ELAN CORP PLC
Form 20-F
February 25, 2010

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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

- þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
  For the fiscal year ended: December 31, 2009

OR

- o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
  For the transition period from to

OR

- o **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
  Date of event requiring this shell company report

Commission file number: 001-13896

Elan Corporation, plc
(Exact name of Registrant as specified in its charter)

Ireland	**Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland**
(Jurisdiction of incorporation or organization)	*(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,	New York Stock Exchange
Par value 0.05 each (Ordinary Shares)	New York Stock Exchange
Ordinary Shares	

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: 583,901,211 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 þ 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 þ

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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 þ 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 þ 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 þ

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General

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

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

Unless otherwise indicated, our Consolidated Financial Statements and other financial data contained in this Form 20-F are presented in United States dollars ($). We prepare our Consolidated Financial Statements on the basis of a calendar fiscal year beginning on January 1 and ending on December 31. References to a fiscal year in this Form 20-F shall be references to the fiscal year ending on December 31 of that year. In this Form 20-F, financial results and operating statistics are, unless otherwise indicated, stated on the basis of such fiscal years.

Forward-Looking Statements

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

This Form 20-F contains forward-looking statements about our financial condition, results of operations and estimates, business prospects and products and potential products that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as anticipate, estimate, project, target, inte plan, will, believe, expect and other words and terms of similar meaning in connection with any discussion of futur 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 (including deaths) associated with *Tysabri* (including cases of progressive multifocal leukoencephalopathy (PML)) and the potential for the successful development and commercialization of additional products; (2) 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 very substantial fines and to take other actions that could have a material adverse effect on us (including the exclusion of our products from reimbursement under government programs); (3) our ability to maintain financial flexibility and sufficient cash, cash equivalents, and investments and other assets capable of being monetized to meet our liquidity requirements; (4) whether restrictive covenants in our debt obligations will adversely affect us; (5) our dependence on Johnson & Johnson and Pfizer (which acquired Wyeth) for the development and potential commercialization of bapineuzumab and any other potential products in the Alzheimer s Immunotherapy Program (AIP); (6) the success of our research and development (R&D) activities and R&D activities in which we retain an interest, 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; (7) Johnson & Johnson is our largest shareholder with an 18.4% interest in our outstanding ordinary

shares and is largely in control of our remaining interest in the AIP. Johnson & Johnson s interest in Elan and the AIP may discourage others from seeking to work with or acquire us; (8) competitive developments affecting our products, including the introduction of generic competition following the loss of patent protection or marketing exclusivity for our products and several of the products from which we derive manufacturing or royalty revenues, which are under patent challenge by potential generic competitors; (9) our ability to protect our patents and other intellectual property; (10) difficulties or delays in manufacturing our products (we are dependent on third parties for the manufacture of our products); (11) pricing pressures and uncertainties regarding healthcare reimbursement and reform; (12) extensive government regulation;

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(13) risks from potential environmental liabilities; (14) failure to comply with our reporting and payment obligations under Medicaid or other government programs; (15) possible legislation affecting pharmaceutical pricing and reimbursement, both domestically and internationally; (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 others from acquiring us; (20) governmental laws and regulations affecting domestic and foreign operations, including tax obligations; (21) general changes in U.S. generally accepted accounting principles and IFRS; (22) growth in costs and expenses; (23) changes in product mix, including in particular that we will cease distributing *Azactam® (aztreonam for injection, USP)* as of March 31, 2010 and cease distributing *Maxipime® (cefepime hydrochloride)* as of September 30, 2010; and (24) the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items. 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,	**2009**	**2008**	**2007**	**2006**	**2005**
		(In millions, except per share data)			
Income Statement Data:					
Total revenue	$ 1,113.0	$ 1,000.2	$ 759.4	$ 560.4	$ 490.3
Operating profit/(loss)	$ 31.9[(1)]	$ (143.5)[(2)]	$ (265.3)[(3)]	$ (166.4)[(4)]	$ (198.5)[(5)]
Net loss from continuing operations	$ (176.2)	$ (71.0)	$ (405.0)	$ (267.3)	$ (384.2)
Net income from discontinued operations (net of tax)	$	$	$	$	$ 0.6
Net loss	$ (176.2)[(6)]	$ (71.0)[(7)]	$ (405.0)[(8)]	$ (267.3)[(4)]	$ (383.6)[(9)]
Basic and diluted loss per Ordinary Share:[(10)]					
Net loss from continuing operations	$ (0.35)	$ (0.15)	$ (0.86)	$ (0.62)	$ (0.93)
Net income from discontinued operations (net of tax)	$	$	$	$	$
Total basic and diluted loss per Ordinary Share	$ (0.35)	$ (0.15)	$ (0.86)	$ (0.62)	$ (0.93)
Other Financial Data:					
Adjusted EBITDA[(11)]	$ 96.3	$ 4.3	$ (30.4)	$ (91.1)	$ (216.9)

At December 31,	**2009**	**2008**	**2007**	**2006**	**2005**
			(In millions)		
Balance Sheet Data:					

Cash and cash equivalents	$ 836.5	$ 375.3	$ 423.5	$ 1,510.6	$ 1,080.7
Restricted cash current and non-current	$ 31.7	$ 35.2	$ 29.6	$ 23.2	$ 24.9
Investment securities current	$ 7.1	$ 30.5	$ 277.6	$ 13.2	$ 11.4
Total assets	$ 2,345.7	$ 1,867.6	$ 1,780.8	$ 2,746.3	$ 2,341.0
Debt	$ 1,540.0	$ 1,765.0	$ 1,765.0	$ 2,378.2	$ 2,017.2
Total shareholders equity/(deficit)	$ 494.2	$ (232.2)	$ (234.7)	$ 85.1	$ 16.9
Weighted-average number of shares outstanding basic and diluted	506.8	473.5	468.3	433.3	413.5

(1) *After a net gain on divestment of business of $108.7 million, and after other net charges of $67.3 million, primarily relating to intangible asset impairment charges of $30.6 million, severance, restructuring and other costs of $29.7 million, other asset impairment charges of $15.4 million, acquired in-process research and development costs of $5.0 million, reduced by net legal awards of $13.4 million.*

(2) *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.*

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(3) *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.*

(4) *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.*

(5) *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.*

(6) *After a net gain on divestment of business of $108.7 million, and after other net charges of $67.3 million, primarily relating to intangible asset impairment charges of $30.6 million, severance, restructuring and other costs of $29.7 million, other asset impairment charges of $15.4 million, acquired in-process research and development costs of $5.0 million, reduced by net legal awards of $13.4 million; and after a net charge on debt retirement of $24.4 million.*

(7) *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.*

(8) *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.*

(9) *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.*

(10) *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.*

(11) *Refer to page 55 for a reconciliation of Adjusted EBITDA to net loss and our reasons for presenting this non-GAAP measure.*

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 (including deaths) associated with Tysabri (including cases of PML) or for other reasons, or if bapineuzumab or other potential products are not successfully developed and commercialized in the AIP by Johnson & Johnson and Pfizer Inc. (Pfizer) and we do not successfully develop and commercialize additional products, we will be materially and adversely affected.

We will cease distributing *Azactam* as of March 31, 2010 and cease distributing *Maxipime* as of September 30, 2010, which will leave *Tysabri* as our only material marketed product. While approximately 25% of our 2009 revenue was generated by our Elan Drug Technologies (EDT) business unit, our future success depends upon the continued successful commercialization of *Tysabri*, which accounted for 65% of our total revenue for 2009, and the development and the successful commercialization of additional products (including bapineuzumab which is being developed by Johnson & Johnson and Pfizer (which acquired Wyeth) and in which we retain an approximate 25% economic interest).

Uncertainty created by the serious adverse events (including death) 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, an increase in the incidence rates of serious adverse events in patients treated with *Tysabri* (including cases of PML), or

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additional restrictive changes in the labeling or distribution system for *Tysabri*, up to and including withdrawal of *Tysabri* from the market mandated by regulatory agencies, then we will be seriously and adversely affected.

We commit substantial resources to our R&D activities, including collaborations with third parties such as Biogen Idec, Inc. (Biogen Idec) with respect to *Tysabri*, and Transition Therapeutics, Inc. (Transition), with respect to a part of our Alzheimer s disease programs. Our collaborators interests may not be aligned with our interests, which may adversely affect the success of our collaborations. We have committed significant resources to the development and the commercialization of *Tysabri* and to the other potential products in our development pipeline. These investments may not be successful.

In the pharmaceutical industry, the R&D process is lengthy, expensive and involves a high degree of risk and uncertainty. This process is conducted in various stages and, during each stage, there is a substantial risk that potential products in our R&D pipeline will experience difficulties, delays or failures. In addition, if the additional products in the AIP are not successfully developed and commercialized by Johnson & Johnson and Pfizer, we may 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 would materially adversely affect us.

The U.S. government is investigating marketing practices concerning our former Zonegran product; this may require us to pay very substantial fines or take other actions that could have a material adverse effect on us.

Over the past few years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities, including the Department of Justice and various U.S. Attorney s Offices, the Office of Inspector General of the Department of Health and Human Services, the Food and Drug Administration (FDA), the

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Federal Trade Commission (FTC) and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with off-label promotion of products, pricing and Medicare and/or Medicaid reimbursement.

In light of the broad scope and complexity of these laws and regulations, the high degree of prosecutorial resources and attention being devoted to the sales practices of pharmaceutical companies by law enforcement authorities, and the risk of potential exclusion from federal government reimbursement programs, many companies have determined that they should enter into settlement agreements in these matters, particularly those brought by federal authorities.

Settlements of these investigations have commonly resulted in the payment of very substantial fines to the government for alleged civil and criminal violations, the entry of a Corporate Integrity Agreement with the federal government, and admissions of guilt with respect to various healthcare program-related offenses. Some pharmaceutical companies have been excluded from participating in federal healthcare programs such as Medicare and Medicaid.

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, a product we divested to Eisai in April 2004. We are continuing to cooperate with the government in its investigation. The resolution of the Zonegran matter could require Elan to pay very substantial civil or criminal fines, and take other actions that could have a material adverse effect on Elan and its financial condition, including the exclusion of our products from reimbursement under government programs. Any resolution of the Zonegran matter could give rise to other investigations or litigation by state government entities or private parties.

We have considered the facts and circumstances known to us in relation to the Zonegran matter and, while any ultimate resolution of this matter could require Elan to pay very substantial civil or criminal fines, at this time we cannot predict or determine the timing of the resolution of this matter, its ultimate outcome, or a reasonable estimate of the amount or range of amounts of any fines or penalties that might result from an adverse outcome. Accordingly, we have not recorded any reserve for liabilities in relation to the Zonegran matter as of December 31, 2009.

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

As of December 31, 2009, we had $1,540.0 million of debt falling due in November 2011 ($300.0 million), December 2013 ($615.0 million) and October 2016 ($625.0 million). At such date, we had cash and cash equivalents, current restricted cash and current investments of $860.4 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

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. 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

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to successfully commercialize *Tysabri*, we may 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.

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;

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.

We depend on Johnson & Johnson, in addition to Pfizer, for the clinical development and potential commercialization of bapineuzumab and any other AIP products.

On September 17, 2009, Janssen Alzheimer Immunotherapy (Janssen AI), a newly formed subsidiary of Johnson & Johnson, completed the acquisition of substantially all of our assets and rights related to AIP. In addition, Johnson & Johnson, through its affiliate Janssen Pharmaceutical, invested $885.0 million in exchange for newly issued American Depositary Receipts (ADRs) of Elan, representing 18.4% of our outstanding Ordinary Shares. Johnson & Johnson has also committed to fund up to $500.0 million towards the further development and commercialization of AIP. We refer to these transactions as the Johnson & Johnson Transaction in this Form 20-F.

The Johnson & Johnson Transaction resulted in the assignment of our AIP collaboration agreement with Wyeth (which has been acquired by Pfizer) and associated business, which primarily constituted intellectual property, to Janssen AI. While we have a 49.9% interest in Janssen AI, Johnson & Johnson exercises effective control over Janssen AI and consequently over our share of the AIP collaboration. Our financial interest in the AIP collaboration has been reduced from approximately 50% to approximately 25%. The success of the AIP will be dependent, in part, on the efforts of Johnson & Johnson. The interests of Johnson & Johnson may not be aligned with our interests. The

failure of Johnson & Johnson to pursue the development and commercialization of AIP products in the same manner we would have pursued such development and commercialization could materially and adversely affect us.

Future returns from the Johnson & Johnson Transaction are dependent, in part, on the commercial success of bapineuzumab and other potential AIP products.

Under the terms of the Johnson & Johnson Transaction we are entitled to receive 49.9% of Janssen AI s future profits and certain royalty payments from Janssen AI in respect of sales of bapineuzumab and other potential AIP products. Royalties will generally only arise after Johnson & Johnson has earned profits from the AIP equal to its

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(up to) $500.0 million investment. Any such payments are dependent on the future commercial success of bapineuzumab and other potential AIP products. If no drug is commercially successful, we may not receive any profit or royalty payments from Janssen AI.

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. In addition, our collaborator on *Tysabri*, Biogen Idec, markets a competing multiple sclerosis (MS) therapy, Avonex®.

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. *Tysabri* sales may be very sensitive to additional new competing products. A number of such products are expected to be approved for use in the treatment of MS in the coming years. If these products have a similar or more attractive overall profile in terms of efficacy, convenience and safety, future sales of *Tysabri* could be limited.

Our product *Azactam* lost its basic U.S. patent protection in October 2005. We will cease distributing *Azactam* as of March 31, 2010.

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*. We will cease distributing *Maxipime* as of September 30, 2010.

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.

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.

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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 or supply 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*® (*ziconotide intrathecal infusion*), *Maxipime* or *Azactam*. We will cease distributing *Maxipime* and *Azactam* in 2010. 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, then sales of these products could be materially and adversely affected. 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.

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.

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The Obama Administration and the 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, some states in the United States have proposed and some 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 healthcare 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 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 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.

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,

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civil penalties, withdrawals of previously approved marketing applications or licenses, recommendations by the FDA or other regulatory authorities against governmental contracts, and criminal prosecutions.

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

All facilities and manufacturing techniques used for the manufacture of products and devices for clinical use or for sale in the United States must be operated in conformity with cGMPs, the FDA s regulations governing the production of pharmaceutical products. There are comparable regulations in other countries. Any finding by the FDA or other regulatory authority that we are not in substantial compliance with cGMP regulations or that we or our employees have engaged in activities in violation of these regulations could interfere with the continued manufacture and distribution of the affected products, up to the entire output of such products, and, in some cases, might also require the recall of previously distributed products. Any such finding by the FDA or other regulatory agency could also affect our ability to obtain new approvals until such issues are resolved. The FDA and other regulatory authorities conduct scheduled periodic regulatory inspections of our facilities to ensure compliance with cGMP regulations. Any determination by the FDA or other regulatory authority that we, or one of our suppliers, are not in substantial compliance with these regulations or are otherwise engaged in improper or illegal activities could 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.

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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.

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 $10.0 million of aggregate claims, but do maintain coverage with our insurers for the next $190.0 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. These actions have been consolidated. The consolidated class action complaint alleges claims under the U.S. federal securities laws. The complaint alleges that we caused the release of materially false or misleading information regarding bapineuzumab. The complaint seeks damages and other relief that the courts may deem just

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and proper. We believe that the claims in the consolidated lawsuits are without merit and intend to defend against them vigorously; however, adverse results in the lawsuits could have a material adverse effect on us.

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 the Johnson & Johnson Transaction, if we are acquired, an affiliate of Johnson & Johnson will be entitled to purchase our 49.9% financial interest in Janssen AI at the then fair value.

Johnson & Johnson is our largest shareholder and is largely in control of our share of the AIP; however, Johnson & Johnson and its affiliates are subject to a standstill agreement until September 17, 2014, pursuant to which, subject to limited exceptions, they will not be permitted to acquire additional shares in Elan or take other actions to acquire control of Elan; and

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.

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, listed on the Irish and New York Stock Exchanges, and 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 registered office and principal executive offices are located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland (Telephone: +353 (0)1 7094000).

We employ over 1,300 people and our principal R&D, manufacturing and marketing facilities are located in Ireland and the United States.

B. Business Overview

Our two principal business areas are BioNeurology (formerly referred to as Biopharmaceuticals) and EDT.

BioNeurology ***Defining the Future of Degenerative Neurological Therapies***

In BioNeurology, we are developing therapies for serious diseases that have long been considered intractable, including MS, Alzheimer s disease and Parkinson s disease.

In 2009, we continued to fulfill our mission of making significant scientific and clinical advancements in neuroscience while sustaining overall growth of the business.

Alzheimer s Disease

Our leadership in neuroscience is marked by more than two decades of research and development in Alzheimer s disease, much of which comprises a significant foundation for the entire Alzheimer s scientific community.

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Our broad scientific approach and clinical development pipeline in Alzheimer s disease encompass four programs, including the beta amyloid aggregation inhibitor ELND005, secretase inhibitors and small molecule (p75) ligands.

As part of the Johnson & Johnson Transaction in September 2009, Janssen AI acquired substantially all of the assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer). Johnson & Johnson has also committed to fund up to $500.0 million towards the further development and commercialization of AIP, which includes multiple compounds being evaluated for slowing the progression of Alzheimer s disease. In consideration for the transfer of the AIP assets and rights, we received a 49.9% equity interest in Janssen AI. We are entitled to a 49.9% share of the future profits of Janssen AI and certain royalty payments upon the commercialization of products under the AIP collaboration.

Parkinson s Disease

We have several active early discovery efforts in Parkinson s disease, guided by our expertise in Alzheimer s disease. Our scientists are exploring multiple therapeutic strategies to tackle this poorly understood, devastating disease; researching mechanics that may prevent disease progression.

Multiple Sclerosis Tysabri

We continued to grow the value of *Tysabri* as an important therapeutic approach to MS. *Tysabri* is an approved therapy for relapsing forms of MS in the United States and for relapsing-remitting MS in the European Union.

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, with evidence of inflammation, who have had an inadequate response to, or are unable to tolerate, conventional Crohn s disease therapies and inhibitors of TNF-alpha.

The medical and scientific opportunity represented by our BioNeurology pipeline remains significant.

Elan Drug Technologies *40 years of Drug Delivery Leadership*

EDT develops and manufactures innovative pharmaceutical products that deliver clinically meaningful benefits to patients, using our extensive experience and proprietary drug technologies in collaboration with pharmaceutical companies.

In 2009, Elan celebrated its 40th anniversary in the drug delivery business. Since our founding, we have applied our skills and knowledge from concept development through to full-scale manufacturing. Because of our successful collaborations with leading pharmaceutical companies, every day more than two million people use products enabled by EDT.

Our portfolio includes 24 products marketed by EDT licensees and 14 products in clinical development.

Our two principal drug technology platforms are our Oral Controlled Release technology (OCR) and *NanoCrystal*® technology capabilities.

Conclusion of Strategic Review

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 was 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.

On September 17, 2009, we completed a definitive transaction with Johnson & Johnson whereby Johnson & Johnson acquired substantially all of our assets and rights related to AIP, through a newly formed Johnson & Johnson subsidiary, Janssen AI. In addition, Johnson & Johnson, through its subsidiary Janssen Pharmaceutical, invested $885.0 million in exchange for 107.4 million newly issued ADRs of Elan, representing 18.4% of our

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outstanding Ordinary Shares. Johnson & Johnson has also committed to fund up to $500.0 million towards the further development and commercialization of AIP. In consideration for the transfer of our AIP assets and rights, we received a 49.9% equity interest in Janssen AI. We are entitled to a 49.9% share of the future profits of Janssen AI and certain royalty payments upon the commercialization of products under the AIP collaboration with Wyeth (which has been acquired by Pfizer). We recognized a net gain on divestment of the AIP business of $108.7 million for 2009.

Subsequent to the completion of the Johnson & Johnson Transaction, we announced a cash tender offer for the outstanding $850.0 million in aggregate principal amount of 7.75% senior notes due November 15, 2011 (7.75% Notes). The 7.75% Notes were fully redeemed by the end of December 2009. In addition, we completed the offering and sale of $625.0 million in aggregate principal amount of 8.75% senior notes due October 15, 2016 (8.75% Notes).

Following completion of the strategic review, and subsequent debt refinancing, our total debt has been reduced from $1,765.0 million at December 31, 2008, to $1,540.0 million at December 31, 2009, and the weighted average maturity of our debt was extended by approximately 70%, from 35 months prior to the refinancing to 60 months after the refinancing.

BIONEUROLOGY Defining the Future of Degenerative Neurological Therapies

Important Clinical Progress: Elan s Alzheimer s Programs

Elan s scientists have been leaders in Alzheimer s disease research for more than 25 years, and insights gained from our work are an important part of the scientific foundation of understanding this disease. We are known and respected for our innovative Alzheimer s disease platforms 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 our landmark basic research that revealed the fundamental biology that leads to the production and accumulation of a toxic protein, beta amyloid, in the brains of Alzheimer s disease patients. The process by which this protein is generated, aggregates and is ultimately deposited in the brain as plaque is often referred to as the beta amyloid cascade. The formation of beta amyloid plaques is the hallmark pathology of Alzheimer s disease.

Beta amyloid forms when a small part of a larger protein called the amyloid precursor protein (APP) is cleaved from the larger protein. This separation happens when enzymes called secretases clip or cleave APP. It is becoming increasingly clear that once beta amyloid is produced, it exists in multiple physical forms with distinct functional activities. It is believed that the toxic effects of some of these forms may be involved in the complex cognitive, functional and behavioral deficits characteristic of Alzheimer s disease.

A growing body of scientific data, discovered by researchers at Elan and other organizations, suggest that modulating the beta amyloid cascade may result in breakthrough treatments for Alzheimer s disease patients. Elan scientists and others continue to study and advance research in this critical therapeutic area.

Three Approaches to Disrupting the Beta Amyloid Cascade

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

Clearing existing beta amyloid from the brain (beta amyloid immunotherapies), through the AIP (transferred to Janssen AI);

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

Preventing production of beta amyloid in the brain with secretase inhibitors.

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Beta amyloid immunotherapies (AIP)

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 (which has been acquired by Pfizer), our scientists developed a series of therapeutic monoclonal antibodies 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. The AIP includes bapineuzumab and ACC-001, as well as other compounds.

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 (passive immunotherapy), rather than prompting patients to produce their own immune responses (active immunotherapy). 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. The Phase 3 program includes four randomized, double-blind, placebo-controlled studies across two subpopulations (based on ApoE4 genotype) with mild to moderate Alzheimer s disease, with patients distributed between North America and the rest of world (ROW).

ACC-001, is a novel vaccine intended to induce a highly specific antibody response by the patient s immune system to beta amyloid (active immunotherapy), and is currently being evaluated in a Phase 2 clinical study. ACC-001 has also been granted fast track designation by the FDA.

As part of the Johnson & Johnson Transaction in September 2009, Janssen AI acquired substantially all of the assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer). Johnson & Johnson has also committed to fund up to $500.0 million towards the further development and commercialization of AIP. In consideration for the transfer of these assets and rights, we received a 49.9% equity interest in Janssen AI. We are entitled to a 49.9% share of the future profits of Janssen AI and certain royalty payments upon the commercialization of products under the AIP collaboration.

ELND005, an A aggregation inhibitor

In 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.

Preclinical data suggest that ELND005 may act through the unique mechanism of preventing and reversing the fibrilisation 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 cognitive decline in a transgenic mouse model of Alzheimer s disease, with reduced amyloid plaque load in the murine brain and increased life span of these animals.

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ELND005 is currently in a Phase 2 clinical study, AD201, which completed enrollment in October 2008. The study is a randomized, double-blind, placebo-controlled, dose-ranging, safety and efficacy study which enrolled approximately 350 patients with mild to moderate Alzheimer s disease. The planned treatment period for each patient is approximately 18 months.

In December 2009, we and Transition announced modifications to the ELND005 Phase 2 and Phase 2 open label extension study (AD251). Patients were withdrawn from the study in the two higher dose groups (1,000mg and 2,000mg dosed twice daily). The Phase 2 study continued unchanged for patients who were assigned to the lower dose (250mg dosed twice daily) and placebo groups.

The decision by the companies to take these actions was made in concurrence with the Independent Safety Monitoring Committee (ISMC) following a review of the ongoing ELND005-AD201 study. Greater rates of serious adverse events, including nine deaths, were observed among patients receiving the two highest doses. A direct relationship between ELND005 and these deaths has not been established.

The ISMC and both companies concurred that the tolerability and safety data are acceptable among patients receiving the 250mg dose and that the blinded study should continue for this dose and the placebo group. We continue to expect the ongoing study to provide important data to guide the next steps in the development of ELND005 for the potential treatment of Alzheimer s disease.

Secretase inhibitors

Beta and gamma secretases are proteases, or enzymes that break down other proteins, that clip APP and result 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 a 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.

Our development program for ELND006, a small molecule gamma secretase inhibitor, continues to progress through Phase 1 clinical studies, with additional gamma secretase inhibitor programs advancing in late stages of preclinical development.

In addition to our internal gamma secretase programs, we also retain certain rights to Eli Lilly and Company s (Lilly) LY450139 compound, which arose from collaborative research between us and Lilly. In 2008, Lilly initiated Phase 3 trials for LY450319 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.

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Small Molecule (p75) Ligands

In June 2009, we entered into an exclusive collaboration with PharmatrophiX, a biotechnology company focused on the development of small molecule ligands for growth factor receptors relevant to neurological disorders. We are working with PharmatrophiX on continued research on all p75 ligands, compounds that mimic the activity of neurotrophins by interacting with neurons that are susceptible to loss in Alzheimer s disease, for neurologic indications.

LM11A-31, which is the lead compound in the PharmatrophiX portfolio, interacts with and potentially protects neurons that are susceptible to loss in Alzheimer s disease. The addition of this compound diversifies our portfolio by adding an orally available therapeutic platform that may attack Alzheimer s disease from a different, and potentially complementary, approach than current investigational molecules in our pipeline.

Parkinson s Research

Elan has several active early discovery efforts in Parkinson s disease, guided by our expertise in Alzheimer s disease. Elan scientists are exploring multiple therapeutic strategies to tackle this poorly understood, devastating disease, with specific focus on the analysis of human genetics and pathology to discover mechanisms to prevent disease progression.

Parkinson s disease may be a result of misfolded proteins in the brain. Parkinson s disease is characterized by the accumulation of aggregated alpha-synuclein, or abnormal fibrils and inclusions known as Lewy bodies, in degenerating neurons in specific regions of the brain.

Alpha-synuclein is a protein genetically linked to Parkinson s disease and a key component in degenerating neurons in brain regions controlling movement. Alterations in alpha-synuclein are believed to play a critical role in Parkinson s disease.

Our scientists have made significant scientific progress in identifying unusual modified forms of alpha-synuclein in human Parkinson s disease brain tissue. In January 2009, our scientists published new research in the *Journal of Biological Chemistry* about the discovery of a protein that may be involved in the modification of alpha-synuclein. The normal function of alpha-synuclein is unknown, but modified forms accumulate during pathological conditions and form Lewy bodies.

Our scientists are studying the nature of these modifications and, in the 2009 paper, reported the identity of a protein that appeared to be a contributor to changes in the alpha-synuclein protein. We are using experimental models of Parkinson s disease to conduct tests to determine the involvement of the protein in the formation of Lewy bodies in brain tissue.

We are also studying parkin, a protein found in the brain that, like alpha-synuclein, has been genetically linked to Parkinson s disease. Parkin may be involved in the elimination of misfolded proteins within neurons, and has demonstrated neuroprotective capabilities in cells. Some familial forms of Parkinson s disease have been linked to mutations in parkin, with more than 50% of early-onset Parkinson s disease being linked to a loss of parkin protein and function in neurons.

Our study of the relationship between parkin activity and neurodegeneration is in the drug discovery stage.

Tysabri

Tysabri for the Treatment of Multiple Sclerosis

Tysabri, which is co-marketed by us and Biogen Idec, is approved in more than 45 countries, including the United States, the European Union, Switzerland, Canada, Australia and New Zealand. In the United States, it is approved for relapsing forms of MS and in the European Union for relapsing-remitting MS.

According to data 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 with placebo, and reduced the relative risk of disability progression by 42% to 54%.

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Tysabri is redefining success in the treatment of MS. In post-hoc analyses of the clinical trial data published in *The Lancet Neurology*, 37% of *Tysabri*-treated patients remained free of their MS activity, based on MRI and clinical measures, compared to 7% of placebo-treated patients.

Additional analyses have provided 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 MS. Patients with a common baseline expanded disability status scale score (an EDSS of 2.0) treated with *Tysabri* showed a significant increase in the probability of sustained improvement in disability; this increase was 69% relative to placebo.

Tysabri increases the risk of PML, an opportunistic viral infection of the brain, caused by the JC virus, that can lead to death or severe disability. The risk of PML increases with increasing duration of use.

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.

On January 21, 2010, the European Medicines Agency (EMA) finalized a review of *Tysabri* and the risk of PML. The EMA s Committee for Medicinal Products for Human Use (CHMP) concluded that the risk of developing PML increases after two years of use of *Tysabri*, although this risk remains low. However, the benefits of the medicine continue to outweigh its risks for patients with highly active relapsing-remitting MS, for whom there are few treatment options available.

For 2009, *Tysabri* global in-market net sales increased by 30% to $1,059.2 million from $813.0 million for 2008.

As of the end of December 2009, approximately 48,800 patients were on therapy worldwide, including approximately 24,500 commercial patients in the United States and approximately 23,700 commercial patients in the ROW.

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 www.*Tysabri*.com. The contents of this website are not incorporated by reference into this Form 20-F.

Tysabri for the Treatment of Crohn s Disease

We evaluated *Tysabri* as a treatment for Crohn s disease 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.

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, with evidence of inflammation, who have had an inadequate response to, or are unable to tolerate, conventional Crohn s disease therapies and inhibitors of TNF-alpha.

Also 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.

We launched *Tysabri* for the treatment of Crohn s disease in the United States in the first quarter of 2008. On December 12, 2008, we announced a realignment of our commercial activities in *Tysabri* for Crohn s disease, shifting our efforts from a traditional sales model to a model based on clinical support and education.

In October 2009, *Tysabri* data was presented at the College of Gastroenterology Annual Scientific Meeting in San Diego showing that treatment with *Tysabri* significantly reduced the rate of hospitalization compared with placebo in patients with moderate to severe Crohn s disease during both induction and maintenance treatment. These results were obtained from retrospective subset analyses of three registrational Phase 3 trials (ENACT-1 (Efficacy of Natalizumab as Active Crohn s Therapy), ENACT-2 (Evaluation of Natalizumab as Continuous Therapy) and ENCORE (Efficacy of Natalizumab in Crohn s Disease Response and Remission)), and one open-label study (ENABLE (Evaluation of the Natalizumab Antibody for Long-term Efficacy)).

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

Prialt for the Treatment of Severe Chronic Pain

Revenue from the sales of *Prialt* was $16.5 million for 2009 and 2008.

In 2009, we recorded an impairment charge of $30.6 million relating to the *Prialt* intangible asset. *Prialt* was launched in the United States in 2005. Revenues from this product have not met expectations and, consequently, we revised our sales forecast for *Prialt* and reduced the carrying value of the intangible asset to $14.6 million as of December 31, 2009.

Prialt is a non-opioid, intrathecal analgesic and represents a 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 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.

Hospital Antibiotics

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 2009, revenue from *Azactam* decreased 16% to $81.4 million, compared to $96.9 million for 2008, principally due to supply shortages. *Azactam* lost its patent exclusivity in October 2005. We will cease distributing *Azactam* as of March 31, 2010.

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 2009, revenue from *Maxipime* decreased 51% to $13.2 million from $27.1 million for the 2008. The decrease was 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. We will cease distributing *Maxipime* as of September 30, 2010.

Unique Scientific Opportunities

Our BioNeurology 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 collaborating opportunities, beyond our core focus in neuroscience.

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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, including ELND002, which is currently being studied for MS and oncology.

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.

Alzheimer s Drug Discovery Foundation (ADDF)

ADDF, a biomedical venture philanthropy, is a public charity solely dedicated to rapidly accelerating the discovery and development of drugs to prevent, treat and cure Alzheimer s disease and cognitive aging. Through the ADDF, Elan sponsors an annual research award program, Novel Approaches to Drug Discovery for Alzheimer s Disease. In 2009, the program funded five research projects.

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 2006, 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 to Drug Discovery provides 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. In 2009, the program funded six research projects.

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

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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.

ACT-AD

ACT-AD is a coalition of national organizations representing multiple stakeholders that are seeking to accelerate development of potential cures and treatments for Alzheimer s disease. ACT-AD supports accelerating research for transforming therapies to potentially slow, halt or reverse the progression of Alzheimer s disease. ACT-AD seeks immediate public and government recognition of Alzheimer s disease as a debilitating, dehumanizing and life-threatening disease that requires urgent attention and to bring interventional therapies to patients, providers and families in the next decade by making the acceleration of promising Alzheimer s disease therapies a top national priority. We are a member of the coalition and support its programs intended to bring transformational therapies to patients and their families.

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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ELAN DRUG TECHNOLOGIES 40 Years of Drug Delivery Leadership

On December 18, 2009, EDT celebrated its official anniversary and 40 years of leadership in the drug delivery business. Since its founding in Ireland in 1969, EDT has been focused on developing and applying technologies to unsolved drug formulation challenges.

Throughout its 40 year history, EDT has been a leader, bringing forth innovative solutions that have addressed real patient needs, with significant benefits across the pharmaceutical industry.

Since 2001, 11 products incorporating EDT technologies have been approved and launched in the United States alone. To date, EDT s drug delivery technologies have been commercialized in 35 products around the world, contributing to annual client sales of more than $3.1 billion.

Highlights

Luvox® CR was launched in the United States in January 2009, using our *SODAS*® technology for the treatment of social anxiety disorder (SAD) and obsessive compulsive disorder (OCD), by Jazz Pharmaceuticals Inc.

In July 2009, Janssen, a division of Ortho-McNeil-Janssen Pharmaceuticals, announced the approval of Invega® Sustenna™, a once monthly atypical antipsychotic injection, by the FDA. The approval of Invega Sustenna was an important milestone as it marks the first long-acting injectable product approved by regulatory authorities using our *NanoCrystal* technology. Invega Sustenna is the fifth licensed product using the *NanoCrystal* technology for various formulations approved by the FDA. Janssen also announced it had submitted an Marketing Authorisation Application (MAA) for paliperidone palmitate with the European Regulatory Agencies.

In October 2009, Emend® (aprepitant) was approved in Japan, thereby becoming the first Japanese product approval incorporating our *NanoCrystal* technology.

In January 2010, the FDA approved Ampyra™ (dalfampridine) as a treatment to improve walking in patients with MS. Ampyra will be marketed and distributed in the United States by Acorda Therapeutics Inc. (Acorda) and outside the United States by Biogen Idec. Ampyra is the first New Drug Application approved by the FDA for a product using the *MXDAS*™ (matrix drug absorption system) technology and is the first medicine approved by the FDA indicated to improve walking speed in people with MS. In addition, in January 2010, Biogen Idec announced the submission of an MAA to the EMA for Fampridine Prolonged Release (Fampridine-PR) tablets. Biogen Idec also announced that it has filed a New Drug Submission (NDS) with Health Canada. EDT will manufacture supplies of Ampyra for the global market at its Athlone, Ireland, facility, under an existing supply agreement with Acorda.

Advancing Technologies, Improving Medicines

EDT is an established, profitable business unit of Elan, that 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 more than two million patients each day.

Throughout its 40 years in business, EDT has remained committed to using its extensive experience, drug delivery technologies and commercial capabilities to help clients develop innovative products that provide clinically meaningful benefits to patients. Committed to innovation whether in the products developed, advancing our existing technologies or developing new technologies EDT has been driven by some of the best scientific talent in the area of drug delivery formulation. We provide a broad range of creative drug formulation 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 11 products in the United States. With 14 pipeline products in the clinic, multiple preclinical programs and a strong client base, EDT plans to maintain its position as the leading drug delivery company worldwide.

During 2009, EDT generated $275.9 million (2008: $301.6 million) in revenue and an operating profit of $70.5 million in 2009 (2008: $85.8 million). 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.

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EDT revenues for 2009 were impacted by the withdrawal of, or significantly decreased, promotional efforts by our clients in respect of Skelaxin® and TriCor® 145. Revenues were also impacted by the scheduled expiry of supply agreements for some smaller legacy products.

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 will seek to attain an increasing proportion of revenue.

EDT s Business Strategy

Throughout our 40-year history, we have invested in the development of innovative technologies, particularly in OCR platform technologies and technologies for poorly water-soluble compounds. Although revenues declined in 2009, over the medium term we are focused on profitably growing as a drug delivery business, underpinned by our product development capabilities and drug delivery technologies.

In the near to medium term, we will drive growth through our existing approved licensed products and pipeline of 14 products in clinical development. We will also 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 drug delivery business model. We will also seek to generate revenue through our scale-up and manufacturing capabilities. 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 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 many patent and patent applications around our key technology and product areas.

Marketed Products

Twenty-four (24) products incorporating EDT technologies are currently marketed by EDT licensees. EDT receives royalties and, in some cases, manufacturing fees on these products, which include:

Licensee	Product	Indication
Abbott Laboratories	TriCor 145	Cholesterol reduction
Acorda Therapeutics, Inc.	Zanaflex Capsules®	Muscle spasticity
Janssen	Invega Sustenna	Schizophrenia
Jazz Pharmaceuticals Inc.	Luvox CR	SAD and OCD
King Pharmaceuticals, Inc.	Avinza®	Chronic pain
Merck & Co., Inc.	Emend	Nausea post chemo

Novartis AG	Focalin® XR/Ritalin® LA	ADHD[1]
Par Pharmaceutical Co., Inc.	Megace® ES	Cachexia
Pfizer (Wyeth)	Rapamune®	Anti-rejection
Victory Pharma	*Naprelan®*	NSAID[2] Pain

[1] *Attention Deficit Hyperactivity Disorder*

[2] *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

EDT has a unique platform of validated technologies to offer our clients including OCR, 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.

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.

Our *NanoCrystal* technology is:

Proven Five licensed products have been launched to date, achieving over $1.9 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 nearly 20 years of development behind the technology. It is applicable to all dosage forms and has been manufactured at commercial scale since 2001.

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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 five licensed and 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 OCR products. OCR 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.

A unique platform of validated technologies to offer our clients:

Validated and Commercialized 19 products currently on the market.

Multiple OCR Technologies Our OCR platform includes specific technologies for tailored delivery profiles including *SODAS* technology (controlled and pulsatile release), *IPDAS*® technology (sustained release), *CODAS*® technology (delayed release) and the *MXDAS* drug absorption system.

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

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

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 North America, Asia, Europe, Latin America and Australasia. EDT s main production facilities are located in Athlone, Ireland, and Gainesville, Georgia, United States. We have manufactured finished solid oral pharmaceutical products for clients for well over 30 years.

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

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Range of Manufacturing Services:

FDA and EMA approved sites with capacity to manufacture up to 1.5 billion units annually of solid oral dosage product.

250,000 square feet of cGMP facilities between our sites in Ireland and the United States.

Other services include regulatory support, supply chain support, and launch management.

ENVIRONMENT

The U.S. market is our most important market. Refer to Note 4 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. 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 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, a product we divested to Eisai in April 2004. We are continuing to cooperate with the government in its investigation. The resolution of the Zonegran matter could require Elan to pay very substantial civil or criminal fines, and take other actions that could have a material adverse effect on Elan and its financial condition, including the exclusion of our products from reimbursement under government programs. Any resolution of the

Zonegran matter could give rise to other investigations or litigation by state government entities or private parties.

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 Investigational New Drug Application before human testing may proceed.

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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 European Union countries, in general, most other countries have their own procedures and requirements.

Once a product has been approved, significant legal and regulatory requirements apply in order to market a product. In the United States, these include, among other things, requirements related to adverse event and other reporting, product advertising and promotion, and ongoing adherence to cGMP requirements, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

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, 2009, we employed 518 people in our manufacturing and supply activities, with 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 OCR 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.

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During 2009, the extent of utilization of our manufacturing facilities was approximately 50% of our total productive capacity. This capacity underutilization principally relates to our Athlone, Ireland, facility.

Patents and Intellectual Property Rights

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

The fundamental U.S. patent covering the use of ziconotide, the active ingredient 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. Following the introduction of generic cefepime to the market, our revenues from, and gross margin for, *Maxipime* were materially and adversely affected. We will cease distributing *Maxipime* as of September 30, 2010.

The basic U.S. patent for *Azactam* expired in October 2005. We will cease distributing *Azactam* as of March 31, 2010.

The primary patent covering Elan s *NanoCrystal* technology expires 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

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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. We will cease distributing *Azactam* and *Maxipime* in 2010.

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.

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, 2009, we had 1,321 employees worldwide, of whom 450 were engaged in R&D activities, 518 were engaged in manufacturing and supply activities, 105 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, 2009, 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, CA, USA
Crimagua Ltd.	Holding company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Drug Delivery, Inc.	R&D	100	3000 Horizon Drive, King of Prussia, PA, USA
Elan Finance plc	Financial services company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Holdings, Inc.	Manufacture of pharmaceutical and medical device products	100	1300 Gould Drive, Gainesville, GA, USA
Elan Holdings Ltd.	Holding company	100	Monksland, Athlone, Co. Westmeath, Ireland
Elan International Insurance Ltd.	Captive insurance company	100	Clarendon House, 2 Church Street, Hamilton, Bermuda
Elan International Services Ltd.	Financial services company	100	Clarendon House, 2 Church Street, Hamilton, Bermuda
Elan Pharma International Ltd.	R&D, manufacture, sale and distribution of pharmaceutical products, management services 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
Elan Science One Ltd.	Holding company	100	Monksland, Athlone, Co. Westmeath, Ireland
Keavy Finance plc	Dormant	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland

D. Property, Plants 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 16 to the Consolidated Financial Statements, which discloses amounts invested in land and buildings and plant and equipment; Note 27 to the Consolidated Financial Statements, which discloses future minimum rental commitments; Note 28 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:

Location and Ownership Interest	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	334,000(1)(2)
Leased: King of Prussia, PA, USA	R&D, manufacturing, sales and administration	113,000(3)
Leased: Dublin, Ireland	Corporate administration	41,000

(1) *In June 2007, we entered into lease agreements for an additional building in South San Francisco. The lease term for this building commenced in March 2009. The square footage for this building is approximately 108,000 square feet and is included in the 334,000 square feet noted above. The building is being utilized for our R&D, sales and administrative functions.*

In December 2007, we entered a lease agreement for a second additional building in South San Francisco, which is currently being fitted out. The square footage for this building is approximately 89,000 square feet and is not included in the 334,000 square feet noted above. The lease term for this building commenced in January 2010. The building will be utilized for our R&D, sales and administrative functions.

(2) *In September 2009, we entered into an agreement to sublease laboratory and office space in South San Francisco, which was no longer being utilized by our R&D, sales and administrative functions, to Janssen AI. The square footage for this laboratory and office space is approximately 38,700 square feet and is included in the 334,000 square feet noted above.*

(3) *In June 2009, we entered into lease extension agreements for our R&D facility in King of Prussia, Pennsylvania. The lease agreements for this facility were originally due to expire in April 2009 and May 2012 but were extended to April 2019 and May 2020, respectively.*

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;

Results of operations for the year ended December 31, 2009, compared to 2008 and 2007, 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: BioNeurology (formerly referred to as Biopharmaceuticals) and EDT. Our BioNeurology business unit engages in research, development and commercial activities primarily in the areas of Alzheimer s disease, Parkinson s disease, MS, Crohn s disease and severe chronic pain. We have a range of products at various stages of development in relation to each of these therapeutic areas. EDT develops and manufactures innovative pharmaceutical products that deliver clinically meaningful benefits to patients, using its extensive experience and proprietary drug technologies in collaboration with pharmaceutical companies. An established, profitable, integrated drug delivery business unit of Elan, EDT has been applying its skills and knowledge in product development and drug delivery technologies 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 amounts of long-lived 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.

Long-Lived Assets and Impairment

Total goodwill and other intangible assets amounted to $417.4 million at December 31, 2009 (2008: $553.9 million). Our property, plant and equipment, and equity method investment had carrying amounts at December 31, 2009 of $292.8 million (2008: $351.8 million) and $235.0 million (2008: $Nil), respectively.

Goodwill and identifiable intangible assets with indefinite useful lives are not amortized, but instead are tested for impairment at least annually. At December 31, 2009, we had no intangible assets with indefinite lives except for goodwill.

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 property, plant and equipment, are reviewed for impairment 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 amount of the asset. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount 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 amounts 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. We have two reporting units: BioNeurology 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 amount, 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 2009, 2008 or 2007. In addition, we performed a goodwill impairment test immediately subsequent to the disposal of the AIP business in September 2009 and the result of our test did not indicate any impairment.

In performing our annual goodwill impairment test and the test immediately subsequent to the disposal of the AIP business, we noted that the combined fair value of our reporting units based on the income approach exceeded our market capitalization at the test dates. Furthermore, both the fair value of our reporting units and our market capitalization exceeded the combined carrying amounts of the reporting units by a substantial margin, at the impairment test dates and as of December 31, 2009.

In December 2009, we recorded an impairment charge of $30.6 million within other net charges in the Consolidated Statement of Operations relating to the *Prialt* intangible asset, thus reducing the carrying value of the intangible asset to $14.6 million. *Prialt* was launched in the United States in 2005. Revenues from this product have not met expectations and, consequently, we revised our sales forecast for *Prialt*. As a result, the revised projected future cumulative undiscounted cash flows were lower than the intangible assets carrying value, thus indicating the intangible assets were not recoverable. The impairment charge was calculated as the excess of the carrying amount over the discounted net present value.

In June 2007, we recorded an impairment charge of $52.2 million, within other net charges in the Consolidated Statement of Operations, 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 amount, thus indicating the intangible assets were not recoverable. Consequently, the impairment charge was calculated as the excess of the carrying amount 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 amount was amortized, on a straight-line basis, through December 31, 2007. There were no material impairment charges relating to intangible assets in 2008. For additional information on goodwill and other intangible assets, refer to Note 17 to the Consolidated Financial Statements.

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 amount of these facilities may become impaired.

Following the transfer of our AIP manufacturing rights as part of the sale of the AIP business to Janssen AI in September 2009, we re-evaluated our longer term biologics manufacturing and fill-finish requirements, and consequently recorded a non-cash asset impairment charge related to these activities of $41.2 million. The assets relating to biologics manufacturing were written off in full. The remaining carrying amount of the fill-finish assets at December 31, 2009 is $5.7 million. In conjunction with the impairment charge, we reviewed the estimated useful life of the fill-finish assets and reduced the useful life of the assets that previously had a useful life beyond 2018 to December 31, 2018.

Our equity method investment is reviewed for impairment whenever events or circumstances indicate the fair value of the investment has fallen below our carrying amount. The factors affecting the assessment of impairments include both general financial market conditions and factors specific to the investee. When such a decline is deemed to be other-than-temporary, an impairment charge is recorded for the difference between the investment s carrying amount

and its estimated fair value at the time. In making the determination as to whether a decline is other-than-temporary, we consider such factors as the duration and extent of the decline and the investee s financial and operating performance. Differing assumptions could affect whether an investment is impaired in any period, or the amount of the impairment.

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Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Up-front fees received by us are deferred and amortized when there is a significant continuing involvement by us (such as an ongoing product manufacturing contract or joint development activities) after an asset disposal. We defer and amortize up-front license fees to the income statement over the performance period. The performance period is the period over which we expect to provide services to the licensee as determined by the contract provisions. Generally, milestone payments are recognized when earned and non-refundable, and when we have no future legal obligation pursuant to the payment. However, the actual accounting for milestones depends on the facts and circumstances of each contract. We apply the substantive milestone method in accounting for milestone payments. This method requires that substantive effort must have been applied to achieve the milestone prior to revenue recognition. If substantive effort has been applied, the milestone is recognized as revenue, subject to it being earned, non-refundable and not subject to future legal obligation. This requires an examination of the facts and circumstances of each contract. Substantive effort may be demonstrated by various factors, including the risks associated with achieving the milestone, the period of time over which effort was expended to achieve the milestone, the economic basis for the milestone payment and licensing arrangement and the costs and staffing to achieve the milestone. It is expected that the substantive milestone method will be appropriate for most contracts. If we determine the substantive milestone method is not appropriate, we apply the proportional performance method to the relevant contract. This method recognizes as revenue the percentage of cumulative non-refundable cash payments earned under the contract, based on the percentage of costs incurred to date compared to the total costs expected under the contract.

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, 2009, we had total provisions of $26.5 million for sales discounts and allowances, of which approximately 58.4%, 20.4% and 18.9% related to *Tysabri, Maxipime* and *Azactam,* respectively. We have almost four 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.

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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,		
	2009	2008	2007
	(In millions)		
Gross revenue subject to discounts and allowances	$ 698.9	$ 627.7	$ 508.3
Net *Tysabri* ROW revenue	215.8	135.5	14.3
Manufacturing revenue and royalties	258.9	282.6	271.3
Contract revenue	18.7	20.0	30.8
Amortized revenue Adalat®/Avinza			4.5
Gross revenue	$ 1,192.3	$ 1,065.8	$ 829.2
Sales discounts and allowances:			
Charge-backs	$ (39.7)	$ (34.7)	$ (41.6)
Managed health care rebates and other contract discounts	(1.2)	(1.3)	(2.9)
Medicaid rebates	(7.1)	(5.4)	(3.5)
Cash discounts	(16.7)	(13.7)	(11.5)
Sales returns	(4.2)	(0.1)	(4.3)
Other adjustments	(10.4)	(10.4)	(6.0)
Total sales discounts and allowances	$ (79.3)	$ (65.6)	$ (69.8)
Net revenue subject to discounts and allowances	619.6	562.1	438.5
Net *Tysabri* ROW revenue	215.8	135.5	14.3
Manufacturing revenue and royalties	258.9	282.6	271.3
Contract revenue	18.7	20.0	30.8
Amortized revenue Adalat/Avinza			4.5
Net revenue	$ 1,113.0	$ 1,000.2	$ 759.4

Total sales discounts and allowances were 11.3% of gross revenue subject to discounts and allowances in 2009, 10.5% in 2008 and 13.7% in 2007, 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 5.7% in 2009, 5.5% in 2008 and 8.2% in 2007. The managed health care rebates and Medicaid rebates as a percentage of gross revenue subject to discounts and allowances were 0.2% and 1.0%, respectively, in 2009; 0.2% and 0.9%, respectively, in 2008; and 0.6% and 0.7%, respectively, in 2007. These changes are due primarily to changes in the product mix.

Cash discounts as a percentage of gross revenue subject to discounts and allowances remained fairly consistent at 2.4% in 2009, compared to 2.2% in 2008 and 2.3% in 2007. 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 0.6% in 2009, Nil in 2008 and 0.8% in 2007. In 2008, sales returns were impacted by 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):

	Charge-Backs	Managed Health Care Rebates and Other Contract Discounts	Medicaid Rebates	Cash Discounts	Sales Returns	Other Adjustments	Total
Balance at December 31, 2007	$ 5.4	$ 0.9	$ 3.0	$ 1.0	$ 7.6	$ 1.0	$ 18.9
Provision related to sales made in current period	34.7	1.3	5.4	13.7	2.8	10.4	68.3
Provision related to sales made in prior periods					(2.7)		(2.7)
Returns and payments	(37.6)	(1.8)	(2.4)	(12.8)	(1.1)	(9.6)	(65.3)
Balance at December 31, 2008	$ 2.5	$ 0.4	$ 6.0	$ 1.9	$ 6.6	$ 1.8	$ 19.2
Provision related to sales made in current period	39.7	1.2	7.1	16.7	3.2	10.4	78.3
Provision related to sales made in prior periods					1.0		1.0
Returns and payments	(36.6)	(1.0)	(4.2)	(16.6)	(3.0)	(10.6)	(72.0)
Balance at December 31, 2009	$ 5.6	$ 0.6	$ 8.9	$ 2.0	$ 7.8	$ 1.6	$ 26.5

(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, 2009, *Tysabri, Azactam* and *Maxipime* represented approximately 41.2%, 6.0% and 52.2% respectively, of the total charge-backs accrual balance of $5.6 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 $4.3 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 of inventory in the distribution channel and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

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(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. At December 31, 2009, *Tysabri* represented approximately 94% of the total Medicaid rebates accrual balance of $8.9 million.

(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 by establishing an accrual in an amount equal to our estimate of revenue recorded for which the related products are expected to be returned.

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, 2009, *Tysabri, Azactam* and *Maxipime* represented approximately 30.7%, 47.4% and 18.0%, respectively, of the total sales returns accrual balance of $7.8 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.

During 2009, we recorded adjustments of $1.0 million to increase (2008: $2.7 million to decrease) the sales returns accrual related to sales made in prior periods.

(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 defined inventory management practices and to perform certain activities such as providing weekly information

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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) 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

Share-based compensation expense for all equity-settled awards made to employees and directors is measured and recognized 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. Share-based compensation cost for RSUs awarded to employees and directors is measured based on the closing fair market value of the Company s common stock on the date of grant. Share-based compensation cost for stock options awarded to employees and directors and common stock issued under employee equity purchase plans is estimated at the grant date based on each option s fair value as calculated using an option-pricing model. The value of awards expected to vest is recognized as an expense over the requisite service periods.

Share-based compensation expense for equity-settled awards to non-employees in exchange for goods or services is based on the fair value of awards on the vest date, which is the date at which the commitment for performance by the non-employees to earn the awards is reached and also the date at which the non-employees performance is complete.

Estimating the fair value of share-based awards at grant or vest date 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 estimating the fair value of share-based awards in future periods, the compensation expense that we record 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.

For additional information on our share-based compensation, refer to Note 25 to the Consolidated Financial Statements.

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 29 to the Consolidated Financial Statements.

We assess the likelihood of any adverse outcomes to contingencies, including legal matters, as well as potential ranges of probable losses. We record accruals for such contingencies when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If an unfavorable outcome is probable, but the amount of the loss cannot be reasonably estimated, we estimate the range of probable loss and accrue the most

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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, 2009, we had accrued $0.6 million (2008: $5.9 million), representing our estimates of liability and costs for the resolution of these matters.

In particular, we have considered the facts and circumstances known to us in relation to the Zonegran matter described in Note 29 to the Consolidated Financial Statements and, while any ultimate resolution of this matter could require Elan to pay very substantial civil or criminal fines, at this time we cannot predict or determine the timing of the resolution of this matter, its ultimate outcome, or a reasonable estimate of the amount or range of amounts of any fines or penalties that might result from an adverse outcome. Accordingly, we have not recorded any reserve for liabilities in relation to the Zonegran matter as of December 31, 2009.

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.

Previously, because of cumulative losses, we determined it was necessary to maintain a valuation allowance against substantially all of our net DTAs, as the cumulative losses in recent years represented a significant piece of negative evidence. However, due to the recent and projected future profitability of our U.S. operations, arising from the continued growth of the BioNeurology business in the United States, we believe there is evidence to support the generation of sufficient future 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 June 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2009-16 Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities, which is effective for financial statements issued for fiscal years beginning on or after November 15, 2009. This update provides guidance on transfers of financial assets. It amends previous guidance to remove the concept of a

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qualifying special-purpose entity and its exemption from consolidation in the transferor s financial statements. This update also establishes conditions for reporting a transfer of a portion of a financial asset as a sale, modifies the financial-asset derecognition criteria, revises how interests retained by the transferor in a sale of financial assets are initially measured, removes the guaranteed mortgage securitization recharacterization provisions, and requires additional disclosures. We do not expect that the adoption of ASU No. 2009-16 will have a material impact on our financial position or results of operations.

In August 2009, the FASB issued ASU No. 2009-05, Measuring Liabilities at Fair Value, in relation to the fair value measurement of liabilities that is effective for financial statements issued for fiscal years beginning after August 27, 2009. The update addresses practice difficulties caused by the tension between fair-value measurements based on the price that would be paid to transfer a liability to a new obligor and contractual or legal requirements that prevent such transfers from taking place. We do not expect that the adoption of ASU No. 2009-05 will have a material impact on our financial position or results of operations.

In October 2009, the FASB issued ASU No. 2009-14 Certain Revenue Arrangements that Include Software Elements, which is effective for financial statements issued for fiscal years beginning on or after June 15, 2010. This update addresses the accounting for revenue transactions involving software. Currently, that guidance applies to revenue arrangements for products or services that include software that is more-than-incidental to the products or services as a whole. This update amends the guidance to exclude from its scope tangible products that contain both software and non-software components that function together to deliver a product s essential functionality. We do not expect that the adoption of ASU No. 2009-14 will have a material impact on our financial position or results of operations.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, which is effective for financial statements issued for fiscal years beginning on or after June 15, 2010. This update sets forth requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. One of those current requirements is that there be objective and reliable evidence of the standalone selling price of the undelivered items, which must be supported by either vendor-specific objective evidence (VSOE) or third-party evidence (TPE). This update eliminates the requirement that all undelivered elements have VSOE or TPE before an entity can recognize the portion of an overall arrangement fee that is attributable to items that already have been delivered. In the absence of VSOE or TPE of the standalone selling price for one or more delivered or undelivered elements in a multiple-element arrangement, entities will be required to estimate the selling prices of those elements. The overall arrangement fee will be allocated to each element (both delivered and undelivered items) based on their relative selling prices, regardless of whether those selling prices are evidenced by VSOE or TPE or are based on the entity s estimated selling price. Application of the residual method of allocating an overall arrangement fee between delivered and undelivered elements will no longer be permitted upon adoption of this update. Additionally, the new guidance will require entities to disclose more information about their multiple-element revenue arrangements. We do not expect that the adoption of ASU No. 2009-13 will have a material impact on our financial position or results of operations.

In October 2009, the FASB issued ASU No. 2009-15, Accounting for Own-Share Lending Arrangements in Contemplation of Convertible Debt Issuance, which is effective for financial statements issued for fiscal years beginning on or after December 15, 2009. This update applies to an equity-classified share lending arrangement on an entity s own shares when executed in contemplation of a convertible debt offering or other financing. The share lending arrangement is required to be measured at fair value and recognized as an issuance cost associated with the convertible debt offering or other financing. If counterparty default is probable, the share lender is required to recognize an expense equal to the then fair value of the unreturned shares, net of the fair value of probable recoveries. In addition, the loaned shares are excluded from basic and diluted earnings per share unless default of the share-lending arrangement occurs, at which time the loaned shares would be included in the common and diluted earnings-per-share calculation. If dividends on the loaned shares are not reimbursed to the entity, any amounts,

including contractual (accumulated) dividends and participation rights in undistributed earnings, attributable to the loaned shares shall be deducted in computing income available to common shareholders, consistent with the two-class method. We do not expect that the adoption of ASU No. 2009-15 will have a material impact on our financial position or results of operations.

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In December 2009, the FASB issued ASU No. 2009-17, Amendments to FASB Interpretation No. 46 (R), which is effective for financial statements issued for fiscal years beginning on or after November 15, 2009. This update provides guidance on the consolidation of variable interest entities. It eliminates the quantitative approach previously required for determining the primary beneficiary of a variable interest entity and requires ongoing qualitative reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. This update also requires additional disclosures about an enterprise s involvement in variable interest entities. We do not expect that the adoption of ASU No. 2009-17 will have a material impact on our financial position or results of operations.

A. RESULTS OF OPERATIONS

2009 Compared to 2008 and 2007 (in millions, except share and per share amounts)

	2009	2008	2007	% Increase/(Decrease) 2009/2008	% Increase/(Decrease) 2008/2007
Product revenue	$ 1,094.3	$ 980.2	$ 728.6	12%	35%
Contract revenue	18.7	20.0	30.8	(7)%	(35)%
Total revenue	1,113.0	1,000.2	759.4	11%	32%
Cost of sales	560.7	493.4	337.9	14%	46%
Gross margin	552.3	506.8	421.5	9%	20%
Operating expenses:					
Selling, general and administrative expenses	268.2	292.7	339.3	(8)%	(14)%
Research and development expenses	293.6	323.4	262.9	(9)%	23%
Net gain on divestment of business	(108.7)			100%	
Other net charges	67.3	34.2	84.6	97%	(60)%
Total operating expenses	520.4	650.3	686.8	(20)%	(5)%
Operating profit/(loss)	31.9	(143.5)	(265.3)	(122)%	(46)%
Net interest and investment gains and losses:					
Net interest expense	137.9	132.0	113.1	4%	17%
Net investment (gains)/losses	(0.6)	21.8	0.9	(103)%	2,322%
Net charge on debt retirement	24.4		18.8	100%	(100)%
Net interest and investment gains and losses	161.7	153.8	132.8	5%	16%
Net loss before income taxes	(129.8)	(297.3)	(398.1)	(56)%	(25)%
Provision for/(benefit from) income taxes	46.4	(226.3)	6.9	(121)%	(3,380)%
Net loss	$ (176.2)	$ (71.0)	$ (405.0)	148%	(82)%
Basic and diluted net loss per Ordinary Share	$ (0.35)	$ (0.15)	$ (0.86)	133%	(83)%

Total Revenue

Total revenue was $1.1 billion in 2009, $1.0 billion in 2008 and $759.4 million in 2007. Total revenue from our BioNeurology business increased 20% in 2009 and 51% in 2008, while revenue from our EDT business decreased 9% in 2009 and increased 2% in 2008. Total revenue is further analyzed between revenue from the BioNeurology and EDT business units.

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	2009	2008	2007	% Increase 2009/2008	% Increase 2008/2007
		(In millions)			
Revenue from the BioNeurology business	$ 837.1	$ 698.6	$ 463.9	20%	51%
Revenue from the EDT business	275.9	301.6	295.5	(9)%	2%
Total revenue	$ 1,113.0	$ 1,000.2	$ 759.4	11%	32%

Revenue from the BioNeurology business

Total revenue from our BioNeurology business increased 20% to $837.1 million from $698.6 million in 2008. The increase was primarily driven by a solid performance from *Tysabri*, which exceeded $1.0 billion in annual global in-market net sales in 2009, and more than offsets the reduced sales of *Azactam* and *Maxipime*.

In 2008, revenue from our BioNeurology 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 was adversely impacted by the introduction of generic competition in 2007.

	2009	2008	2007	% Increase/(Decrease) 2009/2008	% Increase/(Decrease) 2008/2007
		(In millions)			
Product revenue:					
Tysabri- U.S.	$ 508.5	$ 421.6	$ 217.4	21%	94%
Tysabri- ROW	215.8	135.5	14.3	59%	848%
Total *Tysabri*	724.3	557.1	231.7	30%	140%
Azactam	81.4	96.9	86.3	(16)%	12%
Prialt	16.5	16.5	12.3		34%
Maxipime	13.2	27.1	122.5	(51)%	(78)%
Royalties	1.7	1.0	1.8	70%	(44)%
Total product revenue	837.1	698.6	454.6	20%	54%
Contract revenue			9.3		(100)%
Total revenue from BioNeurology business	$ 837.1	$ 698.6	$ 463.9	20%	51%

Tysabri

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

	% Increase

	2009	2008	2007	2009/2008	2008/2007
United States	$ 508.5	$ 421.6	$ 217.4	21%	94%
ROW	550.7	391.4	125.5	41%	212%
Total *Tysabri* in-market net sales	$ 1,059.2	$ 813.0	$ 342.9	30%	137%

Tysabri in-market net sales were $1,059.2 million in 2009, $813.0 million in 2008 and $342.9 million in 2007. The increases in 2009 and 2008 reflect strong patient demand across global markets. At the end of December 2009, approximately 48,800 patients were on therapy worldwide, including approximately 24,500 commercial patients in the United States and approximately 23,700 commercial patients in the ROW, representing an increase of 30% over the approximately 37,600 patients who were on therapy at the end of December 2008. At the end of December 2007, approximately 21,100 patients were on therapy worldwide.

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*

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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, in December 2008, 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. These payments were capitalized as intangible assets and 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.

Tysabri-U.S.

In the U.S. market, we recorded net sales of $508.5 million (2008: $421.6 million; 2007: $217.4 million). Almost all of these sales are in relation to the MS indication.

As of the end of December 2009, approximately 24,500 patients were on commercial therapy in the United States, which represents an increase of 21% since the end of December 2008. At the end of December 2007, approximately 12,900 were on commercial therapy.

On January 14, 2008, the FDA approved the sBLA for *Tysabri* for the treatment of patients with Crohn s disease, 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 Crohn s disease, 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 markets, 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 $215.8 million (2008: $135.5 million; 2007: $14.3 million), which was calculated as follows (in millions):

				% Increase	
	2009	**2008**	**2007**	**2009/2008**	**2008/2007**
ROW in-market sales by Biogen Idec	$ 550.7	$ 391.4	$ 125.5	41%	212%
ROW operating expenses incurred by Elan and Biogen Idec	(280.6)	(236.9)	(138.1)	18%	72%
ROW operating profit/(loss) generated/(incurred) by Elan and Biogen Idec	270.1	154.5	(12.6)	75%	1,326%
	135.0	77.3	(6.3)	75%	1,327%

Elan s 50% share of *Tysabri* ROW collaboration operating profit/(loss)					
Elan s directly incurred costs	80.8	58.2	20.6	39%	183%
Net *Tysabri* ROW revenue	$ 215.8	$ 135.5	$ 14.3	59%	848%

As of the end of December 2009, approximately 23,700 patients, principally in the European Union, were on commercial *Tysabri* therapy, an increase of 40% over the approximately 16,900 patients at the end of December 2008. At the end of December 2007, approximately 7,500 patients were on commercial therapy.

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Other BioNeurology products

Azactam revenue decreased 16% to $81.4 million in 2009 from our 2008 sales level and increased 12% to $96.9 million in 2008 from our 2007 sales level. The decrease in 2009 was principally due to supply shortages and the increase in 2008 mainly reflected increased pricing. Azactam lost its patent exclusivity in October 2005. We will cease distributing Azactam as of March 31, 2010.

Prialt revenue was $16.5 million for 2009 and 2008, and $12.3 million for 2007. The increase in 2008 was primarily due to higher demand for the product. In 2009, we recorded an impairment charge of $30.6 million relating to the *Prialt* intangible asset. *Prialt* was launched in the United States in 2005. Revenues from this product have not met expectations and, consequently, we revised our sales forecast for *Prialt* and reduced the carrying value of the intangible asset to $14.6 million as of December 31, 2009. Refer to page 37 for additional information regarding this impairment.

Maxipime revenue decreased 51% to $13.2 million in 2009 from our 2008 sales level and decreased 78% to $27.1 million in 2008 from our 2007 sales level. The decreases in 2009 and 2008 were principally due to generic competition. We will cease distributing *Maxipime* as of September 30, 2010.

Revenue from the EDT business

Revenue from the EDT business decreased 9% to $275.9 million in 2009 and increased 2% to $301.6 million in 2008 from $295.5 million in 2007.

				% Increase/(Decrease)	
	2009	2008	2007	2009/2008	2008/2007
		(In millions)			
Product revenue:					
Manufacturing revenue and royalties:					
TriCor 145	$ 61.6	$ 67.7	$ 62.5	(9)%	8%
Skelaxin	34.9	39.7	39.3	(12)%	1%
Focalin XR/Ritalin LA	32.6	33.5	28.4	(3)%	18%
Verelan®	22.1	24.6	28.5	(10)%	(14)%
Other	106.0	116.1	110.8	(9)%	5%
Total manufacturing revenue and royalties	257.2	281.6	269.5	(9)%	4%
Amortized revenue Adalat/Avinza			4.5		(100)%
Total product revenue	257.2	281.6	274.0	(9)%	3%
Contract revenue:					
Research revenue and milestones	18.7	17.6	17.2	6%	2%
Amortized fees		2.4	4.3	(100)%	(44)%
Total contract revenue	18.7	20.0	21.5	(7)%	(7)%
Total revenue from the EDT business	$ 275.9	$ 301.6	$ 295.5	(9)%	2%

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 decreased 9% to $257.2 million in 2009 from our 2008 sales level and increased 4% to $281.6 million in 2008 from our 2007 sales level. The decrease in 2009 was primarily due to the withdrawal of, or significantly decreased, promotional efforts by EDT s clients in respect of Skelaxin and TriCor 145. Revenues were also impacted by the scheduled expiry of supply agreements for some smaller legacy products. The increase in 2008 primarily reflected growth across a number of products in our EDT portfolio and increased manufacturing activity.

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Except as noted above, no other single product accounted for more than 10% of our manufacturing revenue and royalties in 2009, 2008 or 2007. In 2009, 47% of these revenues consisted of royalties received on products that we do not manufacture, consistent with 47% in both 2008 and 2007.

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). This award and damages associated with the continuing sales of the Abraxane product are subject to interest based upon the three-month Treasury Bill Rate. Consequently, we estimate the total amount of the award at December 31, 2009, including accrued interest, to be in excess of $80 million. We are awaiting a ruling by the Court on both parties post-trial motions. 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, 2009.

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

In July 2009, Janssen, a division of Ortho-McNeil-Janssen Pharmaceuticals, announced the approval of Invega Sustenna, a once monthly atypical antipsychotic injection, by the FDA. The approval of Invega Sustenna was an important milestone as it marks the first long-acting injectable product approved by regulatory authorities using our *NanoCrystal* technology. Invega Sustenna is the fifth licensed product using the *NanoCrystal* technology for various formulations approved by the FDA. Janssen also announced it had submitted an MAA for paliperidone palmitate with the European Regulatory Agencies.

In October 2009, Emend was approved in Japan, thereby becoming the first Japanese product approval incorporating our *NanoCrystal* technology.

In January 2010, the FDA approved Ampyra as a treatment to improve walking in patients with MS. Ampyra will be marketed and distributed in the United States by Acorda and outside the United States by Biogen Idec. Ampyra is the first New Drug Application approved by the FDA for a product using EDT s *MXDAS* technology and is the first medicine approved by the FDA indicated to improve walking speed in people with MS. In addition, in January 2010, Biogen Idec announced the submission of an MAA to the EMA for Fampridine-PR tablets. Biogen Idec also announced that it has filed an NDS with Health Canada. EDT will manufacture supplies of Ampyra for the global market at its Athlone, Ireland, facility, under an existing supply agreement with Acorda.

Amortized revenue Adalat/Avinza

Amortized revenue of $4.5 million in 2007 related to the licensing to Watson Pharmaceuticals, Inc. (Watson) in 2002 of rights to our generic form of Adalat CC. The deferred revenue relating to Adalat CC was fully amortized by June 30, 2007.

Contract revenue

Contract revenue was $18.7 million in 2009, $20.0 million in 2008 and $21.5 million in 2007. Contract revenue consists of research revenue, license fees and milestones arising from R&D activities we perform on behalf of third

parties. The changes 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 $560.7 million in 2009, compared to $493.4 million in 2008 and $337.9 million in 2007. The fluctuations in the gross profit margin of 50% in 2009, 51% in 2008 and 56% in 2007 principally reflect the change in the mix of product sales, including the impact of increasing sales of *Tysabri* (which has a lower reported gross

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margin than our other products) and decreasing sales of *Maxipime* and *Azactam*. The gross margin increased by 9% in 2009 ($552.3 million), compared to 2008 ($506.8 million), and by 20% in 2008, compared to 2007 ($421.5 million), due to increased gross margin earned from higher sales of *Tysabri* more than replacing loss of gross margin from reduced sales of *Azactam* and *Maxipime.*

The *Tysabri* gross profit margin of 45% in 2009 (2008: 42%; 2007: 32%) 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 2009 (2008: 37%; 2007: 36%), and our reported gross margin on ROW sales of 63% (2008: 58%; 2007: (33)%). The ROW gross margin reflects our share of the profit or loss on ROW sales plus our directly incurred expenses on these sales, 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 expenses were $268.2 million in 2009, $292.7 million in 2008 and $339.3 million in 2007. The decrease of 8% in total SG&A expenses in 2009, compared to 2008, principally reflects lower headcount from the reduction of support activities as a result of a redesign of the R&D organization in 2009, lower legal litigation costs, along with continued cost control.

The decrease of 14% in total SG&A expenses in 2008, compared to 2007, principally reflected 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 expenses related to the *Tysabri* ROW sales are reflected in the *Tysabri* ROW revenue as previously described.

Research and Development Expenses

R&D expenses were $293.6 million in 2009, $323.4 million in 2008 and $262.9 million in 2007. The decrease of 9% in 2009, compared to 2008, primarily relates to the cost savings as a result of the divestment of AIP and the timing of spend on our key R&D programs. R&D expenses in 2009 included $87.0 million (2008: $109.5 million; 2007: $53.5 million) in relation to AIP. The increase of 23% in 2008, compared to 2007, was primarily due to increased expenses associated with the progression of the 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 Business

As part of the Johnson & Johnson Transaction in September 2009, Janssen AI acquired substantially all of the assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer). Johnson & Johnson has also committed to fund up to $500.0 million towards the further development and commercialization of AIP. In consideration for the transfer of these assets and rights, we received a 49.9% equity interest in Janssen AI. We are entitled to a 49.9% share of the future profits of Janssen AI and certain royalty payments upon the commercialization of products under the AIP collaboration. Our equity interest in Janssen AI has been recorded as an equity method investment on the Consolidated Balance Sheet at December 31, 2009, at a carrying amount of $235.0 million.

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The net gain on divestment of the AIP business in 2009 amounted to $108.7 million and was calculated as follows (in millions):

Investment in Janssen AI[1]	$ 235.0
Intangible assets[2]	(68.0)
Biologics and fill-finish impairment[3]	(41.2)
Transaction costs	(16.8)
Share based compensation	1.2
Other	(1.5)
Net gain on divestment of business	$ 108.7

(1) *The investment in Janssen AI was recorded at the estimated fair value of $235.0 million as of the date of the transaction.*

(2) *Includes goodwill of $10.3 million allocated to the AIP business.*

(3) *As a result of the disposal of the AIP business, we re-evaluated the longer term biologics manufacturing and fill-finish requirements, and consequently recorded a non-cash asset impairment charge related to these activities of $41.2 million.*

The estimated fair value of the investment in Janssen AI was based on the fair value of the AIP assets and rights that were divested, which was estimated using a discounted cash flow model. The inputs used in this model reflected management s estimates of assumptions that market participants would use in valuing the AIP business. These assumptions included the forecasting of future cash flows, the probability of clinical success, the probability of commercial success, and the estimated cost of capital.

We did not divest any businesses in 2008 or 2007.

Other Net Charges

The principal items classified as other net charges include intangible asset impairment charges, severance, restructuring and other costs, other asset impairment charges, acquired in-process research and development costs, legal settlements and awards and the write-off of deferred transaction costs. These items have been treated consistently from period to period. We believe that disclosure of significant other charges is meaningful because it provides additional information in relation to analyzing certain items.

	2009	2008	2007
		(In millions)	
(a) Intangible asset impairment charges	$ 30.6	$	$ 52.2
(b) Severance, restructuring and other costs	29.7	22.0	32.4
(c) Other asset impairment charges	15.4		
(d) Acquired in-process research and development costs	5.0		
(e) Legal settlements and awards	(13.4)	4.7	

(f) Write-off of deferred transaction costs		7.5	
Total other net charges	$ 67.3	$ 34.2	$ 84.6

(a) Intangible asset impairment charges

During 2009, we recorded a non-cash impairment charge of $30.6 million relating to the *Prialt* intangible asset. *Prialt* was launched in the United States in 2005. Revenues from this product have not met expectations and, consequently, we revised our sales forecast for *Prialt* and reduced the carrying value of the intangible asset to $14.6 million.

During 2007, we incurred a non-cash impairment charge of $52.2 million related to the *Maxipime* and *Azactam* intangible assets. As a direct result of the approval of a first generic form of *Maxipime* in June 2007 and the anticipated approval of 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 amount thus indicating the intangible assets were not recoverable. Consequently, the impairment charge was

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calculated as the excess of the carrying amount over the discounted net present value. The remaining net intangible assets carrying amount was amortized, on a straight-line basis, through December 31, 2007.

(b) Severance, restructuring and other costs

During 2009, we incurred severance and restructuring charges of $29.7 million principally associated with the strategic redesign and realignment of the R&D organization within our BioNeurology business and reduction of related support activities.

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 Crohn s disease and the announced closure of our offices in New York and Tokyo, which occurred in the first half of 2009.

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*.

(c) Other asset impairment charges

In the first half of 2009, we incurred an asset impairment charge of $15.4 million primarily associated with the postponement of our biologics manufacturing activities. Subsequently, as a result of the disposal of the AIP business in September 2009, we re-evaluated the longer term biologics manufacturing requirements and the remaining carrying amount of these assets was written off. This impairment charge was recorded as part of the net gain on divestment of business. For additional information on the net gain on divestment of business, refer to Note 5.

(d) Acquired in-process research and development costs

The acquired in-process research and development charge of $5.0 million is in relation to a license fee incurred in June 2009 under a collaboration agreement entered into with PharmatrophiX to research, develop and commercialize the neurological indications of PharmatrophiX s portfolio of compounds targeting the p75 neurotrophin receptor.

(e) Legal settlements and awards

The net legal awards and settlement amount of $13.4 million in 2009 is comprised of a legal award of $18.0 million received from Watson and a legal settlement amount of $4.6 million in December 2009 relating to nifedipine antitrust litigation. The $18.0 million legal award related to an agreement with Watson to settle litigation with respect to Watson s marketing of a generic version of *Naprelan*. As part of the settlement, Watson stipulated that our patent at issue is valid and enforceable and that Watson s generic formulations of *Naprelan* infringed our patent.

Following a settlement in late 2007 with the indirect purchaser class of the nifedipine antitrust litigation, in December 2009 we entered into a separate settlement agreement with the individual direct purchasers, resulting in a dismissal of this second segment of the litigation and the payment of a legal settlement amount of $4.6 million.

The legal settlement amount 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 was finalized in 2009 without admission of fault by Dura.

(f) 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.

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Net Interest Expense

Net interest expense was $137.9 million in 2009, $132.0 million in 2008 and $113.1 million in 2007. The increase of 4% in 2009, as compared to 2008, was primarily due to decreased interest income as a result of lower interest rates and net foreign exchange losses, partially offset by lower debt interest expense as a result of lower interest rates associated with the senior floating rate notes due November 15, 2011 (Floating Rate Notes due 2011) and the senior floating rate notes due December 1, 2013 (Floating Rate Notes due 2013).

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 the Floating Rate Notes due 2013.

Net Investment (Gains)/Losses

Net investment gains were $0.6 million in 2009, compared to net losses of $21.8 million in 2008 and net losses of $0.9 million in 2007. The net investment gains in 2009 primarily related to gains realized from a fund that had previously been reclassified from cash equivalents to investments due to dislocations in the capital markets. We fully redeemed our remaining holding in this fund during 2009. The net investment losses in 2008 were primarily comprised of impairment charges of $20.2 million (2007: $6.1 million) and $1.0 million in net realized losses on the sale of investment securities (2007: $6.6 million net gain).

We did not record any impairment charges in relation to investment securities during 2009. In 2008, we recorded a net impairment charge of $10.9 million (2007: $Nil) related to an investment in the fund described above. The remaining impairment charges in 2008 were comprised of $6.0 million (2007: $5.0 million) related to an investment in auction rate securities (ARS) and $3.3 million (2007: $1.1 million) related to various investments in emerging pharmaceutical and biotechnology companies.

At December 31, 2009, we had, at face value, $11.4 million (2008: $11.4 million) of principal invested in ARS, held at a carrying amount of $0.4 million (2008: $0.4 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, 2009, the estimated fair value of the ARS was $0.4 million (2008: $0.4 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 amount, 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). We did not record an impairment charge relating to the ARS in 2009.

The framework used for measuring the fair value of our investment securities, including the ARS, is described in Note 26 to the Consolidated Financial Statements.

In 2008, the $1.0 million in net losses on the sale of investment securities includes losses of $1.4 million associated with the disposal of the fund described above.

In 2007, the $6.6 million in gains on the sale of investment securities includes gains on sale of securities of Adnexus Therapeutics, Inc. of $3.0 million and Women s First Healthcare, Inc. of $1.3 million.

Net charge on debt retirement

During 2009, we redeemed the 7.75% Notes in full and recorded a net charge on debt retirement of $24.4 million, comprised of an early redemption premium of $16.4 million, write-off of unamortized deferred financing costs of $6.7 million and transaction costs of $1.3 million.

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 in 2007.

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Provision for/(Benefit from) Income Taxes

We had a net tax provision of $46.4 million for 2009, compared to a net tax benefit of $226.3 million in 2008 and a net tax provision of $6.9 million for 2007.

The overall tax provision for 2009 was $50.0 million (2008: $228.7 million benefit; 2007: $5.1 million provision). Of this amount $3.6 million was deducted from shareholders equity (2008: $2.4 million added; 2007: $1.8 million added) to reflect the net shortfalls related to equity awards. The remaining $46.4 million provision (2008: $226.3 million benefit; 2007: $6.9 million provision) is allocated to ordinary activities.

The 2009 tax provision reflects federal alternative minimum taxes (AMT) and state taxes, income derived from Irish Patents, other taxes at standard rates in jurisdictions in which we operate, foreign withholding tax and includes a deferred tax expense of $36.8 million for 2009 (2008: $236.6 million benefit; 2007: $1.3 million benefit) primarily related to the DTA recognized in 2008 as the underlying loss carryforwards and other DTAs are utilized to shelter taxable income in 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. Previously, because of cumulative losses in the year ended December 31, 2007 and the two preceding years, we determined it was necessary to maintain a valuation allowance against substantially all of our net DTAs, as the cumulative losses in recent years represented a significant piece of negative evidence. However, as a result of the U.S. business generating cumulative earnings for the three years ended December 31, 2008 and projected recurring U.S. profitability arising from the continued growth of the BioNeurology business in the United States, there was 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. Our U.S. business carries out a number of activities that are remunerated on a cost-plus basis, therefore future U.S. profitability is expected. As part of our assessment in 2009 we updated our detailed future income forecasts for the U.S. business, which cover the period through 2019 and demonstrate significant future recurring profitability. The cumulative level of taxable income required to realize the federal DTAs is approximately $417.0 million and approximately $930.0 million to realize the state DTAs. U.S. pre-tax book income for 2009 was $163.1 million and the quantum of projected earnings is significantly in excess of the pre-tax income necessary to realize the DTAs. The DTAs recoverability is not dependent on material improvements over present levels of pre-tax income for the U.S. business, material changes in the present relationship between income reported for financial and tax purposes, or material asset sales or other non-routine transactions. In weighing up the positive and negative evidence for releasing the valuation allowance we considered future taxable income exclusive of reversing temporary differences and carry-forwards; the timing of future reversals of existing taxable temporary differences; the expiry dates of operating losses and tax credit carry-forwards and various other factors which may impact on the level of future profitability in the United States. Accordingly, there was no need to materially alter our valuation allowance in the United States during 2009.

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Adjusted EBITDA Non-GAAP Financial Information

	2009	2008	2007	2006	2005
			(In millions)		
Net loss	$ (176.2)	$ (71.0)	$ (405.0)	$ (267.3)	$ (383.6)
Net interest expense	137.9	132.0	113.1	111.5	125.7
Provision for/(benefit from) income taxes	46.4	(226.3)	6.9	(9.0)	1.0
Depreciation and amortization	75.0	70.1	118.3	135.6	130.8
Amortized fees, net	(0.2)	(2.5)	(11.4)	(44.0)	(50.2)
EBITDA	82.9	(97.7)	(178.1)	(73.2)	(176.3)
Share based compensation	31.0	46.0	43.4	47.1	
Net gain on divestment of businesses and products	(108.7)			(43.1)	(103.4)
Other net charges/(gains)	67.3	34.2	84.6	(20.3)	4.4
Net investment (gains)/losses	(0.6)	21.8	0.9	(1.6)	7.2
Net charge on debt retirement	24.4		18.8		51.8
Net income from discontinued operations					(0.6)
Adjusted EBITDA	$ 96.3	$ 4.3	$ (30.4)	$ (91.1)	$ (216.9)

EBITDA (Earnings Before Interest, Taxes, Depreciation and Amortization) and Adjusted EBITDA are non-GAAP measures of operating results. Elan s managements use these measures to evaluate our operating performance and they are among the factors considered as a basis for our planning and forecasting for future periods. We believe that EBITDA and Adjusted EBITDA are measures of performance used by some investors, equity analysts and others to make informed investment decisions.

Adjusted EBITDA is defined as EBITDA plus or minus share-based compensation, net gain on divestment of businesses or products, other net charges or gains, net investment gains or losses, net charge on debt retirement and net income from discontinued operations. EBITDA and Adjusted EBITDA are not presented as, and should not be considered alternative measures of, operating results or cash flows from operations, as determined in accordance with U.S. GAAP. Reconciliations of EBITDA and Adjusted EBITDA to net loss are set out in the table above.

In 2009, we reported Adjusted EBITDA of $96.3 million, compared to Adjusted EBITDA of $4.3 million in 2008. The improvement reflects the 11% increase in revenue and the resulting increase in gross margin, combined with the 9% decrease in combined SG&A and R&D expenses, and reflects the significant operating leverage associated with *Tysabri*, where revenue increased 30% to $724.3 million for 2009 from $557.1 million for 2008.

In 2008, we reported Adjusted EBITDA of $4.3 million, compared to Adjusted EBITDA losses of $30.4 million in 2007. The improvement in Adjusted EBITDA reflects the improved operating performance in 2008, driven by a 32% increase in revenue while combined SG&A and R&D expenses increased by only 2%, and reflects the strong performance of *Tysabri*, where revenue increased 140% to $557.1 million for 2008 from $231.7 million for 2007.