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.