contains a summary of our corporate governance practices and those required of domestic companies under NYSE listing standards. There are no significant differences between our corporate governance practices and those required of domestic companies under NYSE listing standards.

# NYSE Standards for U.S. Listed Companies under Listed Company Manual Section 303A

A NYSE-listed company must have a majority of independent directors on its board of directors.

NYSE Section 303A.02

NYSE Section 303A.01

NYSE Section 303A.02 establishes general standards to evaluate directors independence.

NYSE Section 303A.03

Non-management directors must meet at regularly scheduled executive meetings not attended by management.

#### NYSE Section 303A.04

U.S. listed companies must have a nominating/corporate governance committee comprised entirely of independent directors. The committee must have a written charter establishing certain minimum responsibilities as set forth in NYSE Section 303A.04(b)(i) and providing for an annual evaluation of the committee s performance.

# **Elan Corporate Governance Practices**

At minimum, two-thirds of the members of our board of directors are independent directors.

We have adopted the definition of independent director under NYSE Section 303A.02, as described in Elan's Corporate Governance Guidelines.

Our Corporate Governance Guidelines provide that the non-management directors of the board will meet without management at regularly scheduled executive sessions, and at such other times as they deem appropriate, under the chairmanship of the Lead Independent Director.

Our board of directors maintains a Nominating & Governance Committee composed entirely of independent directors. The Nominating & Governance Committee has a written charter which, among other things, meets the requirements set forth in NYSE Section 303A.04(b)(i) and provides for an annual evaluation of the Nominating & Governance

#### NYSE Section 303A.05

U.S. listed companies must have a compensation committee comprised entirely of independent directors. The committee must have a written charter establishing certain minimum responsibilities as set forth in NYSE Section 303A.05(b)(i) and providing for an annual evaluation of the committee s performance.

#### NYSE Section 303A.06

U.S. listed companies must have an audit committee that satisfies the requirements of Rule 10A-3 under the Securities Exchange Act of 1934 (the Exchange Act ). Foreign private issuers must satisfy the requirements of Rule 10A-3 under the Exchange Act by July 31, 2005.

Committee s performance.

Our board of directors maintains a LDCC composed entirely of independent directors. The LDCC has a written charter which, among other things, meets the requirements set forth in NYSE Section 303A.05(b)(i) (except that the LDCC s report set forth in Elan s annual report is based on Irish rules and regulations rather than the SEC proxy rules) and provides for an annual evaluation of the LDCC s performance.

Our board of directors maintains an Audit Committee that meets the requirements of Rule 10A-3 of the Exchange Act.

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# NYSE Standards for U.S. Listed Companies under Listed Company Manual Section 303A

#### NYSE Section 303A.07

The audit committee must consist of at least three members, all of whom must be independent under NYSE Section 303A.02 and be financially literate or must acquire such financial knowledge within a reasonable period. At least one member must have experience in accounting or financial administration. The committee must have a written charter establishing certain minimum responsibilities as set forth in NYSE Section 303A.07(c)(iii) and providing for an annual evaluation of the committee s performance.

#### NYSE Section 303A.07(d)

Each U.S. listed company must have an internal audit function in order to provide to management and to the audit committee permanent assessments on the company s risk management processes and internal control system.

#### NYSE Section 303A.08

Shareholders must be given the opportunity to vote on all equity-based compensation plans and material revisions thereto with certain exceptions.

#### NYSE Section 303A.09

U.S. listed companies must adopt and disclose corporate governance guidelines, including several issues for which such reporting is mandatory, and include such information on the company s website, which should also include the charters of the audit committee, the nominating committee, and the compensation committee. In addition, the board of directors must make a self-assessment of its performance at least once a year to determine if it or its committees function effectively and report thereon.

#### NYSE Section 303A.10

U.S. listed companies must adopt a Code of Business Conduct and Ethics for directors, officers and employees.

#### NYSE Section 303A.12

The CEO of each listed U.S. company must, on a yearly basis, certify to the NYSE that he or she knows of no violation by the

### **Elan Corporate Governance Practices**

Our Audit Committee is comprised of no fewer than three directors, each of whom is an independent director under NYSE Section 303A.02 and each member of the Audit Committee meets all applicable financial literacy requirements.

The Audit Committee has a written charter that meets the requirements set forth in NYSE Section 303A.07(c)(iii) and provides for an annual evaluation of the Audit Committee s performance.

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.

Under Section 13.13 of the Listing Rules of the Irish Stock Exchange, in general, all employee share plans that contemplate the issuance of new shares must, with certain limited exceptions, be approved by our shareholders prior to their adoption.

We have adopted Corporate Governance Guidelines that, together with the charters of the Audit Committee, the Nominating & Governance Committee and the LDCC, are published on our website.

Our Corporate Governance Guidelines require that our board of directors conducts a self-assessment at least annually to determine whether the board of directors and its committees function effectively.

We have adopted a Code of Conduct for directors, officers and employees that is published on our website.

Our CEO will notify the NYSE in writing whenever any executive officer of Elan becomes aware of any

company of NYSE rules relating to corporate governance. The CEO must notify the NYSE in writing whenever any executive officer of the company becomes aware of any substantial non-fulfillment of any applicable provision under NYSE Section 303A. Finally, each U.S. listed company must submit an executed Written Affirmation annually to the NYSE and Interim Written Affirmation each time a change occurs in the board or any of the committees subject to NYSE Section 303A.

substantial non-fulfillment of any applicable provision under NYSE Section 303A. In addition, we will comply with the NYSE s rules relating to the submission of annual and interim affirmations.

In accordance with Section 303A.12(a) of the NYSE Listed Company Manual, the CEO of the Company submits annual certifications to the NYSE stating that he is not aware of any violations by the Company of the NYSE corporate governance listing standards, qualifying the certification to the extent necessary. The last such annual certification was submitted on March 3, 2008, without qualification.

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# Part III

Item 17. Consolidated Financial Statements.

Not applicable.

Item 18. Consolidated Financial Statements.

Report of Independent Registered Public Accounting Firm

Consolidated Financial Statements of Elan Corporation, plc and subsidiaries

Notes to the Consolidated Financial Statements

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders Elan Corporation, plc:

We have audited the accompanying consolidated balance sheets of Elan Corporation, plc and subsidiaries (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders equity/(deficit) and other comprehensive income/(loss) and cash flows for each of the years in the three-year period ended December 31, 2008. We have also audited the accompanying financial statement schedule. These consolidated financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elan Corporation, plc and subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2008, the Company adopted the provisions of Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, and effective January 1, 2007, the Company adopted the provisions of the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of SFAS No. 109.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Elan Corporation plc s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 26, 2009 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG

Dublin, Ireland February 26, 2009

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# Elan Corporation, plc

# Consolidated Statements of Operations For the Years Ended December 31, 2008, 2007 and 2006

	Notes (I	Notes 2008 2007 200 (In millions, except per share data)					2006 a)
Product revenue Contract revenue		\$	980.2 20.0	\$	728.6 30.8	\$	532.9 27.5
Total revenue Cost of sales	3		1,000.2 493.4		759.4 337.9		560.4 210.3
Gross margin Operating expenses:			506.8		421.5		350.1
Selling, general and administrative expenses			292.7		339.3		360.3
Research and development expenses			323.4		262.9		219.6
Net gain on sale of products and businesses	4						(43.1)
Other net charges/(gains)	5		34.2		84.6		(20.3)
Total operating expenses			650.3		686.8		516.5
Operating loss			(143.5)		(265.3)		(166.4)
Net interest and investment losses:							
Net interest expense	6		132.0		113.1		111.5
Net investment (gains)/losses	11		21.8		0.9		(1.6)
Net charge on debt retirement	7				18.8		,
Net interest and investment losses			153.8		132.8		109.9
Loss before income taxes			(297.3)		(398.1)		(276.3)
Provision for/(benefit from) income taxes	20		(226.3)		6.9		(9.0)
Net loss		\$	(71.0)	\$	(405.0)	\$	(267.3)
Basic and diluted net loss per Ordinary Share	8	\$	(0.15)	\$	(0.86)	\$	(0.62)
Weighted-average number of Ordinary Shares outstanding			473.5		468.3		433.3

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

# Elan Corporation, plc

# Consolidated Balance Sheets As of December 31, 2008 and 2007

	Notes (In millio	2008 ns, except sh values)	2007 ares and par
ASSETS			
Current Assets:			
Cash and cash equivalents	\$	375.3	\$ 423.5
Restricted cash current	9	20.2	20.1
Accounts receivable, net	10	196.1	137.4
Investment securities current	11	30.5	277.6
Inventory	12	29.8	36.7
Deferred tax assets current	20	95.9	4.6
Prepaid and other current assets	13	14.2	17.2
Total current assets		762.0	917.1
Property, plant and equipment, net	14	351.8	328.9
Goodwill and other intangible assets, net	15	553.9	457.6
Investment securities non-current	11	8.1	21.2
Restricted cash non-current	9	15.0	9.5
Deferred tax assets non-current	20	145.3	
Other assets	16	31.5	46.5
Total assets	\$	5 1,867.6	\$ 1,780.8
LIABILITIES AND SHAREHOLDERS	DEFICIT		
Current Liabilities:			
Accounts payable		37.7	27.3
Accrued and other current liabilities	17	242.6	176.1
Total current liabilities		280.3	203.4
Long-term debt	18	1,765.0	1,765.0
Other liabilities	17	54.5	47.1
Other Habilities	1 /	34.3	47.1
Total liabilities		2,099.8	2,015.5
Shareholders Deficit: Ordinary shares, 0.05 par value, 670,000,000 shares authorized, 474,728,31 and 470,195,498 shares issued and outstanding at December 31, 2008 and	9		
2007, respectively	22	27.6	27.4
Executive shares, 1.25 par value, 1,000 shares authorized, 1,000 shares			
issued and outstanding at December 31, 2008 and 2007	22		
<i>C</i> ,	22		

B Executive shares, 0.05 par value, 25,000 shares authorized, 21,375 shares issued and outstanding at December 31, 2008 and 2007

issued and outstanding at December 31, 2008 and 2007			
Additional paid-in capital		5,521.5	5,421.1
Accumulated deficit		(5,742.5)	(5,671.5)
Accumulated other comprehensive loss	23	(38.8)	(11.7)
Shareholders deficit		(232.2)	(234.7)
Total liabilities and shareholders deficit		\$ 1.867.6	\$ 1.780.8

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

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# Elan Corporation, plc

# Consolidated Statements of Shareholders Equity/(Deficit) and Other Comprehensive Income/(Loss) For the Years Ended December 31, 2008, 2007 and 2006

	Number		Additional			Accumulated Other	Total
	of Shares	Share Capital	Paid-in Capital	Treasury Stock (In millio	Deficit	domprehensiSl Income/(LoEs)	
Balance at December 31, 2005 Comprehensive loss:	428.8	\$ 24.7	\$ 5,024.5	\$ (17.4)	\$ (4,988.3)	\$ (26.6)	\$ 16.9
Net loss Unrealized gain on investment					(267.3)		(267.3)
securities						5.0	5.0
Minimum pension liability adjustment Currency translation						10.7	10.7
adjustments						3.9	3.9
Total comprehensive loss							(247.7)
Adjustment on initial application of SFAS 158 Conversion of convertible debt Tax benefit of stock option	34.2	2.3	249.5			(14.8)	(14.8) 251.8
deductions Stock issued, net of issuance			2.0				2.0
costs Share-based compensation	3.6	0.2	29.6 47.1				29.8 47.1
Balance at December 31, 2006 Comprehensive loss:	466.6	27.2	5,352.7	(17.4)	(5,255.6)	(21.8)	85.1
Net loss Unrealized loss on investment					(405.0)		(405.0)
securities Unrealized components of						(0.9)	(0.9)
defined pension plans Currency translation						10.3	10.3
adjustments						0.7	0.7
Total comprehensive loss							(394.9)
Treasury stock retirement Tax benefit of stock option	(0.9)	(0.1)	(6.4)	17.4	(10.9)		
deductions			1.8				1.8

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Stock issued, net of issuance costs Share-based compensation	4.5	0.3	27.9 45.1			28.2 45.1
Balance at December 31, 2007 Comprehensive loss:	470.2	27.4	5,421.1	(5,671.5)	(11.7)	(234.7)
Net loss				(71.0)		(71.0)
Unrealized loss on investment				,		,
securities					(3.5)	(3.5)
Unrealized components of defined pension plans					(23.6)	(23.6)
Total comprehensive loss						(98.1)
Tax benefit of stock option						
deductions			2.4			2.4
Stock issued, net of issuance						
costs	4.5	0.2	49.8			50.0
Share-based compensation			48.2			48.2
Balance at December 31, 2008	474.7	\$ 27.6	\$ 5,521.5	\$ \$ (5,742.5)	\$ (38.8)	\$ (232.2)

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

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# Elan Corporation, plc

## Consolidated Statements of Cash Flows For the Years Ended December 31, 2008, 2007 and 2006

	2008			2007 (In millions)		2006	
Cash flows from operating activities:							
Net loss	\$	(71.0)	\$	(405.0)	\$	(267.3)	
Adjustments to reconcile net loss to net cash used in operating activities:							
Amortization of deferred revenue		(2.5)		(11.4)		(44.0)	
Amortization of financing costs		5.1		4.8		6.9	
Depreciation and amortization		70.1		118.3		135.6	
(Gains)/loss on sale of investment securities		1.0		(6.6)		(8.3)	
Impairment of intangible assets				52.2			
Impairment of investments		20.2		6.1		7.3	
Gain on sale of products and businesses						(43.1)	
Share-based compensation		47.2		45.1		47.1	
Excess tax benefit from share-based compensation		(2.4)		(1.8)		(2.0)	
Deferred tax asset		(236.6)		(1.3)		(3.4)	
Net charge on debt retirement				18.8			
Derivative fair value (gain)/loss		0.6		(0.4)		(4.9)	
Other		5.8		6.6		4.8	
Net changes in assets and liabilities:							
Increase in accounts receivable		(58.7)		(30.1)		(25.6)	
Decrease/(increase) in prepaid and other assets		(1.4)		60.3		(56.4)	
Decrease/(increase) in inventory		6.9		(7.4)		(7.1)	
Increase/(decrease) in debt interest accrual		(1.3)		(17.5)		4.0	
Increase/(decrease) in accounts payable and accruals and other liabilities		22.7		1.8		14.9	
Net cash used in operating activities		(194.3)		(167.5)		(241.5)	
Cash flows from investing activities:							
Decrease/(increase) in restricted cash		(5.6)		(6.8)		2.8	
Proceeds from disposal of property, plant and equipment				0.2		0.6	
Purchase of property, plant and equipment		(58.8)		(26.1)		(29.9)	
Purchase of intangible assets		(79.1)		(2.5)		(4.1)	
Purchase of non-current investment securities		(0.1)		(12.3)		(0.2)	
Transfer of fund to investment securities				(305.9)			
Sale of non-current investment securities		3.5		3.4		13.2	
Sale of current investment securities		232.6		27.9		0.9	
Proceeds from product and business disposals		2.0		4.0		54.2	
Net cash provided by/(used in) investing activities		94.5		(318.1)		37.5	
Cash flows from financing activities:							
Proceeds from employee stock issuances		50.0		28.2		29.8	

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Repayment of loans and capital lease obligations	(0.9)	(629.6)	(5.7)
Net proceeds from debt issuances		(0.1)	602.8
Excess tax benefit from share-based compensation	2.4	1.8	2.0
Proceeds from government grants			0.4
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 increase/(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
Supplemental cash flow information:			
Cash paid during the year for:			
Interest	\$ (141.0)	\$ (169.2)	\$ (154.0)
Income taxes	\$ (7.4)	\$ (5.2)	\$ (4.6)
Non-cash financing activities:			
Issuance of stock for debt conversion	\$	\$	\$ 251.8

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

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### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Description of Business

Elan Corporation, plc, an Irish public limited company (also referred to hereafter as we, our, us, Elan or the 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 (R&D), manufacturing and marketing facilities are located in Ireland and the United States.

Our business is organized into two business units: Biopharmaceuticals and Elan Drug Technologies (EDT). Biopharmaceuticals engages in research, development and commercial activities primarily in Alzheimer s disease, Parkinson s disease, multiple sclerosis (MS), Crohn s disease (CD), severe chronic pain and infectious diseases. EDT is an established, profitable specialty pharmaceutical business unit of Elan.

#### 2. Significant Accounting Policies

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

### (a) Basis of consolidation and presentation of financial information

The accompanying Consolidated Financial Statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). In addition to the financial statements included in this Form 20-F, we also prepared 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 financial statements and other financial data contained in this Form 20-F are presented in U.S. dollars (\$). The accompanying Consolidated Financial Statements include our financial position, results of operations and cash flows and those of our subsidiaries, all of which are wholly owned. All significant intercompany amounts have been eliminated.

We have incurred significant losses during the last three fiscal years and anticipate to continue to incur operating losses in 2009. However, our directors believe that we have adequate resources to continue in operational existence for at least the next 12 months and that it is appropriate to continue to prepare our Consolidated Financial Statements on a going concern basis.

#### (b) Use of estimates

The preparation of the Consolidated Financial Statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of

making the judgments about carrying values of assets and liabilities that are not readily apparent from other sources. 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, 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.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### (c) Reclassifications

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

#### (d) Fair value measurements

We adopted SFAS No. 157, Fair Value Measurements, (SFAS 157) effective January 1, 2008 for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The adoption of SFAS 157 for financial assets and liabilities and non-financial assets and liabilities that are remeasured and reported at fair value, at least annually, did not have an impact on our financial results.

SFAS 157 defines fair value as the price that would be received upon sale of an asset or paid upon transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. The fair value should be calculated based on assumptions that market participants would use in pricing the asset or liability, not on assumptions specific to the entity. In addition, the fair value of liabilities should include consideration of non-performance risk including our own credit risk.

In addition to defining fair value, SFAS 157 expands the disclosure requirements around fair value and establishes a fair value hierarchy for valuation inputs. The hierarchy prioritizes the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of the three levels, which is determined by the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1: Inputs are based upon unadjusted quoted prices for identical instruments traded in active markets.
- Level 2: Inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Inputs are generally unobservable and typically reflect management s estimates of assumptions that market participants would use in pricing the asset or liability.

### (e) Cash and cash equivalents

Cash and cash equivalents include cash and highly liquid investments with original maturities of three months or less.

### (f) Investment securities and impairment

Marketable equity securities and debt securities are classified into one of three categories in accordance with the Financial Accounting Standards Board's (FASB) Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, (SFAS 115), including trading, held-to-maturity, or available-for-sale.

Marketable equity and debt securities are considered trading when purchased principally for the purpose of selling in the near term. These securities are recorded as short-term investments and are carried at fair value. Unrealized holding gains and losses on trading securities are included in other income. We did not hold any trading securities at December 31, 2008 and 2007.

Marketable debt securities are considered held-to-maturity when we have the positive intent and ability to hold the securities to maturity. These securities are carried at amortized cost, less any impairment. We did not hold any held-to-maturity securities at December 31, 2008 and 2007.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Marketable equity and debt securities not classified as trading or held-to-maturity are considered available-for-sale. These securities are recorded as either short-term or long-term investments and are carried at fair value, with unrealized gains and losses included in accumulated other comprehensive income/(loss) in shareholders equity/(deficit). The assessment for impairment of marketable securities classified as available-for-sale is based on established financial methodologies, including quoted market prices for publicly traded equity and debt securities.

Non-marketable equity securities are carried at cost, less write-down-for-impairments, and are adjusted for impairment based on methodologies, including the Black-Scholes option-pricing model, the valuation achieved in the most recent private placement by an investee, an assessment of the impact of general private equity market conditions, and discounted projected future cash flows.

The factors affecting the assessment of impairments include both general financial market conditions and factors specific to a particular company. In the case of equity classified as available-for-sale, a significant and prolonged decline in the fair value of the security below its carrying value is considered in determining whether the security is impaired. If any such evidence exists, an impairment loss is recognized.

### (g) Inventory

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

#### (h) Property, plant and equipment

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

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

Land is not depreciated as it is deemed to have an indefinite useful life.

Where events or circumstances indicate that the carrying amount of a tangible asset may not be recoverable, we compare the carrying amount of the asset to its fair value. The carrying amount of the asset is not deemed recoverable if its carrying value exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of that asset. In such event, an impairment loss is recognized for the excess of the carrying amount over the asset is fair value.

#### (i) Leasing

Property, plant and equipment acquired under a lease that transfers substantially all of the risks and rewards of ownership to us (a capital lease) are capitalized. Amounts payable under such leases, net of finance charges, are shown as current or long-term liabilities as appropriate. An asset acquired through capital lease is stated at an amount equal to the lower of its fair value or the present value of the minimum lease payments at the inception of the lease, less accumulated depreciation and impairment losses, and is included in property, plant and equipment. Finance charges on capital leases are expensed over the term of the lease to give a constant periodic rate of interest charge in proportion to the capital balances outstanding. All other that are not capital leases are considered operating leases. Rentals on operating leases are charged to expense on a straight-line basis.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### (j) Goodwill, other intangible assets and impairment

We account for goodwill and identifiable intangible assets in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS 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*, (SFAS 144) 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.

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. 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 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.

#### (k) Financing costs

Debt financing costs comprise of transaction costs on borrowings. Debt financing costs are allocated to financial reporting periods over the term of the related debt using the effective interest rate method.

#### (l) Derivative financial instruments

We enter into transactions in the normal course of business using various financial instruments in order to hedge against exposures to fluctuating exchange and interest rates. We use derivative financial instruments to reduce exposure to fluctuations in foreign exchange rates and interest rates. A derivative is a financial instrument or other contract whose value changes in response to some underlying variable, that has an initial net investment smaller than would be required for other instruments that have a similar response to the variable and that will be settled at a future date. We do not enter into derivative financial instruments for trading or speculative purposes.

Gains and losses on derivative financial instruments that qualify as fair value hedges under SFAS No. 133, *Accounting for Derivative Instruments in Hedging Activities*, (SFAS 133), are recognized as an offset to the

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

related income or expense of the underlying hedged transaction. The carrying value of derivative financial instruments is reported within current assets or other current liabilities. We did not hold any interest rate swap contracts or forward currency contracts at December 31, 2008 or 2007. Interest rate swaps held during the year ended December 31, 2006, qualified for hedge accounting under SFAS 133. Forward currency contracts held during the year ended December 31, 2006, did not qualify for hedge accounting under SFAS 133, and were marked to market at the balance sheet date, with the resulting gains and losses recognized in income.

We record at fair value certain freestanding warrants that were acquired in investment transactions. Changes in their fair value are recorded in the income statement and their carrying value is recorded within current investment securities.

#### (m) Revenue

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenues are classified into two categories: product revenue and contract revenue.

*Product Revenue* Product revenue includes: (i) the sale of our products, (ii) royalties and (iii) manufacturing fees. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. Revenue is recorded net of applicable sales tax and sales discounts and allowances, which are described below.

- i. The sale of our products consists of the sale of pharmaceutical drugs, primarily to wholesalers and physicians.
- ii. We earn royalties on licensees sales of our products or third-party products that incorporate our technologies. Royalties are recognized as earned in accordance with the contract terms when royalties can be reliably measured and collectability is reasonably assured.
- iii. We receive manufacturing fees for products that we manufacture on behalf of other third-party customers.

Tysabri® (natalizumab) was developed and is now being marketed in collaboration with Biogen Idec Inc. In general, subject to certain limitations imposed by the parties, we share with Biogen Idec most development and commercialization costs. Biogen Idec is responsible for manufacturing the product. In the United States, we purchase Tysabri from Biogen Idec and are responsible for distribution. Consequently, we record as revenue the net sales of Tysabri in the U.S. market. We purchase product from Biogen Idec as required at a price, which includes the cost of manufacturing, plus Biogen Idec s gross profit on Tysabri and this cost, together with royalties payable to other third parties, is included in cost of sales. Outside of the United States, Biogen Idec is responsible for distribution and we record as revenue our share of the profit or loss on rest of world (ROW) sales of Tysabri, plus our directly incurred expenses on these sales.

Contract Revenue Contract revenue arises from contracts to perform R&D services on behalf of clients or technology licensing. Contract revenue is recognized when earned and non-refundable, and when we have no future obligation with respect to the revenue, in accordance with the terms prescribed in the applicable contract. Contract research revenue consists of payments or milestones arising from R&D activities we perform on behalf of third parties. Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met,

including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

The U.S. Securities and Exchange Commission s (SEC) Staff Accounting Bulletin No. 104, *Revenue Recognition*, (SAB 104), provides guidance on revenue recognition. SAB 104 requires the deferral and amortization of up-front fees when there is a significant continuing involvement (such as an ongoing product

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

manufacturing contract or joint development activities) by the seller after an asset disposal. We defer and amortize up-front license fees to income over the performance period as applicable. The performance period is the period over which we expect to provide services to the licensee as determined by the contract provisions.

Accounting for milestone payments depends on the facts and circumstances of each contract. We apply the substantive milestone method in accounting for milestone payments. This method requires that substantive effort must have been applied to achieve the milestone prior to revenue recognition. If substantive effort has been applied, the milestone is recognized as revenue, subject to it being earned, non-refundable and not subject to future legal obligation. This requires an examination of the facts and circumstances of each contract. Substantive effort may be demonstrated by various factors, including the risks associated with achieving the milestone, the period of time over which effort was expended to achieve the milestone, the economic basis for the milestone payment and licensing arrangement and the costs and staffing necessary to achieve the milestone. It is expected that the substantive milestone method will be appropriate for most contracts. If we determine the substantive milestone method is not appropriate, then we apply the proportional performance method to the relevant contracts. 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.

#### (n) 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 our 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 healthcare 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.

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. 01-09, 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.

#### 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.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 of inventory in the distribution channel and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

#### 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.

#### 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.

### 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.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 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 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.

### Use of information from external sources

We use information from external sources to identify prescription trends and patient demand, including inventory pipeline data from the 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.

#### (o) Advertising expenses

We expense the costs of advertising as incurred. Advertising expenses were \$5.3 million in 2008 (2007: \$5.1 million; 2006: \$4.9 million).

#### (p) Research and development

R&D costs are expensed as incurred. Acquired in-process research and development is expensed as incurred. Costs to acquire intellectual property, product rights and other similar intangible assets are capitalized and amortized on a straight-line basis over the estimated useful life of the asset. The method of amortization chosen best reflects the manner in which individual intangible assets are consumed.

#### (q) Taxation

We account for income tax expense based on income before taxes and it is computed 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 the enacted tax rates projected to be in effect for the year in which the differences are expected to reverse. 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.

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

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Effective January 1, 2007, we adopted the provisions of FASB Financial Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109*, (FIN 48), under which we recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Prior to the adoption of FIN 48, we recognized the income tax positions only if such positions were probable of being sustained. We account for interest and penalties related to unrecognized tax benefits in income tax expense.

#### (r) Accumulated other comprehensive income/(loss)

Comprehensive income/(loss) is comprised of our net income or loss and other comprehensive income/(loss) (OCI). OCI includes certain changes in shareholders equity/(deficit) that are excluded from net income. Specifically, we include in OCI changes in the fair value of unrealized gains and losses on our investment securities, foreign currency translation adjustments, and adjustments relating to our defined benefit pension plans. Comprehensive loss for the years ended December 31, 2008, 2007 and 2006 has been reflected in the Consolidated Statements of Shareholders Equity/(Deficit) and Other Comprehensive Income/(Loss).

### (s) Foreign operations

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

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

### (t) 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, Restricted Stock Units (RSUs) and stock purchases related to our employee equity purchase plans.

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.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### (u) Pensions and other employee benefit plans

We have two defined benefit pension plans covering our employees based in Ireland. We account for pension benefit obligations and related costs in accordance with SFAS No. 87, *Employer s Accounting for Pensions*, (SFAS 87) as amended by SFAS No. 158, *Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Nos.* 87, 88, 106 and 132R, (SFAS 158) and our disclosures are in accordance with SFAS No. 132 (Revised 2003), *Employers Disclosures about Pensions and Other Postretirement Benefits*, (SFAS 132R), as amended by SFAS 158. These plans are managed externally and the related pension costs and liabilities are assessed at least annually in accordance with the advice of a qualified professional actuary. Two significant assumptions, the discount rate and the expected rate of return on plan assets, are important elements of expense and/or liability measurement. We evaluate these assumptions at least annually, with the assistance of an actuary. Other assumptions involve employee demographic factors such as retirement patterns, mortality, turnover and the rate of compensation increase. We use a December 31 measurement date. All plan assets and liabilities are reported as of that date. The cost or benefit of plan changes, which increase or decrease benefits for prior employee service, is included in expense on a straight-line basis over the period the employee is expected to receive the benefits.

We recognize actuarial gains and losses using the corridor method. Under the corridor method, to the extent that any cumulative unrecognized net actuarial gain or loss exceeds 10 percent of the greater of the present value of the defined benefit obligation and the fair value of the plan assets, that portion is recognized over the expected average remaining working lives of the plan participants. Otherwise, the net actuarial gain or loss is not recognized.

In accordance with SFAS 158, we recognize the funded status of benefit plans in our Consolidated Balance Sheet. In addition, we recognize as a component of other comprehensive income the gains or losses and prior service costs or credits that arise during the period but are not recognized as components of net periodic pension cost of the period pursuant to SFAS 87.

We also have a number of other defined contribution benefit plans, primarily for employees outside of Ireland. The cost of providing these plans is expensed as incurred. For additional information on our pension and other employee benefit plans, refer to Note 24.

#### (v) Contingencies

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 the potential range of probable losses. We record accruals for such contingencies when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If an unfavorable outcome is probable, but the amount of the loss cannot be reasonably estimated, we estimate the range of probable loss and accrue the most probable loss within the range. If no amount within the range is deemed more probable, we accrue the minimum amount within the range. If neither a range of loss nor a minimum amount of loss is estimable, then appropriate disclosure is provided, but no amounts are accrued. For additional information relating to our commitments and contingencies, refer to Notes 26 and 27.

#### 3. Revenue

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

		2008		2007		2006
Revenue from the Biopharmaceuticals business Revenue from the EDT business		\$	698.6 301.6	\$	463.9 295.5	\$ 278.3 282.1
Total revenue		\$	1,000.2	\$	759.4	\$ 560.4
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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue from the Biopharmaceuticals business can be further analyzed as follows (in millions):

	2008	2007	2006
Product revenue:			
Tysabri U.S.	\$ 421.6	\$ 217.4	\$ 28.2
Tysabri ROW	135.5	14.3	(10.7)
Total Tysabri	557.1	231.7	17.5
Azactam® (aztreonam for injection, USP)	96.9	86.3	77.9
Maxipime® (cefepime hydrochloride)	27.1	122.5	159.9
Prialt® (ziconotide intrathecal infusion)	16.5	12.3	12.1
Royalties	1.0	1.8	2.4
Total product revenue	698.6	454.6	269.8
Contract revenue		9.3	8.5
Total revenue from Biopharmaceuticals business	\$ 698.6	\$ 463.9	\$ 278.3

*Tysabri* was developed and is now being marketed in collaboration with Biogen Idec. In general, subject to certain limitations imposed by the parties, we share with Biogen Idec most 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 profit on *Tysabri*, and this cost, together with royalties payable to other third parties, is included in cost of sales.

Global in-market net sales of *Tysabri* were as follows (in millions):

	2008	2007	2006
United States ROW	\$ 421.6 391.4	\$ 217.4 125.5	\$ 28.2 9.9
Total <i>Tysabri</i> global in-market net sales	\$ 813.0	\$ 342.9	\$ 38.1

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.

In 2008, we recorded net *Tysabri* 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
ROW in-market sales by Biogen Idec ROW operating expenses incurred by Elan and Biogen Idec	\$ 391.4 (236.9)	\$ 125.5 (138.1)	\$ 9.9 (34.3)
ROW operating profit/(loss) generated/(incurred) by Elan and Biogen Idec	154.5	(12.6)	(24.4)
Elan s 50% share of <i>Tysabri</i> ROW collaboration operating profit/(loss) Elan s directly incurred costs	77.3 58.2	(6.3) 20.6	(12.2) 1.5
Net Tysabri ROW revenue	\$ 135.5	\$ 14.3	\$ (10.7)

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue from the EDT business can be further analyzed as follows (in millions):

	2008	2007	2006
Product revenue:			
Manufacturing revenue and royalties:			
TriCor® 145	\$ 67.7	\$ 62.5	\$ 52.1
Skelaxin®	39.7	39.3	36.5
Focalin XR®/Ritalin LA®	33.5	28.4	22.5
<i>Verelan</i> <sup>®</sup>	24.6	28.5	36.3
Diltiazem®	13.7	18.7	19.5
Zanaflex®	12.8	13.1	4.9
Other	89.6	79.0	60.6
Total manufacturing revenue and royalties	281.6	269.5	232.4
Amortized revenue Adala Avinza®		4.5	30.7
Total product revenue	281.6	274.0	263.1
Contract revenue:	201.0	271.0	203.1
Amortized fees	2.4	4.3	4.2
Research revenue and milestones	17.6	17.2	14.8
Total contract revenue	20.0	21.5	19.0
Total revenue from the EDT business	\$ 301.6	\$ 295.5	\$ 282.1

#### 4. Sales of Products and Businesses

We did not dispose of any products or businesses in 2008 or 2007. For the year ended December 31, 2006, the net gain from the disposal was principally related to the sale of *Prialt* European rights as described below.

In March 2006, we sold the *Prialt* European rights to Eisai Co. Ltd. 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, of which \$2.0 million was received in 2008. 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.

#### 5. Other Net Charges/(Gains)

The principal items classified as other net 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.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Other net charges/(gains) for the years ended December 31 consisted of (in millions):

	2008	2007	2006
(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) Maxipime and Azactam 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. For additional information regarding the activity related to the severance and restructuring accruals, refer to Note 17.

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

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. For additional information, refer to Note 27.

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.

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### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The *Maxipime* and *Azactam* asset impairment charge of \$52.2 million was related to the approval of a first generic formulation of *Maxipime* in June 2007 and the anticipated approval of a generic form of *Azactam*. For additional information, refer to Note 15.

### (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 Therapeutics, Inc. (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.

### 6. Net Interest Expense

The net interest expense for the years ended December 31, 2008, 2007 and 2006 is as follows (in millions):

	2008			2007		2006
Interest expense:						
Interest on 7.75% Notes	\$	65.9	\$	65.9	\$	65.9
Interest on Floating Rate Notes due 2011		21.4		28.4		27.5
Interest on 8.875% Notes		41.3		41.3		4.4
Interest on Floating Rate Notes due 2013		11.2		14.5		1.5
Interest on Athena Notes				1.6		44.5
Interest on 6.5% Convertible Notes						15.9
Amortization of deferred financing costs		5.1		4.8		6.9
Foreign exchange (gain)/loss		(2.4)		0.3		(4.2)
Swap interest expense/(income)				0.4		3.4
Other		0.7		(1.8)		(0.4)
Interest expense	\$	143.2	\$	155.4	\$	165.4
Interest income:						
Cash and cash equivalents interest	\$	(11.0)	\$	(42.1)	\$	(53.8)
Investment interest		(0.2)		(0.2)		(0.1)
Interest income	\$	(11.2)	\$	(42.3)	\$	(53.9)
Net interest expense	\$	132.0	\$	113.1	\$	111.5

For additional information on our debts, refer to Note 18.

### 7. Net Charge on Debt Retirement

In December 2006, we issued an early redemption notice for the 7.25% senior notes (Athena Notes). In January 2007, the remaining aggregate principal amount of \$613.2 million of the Athena Notes was redeemed and the related \$300.0 million of interest rate swaps were cancelled. As a result, we incurred a net charge on debt retirement of \$18.8 million.

For additional information related to our debts, refer to Note 18.

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### **Elan Corporation, plc**

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 8. Net Loss Per Share

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

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

	:	2008	2007	2006
Net loss (in millions)	\$	(71.0)	\$ (405.0)	\$ (267.3)
Weighted-average number of Ordinary Shares outstanding (in millions)	basic and diluted	473.5	468.3	433.3
Basic and diluted net loss per Ordinary Share	\$		\$ (0.86)	\$ (0.62)

As of December 31, 2008, there were stock options and RSUs outstanding of 22.2 million shares (2007: 24.2 million shares; 2006: 26.1 million shares including warrants), which could potentially have a dilutive impact in the future, but which were anti-dilutive in 2008, 2007 and 2006.

### 9. Restricted Cash

We had total restricted cash (current and non-current) of \$35.2 million at December 31, 2008 (2007: \$29.6 million), which has been pledged to secure certain letters of credit.

#### 10. Accounts Receivable, Net

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

	2008	2007
Trade receivables Less amounts provided for doubtful accounts	\$ 197.0 (0.9)	\$ 137.4
Trade receivables, net	\$ 196.1	\$ 137.4

The following customers or collaborator account for more than 10% of our trade receivables at December 31, 2008 and/or 2007:

	2008	2007
AmerisourceBergen Corp.	28%	28%
Fournier Pharma Corp.	21%	25%
Biogen Idec	15%	5%

No other customer accounted for more than 10% of our trade receivable balance at either December 31, 2008 or 2007.

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### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 11. Investment Securities

#### Current investment securities

The following information on current investment securities is presented in accordance with the requirements of SFAS 115 at December 31, 2008 and 2007 (in millions):

	2008	2007
Debt securities current	\$ 27.7	\$ 268.1
Equity securities current, at cost	2.5	5.0
Unrealized gains on equity securities	0.2	4.4
Unrealized losses on equity securities		(0.6)
Derivatives	0.1	0.7
Total investment securities current	\$ 30.5	\$ 277.6

#### Debt securities current

At December 31, 2007, all of our liquid investments were invested in bank deposits and funds. In December 2007, due to dislocations in the capital markets, one of these funds was closed. As a result, the total carrying value of our holding in the fund of \$274.8 million (current: \$268.1 million; non-current: \$6.7 million) at December 31, 2007 no longer qualified as cash equivalents and was presented as an investment. The balance had been reclassified to current and non-current debt securities based on the expected liquidation of investments in the fund. In conjunction with the closure of the fund, an impairment charge of \$13.1 million (2007: \$3.8 million) was incurred in 2008, \$10.9 million of which was included within net investment losses and the remaining \$2.2 million (2007: \$3.8 million) was classified within net interest expense. At December 31, 2008, the total fair market value of our remaining holding of \$27.7 million in the fund was held in current debt securities. The remaining underlying securities in the fund have various contractual maturity dates through 2050.

#### Equity securities current

At December 31, 2008, marketable equity securities primarily consisted of investments in emerging pharmaceutical and biotechnology companies. The fair market value of these securities was \$2.7 million at December 31, 2008 (2007: \$8.8 million).

### Non-current investment securities

Non-current investment securities at December 31, 2008 and 2007 are as follows (in millions):

2008	2007

Debt securities non-current, at cost	\$ 0.3	\$ 13.0
Equity securities non-current, at cost less impairments	7.7	8.2
Unrealized gains on debt securities	0.1	
Total investment securities current	\$ 8.1	\$ 21.2

At December 31, 2008, the non-current debt securities balance consisted of an investment in auction rate securities (ARS), which had a fair market value of \$0.4 million, including an unrealized gain of \$0.1 million. The collateralized debt obligations underlying the ARS have various contractual maturity dates through 2043. At December 31, 2007, the non-current debt securities balance consisted of investments in ARS and the fund described above, which had fair market values of \$6.3 million and \$6.7 million, respectively.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Non-current equity investments are comprised of investments held in privately held biotech companies recorded at cost, less write-down for impairments.

### Net Investment (Gains)/Losses (in millions)

	2008	2007	2006
Net (gains)/losses on sale of current investment securities	\$ 1.4	\$	\$ (0.4)
Net gains on sale of non-current investment securities	(0.4)	(6.6)	(7.9)
Derivative fair value (gains)/losses	0.6	1.4	(0.6)
Impairment charges	20.2	6.1	7.3
Net investment (gains)/losses	\$ 21.8	\$ 0.9	\$ (1.6)

In 2008, the cash inflow arising from the sale of current investment securities was \$232.6 million (2007: \$27.9 million; 2006: \$0.9 million). There were no cash outflows arising from the purchase of current investment securities in 2008, 2007 or 2006.

In 2008, the cash inflow arising from the sale of non-current investment securities was \$3.5 million (2007: \$3.4 million; 2006: \$13.2 million). In 2008, the cash used for the purchase of non-current investment securities was \$0.1 million (2007: \$12.3 million; 2006: \$0.2 million).

The above impairment charges include all other-than-temporary impairments. 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 ARS. The remaining impairment charges of \$3.3 million (2007: \$1.1 million; 2006: \$7.3 million) related to various investments in emerging pharmaceutical and biotechnology companies.

The framework used for measuring the fair value of our investment securities is described in Note 19.

### 12. Inventory

Product inventories at December 31 of each year consisted of the following (in millions):

	2008	2007
Raw materials Work-in-process Finished goods	\$ 9.6 7.7 12.5	\$ 8.9 5.8 22.0
Total inventory	\$ 29.8	\$ 36.7

# 13. Prepaid and Other Current Assets

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

	2	2008	2	2007
Prepayments Other current assets	\$	13.4 0.8	\$	9.4 7.8
Total prepaid and other current assets	\$	14.2	\$	17.2

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Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 14. Property, Plant and Equipment

	Land & Buildings	Plant & Equipment (In millions)	Total
Cost: At January 1, 2007 Additions Disposals	\$ 290.3 5.4 (3.0)	\$ 283.8 17.2 (10.7)	\$ 574.1 22.6 (13.7)
At December 31, 2007	\$ 292.7	\$ 290.3	\$ 583.0
Additions Disposals	34.8 (2.1)	24.4 (2.9)	59.2 (5.0)
At December 31, 2008	\$ 325.4	\$ 311.8	\$ 637.2
Accumulated depreciation: At January 1, 2007 Charged in year Disposals	\$ (66.5) (9.4) 1.5	\$ (165.6) (23.8) 9.7	\$ (232.1) (33.2) 11.2
At December 31, 2007	\$ (74.4)	\$ (179.7)	\$ (254.1)
Charged in year Disposals	(10.5) 0.9	(24.2) 2.5	(34.7) 3.4
At December 31, 2008	(84.0)	(201.4)	(285.4)
Net book value: December 31, 2008	\$ 241.4	\$ 110.4	\$ 351.8
Net book value: December 31, 2007	\$ 218.3	\$ 110.6	\$ 328.9

Property and equipment disposals during 2008 primarily relate to the realignment of our commercial activities in *Tysabri* for CD and the announced closure of our New York office, which is to occur in the first half of 2009. The disposals during 2007 primarily relate to the 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.

Included in the net book value of property, plant and equipment is \$210.3 million (2007: \$222.5 million) relating to our manufacturing and fill-finish facilities in Athlone, Ireland.

The net book value of assets acquired under capital leases at December 31, 2008 amounted to \$5.0 million (2007: \$7.3 million), which includes \$68.3 million of accumulated depreciation (2007: \$66.0 million). Depreciation expense for the period amounted to \$2.3 million (2007: \$3.0 million; 2006: \$4.5 million).

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# Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# 15. Goodwill and Other Intangible Assets

	Goodwill	Other Intangible Assets (In millions)	Total
Cost: At January 1, 2007 Additions Disposals	\$ 268.0	\$ 773.8 6.0 (0.3)	\$ 1,041.8 6.0 (0.3)
At December 31, 2007	\$ 268.0	\$ 779.5	\$ 1,047.5
Additions Disposals		131.7 (0.5)	131.7 (0.5)
At December 31, 2008	\$ 268.0	\$ 910.7	\$ 1,178.7
Accumulated amortization: At January 1, 2007 Charged in year Disposals	\$	\$ (459.6) (80.9) (49.4)	\$ (459.6) (80.9) (49.4)
At December 31, 2007	\$	\$ (589.9)	\$ (589.9)
Charged in year Disposals		(35.4) 0.5	(35.4) 0.5
At December 31, 2008	\$	\$ (624.8)	\$ (624.8)
Net book value: December 31, 2008	\$ 268.0	\$ 285.9	\$ 553.9
Net book value: December 31, 2007	\$ 268.0	\$ 189.6	\$ 457.6

Other intangible assets consist primarily of patents, licenses and intellectual property as follows (in millions):

	2008	2007
Tysabri Alzheimer s disease	\$ 134.8 63.1	\$ 15.2 70.1

Prialt	51.6	58.1
Verelan	21.5	32.2
Other intangible assets	14.9	14.0
Total other intangible assets	\$ 285.9	\$ 189.6

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 our 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.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2007, we recorded an impairment charge of \$52.2 million (comprised of \$49.4 million relating to intangible assets and \$2.8 million relating to other non-current assets), 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.

The weighted-average remaining useful life for other intangible assets at December 31, 2008 was 9.3 years.

Amortization expense for the year ended December 31, 2008 amounted to \$35.4 million (2007: \$80.9 million; 2006: \$95.5 million) and is recorded as cost of sales, selling, general and administrative expenses and R&D expenses in the Consolidated Statements of Operations, as it relates to the respective functions.

As of December 31, 2008, our expected future amortization expense of current other intangible assets is as follows (in millions):

Year ending December 31, 2009	\$ 41.6
2010	39.9
2011	27.5
2012	25.5
2013	24.8
2014 and thereafter	126.6
Total	\$ 285.9

#### 16. Other Assets

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

	2008	2007
Deferred financing costs Overfunded pension plan asset	\$ 22.0	\$ 26.6 8.8
Other	9.5	11.1
Total other assets	\$ 31.5	\$ 46.5

The overfunded pension plan asset at December 31, 2007 relates to two defined benefit pension plans. For additional information, refer to Note 24.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 17. Accrued and Other Current Liabilities, and Other Long-Term Liabilities

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

	2008	2007
Tysabri milestone payment	\$ 50.0	\$
Accrued royalties payable	42.3	23.4
Payroll and related taxes	38.9	46.2
Clinical trial accruals	24.0	15.0
Accrued interest	14.7	16.0
Restructuring accruals	10.9	10.6
Sales and marketing accruals	9.6	23.3
Litigation accruals	5.9	1.7
Deferred rent	5.5	1.8
Deferred revenue	0.7	3.2
Other accruals	40.1	34.9
Total accrued and other current liabilities	\$ 242.6	\$ 176.1

We exercised our option to pay a \$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. Refer to Notes 15 and 29 for additional information.

Other long-term liabilities at December 31 consisted of the following (in millions):

	2008	2007
Deferred rent	\$ 22.7	\$ 25.5
Unfunded pension liability	13.4	
Accrued income tax payable	7.4	6.8
Deferred revenue	1.5	1.5
Other	9.5	13.3
Total other long-term liabilities	\$ 54.5	\$ 47.1

The unfunded pension liability at December 31, 2008 relates to two defined benefit pension plans. For additional information, refer to Note 24.

### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### Severance, restructuring and other charges accrual

The following table summarizes activities related to the severance, restructuring and other charges and the rollforward of the related accruals (in millions):

	Facilities	Severance	Other Costs	Total
Balance at December 31, 2005	\$ 12.6	\$ 5.8	\$ 0.5	\$ 18.9
Restructuring and other charges	1.1	14.8	1.1	17.0
Reversal of prior year accrual <sup>(1)</sup>	(9.4)	(0.1)		(9.5)
Cash payments	(3.7)	(14.3)	(0.5)	(18.5)
Non-cash charges			(1.1)	(1.1)
Balance at December 31, 2006	\$ 0.6	\$ 6.2	\$	\$ 6.8
Restructuring and other charges	1.3	30.7	1.3	33.3
Reversal of prior year accrual		(0.9)		(0.9)
Cash payments	(0.8)	(24.8)	(0.1)	(25.7)
Non-cash charges		(1.7)	(1.2)	(2.9)
Balance at December 31, 2007	\$ 1.1	\$ 9.5	\$	\$ 10.6
Restructuring and other charges	0.8	20.2	1.6	22.6
Reversal of prior year accrual		(0.6)		(0.6)
Cash payments	(1.9)	(17.2)		(19.1)
Non-cash charges	, ,	(1.2)	(1.4)	(2.6)
Balance at December 31, 2008	\$	\$ 10.7	\$ 0.2	\$ 10.9

### 18. Long-Term Debt

Long-term debt at December 31, 2008 and 2007 consisted of the following (in millions):

	Original Maturity		2008		2007	
7.75% Notes	November 2011	\$	850.0	\$	850.0	
Floating Rate Notes due 2011	November 2011		300.0		300.0	

<sup>(1)</sup> Principally related to the reversal of a charge for future lease payments on an unutilized facility in South San Francisco. As part of the restructuring of our Biopharmaceuticals R&D activities in 2006, this facility was brought back into use.

8.875% Notes	November 2013	465.0	465.0
Floating Rate Notes due 2013	November 2013	150.0	150.0
Total debt		\$ 1,765.0	\$ 1,765.0

#### 7.75% Notes

In November 2004, we completed the offering and sale of \$850.0 million in aggregate principal amount of 7.75% senior notes (7.75% Notes) due November 15, 2011, issued by Elan Finance plc. Elan Corporation, plc and certain of our subsidiaries have guaranteed the 7.75% Notes. At any time prior to November 15, 2008, we may redeem the 7.75% Notes, in whole, but not in part, at a price equal to 100% of their principal amount, plus a make-whole premium and accrued but unpaid interest. We may redeem the 7.75% Notes, in whole or in part, beginning on November 15, 2008 at an initial redemption price of 103.875% of their principal amount, which decreases to par over time, plus accrued and unpaid interest. Interest is paid in cash semi-annually. For additional information, refer to Note 31.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### Floating Rate Notes due 2011

In November 2004, we also completed the offering and sale of \$300.0 million in aggregate principal amount of senior floating rate notes due November 15, 2011 (Floating Rate Notes due 2011), also issued by Elan Finance plc. The Floating Rate Notes due 2011 bear interest at a rate, adjusted quarterly, equal to the three-month London Interbank Offer Rate (LIBOR) plus 4.0%, except the first interest payment, which bore interest at a rate equal to the six-month LIBOR plus 4.0%. Elan Corporation, plc and certain of our subsidiaries have guaranteed the Floating Rate Notes due 2011. We may redeem the Floating Rate Notes due 2011, in whole or in part, at par, plus accrued and unpaid interest. Interest is paid in cash quarterly. For additional information, refer to Note 31.

#### 8.875% Notes

In November 2006, we completed the offering and sale of \$465.0 million in aggregate principal amount of 8.875% senior notes (8.875% Notes) due December 1, 2013, issued by Elan Finance plc. Elan Corporation, plc and certain of our subsidiaries have guaranteed the 8.875% Notes. At any time prior to December 1, 2010, we may redeem the 8.875% Notes, in whole, but not in part, at a price equal to 100% of their principal amount, plus a make-whole premium and accrued but unpaid interest. We may redeem the 8.875% Notes, in whole or in part, beginning on December 1, 2010 at an initial redemption price of 104.438% of their principal amount, plus accrued and unpaid interest. In addition, at any time after February 23, 2008 and on or prior to December 1, 2009, we may redeem up to 35% of the 8.875% Notes using the proceeds of certain equity offerings at a redemption price of 108.875% of the principal, which decreases to par over time, plus accrued and unpaid interest. Interest is paid in cash semi-annually. The proceeds from the offering, including the Floating Rate Note due 2013 below, were used principally to redeem the Athena Notes in January 2007. For additional information, refer to Note 31.

### Floating Rate Notes due 2013

In November 2006, we also completed the offering and sale of \$150.0 million in aggregate principal amount of senior floating rate notes due December 1, 2013 (Floating Rate Notes due 2013), also issued by Elan Finance plc. The Floating Rate Notes due 2013 bear interest at a rate, adjusted quarterly, equal to the three-month LIBOR plus 4.125%. Elan Corporation, plc and certain of our subsidiaries have guaranteed the Floating Rate Notes due 2013. We may redeem the Floating Rate Notes due 2013, in whole or in part, beginning on December 1, 2008 at an initial redemption price of 102% of their principal amount, which decreases to par over time, plus accrued and unpaid interest. Interest is paid in cash quarterly. For additional information, refer to Note 31.

For additional information related to interest expense on our debts, refer to Note 6.

#### **Covenants**

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

Incur additional debt:

Create liens;

Enter into certain transactions with related parties;

Enter into certain types of investment transactions;

Engage in certain asset sales or sale and leaseback transactions;

Pay dividends or buy back our Ordinary Shares; and

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

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The breach of any of these covenants may result in a default under the applicable agreement, which could result in the indebtedness under the agreement becoming immediately due and payable and may result in a default under our other indebtedness subject to cross acceleration provisions.

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.

### 19. Fair Value Measurements

#### Assets Measured at Fair Value on a Recurring Basis

As of December 31, 2008, we did not hold any financial liabilities that are recognized at fair value in the financial statements on a recurring or non-recurring basis. The following table sets forth the fair value of our financial assets measured on a recurring basis, as of December 31, 2008 (in millions):

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total
Cash and cash equivalents	\$ 375.3	\$	\$	\$ 375.3
Restricted cash current	20.2			20.2
Restricted cash non-current	15.0			15.0
Available-for-sale debt securities current			27.7	27.7
Available-for-sale equity securities current	2.7			2.7
Available-for-sale debt securities non-current			0.4	0.4
Derivatives			0.1	0.1
Total	\$ 413.2	\$	\$ 28.2	\$ 441.4

As of December 31, 2008, the fair value of our Level 1 assets was \$413.2 million, primarily consisting of bank deposits, holdings in U.S. Treasuries funds, restricted cash, and marketable equity securities in emerging pharmaceutical and biotechnology companies. Included in this amount were unrealized gains of \$0.2 million related to marketable equity securities.

The following table sets forth a summary of the changes in the fair value of our Level 3 financial assets, which were measured at fair value on a recurring basis for the year ended December 31, 2008 (in millions).

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	Auction Rate			
	Fund	Securities	Warrants	Total
Beginning balance at January 1, 2008	\$ 274.8	\$ 6.3	\$ 0.7	\$ 281.8
Impairment charge included in net investment losses	(10.9)	(6.0)		(16.9)
Impairment charge included in net interest expense	(2.2)			(2.2)
Realized losses included in net investment losses	(1.4)		(0.6)	(2.0)
Unrealized gain included in accumulated OCI		0.1		0.1
Redemptions	(232.6)			(232.6)
Ending balance at December 31, 2008	\$ 27.7	\$ 0.4	\$ 0.1	\$ 28.2

As of December 31, 2008, we held \$28.2 million of investments, which were measured using unobservable (Level 3) inputs. The investment in a fund that had been reclassified from cash in December 2007, as a result of dislocations in the capital markets, was valued at \$27.7 million as of December 31, 2008, based on a net asset value (NAV) provided by the fund manager. The fund manager determines the NAV using a third-party accounting agent,

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

which collates data from third-party pricing services on the underlying security valuations based on widely available market data and sources to the accounting agent. For securities where prices from third-party valuation services are not available, the fund manager s valuation committee determines a value based on an evaluation of available data, portfolio manager input, trading desk input as well as any other appropriate factors. We have classified the NAV provided by the fund manager as a Level 3 input because we do not have access to the data used to calculate the NAV.

ARS of \$0.4 million as of December 31, 2008 were valued by a third-party valuation firm, which primarily used a discounted cash flow model (expected cash flows of the ARS were discounted using a yield that incorporates compensation for illiquidity) in combination with a market comparables method, where the ARS were valued based on indications (from the secondary market) of what discounts buyers demand when purchasing similar collateral debt obligations. The secondary market indications were given less weight in this approach due to the lack of data on trades in securities that are substantially similar to the ARS. The remaining Level 3 assets were freestanding warrants, which were valued at \$0.1 million as of December 31, 2008, using the Black-Scholes option-pricing model.

#### Assets Measured at Fair Value on a Non-recurring Basis

We measure certain assets, including equity investments in privately held companies, at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. During 2008, we recognized an impairment charge of \$0.9 million as a result of measuring at fair value a non-current investment in a privately held biotechnology company. At December 31, 2008, the fair value of this investment was measured at \$1.1 million based on Level 3 inputs, with estimates derived from the company s financial statements and benchmarking to similar public companies. This investment is included in the non-current equity securities balance of \$7.7 million presented in Note 11, with the remaining \$6.6 million comprised of equity securities carried at cost.

### **Debt Instruments**

The carrying values and fair values (based on unadjusted quoted prices) of our debt instruments were as follows (in millions):

	At Decembe Carrying Value		er 31, 2008 Fair Value		At Decemb Carrying Value		ber 31, 2007 Fair Value	
7.75% Notes	\$	850.0	\$	493.0	\$	850.0	\$	795.8
Floating Rate Notes due 2011		300.0		159.0		300.0		284.3
8.875% Notes		465.0		240.1		465.0		456.3
Floating Rate Notes due 2013		150.0		70.7		150.0		144.2
Total convertible debt and guaranteed notes	\$	1,765.0	\$	962.8	\$	1,765.0	\$	1,680.6

#### **Forward Contracts**

We did not enter into any forward contracts in 2008. During 2007, we entered into a number of Euro forward currency contracts at various rates of exchange that required us to sell U.S. dollars for Euros on various dates. These forward contracts expired on various dates throughout 2007. There were no forward contracts outstanding at December 31, 2008 and 2007.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### **20.** Income Taxes

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

	2008	2	007	2	2006
Irish corporation tax current Irish corporation tax deferred	\$ 0.3 0.3	\$	0.3 0.6	\$	(12.1) (2.8)
Foreign taxes current Foreign taxes deferred	10.0 (236.9)		7.9 (1.9)		6.5 (0.6)
Income tax expense/(benefit)	\$ (226.3)	\$	6.9	\$	(9.0)
Tax benefit reported in shareholders deficit related to exercise of stock options	\$ (2.4)	\$	(1.8)	\$	(2.0)

Current tax, including Irish corporation tax and foreign taxes, is provided on our taxable profits, using the tax rates and laws that have been enacted by the balance sheet date. In each of the three years ended December 31, 2008, 2007 and 2006, substantially all of our income in Ireland was exempt from tax by virtue of tax losses incurred or relief granted on income derived from patents. The total tax benefit of \$226.3 million for 2008 reflects 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. The total tax provision of \$6.9 million for 2007 reflects 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.

The deferred tax benefit of \$236.6 million for 2008 (2007: \$1.3 million benefit; 2006: \$3.4 million benefit) reflects the release of the U.S. valuation allowance and the availability of net operating losses in Ireland and the United States.

We released \$236.6 million of the U.S. valuation allowance during 2008. 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. The recognition of this deferred tax asset will result in higher deferred tax expense in future years as the asset is utilized to reduce cash taxes payable on U.S. taxable income in the future.

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

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	2008	2007	2006
Irish standard tax rate Taxes at the Irish standard rate Irish income at reduced rates Foreign income at rates other than the Irish standard rate Losses creating no tax benefit Release of U.S. valuation allowance	12.5% \$ (37.2) (0.9) (39.9) 88.3 (236.6)	12.5% \$ (49.8) (18.3) (31.1) 106.1	12.5% \$ (34.5) (8.6) (37.5) 71.6
Income tax expense/(benefit)	\$ (226.3)	\$ 6.9	\$ (9.0)

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2008	2007	2006
Ireland Foreign	\$ (848.9) 551.6	\$ (705.5) 307.4	\$ (581.5) 305.2
Loss before provision for income taxes	\$ (297.3)	\$ (398.1)	\$ (276.3)

### **Deferred Tax**

The full potential amounts of deferred tax comprised the following deferred tax assets and liabilities at December 31 (in millions):

	2008	2007
Deferred tax liabilities:		
Property, plant and equipment	\$ (7.1)	\$ (8.1)
Total deferred tax liabilities	\$ (7.1)	\$ (8.1)
Deferred tax assets:		
Net operating losses	\$ 373.6	\$ 353.2
Deferred interest	160.9	170.8
Intangibles/capitalized items	47.4	58.7
Tax credits	82.6	83.3
Reserves/provisions	30.1	31.2
Fixed assets	0.6	0.6
Share-based compensation expense under SFAS 123R	31.9	25.3
Other	10.0	5.1
Total deferred tax assets	\$ 737.1	\$ 728.2
Valuation allowance	\$ (488.8)	\$ (715.5)
Net deferred tax asset	\$ 241.2	\$ 4.6

The valuation allowance recorded against the deferred tax assets as of December 31, 2008 was \$488.8 million. The net change in the valuation allowance for 2008 was a decrease of \$226.7 million (2007: increase of \$6.2 million; 2006:

increase of \$137.0 million).

We have adjusted the above deferred tax assets in relation to net operating losses to exclude stock option deductions. In 2008, we have credited \$2.4 million (2007: \$1.8 million; 2006: \$2.0 million) to shareholders deficit to reflect recognition of U.S. state and alternative minimum taxes and U.K. corporation tax benefits from the utilization of stock option deductions.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The gross amount of unused tax loss carryforwards with their expiration dates after adjusting for uncertain tax positions are as follows (in millions):

	<b>At December 31, 2008</b>					
		U.S.	U.S.	Rest of		
	Ireland	State	Federal	World	Total	
One year	\$	\$	\$	\$	\$	
Two years						
Three years			39.2	10.2	49.4	
Four years		2.4	1.0	6.6	10.0	
Five years				5.5	5.5	
More than five years	2,615.7	177.2	526.0	3.2	3,322.1	
Total	\$ 2,615.7	\$ 179.6	\$ 566.2	\$ 25.5	\$ 3,387.0	

At December 31, 2008, certain of our Irish subsidiaries had net operating loss carryovers for income tax purposes of \$2,615.7 million. These can be carried forward indefinitely but are limited to the same trade/trades.

At December 31, 2008, certain U.S. subsidiaries had net operating loss carryovers for federal income tax purposes of approximately \$566.2 million and for state income tax purposes of approximately \$179.6 million. These net operating losses include stock option deductions. The federal net operating losses expire from 2011 to 2025. The state net operating losses expire from 2012 to 2025. In addition, at December 31, 2008, certain U.S. subsidiaries had federal research and orphan drug credit carryovers of \$50.8 million and alternative minimum tax (AMT) credits of \$5.0 million. The \$36.7 million of research credit will expire from 2009 through 2028 and the \$14.1 million of orphan drug credit will expire from 2011 through 2020. The AMT credits will not expire. Certain U.S. subsidiaries also had state credit carryovers of \$41.2 million, mostly research credits, of which \$40.9 million can be carried to subsequent tax years indefinitely, and \$0.3 million which will expire from 2009 to 2011. We may have had changes in ownership as described in the U.S. Internal Revenue Code (IRC) Section 382 in 2008. Consequently, utilization of federal and state net operating losses and credits may be subject to certain annual limitations.

The remaining loss carryovers of \$25.5 million have arisen in The Netherlands and are subject to time limits and other local rules.

At December 31, 2008, approximately \$508.7 million of the net operating losses set out above are derived from stock option exercises, and accordingly, we would record a credit of up to approximately \$158.1 million to shareholders deficit to reflect the recognition of tax benefits to the extent that these stock option deductions are utilized in the future.

No taxes have been provided for the unremitted earnings of our overseas subsidiaries as these are considered permanently employed in the business of these companies. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$2,179.1 million at December 31, 2008. Unremitted earnings may be liable to overseas taxes or

Irish taxation if they were to be distributed as dividends. It is impracticable to determine at this time the potential amount of additional tax due upon remittance of such earnings.

On January 1, 2007, we adopted the provisions of FIN 48. This interpretation clarifies the criteria for recognizing income tax benefits under SFAS 109 and requires additional disclosures about uncertain tax positions.

As a result of adoption, we recorded no adjustments to retained earnings as of January 1, 2007. Our gross unrecognized tax benefits at December 31, 2008 were \$68.9 million, of which \$61.9 million, if recognized, would effect the tax charge and as such would impact the effective tax rate.

We report accrued interest and penalties related to unrecognized tax benefits in income tax expense. During 2008, we accrued interest of \$0.3 million related to unrecognized tax benefits and in total, as of December 31, 2008, we have recorded a liability for potential penalties and interest of \$0.6 million and \$1.6 million, respectively.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We do not expect our unrecognized tax benefits to change significantly over the next 12 months.

The following table summarizes the activity related to our unrecognized tax benefits (in millions):

	2008	3 2007
Balance at January 1	\$ 50	.4 \$ 30.3
Tax positions related to current year:		
Additions	3	.8 0.7
Tax positions related to prior years:		
Additions	14	.8 20.6
Settlements		(0.1)
Expiration of statutes of limitations	(0	.1) (1.1)
Balance at December 31	\$ 68	.9 \$ 50.4

Our major taxing jurisdictions include Ireland and the United States (federal and state). These jurisdictions have varying statutes of limitations. In the United States, the 2004 through 2008 tax years generally remain subject to examination by the respective tax authorities. Additionally, because of our U.S. loss carryforwards, years from 1992 through 2003 may be adjusted. These years generally remain open for three to four years after the loss carryforwards have been utilized. In Ireland, the tax years 2004 to 2008 remain subject to examination by the Irish tax authorities.

### 21. Leases

#### **Operating Leases**

We lease certain of our facilities under non-cancelable operating lease agreements that expire at various dates through 2024. The major components of our operating leases that were in effect at December 31, 2008 are as described below.

In August 1998, we entered into an agreement for the lease of four buildings located in South San Francisco, California. These buildings are utilized for R&D, administration and other corporate functions. The leases expire between December 2012 and December 2014. Thereafter, we have an option to renew for two additional five-year periods.

In August 1996 and August 2000, we entered into lease agreements for our R&D facility located in King of Prussia, Pennsylvania. The lease agreements expire in May 2012 and April 2011, respectively.

In September 2004, we entered into a lease agreement for our corporate headquarters located in the Treasury Building, Dublin, Ireland. This lease expires in July 2014, with an option to renew for two additional 10-year periods. In April 2008, we entered into another lease agreement for an additional space at the Treasury Building. This lease expires in July 2014, with an option to renew for two additional 10-year periods. The agreement provides us with a 15-month rent-free period commencing at the beginning of the lease.

In June 2007, we entered into a lease agreement for a building in South San Francisco, California. The building is under construction and will be utilized for R&D, sales and administrative functions. We expect the lease term to commence in March 2009. The lease term is 15 years, with an option to renew for one additional five-year period. The agreement provides us with the option to cancel 10 years from the commencement date. The cancellation will require a one-year written notice and will include a penalty equal to nine months of rental payments and any unamortized landlord costs for tenant improvements. At December 31, 2008, we estimate the total rental payments and leasehold improvement incentives to be \$99.9 million and \$7.2 million, respectively. The rental payments and leasehold improvement incentives will be finalized upon completion of the building.

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In July 2007, we entered into a lease agreement for a portion of a building in South San Francisco, California. The leased space is for our sales and administrative functions. The lease period expires in August 2009. We have notified the landlord that we will not renew the lease after the expiration of the lease in August 2009.

In December 2007, we entered into a lease agreement for a building in South San Francisco, California. The building is under construction and will be utilized for R&D, sales and administrative functions. We expect the lease term to commence in the first quarter of 2010. The lease term is 15 years, with an option to renew for one additional five-year period. The agreement provides us with the option to cancel 10 years from the commencement date. The cancellation will require a one-year written notice and will include a penalty equal to nine months of rental payments and any unamortized landlord costs for tenant improvements. At December 31, 2008, we estimate the total rental payments and leasehold improvement incentives to be \$82.7 million and \$5.6 million, respectively. The rental payments and leasehold improvement incentives will be finalized upon completion of the building.

In December 2008, we announced the planned closure of the New York office, to occur in the first half of 2009. The lease period expires in February 2015. The future rental commitments relating to this lease are included in the table below.

In addition, we also have various operating leases for equipment and vehicles, with lease terms that range from three to five years.

We recorded expense under operating leases of \$19.4 million in 2008 (2007: \$22.7 million; 2006: \$23.2 million). We had no sublease income in any of these periods. As of December 31, 2008, our future minimum rental commitments for operating leases with non-cancelable terms in excess of one year are as follows (in millions):

Due in:	
2009	\$ $19.2_{(1)}$
2010	$28.3_{(1)}$
2011	$29.8_{(1)}$
2012	29.9
2013	18.9
2014 and thereafter	143.2
Total	\$ 269.3

#### Capital Leases

The net book value of assets acquired under capital leases at December 31, 2008 amounted to \$5.0 million (2007: \$7.3 million), which includes \$68.3 million of accumulated depreciation (2007: \$66.0 million). Depreciation expense

<sup>(1)</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.

related to assets under capital leases for 2008 amounted to \$2.3 million (2007: \$3.0 million; 2006: \$4.5 million).

In prior years, we disposed of plant and equipment and subsequently leased them back and also entered into an arrangement with a third-party bank, the substance of which allows us a legal right to require a net settlement of our obligations under the leases. The cash and borrowings relating to the previous sale and leaseback transactions have been offset in the Consolidated Financial Statements in the amount of \$32.8 million at December 31, 2008 (2007: \$37.6 million).

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 22. Share Capital

Share capital at December 31, 2008 and 2007 was as follows:

	No. of Ordinary Shares	
Authorized Share Capital	2008	2007
Ordinary Shares (par value 0.05)	670,000,000	670,000,000
Executive Shares (par value 1.25) (the Executive Shares)	1,000	1,000
B Executive Shares (par value 0.05) (the B Executive Shares)	25,000	25,000

	At December 3	31, 2008	At December 3	31, 2007
Issued and Fully Paid Share Capital	Number	\$000s	Number	\$000s
Ordinary Shares	474,728,319	27,573	470,195,498	27,412
Executive Shares	1,000	2	1,000	2
B Executive Shares	21,375	2	21,375	2

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

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

On September 6, 2007, the board of directors approved the cancellation of 850,947 Ordinary Shares that were previously held in treasury stock and, accordingly, all of the treasury stock shares were retired in 2007.

### 23. Accumulated Other Comprehensive Income/(Loss)

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

	2008	2007
Net unrealized gains on investment securities	\$ 0.3	\$ 3.8
Currency translation adjustments	(11.0)	(11.0)
Unamortized net actuarial loss on pension plans	(27.4)	(3.6)
Unamortized prior service cost on pension plans	(0.7)	(0.9)
Accumulated other comprehensive loss	\$ (38.8)	\$ (11.7)

### 24. Pension and Other Employee Benefit Plans

#### Pension

The pension costs of the Irish retirement plans have been presented in the following tables in accordance with the requirements of SFAS 132R, as amended by SFAS 158. We fund the pensions of certain employees based in Ireland through two defined benefit plans. In general, on retirement, eligible employees in the staff scheme are entitled to a pension calculated at 1/60th (1/52nd for the executive scheme) of their final salary for each year of service, subject to a maximum of 40 years. These plans are managed externally and the related pension costs and liabilities are assessed in accordance with the advice of a qualified professional actuary. The investments of the

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# Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

plans at December 31, 2008 consisted of units held in independently administered funds. The change in projected benefit obligation was (in millions):

	2008	2007
Projected benefit obligation at January 1	\$ 67.7	\$ 69.9
Service cost	4.1	3.3
Interest cost	3.7	3.1
Plan participants contributions	1.9	1.8
Actuarial gain	(9.2)	(16.9)
Benefits paid and other disbursements	(0.8)	(0.4)
Foreign currency exchange rate changes	(3.1)	6.9
Projected benefit obligation at December 31	\$ 64.3	\$ 67.7
The changes in plan assets at December 31 were (in millions):		
	2008	2007
Fair value of plan assets at beginning of year	\$ 76.5	\$ 66.7
Actual loss on plan assets	(27.7)	(1.8)
Employer contribution	3.6	2.9
Plan participants contributions	1.9	1.8
Benefits paid and other disbursements	(0.8)	(0.4)
Foreign currency exchange rate changes	(2.6)	7.3
Fair value of plan assets at end of year	\$ 50.9	\$ 76.5
Overfunded/(unfunded) status at end of year	\$ (13.4)	\$ 8.8
Unamortized net actuarial loss in accumulated OCI	27.4	3.6
Unamortized prior service cost in accumulated OCI	0.7	0.9
Net amount recognized	\$ 14.7	\$ 13.3
Amounts recognized in the Consolidated Balance Sheet at December 31 (in millions):		

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Overfunded/(unfunded) status non-current asset/(liability)

2008

\$ (13.4)

2007

8.8

Accumulated OCI	28.1	4.5
Net amount recognized	\$ 14.7	\$ 13.3

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

	2008	2007	2006
Service cost	\$ 4.1	\$ 3.3	\$ 2.8
Interest cost	3.7	3.1	2.5
Expected return on plan assets	(5.3)	(4.5)	(3.3)
Amortization of net actuarial loss	0.1	0.4	0.6
Amortization of prior service cost	0.1	0.1	0.1
Net periodic pension cost	\$ 2.7	\$ 2.4	\$ 2.7

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### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2008	2007
Discount rate	5.5%	5.4%
Expected return on plan assets	6.3%	6.7%
Rate of compensation increase	3.4%	3.8%

Pursuant to SFAS 87 (as amended by SFAS 158), we look to rates of return on high-quality fixed-income investments in determining the assumed discount rate. Since no significant market exists for high-quality fixed income investments in Ireland, the assumed discount rate at December 31, 2008 of 5.5% per annum was determined based on the Merrill Lynch AA Corporate 10+ index for AA corporate bonds with durations of 10 years or more (Merrill Lynch Index). The estimated expected cash outflows for each of the next 10 years are projected to be less than the estimated contribution inflows. Therefore, we consider the Merrill Lynch Index to be the closest available match for the expected defined benefit payments in the longer term. At December 31, 2007, the assumed discount rate of 5.4% was determined based on the iBoxx Corporate Bond Index for AA rated corporate bonds (iBoxx Index). The Merrill Lynch Index yield was chosen as of December 31, 2008 as there is no need to adjust the index to exclude bonds that were downgraded during December 2008 but were not excluded from the iBoxx Index until January 2, 2009.

The expected long-term rate of return on assets of 6.3% was calculated based on the assumptions of the following returns for each asset class: Equities 7.5%, Property 7.0%, Bonds 4.0% and Cash 2.0%. The fixed interest yield at December 31, 2008 was 4.0%; hence the assumed return on bonds is 4.0%. Returns for the other asset classes are set by reference to the fixed interest yield plus a risk premium. For equities, the risk premium is 3.5% and, for property, the premium is 3.0%.

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

	2008	2007
Equities	68.8%	77.0%
Bonds	16.5%	12.5%
Property	3.3%	3.4%
Cash	11.4%	7.1%
Total	100.0%	100.0%

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

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

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

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

The total accumulated benefit obligation for the defined benefit pension plans was \$56.4 million at December 31, 2008 (2007: \$58.9 million).

At December 31, 2008, the expected future cash benefits per year to be paid in respect of the plans for the period of 2009-2013 are collectively less than \$0.5 million. The expected cash benefits to be paid in the period of

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### Elan Corporation, plc

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2014-2018 are approximately \$2.8 million. We expect to contribute approximately \$3.4 million to our defined benefit plans in 2009.

The expected benefits to be paid are based on the same assumptions used to measure our benefit obligation at December 31, 2008, including the estimated future employee service.

During 2009, we expect to recognize \$1.3 million of the unamortized net actuarial loss and \$0.1 million of the unamortized prior service cost that is included in accumulated OCI at December 31, 2008.

In addition to the defined benefit pension plans, we operate a number of defined contribution retirement plans, primarily for employees outside of Ireland. The costs of these plans are charged to the income statement in the period they are incurred. The costs of the defined contribution plans were \$4.1 million (2007: \$4.7 million; 2006: \$5.9 million).

### 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.

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

We maintain a 401(k) retirement savings plan for our employees based in the United States. Participants in the 401(k) plan may contribute up to 100% of their annual compensation, limited by the maximum amount allowed by the IRC. We match 3% of each participating employee s annual compensation on a quarterly basis and may contribute additional discretionary matching up to another 3% of the employee s annual qualified compensation. Our matching contributions are vested immediately. For the year ended December 31, 2008, we recorded \$3.9 million (2007: \$4.7 million; 2006: \$5.5 million), of expense in connection with the matching contributions under the 401(k) plan.

### 25. Share-based Compensation

At our Annual General Meeting held on May 25, 2006, the Company s shareholders approved a single Long Term Incentive Plan (2006 LTIP), which provides for the issuance of share options, RSUs and other equity awards. The shareholders also approved the closure of all pre-existing share option and RSU plans. Our equity award program is a long-term retention program that is intended to attract, retain and provide incentives for Elan employees, officers and directors, and to align shareholder and employee interests. We consider our equity award program critical to our operation and productivity. Currently, we grant equity awards from the 2006 LTIP, under which awards can be granted to all directors, employees and consultants.

In May 2008, our shareholders approved an amendment to the 2006 LTIP that provides for an additional 18,000,000 shares to be reserved for issuance under the 2006 LTIP. As of December 31, 2008, there were 18,409,620 shares reserved for issuance under the 2006 LTIP (2007: 4,138,640).

#### Stock Options

Stock options are granted at the price equal to the market value at the date of grant and will expire on a date not later than 10 years after their grant. Options generally vest between one and four years from the grant date.

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#### Elan Corporation, plc

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the number of options outstanding as of December 31 (in thousands):

	2008	2007
1996 Plan	5,471	7,240
1998 Plan	593	1,206
1999 Plan	6,761	9,038
2006 LTIP	6,335	4,312
Total	19,160	21,796

We also had granted stock options as part of past acquisition transactions. As of December 31, 2008, there were 64,030 (2007: 69,743) options outstanding in relation to the Liposome Company, Inc. and 11,848 (2007: 31,100) related to the Dura acquisitions.

The stock options outstanding, vested and expected to vest, and exercisable are summarized as follows:

			Weighted Average Remaining Contractual	Aggregate Intrinsic
	No. of Options	WAEP <sup>(1)</sup>	Life	Value (In
	(In thousands)		(In years)	millions)
Outstanding at December 31, 2006	24,190	\$ 17.52		
Exercised	(3,765)	6.48		
Granted	3,870	14.55		
Forfeited	(736)	16.17		
Expired	(1,662)	30.46		
Outstanding at December 31, 2007	21,897	\$ 17.89		
Exercised	(3,596)	12.62		
Granted	2,843	19.11		
Forfeited	(596)	17.84		
Expired	(1,312)	32.45		
Outstanding at December 31, 2008	19,236	\$ 18.00	6.0	\$ 6.1
Vested and expected to vest at December 31,				
2008	18,111	\$ 18.07	5.8	\$ 6.1

Exercisable at December 31, 2008

12,781

\$ 19.04

4.7

\$ 6.1

## (1) Weighted-average exercise price

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between our closing stock price on the last trading day of 2008 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2008. This amount changes based on the fair market value of our stock. The total intrinsic value of options exercised in 2008 was \$53.1 million (2007: \$46.2 million). The total fair value of options vested in 2008 was \$41.2 million (2007: \$29.7 million).

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

At December 31, 2008, the range of exercise prices and weighted-average remaining contractual life of outstanding and exercisable options were as follows:

	Options	tions Outstandin Weighted- Average Remaining	ng	Options Options	tions Exercisabl Weighted- Average Remaining	e	
Range	Outstanding (In thousands)	Contractual Life (In years)	WAEP	Outstanding (In thousands)	Contractual Life (In years)	WAEP	
\$1.93-\$10.00	5,071	5.5	\$ 5.33	4,112	4.8	\$ 4.91	
\$10.01-\$25.00	9,422	7.1	\$ 15.45	5,129	6.1	\$ 15.78	
\$25.01-\$40.00	3,330	5.0	\$ 29.58	2,127	2.7	\$ 31.53	
\$40.01-\$58.60	1,413	2.3	\$ 53.24	1,413	2.3	\$ 53.24	
\$1.93-\$58.60	19,236	6.0	\$ 18.00	12,781	4.7	\$ 19.04	

Equity-settled share-based payments made to employees have been recognized in the financial statements based on the fair value of the awards measured at the date of grant. We use the graded-vesting attribution method for recognizing share-based compensation expense over the requisite service period for each separately vesting tranche of award as though the awards were, in substance, multiple awards. The fair value of share options is calculated using a binomial option-pricing model and the fair value of options issued under employee equity purchase plans is calculated using the Black-Scholes option-pricing model, taking into account the relevant terms and conditions. The binomial option-pricing model is used to estimate the fair value of our share options because it better reflects the possibility of exercise before the end of the options life. The binomial option-pricing model also integrates possible variations in model inputs, such as risk-free interest rates and other inputs, which may change over the life of the options. Options issued under our employee equity purchase plans have relatively short contractual lives, or must be exercised within a short period of time after the vesting date, and the input factors identified above do not apply. Therefore, the Black-Scholes option-pricing model produces a fair value that is substantially the same as a more complex binomial option-pricing model for our employee equity purchase plans. The amount recognized as an expense is adjusted each period to reflect actual and estimated future levels of vesting.

We use the implied volatility for traded options on our stock with remaining maturities of at least one year to determine the expected volatility assumption required in the binomial model. The risk-free interest rate assumption is based upon observed interest rates appropriate for the term of our employee stock options. The dividend yield assumption is based on the history and expectation of dividend payouts.

As share-based compensation expense recognized in the Consolidated Statement of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from

estimates. Forfeitures were estimated based on historical experience and our estimate of future employee turnover.

The estimated weighted-average grant date fair values of the individual options granted during the years ended December 31, 2008, 2007 and 2006 were \$11.25, \$8.85 and \$10.45, respectively. The fair value of options granted during these years was estimated using the binomial option-pricing model with the following weighted-average assumptions:

	2008	2007	2006
Risk-free interest rate	2.88%	4.88%	4.48%
Expected volatility	76.7%	63.0%	72.3%
Expected dividend yield			
Expected life <sup>(1)</sup>			

<sup>(1)</sup> The expected lives of options granted in 2008, as derived from the output of the binomial model, ranged from 4.4 years to 7.3 years (2007: 5.0 years to 8.0 years; 2006: 5.1 years to 8.1 years). The contractual life of the options, which is not later than 10 years from the date of grant, is used as an input into the binomial model.

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### Restricted Stock Units

In February 2006, we began granting RSUs to certain employees. The RSUs generally vest between one and four years from the grant date, and shares are issued to employees as soon as practicable following vesting. The fair value of services received in return for the RSUs is measured by reference to the fair value of the underlying shares at grant date.

The non-vested RSUs are summarized as follows:

		Weighted-Average Grant Date
	No. of RSUs	Fair Value
	(In the	ousands)
Non-vested at December 31, 2006	1,297	\$ 15.90
Granted	1,723	13.95
Vested	(366)	15.65
Forfeited	(372)	14.98
Non-vested at December 31, 2007	2,282	14.62
Granted	1,601	25.01
Vested	(653)	14.90
Forfeited	(329)	17.72
Non-vested at December 31, 2008	2,901	\$ 19.94

#### 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 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 common stock 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.

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.

The options issued under the Sharesave Plans were granted in 2005 and the estimated fair values of the options were expensed over the 36-month saving period from the grant date. The fair value per option granted under the Sharesave Plans in 2005 was \$11.68. The weighted-average fair value of options granted under the U.S. Purchase Plan during the 12 months ended December 31, 2008 was \$6.40. The estimated fair values of these options were charged to expense over the respective three-month offering periods. The estimated fair values of options granted

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

under the U.S. Purchase Plan in the years ended December 31, were calculated using the following inputs into the Black-Scholes option-pricing model:

	2008			2007		2006
Weighted-average share price	\$	21.56	\$	16.36	\$	14.88
Weighted-average exercise price	\$	18.33	\$	13.91	\$	12.65
Expected volatility <sup>(1)</sup>		74.0%	53.2%			73.3%
Expected life	3	3 months	3	3 months	3 months	
Expected dividend yield						
Risk-free interest rate		1.46%		4.87%		4.72%

<sup>(1)</sup> The expected volatility was determined based on the implied volatility of traded options on our stock.

#### Share-based Compensation Expense

For awards granted prior to the adoption of SFAS 123R, we determined the pro-forma share-based compensation expense based on the nominal vesting period of the awards. For awards granted subsequent to the adoption of SFAS 123R, we recognize share-based compensation expense over the requisite service period, which is the period from the grant date to the date the employee is eligible to vest in the award, while continuing to reflect compensation expense over the nominal vesting period for awards granted prior to the adoption of SFAS 123R. The share-based compensation expense recognized in 2008 for awards granted prior to the adoption of SFAS 123R, which would have been included in the pro-forma expense for previous periods had the requisite service period guidance in SFAS 123R been applied, was \$0.1 million (2007: \$0.3 million; 2006: \$0.4 million).

As permitted by SFAS 123, we determined the pro-forma share-based compensation expense by assuming all awards will vest, adjusting for actual forfeitures as they occurred. On adoption of SFAS 123R, the impact of estimating forfeitures of awards granted prior to the adoption of SFAS 123R was an additional \$1.3 million of the share-based compensation expense in 2006.

In April 2007, we modified outstanding stock option grants and outstanding 2007 RSUs held by members of the Operating Committee of Elan (15 members at the modification date) to provide for the accelerated vesting of the awards upon involuntary termination, for any reason other than cause, together with the extension of the period to exercise outstanding stock options for a two-year period (previously 90 days) from the termination date. This resulted in the fair value of the outstanding options being remeasured at the modification date. The impact of the modification for all applicable outstanding awards amounted to additional share-based compensation expense of \$0.8 million, which has been and will be taken into account over the remaining vesting terms of the awards from the modification date.

For 2008, we recognized total compensation expense related to equity-settled share-based awards of \$47.2 million (excluding share-based compensation capitalized to property, plant and equipment of \$1.0 million; 2007: \$Nil; 2006: \$Nil) (2007: \$45.1 million; 2006: \$47.1 million). The expense has been recognized in the following line items in the

# Consolidated Statement of Operations (in millions):

	2008	2007	2006		
Cost of sales Selling, general and administrative expenses Research and development expenses Other net charges	\$ 2.3 25.0 18.7 1.2	\$ 4.0 23.9 15.5 1.7	\$ 4.2 28.8 14.1		
Total	\$ 47.2	\$ 45.1	\$ 47.1		

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Share-based compensation (including share-based compensation capitalized to property, plant and equipment of \$1.0 million; 2007: \$Nil; 2006: \$Nil) arose under the following awards (in millions):

	2008	2007	2006
Stock options	\$ 22.3	\$ 29.7	\$ 34.4
RSUs	23.9	14.1	10.8
Employee equity purchase plans	2.0	1.3	1.9
Total	\$ 48.2	\$ 45.1	\$ 47.1

The total equity-settled share-based compensation expense related to unvested awards not yet recognized, adjusted for estimated forfeitures, is \$36.1 million at December 31, 2008. This expense is expected to be recognized over a weighted-average of 1.3 years.

#### 26. Commitments and Contingencies

As of December 31, 2008, the directors had authorized capital commitments for the purchase of property, plant and equipment 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.

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

For information on lease commitments, refer to Note 21. For litigation and administrative proceedings related to contingencies, refer to Note 27.

#### 27. Litigation

We are involved in legal and administrative proceedings that could have a material adverse effect on us.

#### Securities matters

Commencing in January 1999, several class actions were filed in the U.S. District Court for the Southern District of California against Dura, one of our subsidiaries, and various then-current or former officers of Dura. The actions, which 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. A preliminary settlement agreement has been entered into with respect to this matter. If this agreement is finalized, we will pay approximately \$4.7 million, net of insurance coverage, as our share of the settlement. We have accrued \$4.7 million in the Consolidated Financial Statements as of December 31, 2008.

We and some of our officers and directors were named as defendants in putative class actions originally filed in the U.S. District Courts for the District of Massachusetts (on March 4, 2005 and March 14, 2005) and the Southern

District of New York (on March 15, 2005 and March 23, 2005). On August 4, 2005, the U.S. District Court for the Southern District of New York issued an order consolidating the New York actions. The cases originally filed in Massachusetts were subsequently transferred to the Southern District of New York on or about August 29, 2005. The plaintiffs amended, consolidated class action complaint alleged claims under the U.S. federal securities laws and state laws and sought damages on behalf of a class of shareholders who purchased our stock prior to the announcement of the voluntary suspension of *Tysabri* on February 28, 2005. On March 27, 2008, the Court granted our motion to dismiss the plaintiffs complaint in its entirety, finding that the plaintiffs failed to plead adequately the key elements of securities law violations. The complaint was dismissed with prejudice after plaintiffs appealed the Court s decision.

In March 2005, we received a letter from the SEC stating that the SEC s Division of Enforcement was conducting an informal inquiry into actions and securities trading relating to *Tysabri* events. The SEC s inquiry

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

primarily relates to events surrounding the February 28, 2005 announcement of the decision to voluntarily suspend the marketing and clinical dosing of *Tysabri*. We have provided materials to the SEC in connection with the inquiry but have not received any additional requests for information or interviews relating to the inquiry.

The SEC notified us in January 2009 that the SEC was conducting an informal inquiry primarily relating to the July 31, 2008 announcement concerning the initial two *Tysabri*-related PML cases that occurred subsequent to the resumption of marketing of *Tysabri* in 2006. We intend to provide the SEC with materials in connection with the inquiry.

We and some of our officers and directors have been named as defendants in putative class action lawsuits filed in the U.S. District Court for the Southern District of New York on October 14, October 27, November 13, November 25 and December 11, 2008. The various cases allege claims under the U.S. federal securities laws and seek damages on behalf of all purchasers of our stock during periods ranging between May 21, 2007 and October 21, 2008. The complaints allege that we issued false and misleading public statements concerning the safety and efficacy of bapineuzumab (AAB-001). We intend to vigorously defend these actions.

#### Antitrust matters

On August 12, 2008, the U.S. District Court for the Southern District of Florida held that Watson Pharmaceuticals naproxen sodium ER tablets, the generic version of Naprelan®, infringes our U.S. Pat No. 5,637,320 (the 320 Patent). The District Court also held that Watson's infringement of our 320 Patent was willful. The infringement action was initially brought by us in October 1998 following the filing of a Paragraph IV certification. The District Court held a further hearing on the matter to address issues related to the remedy/damages phase of the trial and the appropriateness of permanent injunctive relief. We expect that the damages phase of the trial will occur sometime during the second quarter of 2009.

Indirect purchasers of Naprelan have filed three putative class actions in the U.S. District Court for the Eastern District of Pennsylvania against Elan and Skye Pharma, Inc. In September 2002, the cases were consolidated and in October 2002, a consolidated amended class action complaint was filed. The consolidated complaint alleges that we violated the antitrust laws by engaging in sham patent litigation and entering into an unlawful settlement agreement in an effort to prevent or delay the entry of a generic alternative to Naprelan. The damages claimed are unspecified. Other than preliminary document production, the litigation has been stayed and the case placed on the court s suspense docket.

In 2002 and 2003, 10 actions were filed in the U.S. District Courts (seven in the District of Columbia and three in the Southern District of New York) claiming that we (and others) violated federal and state antitrust laws based on licensing arrangements between Elan and Biovail Corporation relating to nifedipine. The complaints seek various forms of remedy, including damages and injunctive relief. The actions have been brought by putative classes of direct purchasers, individual direct purchasers, and putative classes of indirect purchasers. On May 29, 2003, the Judicial Panel for Multidistrict Litigation coordinated and consolidated for pre-trial proceedings all pending cases in the U.S. District Court for the District of Columbia. On September 1, 2004, the Court issued a Memorandum Opinion and Order granting in part and denying in part the defendants motions to dismiss. The Court held that none of the claims for injunctive relief had any basis and, accordingly, the Court lacked jurisdiction over the indirect purchaser federal and state claims. Consequently, the Court granted the motion as it related to the putative class of indirect purchasers

and dismissed that consolidated class complaint without prejudice. The Court also dismissed the claims for injunctive relief of the purported direct purchaser plaintiffs. The Court declined to dismiss the damage claims of the purported direct purchaser plaintiffs, ruling that it would be premature to do so without allowing discovery given the Court s obligation to accept as true all allegations when tested on a motion to dismiss. Summary judgment briefings will occur throughout the first half of 2009, with a ruling on such motion expected during the second half of 2009.

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2001, we received a letter from the U.S. Federal Trade Commission (FTC) stating that the FTC was conducting a non-public investigation to determine whether Brightstone Pharma, Inc., Elan or others may have engaged in an effort to restrain trade by entering into an agreement that may restrict the ability of Brightstone or others to market a bioequivalent or generic version of Naprelan. In October 2001, our counsel met informally with FTC staff to discuss the matter. No further communication from the FTC was received until December 2002, when we were served with a subpoena from the FTC for the production of documents related to Naprelan. We provided documents and witness testimony in response to the subpoena and continue to cooperate with the FTC relating to this investigation.

#### Paragraph IV Litigation

We and/or our product licensees are involved in various sets of so-called Paragraph IV litigation proceedings in the United States. In the United States, putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file Abbreviated New Drug Applications (ANDAs) and, in doing so, they are not required to include preclinical and clinical data to establish safety and effectiveness of their drug. Instead, they would rely on such data provided by the innovator drug NDA holder. However, to benefit from this less costly abbreviated procedure, the ANDA applicant must demonstrate that its drug is generic or bioequivalent to the innovator drug, and, to the extent that patents protect the innovator drug that are listed in the Orange Book, the ANDA applicant must write to the innovator NDA holder and the patent holder (to the extent that the Orange Book-listed patents are not owned by the innovator NDA holder) certifying that their product either does not infringe the innovator s patents and/or that the relevant patents are invalid. The innovator and the patent holder may sue the ANDA applicant within 45 days of receiving the certification and, if so, the U.S. Food and Drug Administration (FDA) may not approve the ANDA for 30 months from the date of certification unless, at some point before the expiry of those 30 months, a court makes a final decision in the ANDA applicant s favor.

We are involved in a number of Paragraph IV suits in respect of seven different products (TriCor 145, Skelaxin, Ritalin LA, Focalin XR, Avinza, Zanaflex, and Cardizem CD) either as plaintiff or as an interested party (where the suit is being taken in the name of one of our licensees).

In January 2009, the U.S. District Court for the Eastern District of New York issued a memorandum and order indicating that the two patents at issue in the Skelaxin litigation are invalid. We and our collaborator, King Pharmaceuticals, Inc., disagree with the court s decision. King intends to appeal this decision to the Federal Circuit Court after the judgment is entered in the lower court.

If we are unsuccessful in these and other similar type suits, our or our licensees products may be subject to generic competition, and our manufacturing revenue and royalties would be materially and adversely affected.

#### Other matters

In January 2006, our subsidiary Elan Pharmaceuticals, Inc. (EPI) received a letter and subpoena from the U.S. Department of Justice and the U.S. Department of Health and Human Services asking for documents and materials primarily related to marketing practices concerning our former Zonegran product. 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 us. In April 2006, Eisai delivered to us a notice making a contractual claim for indemnification in connection with a similar subpoena received by Eisai.

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 EDT s *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,

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

#### 28. Related Parties

#### Mr. John Groom

Mr. Groom, a former director of Elan, had a consultancy agreement with us. Effective July 1, 2003, the consultancy agreement was cancelled and we entered into a pension agreement of \$200,000 per year payable until May 16, 2008. Mr. Groom received total payments of \$75,556 in 2008 (2007: \$200,000; 2006: \$200,000) under this pension agreement. On May 26, 2005, Mr. Groom retired from the board of Elan.

#### Dr. Lars Ekman

Effective December 31, 2007, Dr. Lars Ekman resigned from his operational role as president of research and development and has continued to serve as a member of the board of directors of Elan.

Under the agreement reached with Dr. Ekman, we agreed by reference to Dr. Ekman s contractual entitlements and in accordance with our severance plan to (a) make a lump-sum payment of \$2,500,000; (b) make milestone payments to Dr. Ekman, subject to a maximum amount of \$1,000,000, if we achieve certain milestones in respect of our Alzheimer s disease program; (c) accelerate the vesting of, and grant a two-year exercise period, in respect of certain of his equity awards, with a cash payment being made in respect of one grant of RSUs (which did not permit accelerated vesting); and (d) continue to make annual pension payments in the amount of \$60,000 per annum, provide the cost of continued health coverage and provide career transition services to Dr. Ekman for a period of up to two years. A total severance charge of \$3.6 million was expensed in 2007 for Dr. Ekman, excluding potential future success milestone payments related to our Alzheimer s disease program. To date, none of the milestones have been triggered, and they remain in effect at December 31, 2008.

#### Dr. Dennis Selkoe

On July 1, 2006, EPI entered into a consultancy agreement with Dr. Selkoe whereby Dr. Selkoe agreed to provide consultant services with respect to the treatment and/or prevention of neurodegenerative and autoimmune diseases. We will pay Dr. Selkoe a fee of \$12,500 per quarter. The agreement is effective for three years unless terminated by either party upon 30 days written notice and supersedes all prior consulting agreements between Dr. Selkoe and Elan. Prior thereto, Dr. Selkoe was party to various consultancy agreements with EPI and Athena Neurosciences, Inc. Under the consultancy agreements, Dr. Selkoe received \$50,000 in 2008, 2007 and 2006.

#### 29. Development and Marketing Collaboration Agreements

#### Biogen Idec

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

In November 2004, *Tysabri* received regulatory approval in the United States for the treatment of relapsing forms of MS. In February 2005, Elan and Biogen Idec voluntarily suspended the commercialization and dosing in clinical trials of *Tysabri*. This decision was based on reports of two serious adverse events, one of which was fatal, in patients treated with *Tysabri* in combination with Avonex<sup>®</sup> in clinical trials. These events involved two cases of progressive multifocal leukoencephalopathy (PML), a rare and potentially fatal, demyelinating disease of the central nervous system. Both patients received more than two years of *Tysabri* therapy in combination with Avonex. In March 2005, the companies announced that their ongoing safety evaluation of *Tysabri* led to a previously

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

diagnosed case of malignant astrocytoma being reassessed as PML, in a patient in an open label CD clinical trial. The patient had received eight doses of *Tysabri* over an 18-month period. The patient died in December 2003.

A comprehensive safety evaluation of more than 3,000 *Tysabri* patients was performed in collaboration with leading experts in PML and neurology. The results of the safety evaluation performed in 2005 yielded no new confirmed cases of PML beyond the three previously reported.

In September 2005, Elan and Biogen Idec submitted to the FDA a supplemental Biologics License Application for *Tysabri*, which the FDA subsequently designated for Priority Review. On March 7-8, 2006, the Peripheral Central Nervous System Drug Advisory Committee reviewed and voted unanimously to recommend that *Tysabri* be reintroduced as a treatment for relapsing forms of MS.

In June 2006, the FDA approved the reintroduction of *Tysabri* for the treatment of relapsing forms of MS. Approval for the marketing of *Tysabri* in the European Union was also received in June 2006 and has subsequently been received in a number of other countries. The distribution of *Tysabri* in both the United States and the European Union commenced in July 2006. Global in-market net sales of *Tysabri* in 2008 were \$813.0 million (2007: \$342.9 million; 2006: \$38.1 million), consisting of \$421.6 million (2007: \$217.4 million; 2006: \$28.2 million) in the U.S. market and \$391.4 million (2007: \$125.5 million; 2006: \$9.9 million) in the ROW.

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

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 revenue of \$135.5 million (2007: \$14.3 million; 2006: negative \$10.7 million).

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 our 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.

For additional information relating to *Tysabri*, refer to Note 3.

#### Wyeth

In March 2000, we entered into a research, development and commercialization collaboration agreement with Wyeth, successor to American Home Products, Inc., to collaborate in the research, development and commercialization of beta amyloid immunotherapies, including bapineuzumab, and ACC-001, a novel beta amyloid immunoconjugate, for the treatment and prevention of some neurodegenerative conditions in humans.

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In May 2007, Elan and Wyeth announced their decision to initiate a Phase 3 clinical program for bapineuzumab. The Phase 3 program encompasses studies in North America and the ROW. In December 2007, we announced that the first patient had been dosed in the studies taking place in North America. ROW studies began enrolling patients during the second half of 2008. We are responsible for conducting the studies in North America, while Wyeth is responsible for conducting the studies in the ROW.

The Phase 3 program includes four randomized, double-blinded, placebo controlled studies across two subpopulations, which are designed to total approximately 4,000 patients with mild to moderate AD at approximately 350 sites. The treatment duration for each patient is 18 months with patients intended to be equally distributed between North America and the ROW. The studies stratify patients by ApoE4 genotype, and all studies have co-primary efficacy end points—one cognitive and one functional.

Under our collaboration with Wyeth, in general, subject to certain limitations imposed by the parties, we share most of the research, development and commercialization costs. We are responsible for the manufacture and supply of products, while Wyeth is responsible for distribution. We continue to discuss with Wyeth a joint commercialization plan. We are eligible to earn milestone payments from Wyeth for such events as first regulatory approval filings and product approvals and achieving a certain sales level.

#### **Transition Therapeutics**

In September 2006, we 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. In December 2007, the first patient was 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. The patient enrollment target for this study was achieved in October 2008.

Under our collaboration with Transition, we shall make a \$25.0 million milestone payment to Transition after the initiation of the first Phase 3 clinical trial for ELND005.

#### **30.** Segment Information

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.

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our segment results of operations and revenue for the years ended December 31, 2008, 2007 and 2006, together with goodwill and total assets by segment at December 31, 2008 and 2007 are as follows:

Analysis of results of operations by segment (in millions):

	Biop 2008	•	rmaceuti 2007	ls 2006	,	2008	EDT 2007	2006	2008	Total 2007	2006
Product revenue Contract revenue	\$ 698.6	\$	454.6 9.3	\$ 269.8 8.5	\$	281.6 20.0	\$ 274.0 21.5	\$ 263.1 19.0	\$ 980.2 20.0	\$ 728.6 30.8	\$ 532.9 27.5
Total revenue	698.6		463.9	278.3		301.6	295.5	282.1	1,000.2	759.4	560.4
Cost of sales	369.7		223.7	87.0		123.7	114.2	123.3	493.4	337.9	210.3
Gross margin Dperating expenses: Selling, general and	328.9		240.2	191.3		177.9	181.3	158.8	506.8	421.5	350.1
idministrative expenses Research and	248.2		294.8	320.9		44.5	44.5	39.4	292.7	339.3	360.3
levelopment expenses Net gain on sale of	275.8		214.5	172.2		47.6	48.4	47.4	323.4	262.9	219.6
products and businesses Other net (gains)/charges	34.2		81.0	(43.1) 26.3			3.6	(46.6)	34.2	84.6	(43.1) (20.3)
Total operating expenses	558.2		590.3	476.3		92.1	96.5	40.2	650.3	686.8	516.5
Operating income/(loss)	\$ (229.3)	\$	(350.1)	\$ (285.0)	\$	85.8	\$ 84.8	\$ 118.6	\$ (143.5)	\$ (265.3)	\$ (166.4)
Depreciation and											
mortization Share-based	\$ 33.5	\$	81.5	\$ 86.3	\$	36.6	\$ 36.8	\$ 49.3	\$ 70.1	\$ 118.3	\$ 135.6
ompensation expense	\$ 37.3	\$	34.9	\$ 38.3	\$	9.9	\$ 10.2	\$ 8.8	\$ 47.2	\$ 45.1	\$ 47.1
Capital expenditures	\$ 176.5	\$	17.4	\$ 21.4	\$	14.4	\$ 11.2	\$ 15.9	\$ 190.9	\$ 28.6	\$ 37.3

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

	2008	2007	2006		
Operating loss Net interest and investment losses Provision for/(benefit from) income taxes	\$ (143.5)	\$ (265.3)	\$ (166.4)		
	153.8	132.8	109.9		
	(226.3)	6.9	(9.0)		

Net loss \$ (71.0) \$ (405.0) \$ (267.3)

## Revenue analysis by segment (in millions):

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

	2008	2007	2006
Revenue from the Biopharmaceuticals business Revenue from the EDT business	\$ 698.6 301.6	\$ 463.9 295.5	\$ 278.3 282.1
Total revenue	\$ 1,000.2	\$ 759.4	\$ 560.4

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Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue from the Biopharmaceuticals business can be further analyzed as follows (in millions):

	2008	2007	2006
Product revenue:			
Tysabri U.S.	\$ 421.6	\$ 217.4	\$ 28.2
Tysabri ROW	135.5	14.3	(10.7)
Total Tysabri	557.1	231.7	17.5
Azactam	96.9	86.3	77.9
Maxipime	27.1	122.5	159.9
Prialt	16.5	12.3	12.1
Royalties	1.0	1.8	2.4
Total product revenue	698.6	454.6	269.8
Contract revenue		9.3	8.5
Total revenue from Biopharmaceuticals business	\$ 698.6	\$ 463.9	\$ 278.3

Revenue from the EDT business can be further analyzed as follows (in millions):

	2008		2007		2006	
Product revenue: Manufacturing revenue and royalties: TriCor 145 Skelaxin Focalin XR/Ritalin LA	\$	67.7 39.7 33.5	\$	62.5 39.3 28.4	\$	52.1 36.5 22.5
Verelan Diltiazem Zanaflex Other		24.6 13.7 12.8 89.6		28.5 18.7 13.1 79.0		36.3 19.5 4.9 60.6
Total manufacturing revenue and royalties Amortized revenue Adalat/Avinza		281.6		269.5 4.5		232.4 30.7
Total product revenue  Contract revenue:		281.6		274.0		263.1
Amortized fees Research revenue and milestones		2.4 17.6		4.3 17.2		4.2 14.8

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Total contract revenue	20.0	21.5		19.0
Total revenue from the EDT business	\$ 301.6	\$ 295.5	\$	282.1
Goodwill (in millions):				
		2008	2	2007
Biopharmaceuticals EDT		\$ 218.3 49.7	\$	218.3 49.7
Total goodwill		\$ 268.0	\$	268.0
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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### Total assets (in millions):

	2008	2007
Biopharmaceuticals assets EDT assets	\$ 1,333.4 534.2	\$ 1,251.0 529.8
Total assets	\$ 1,867.6	\$ 1,780.8

For fiscal years 2008, 2007 and 2006, our revenue is presented below by geographical area. Similarly, total assets, property, plant and equipment, and goodwill and intangible assets are presented below on a geographical basis at December 31, 2008 and 2007.

## Revenue by region (by destination of customers) (in millions):

	2008	2007	2006	
Region:				
Ireland	\$ 71.5	\$ 72.2	\$ 65.3	
United States	732.5	612.4	431.5	
Rest of world	196.2	74.8	63.6	
Total revenue	\$ 1,000.2	\$ 759.4	\$ 560.4	

#### Total assets by region (in millions):

	2008	2007
Ireland	\$ 702.0	\$ 569.3
United States	1,093.1	912.3
Bermuda	54.4	139.4
Rest of world	18.1	159.8
Total assets	\$ 1,867.6	\$ 1,780.8

#### Property, plant and equipment by region (in millions):

	2008	2007
Ireland United States Bermuda	\$ 240.5 111.3	\$ 229.1 99.7 0.1
Total property, plant and equipment, net	\$ 351.8	\$ 328.9
Goodwill and other intangible assets by region (in millions):		
	2008	2007
Ireland United States Rest of world	\$ 233.9 311.3 8.7	\$ 130.3 318.6 8.7
Total goodwill and other intangible assets, net	\$ 553.9	\$ 457.6
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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### Major customers

The following customers or collaborator contributed 10% or more of our total revenue in 2008, 2007 and/or 2006:

	2008	2007	2006
AmerisourceBergen	46%	38%	18%
Biogen Idec	14%	2%	
Cardinal Health	4%	9%	16%
McKesson Corporation	4%	7%	11%

No other customer accounted for more than 10% of our total revenue in 2008, 2007 or 2006.

#### 31. Supplemental Guarantor Information

As part of the offering and sale of the \$850.0 million in aggregate principal amount of 7.75% Notes due November 15, 2011 and the \$300.0 million Floating Rate Notes due November 15, 2011, Elan Corporation, plc and certain of its subsidiaries have guaranteed the 7.75% Notes and the Floating Rate Notes due 2011. Substantially equivalent guarantees have also been given to the holders of the 8.875% Notes and the Floating Rate Notes due in 2013, which were issued in November 2006.

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

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## Elan Corporation, plc

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Statements of Operations For the Year Ended December 31, 2008

	Elan Finance, plc	Parent Company	Subsidiaries		Elimination Adjustments	Consolidated
Revenue	\$	\$	\$ 1,671.6	\$ 2.1	\$ (673.5)	\$ 1,000.2
Cost of sales			808.4		(315.0)	493.4
Gross margin Operating expenses:			863.2	2.1	(358.5)	506.8
Selling, general and administrative expenses		61.3	285.2		(53.8)	292.7
Research and development expenses Net gain on sale of products and businesses		01.5	639.8	1.1	(317.5)	323.4
Other net (gains)/charges		0.3	33.0	1.0	(0.1)	34.2
Total operating expenses		61.6	958.0	2.1	(371.4)	650.3
Operating income/(loss)		(61.6)	(94.8)		12.9	(143.5)
Share of net losses of subsidiaries Net interest and investment		(10.4)			10.4	
(gains)/losses	(3.9)	(1.0)	151.8		6.9	153.8
Income/(loss) before provision for/(benefit from) income taxes	3.9	(71.0)	(246.6)		16.4	(297.3)
Provision for/(benefit from) income	3.5	(71.0)	(210.0)		10.1	(2) (1.3)
taxes	1.0		(227.3)			(226.3)
Net income/(loss)	\$ 2.9	\$ (71.0)	\$ (19.3)	\$	\$ 16.4	\$ (71.0)
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## Elan Corporation, plc

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Statements of Operations For the Year Ended December 31, 2007

	Elan Finance, plc	Parent Company	Subsidiaries		Elimination Adjustments	Consolidated
Revenue	\$	\$	\$ 1,123.8	\$ 1.6	\$ (366.0)	\$ 759.4
Cost of sales			476.9		(139.0)	337.9
Gross margin Operating expenses: Selling, general and administrative			646.9	1.6	(227.0)	421.5
expenses		52.9	304.3		(17.9)	339.3
Research and development expenses Net gain on sale of products and businesses		0.2	482.1	1.6	(221.0)	262.9
Other net (gains)/charges		(158.8)	84.1	0.1	159.2	84.6
Total operating expenses		(105.7)	870.5	1.7	(79.7)	686.8
Operating income/(loss)		105.7	(223.6)	(0.1)	(147.3)	(265.3)
Share of net losses of subsidiaries Net interest and investment		510.7			(510.7)	
(gains)/losses	(2.2)		267.1	(0.4)	(131.7)	132.8
Income/(loss) before provision for/(benefit from) income taxes Provision for/(benefit from) income	2.2	(405.0)	(490.7)	0.3	495.1	(398.1)
taxes	0.6		3.8		2.5	6.9
Net income/(loss)	\$ 1.6	\$ (405.0)	\$ (494.5)	\$ 0.3	\$ 492.6	\$ (405.0)
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# Elan Corporation, plc NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Statements of Operations For the Year Ended December 31, 2006

	Elan Finance, plc	Parent Company	Subsidiaries		Elimination sAdjustments	Consolidated
Revenue	\$	\$ 65.9	\$ 736.5	\$ 1.6	\$ (243.6)	\$ 560.4
Cost of sales		11.6	218.7		(20.0)	210.3
Gross margin Operating expenses: Selling, general and administrative		54.3	517.8	1.6	(223.6)	350.1
expenses		72.4	381.1	0.1	(93.3)	360.3
Research and development expenses Net gain on sale of products and		11.0	366.3	1.6	(159.3)	219.6
businesses			(43.1)			(43.1)
Other net (gains)/charges		(59.6)	32.3	(0.2)	7.2	(20.3)
Total operating expenses		23.8	736.6	1.5	(245.4)	516.5
Operating income/(loss)		30.5	(218.8)	0.1	21.8	(166.4)
Share of net losses of subsidiaries Net interest and investment		291.6			(291.6)	
(gains)/losses	1.3	6.1	118.7	(1.1)	(15.1)	109.9
Income/(loss) before provision						
for/(benefit from) income taxes Provision for/(benefit from) income	(1.3)	(267.2)	(337.5)	1.2	328.5	(276.3)
taxes	(2.8)	0.1	3.4	0.1	(9.8)	(9.0)
Net income/(loss)	\$ 1.5	\$ (267.3)	\$ (340.9)	\$ 1.1	\$ 338.3	\$ (267.3)
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## Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Balance Sheets As of December 31, 2008

	Elan Finance, plc	Parent Company		Subsidiarie	Elimination sAdjustments	Consolidated		
		ASSET	'S					
Current Assets: Cash and cash equivalents Restricted cash current Accounts receivable, net Investment securities current Inventory Intercompany receivables	\$ 10.2 16.9	\$ 1.4	\$ 361.7 20.2 196.1 30.9 35.5 3,473.9	\$ 2.0	\$ (0.4) (5.7) (5,617.2)	\$ 375.3 20.2 196.1 30.5 29.8		
Deferred tax assets current Prepaid and other current assets	0.5	2,120.0	95.4 14.4		(0.2)	95.9 14.2		
Total current assets Property, plant and equipment,	27.6	2,126.9	4,228.1	2.9	(5,623.5)	762.0		
net Goodwill and other intangible			354.3		(2.5)	351.8		
assets, net Investment securities			386.4		167.5	553.9		
non-current Investments in subsidiaries Restricted cash non-current			10.7 12,045.7 15.0		(2.6) (12,045.7)	8.1 15.0		
Intercompany receivables Deferred tax assets non-current	1,725.9 0.8		6,543.6 144.5		(8,269.5)	145.3		
Other assets	22.0		9.5			31.5		
Total assets	\$ 1,776.3	\$ 2,126.9	\$ 23,737.8	\$ 2.9	\$ (25,776.3)	\$ 1,867.6		
LIABILITIES AND SHAREHOLDERS EQUITY/(DEFICIT)								
Current Liabilities: Accounts payable Accrued and other current	\$	\$	\$ 37.7	\$	\$	\$ 37.7		
liabilities Intercompany payables	14.9 0.2	5.0 2,117.2	223.9 4,761.0		(1.2) (6,878.4)	242.6		

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Total current liabilities Long term debts	15.1 1,765.0	2,122.2	5,022.6		(6,879.6)	280.3 1,765.0
Intercompany payables		223.5	12,397.5	4.3	(12,625.3)	
Other liabilities		13.4	41.1			54.5
Total liabilities	1,780.1	2,359.1	17,461.2	4.3	(19,504.9)	2,099.8
Shareholders equity/(deficit)	(3.8)	(232.2)	6,276.6	(1.4)	(6,271.4)	(232.2)
Total liabilities and shareholders						
equity/(deficit)	\$ 1,776.3	\$ 2,126.9	\$ 23,737.8	\$ 2.9	\$ (25,776.3)	\$ 1,867.6

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## Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Balance Sheets As of December 31, 2007

	Elan Finance, Parent plc Company		Guarantor Subsidiaries (In mi	Consolidated				
ASSETS								
Current Assets:		<b>.</b>	<b>.</b>	<b>.</b>	•	<b>*</b> 422.7		
Cash and cash equivalents	\$ 6.4	\$ 2.0	\$ 413.0	\$ 2.1	\$	\$ 423.5		
Restricted cash current			20.1			20.1		
Accounts receivable, net			137.4 292.3		(147)	137.4 277.6		
Investment securities current Inventory			292.3 41.8		(14.7) (5.1)	36.7		
Intercompany receivables	18.1	2,090.5	3,090.0	0.3	(5,198.9)	30.7		
Deferred tax assets current	2.3	2,090.3	2.3	0.3	(3,196.9)	4.6		
Prepaid and other current assets	2.3	12.0	15.4	0.1	(10.3)	17.2		
repaid and other current assets		12.0	13.4	0.1	(10.5)	17.2		
Total current assets	26.8	2,104.5	4,012.3	2.5	(5,229.0)	917.1		
Property, plant and equipment,	20.0	2,10	.,012.0		(0,==>10)	717.1		
net			331.5		(2.6)	328.9		
Goodwill and other intangible					,			
assets, net			294.8		162.8	457.6		
Investment securities								
non-current			8.7		12.5	21.2		
Investments in subsidiaries			12,024.1		(12,024.1)			
Restricted cash non-current			9.5			9.5		
Intercompany receivables	1,720.9		6,088.2		(7,809.1)			
Other assets	26.6		11.0		8.9	46.5		
Total assets	\$ 1,774.3	\$ 2,104.5	\$ 22,780.1	\$ 2.5	\$ (24,880.6)	\$ 1,780.8		
LIADILITIES AND SHADEHOLDEDS EQUITY//DEELCTY								
LIABILITIES AND SHAREHOLDERS EQUITY/(DEFICIT)  Current Liabilities:								
Accounts payable	\$	\$	\$ 27.2	\$	\$ 0.1	\$ 27.3		
Accrued and other current	Ψ	Ψ	ψ 21.2	Ψ	ψ 0.1	ψ 21.3		
liabilities	16.0	4.6	143.1	0.2	12.2	176.1		
Intercompany payables	10.0	2,234.9	4,272.1	0.2	(6,507.0)	170.1		
The state of the s		_,	.,		(2,20,.0)			

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Total current liabilities Long term debts	16.0 1,765.0	2,239.5	4,442.4	0.2	(6,494.7)	203.4 1,765.0
Intercompany payables		99.7	11,994.9	4.2	(12,098.8)	
Other liabilities			47.1			47.1
Total liabilities	1,781.0	2,339.2	16,484.4	4.4	(18,593.5)	2,015.5
Shareholders equity/(deficit)	(6.7)	(234.7)	6,295.7	(1.9)	(6,287.1)	(234.7)
Total liabilities and shareholders equity/(deficit)	\$ 1,774.3	\$ 2,104.5	\$ 22,780.1	\$ 2.5	\$ (24,880.6)	\$ 1,780.8

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## Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Elan Corporation, plc

## Condensed Consolidating Statement of Cash Flows For the Year Ended December 31, 2008

	Elan Finance, plc		Subsidiaries	Non- Guarantor Subsidiarie iillions)	Eliminati	orConsolidated
Cash flows from operating activities: Net cash provided by/(used in) operating activities	\$ 3.8	\$ (50.6)	\$ (147.4)	\$ (0.1)	\$	\$ (194.3)
Cash flows from investing activities: Increase in restricted cash Purchase of property, plant and equipment Purchase of non-current investment securities Sale of non-current investment securities Sale of current investment securities Purchase of intangible assets Proceeds from product and business disposals			(5.6) (58.8) (0.1) 3.5 232.6 (79.1) 2.0			(5.6) (58.8) (0.1) 3.5 232.6 (79.1) 2.0
Net cash provided by investing activities			94.5			94.5
Cash flows from financing activities: Proceeds from employee stock issuances Repayment of loans and capital lease obligations Excess tax benefit from share-based compensation		50.0	(0.9)			50.0 (0.9) 2.4
Net cash provided by/(used in) financing activities		50.0	1.5			51.5
Effect of exchange rate changes on cash			0.1			0.1
Net increase/(decrease) in cash and cash equivalents Cash and cash equivalents at beginning of year	3.8 6.4	(0.6)	(51.3) 413.0	(0.1)		(48.2) 423.5

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Cash and cash equivalents at end of year \$ 10.2 \$ 1.4 \$ 361.7 \$ 2.0 \$ \$ 375.3

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# Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# Elan Corporation, plc

# Condensed Consolidating Statement of Cash Flows For the Year Ended December 31, 2007

	Elan Finance, plc	Athena Finance		Guarantor Subsidiaries (In millions)		onConsolidated
Cash flows from operating activities:						
Net cash provided by/(used in) operating activities	\$ (606.0)	\$ 626.6	\$ (31.2)	\$ (156.8)	\$ (0.1)	\$ \$ (167.5)
Cash flows from investing activities:						
Increase in restricted cash Proceeds from disposal of				(6.8)		(6.8)
property, plant and equipment Purchase of property, plant and				0.2		0.2
equipment Purchase of non-current				(26.1)		(26.1)
investment securities Transfer of fund to investment				(12.3)		(12.3)
securities Sales of non-current				(305.9)		(305.9)
investment securities Sale of current investment				3.4		3.4
securities				27.9		27.9
Purchase of intangible assets Proceeds from product and				(2.5)		(2.5)
business disposals				4.0		4.0
Net cash provided by investing activities				(318.1)		(318.1)
Cash flows from financing activities:						
Proceeds from employee stock issuances			28.2			28.2
Repayment of loans and capital lease obligations		(626.6)	(0.2)	(2.8)		(629.6)

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Issue of loan notes Excess tax benefit from		(0.1)						(0	0.1)
share-based compensation						1.8		1	.8
Net cash provided by/(used in) financing activities		(0.1)	(626.6)		28.0	(1.0)		(599	0.7)
Effect of exchange rate changes on cash						(1.8)		(1	.8)
Net increase/(decrease) in cash and cash equivalents Cash and cash equivalents at	((	506.1)			(3.2)	(477.7)	(0.1)	(1,087	'.1)
beginning of year	(	512.5			5.2	890.7	2.2	1,510	).6
Cash and cash equivalents at end of year	\$	6.4	\$	\$	2.0	\$ 413.0	\$ 2.1	\$ \$ 423	5.5
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# Elan Corporation, plc

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# Elan Corporation, plc

# Condensed Consolidating Statement of Cash Flows For the Year Ended December 31, 2006

	Fin	clan ance, plc	Parent Company	bsidiaries	Non- Guarantor Subsidiarie illions)	Eliminatio	onCor	nsolidated
Cash flows from operating activities: Net cash provided by/(used in) operating activities	\$	8.5	\$ (50.9)	\$ (198.8)	\$ (0.3)	\$	\$	(241.5)
Cash flows from investing activities: Decrease in restricted cash Proceeds from disposal of property,				2.8				2.8
plant and equipment Purchase of property, plant and equipment				0.6 (29.9)				0.6 (29.9)
Purchase of non-current investment securities Sale of non-current investment securities Sale of current investment securities				(0.2) 13.2 0.9				(0.2) 13.2 0.9
Purchase of intangible assets Proceeds from product and business disposals				(4.1) 54.2				(4.1) 54.2
Net cash provided by investing activities				37.5				37.5
Cash flows from financing activities: Proceeds from employee stock issuances Repayment of loans and capital lease			29.8					29.8
obligations Net proceeds from debt issuance Excess tax benefit from share-based	6	02.8	(1.2)	(4.5)				(5.7) 602.8
compensation Proceeds from government grants			2.0	0.4				2.0 0.4
Net cash provided by/(used in) financing activities	6	502.8	30.6	(4.1)				629.3
Effect of exchange rate changes on cash				4.6				4.6

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Net increase/(decrease) in cash and cash equivalents	611.3	(20.3)	(160.8)	(0.3)	429.9
Cash and cash equivalents at beginning of year	1.2	25.5	1,051.5	2.5	1,080.7
Cash and cash equivalents at end of year	\$ 612.5	\$ 5.2	\$ 890.7	\$ 2.2	\$ \$ 1,510.6

#### 32. 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.

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#### Elan Corporation, plc

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 FSF 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.

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#### **Elan Corporation, plc**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 33. 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.

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#### Item 19. Exhibits.

31, 2001).

4(c)(3)

Exhibit Number	Description
1.1	Memorandum and Articles of Association of Elan Corporation, plc (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form S-8 of Elan Corporation, plc (SEC File No. 333-135185) filed with the Commission on June 21, 2006).
2(b)(1)	Indenture dated as of November 16, 2004, among Elan Finance public limited company, Elan Finance Corp., Elan Corporation, plc, the Subsidiary Note Guarantors party thereto and The Bank of New York, as Trustee (incorporated by reference to Exhibit 99.2 of the Report of Foreign Issuer on Form 6-K of Elan
2(b)(2)	Corporation, plc (SEC File No. 001-13896) filed with the Commission on November 19, 2004). Indenture dated as of November 22, 2006, among Elan Finance public limited company, Elan Finance Corp., Elan Corporation, plc, the Subsidiary Note Guarantors party thereto and The Bank of New York, as Trustee (including Forms of Global Exchange Notes) (incorporated by reference to Exhibit 2(b)(2) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2006).
4(a)(1)	Antegren Development and Marketing Collaboration Agreement, dated as of August 15, 2000, by and between Biogen, Inc. and Elan Pharma International Limited (incorporated by reference to Exhibit 4(a)(1) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2002 confidential treatment has been granted for portions of this exhibit).
4(a)(2)	Amended and Restated Asset Purchase Agreement, dated as of May 19, 2003, by and among Elan Corporation, plc, Elan Pharma International Limited, Elan Pharmaceuticals, Inc., King Pharmaceuticals, Inc., Jones Pharma Incorporated and Monarch Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(a)(3) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2002).
4(a)(3)	Research, Development and Commercialization Agreement by and among Wyeth (formerly known as American Home Products Corporation acting through American Home Products Corporation s Wyeth-Ayerst Laboratories Division) and Elan Pharma International Limited (by assignment from Neuralab Limited) dated March 17, 2000, Amendment No. 1, dated as of April 4, 2000, to Research, Development and Commercialization Agreement, Amendment No. 2, dated as of April 4, 2002, to Research, Development and Commercialization Agreement, Amendment No. 3, dated as of May 1, 2005, to the Research, Development and Commercialization Agreement, and Amendment No. 4, dated as of May 1, 2007, to the Research, Development and Commercialization Agreement. (incorporated by reference to Exhibit 4(a)(3) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007 confidential treatment has been granted for portions of this exhibit).
4(b)(1)	Lease dated as of June 1, 2007 between Chamberlin Associates 180 Oyster Point Blvd., LLC and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(b)(1) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(b)(2)	Lease dated as of December 17, 2007 between Chamberlin Associates 200 Oyster Point, L.P. and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(b)(2) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(1)	Elan Corporation, plc 1999 Stock Option Plan (2001 Amendment) (incorporated by reference to Exhibit 4(c)(1) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
4(c)(2)	Elan Corporation, plc 1998 Long-Term Incentive Plan (2001 Restatement) (incorporated by reference to

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Exhibit 4(c)(2) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December

- Elan Corporation, plc 1996 Long-Term Incentive Plan (2001 Restatement) (incorporated by reference to Exhibit 4(c)(3) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
- 4(c)(4) Elan Corporation, plc 1996 Consultant Option Plan (2001 Restatement) (incorporated by reference to Exhibit 4(c)(4) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
- 4(c)(5) Elan Corporation, plc Employee Equity Purchase Plan (U.S.), as amended (incorporated by reference to Exhibit 4.2 of the Registration Statement on Form S-8 of Elan Corporation, plc (SEC File No. 333-135184) filed with the Commission on June 21, 2006).

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#### **Table of Contents**

Exhibit Number	Description
4(c)(6)	Elan Corporation, plc Employee Equity Purchase Plan Irish Sharesave Option Scheme (incorporated by reference to Exhibit 4(c)(6) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2004).
4(c)(7)	Elan Corporation, plc Employee Equity Purchase Plan U.K. Sharesave Plan (incorporated by reference to Exhibit 4(c)(8) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(8)	Elan Corporation, plc 2004 Restricted Stock Unit Plan (incorporated by reference to Exhibit 4(c)(8) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(9)	Letter Agreement, dated as of February 12, 2002, between John Groom and Elan Corporation, plc (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-3 of Elan Corporation,
4(c)(10)	plc, Registration Statement No. 333-100252, filed with the Commission on October 1, 2002). Consulting Agreement, dated as of July 1, 2006, between Dr. Dennis J. Selkoe and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(c)(10) of Elan Corporation, plc s Annual Report on Form 20-F filed with the Commission on February 28, 2007).
4(c)(11)	Employment Agreement, dated as of December 7, 2005, as amended by Amendment 2008-1 dated as of December 19, 2008, among Elan Pharmaceuticals, Inc., Elan Corporation, plc and G. Kelly Martin.
4(c)(12)	July 18, 2007 Letter Agreement between Dr. Lars Ekman and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(c)(12) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(13)	Elan Corporation, plc Cash Bonus Plan effective January 1, 2006, and revised as of January 1, 2009.
4(c)(14)	Elan Corporation, plc Profit Sharing Scheme 2006 (incorporated by reference to Exhibit 4(c)(16) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(15)	Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement).
4(c)(16)	Letter Agreement dated as of January 1, 2007 between Elan Corporation, plc and Shane Cooke
	(incorporated by reference to Exhibit $4(c)(17)$ of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2006).
4(c)(17)	Form of Deed of Indemnity between Elan Corporation, plc and directors and certain officers of Elan Corporation, plc (incorporated by reference to Exhibit 99.2 of the Report of Foreign Issuer on Form 6-K of Elan Corporation, plc filed with the Commission on November 15, 2006).
4(c)(18)	Elan U.S. Severance Plan (incorporated by reference to Exhibit 4(c)(18) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(19)	Form of Memo Agreement dated May 17, 2007 amending certain outstanding grant agreements for restricted stock units and stock option agreements held by senior officers who are members of the
	Operating Committee of Elan Corporation, plc. (incorporated by reference to Exhibit 4(c)(19) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(20)	Form of Restricted Stock Unit Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for certain senior officers who are members of the Operating
47.57	Committee of Elan Corporation, plc.
4(c)(21)	Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for certain senior officers who are members of the Operating

4(c)(22) Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for new members of the Board of Directors of Elan Corporation, plc.

4(c)(23)

Committee of Elan Corporation, plc.

- Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for members of the Board of Directors of Elan Corporation, plc.
- 4(c)(24) Form of Restricted Stock Unit Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for non-executive members of the Board of Directors of Elan Corporation, plc.
- 4(c)(25) Employment Agreement dated as of November 26, 2008 by and among Elan Pharmaceuticals, Inc., Elan Corporation, plc and Dr. Carlos Paya.

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## **Table of Contents**

Exhibit Number	Description
8.1	Subsidiaries of Elan Corporation, plc.
12.1	Certification of G. Kelly Martin pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification of Shane Cooke pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification of G. Kelly Martin pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification of Shane Cooke pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm, KPMG.
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### **SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

# Elan Corporation, plc

/s/ SHANE COOKE

Shane Cooke

Executive Vice President and Chief Financial Officer

Date: February 26, 2009

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### Elan Corporation, plc

### **Schedule II**

# Valuation and Qualifying Accounts and Reserves Years ended December 31, 2008, 2007 and 2006

Description	Balance at Beginning of Year	Additions <sup>(1)</sup> (In n	Deductions <sup>(2)</sup> nillions)	Balance at End of Year
Allowance for doubtful accounts:				
Year ended December 31, 2008	\$	\$ 0.9	\$	\$ 0.9
Year ended December 31, 2007	\$ 0.7	\$	\$ (0.7)	\$
Year ended December 31, 2006	\$ 3.9	\$ 0.7	\$ (3.9)	\$ 0.7
Sales returns and allowances, discounts, chargebacks				
and rebates <sup>(3)</sup> :				
Year ended December 31, 2008	\$ 18.9	\$ 65.6	\$ (65.3)	\$ 19.2
Year ended December 31, 2007	\$ 16.5	\$ 69.8	\$ (67.4)	\$ 18.9
Year ended December 31, 2006	\$ 17.2	\$ 43.9	\$ (44.6)	\$ 16.5

<sup>(1)</sup> Additions to allowance for doubtful accounts are recorded as an expense.

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<sup>(2)</sup> Represents amounts written off or returned against the allowance or reserves, or returned against earnings. Deductions to sales discounts and allowances relate to sales returns and payments.

<sup>(3)</sup> Additions to sales discounts and allowances are recorded as a reduction of revenue.

4(c)(3)

## **EXHIBIT INDEX**

Exhibit Number	Description
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4(a)(3)	Research, Development and Commercialization Agreement by and among Wyeth (formerly known as American Home Products Corporation acting through American Home Products Corporation s Wyeth-Ayerst Laboratories Division) and Elan Pharma International Limited (by assignment from Neuralab Limited) dated March 17, 2000, Amendment No. 1, dated as of April 4, 2000, to Research, Development and Commercialization Agreement, Amendment No. 2, dated as of April 4, 2002, to Research, Development and Commercialization Agreement, Amendment No. 3, dated as of May 1, 2005, to the Research, Development and Commercialization Agreement, and Amendment No. 4, dated as of May 1, 2007, to the Research, Development and Commercialization Agreement. (incorporated by reference to Exhibit 4(a)(3) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007 confidential treatment has been granted for portions of this exhibit).
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4(c)(2)	Elan Corporation, plc 1998 Long-Term Incentive Plan (2001 Restatement) (incorporated by reference to Exhibit 4(c)(2) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
4()(0)	

- Elan Corporation, plc 1996 Long-Term Incentive Plan (2001 Restatement) (incorporated by reference to Exhibit 4(c)(3) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
- 4(c)(4) Elan Corporation, plc 1996 Consultant Option Plan (2001 Restatement) (incorporated by reference to Exhibit 4(c)(4) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2001).
- 4(c)(5) Elan Corporation, plc Employee Equity Purchase Plan (U.S.), as amended (incorporated by reference to Exhibit 4.2 of the Registration Statement on Form S-8 of Elan Corporation, plc (SEC File No. 333-135184) filed with the Commission on June 21, 2006).

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#### **Table of Contents**

Exhibit Number	Description
4(c)(6)	Elan Corporation, plc Employee Equity Purchase Plan Irish Sharesave Option Scheme (incorporated by reference to Exhibit 4(c)(6) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2004).
4(c)(7)	Elan Corporation, plc Employee Equity Purchase Plan U.K. Sharesave Plan (incorporated by reference to Exhibit 4(c)(8) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(8)	Elan Corporation, plc 2004 Restricted Stock Unit Plan (incorporated by reference to Exhibit 4(c)(8) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(9)	Letter Agreement, dated as of February 12, 2002, between John Groom and Elan Corporation, plc (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-3 of Elan Corporation, plc, Registration Statement No. 333-100252, filed with the Commission on October 1, 2002).
4(c)(10)	Consulting Agreement, dated as of July 1, 2006, between Dr. Dennis J. Selkoe and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(c)(10) of Elan Corporation, plc s Annual Report on Form 20-F filed with the Commission on February 28, 2007).
4(c)(11)	Employment Agreement, dated as of December 7, 2005, as amended by Amendment 2008-1 dated as of December 19, 2008, among Elan Pharmaceuticals, Inc., Elan Corporation, plc and G. Kelly Martin.
4(c)(12)	July 18, 2007 Letter Agreement between Dr. Lars Ekman and Elan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4(c)(12) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(13)	Elan Corporation, plc Cash Bonus Plan effective January 1, 2006, and revised as of January 1, 2009.
4(c)(14)	Elan Corporation, plc Profit Sharing Scheme 2006 (incorporated by reference to Exhibit 4(c)(16) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2005).
4(c)(15)	Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement).
4(c)(16)	Letter Agreement dated as of January 1, 2007 between Elan Corporation, plc and Shane Cooke
	(incorporated by reference to Exhibit $4(c)(17)$ of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2006).
4(c)(17)	Form of Deed of Indemnity between Elan Corporation, plc and directors and certain officers of Elan Corporation, plc (incorporated by reference to Exhibit 99.2 of the Report of Foreign Issuer on Form 6-K of Elan Corporation, plc filed with the Commission on November 15, 2006).
4(c)(18)	Elan U.S. Severance Plan (incorporated by reference to Exhibit 4(c)(18) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(19)	Form of Memo Agreement dated May 17, 2007 amending certain outstanding grant agreements for restricted stock units and stock option agreements held by senior officers who are members of the Operating Committee of Elan Corporation, plc. (incorporated by reference to Exhibit 4(c)(19) of Elan Corporation, plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2007).
4(c)(20)	Form of Restricted Stock Unit Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for certain senior officers who are members of the Operating Committee of Elan Corporation, plc.
4(c)(21)	Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for certain senior officers who are members of the Operating

Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for new members of the Board of Directors of Elan Corporation,

4(c)(23)

4(c)(22)

Committee of Elan Corporation, plc.

- Form of Nonstatutory Stock Option Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for members of the Board of Directors of Elan Corporation, plc.
- 4(c)(24) Form of Restricted Stock Unit Agreement under the Elan Corporation, plc 2006 Long Term Incentive Plan (2009 Amendment and Restatement) for non-executive members of the Board of Directors of Elan Corporation, plc.
- 4(c)(25) Employment Agreement dated as of November 26, 2008 by and among Elan Pharmaceuticals, Inc., Elan Corporation, plc and Dr. Carlos Paya.

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## **Table of Contents**

Exhibit Number	Description
8.1	Subsidiaries of Elan Corporation, plc.
12.1	Certification of G. Kelly Martin pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification of Shane Cooke pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification of G. Kelly Martin pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906
	of the Sarbanes-Oxley Act of 2002.
13.2	Certification of Shane Cooke pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of
	the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm, KPMG.

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