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.