ELAN CORP PLC
Form 20-F
February 23, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 20-F

(Mark One)

¨ **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, 2011

OR

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

OR

¨ **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,**
(Jurisdiction of	**Dublin 2, Ireland**
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),	New York Stock Exchange
representing Ordinary Shares, 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: 589,346,275 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 ¨

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ¨ No 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 ¨

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 þ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨

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

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: Item 17 ¨ Item 18 ¨

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ¨ No 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 its 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, intend, plan, will, believe, expect and other words and terms of similar meaning in co any discussion of future operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: (1) any negative developments relating to *Tysabri*® (natalizumab), such as safety or efficacy issues (including increased incidence of deaths and cases of progressive multifocal leukoencephalopathy (PML)), the introduction or greater acceptance of competing products, including biosimilars, or adverse regulatory or legislative developments may reduce our revenues and adversely affect our results of operations; (2) the potential for the successful discovery, development and commercialization of additional products; (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 Inc. (Pfizer) for the development and potential commercialization, and the funding required from us for such development and potential commercialization, of bapineuzumab and any other potential products in the Alzheimer s Immunotherapy Program (AIP); (6) the success of research and development (R&D) activities in which we retain an interest, including, in particular, whether the Phase 3 clinical trials for bapineuzumab (AAB-001) are successful or whether other potential AIP products are successfully developed, and the speed with which regulatory authorizations and product launches may be achieved; (7) while we own approximately 25% of the outstanding shares of Alkermes plc, the transfer or disposition of the shares is restricted by securities law and contract and we do not know when or whether we will be able to dispose of these shares or what value we will receive for the shares if we are able to dispose of them; (8) competitive developments, including the introduction of new oral therapies competitive with *Tysabri* and potentially biosimilar competition if we lost patent protection for *Tysabri*; (9) our ability to protect our patents and other intellectual property and defend against intellectual property lawsuits asserted against us or our collaborator Biogen Idec, Inc. (Biogen Idec); (10) difficulties or delays in manufacturing *Tysabri* (we are dependent on Biogen Idec for the manufacture of *Tysabri*); (11) pricing pressures and uncertainties regarding

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healthcare reimbursement and reform and from countries seeking to reduce their public expenditures on healthcare, in particular as the result of the sovereign debt crisis in Europe; (12) the effects of our settlement with the U.S. government relating to marketing practices with respect to our former Zonegran® (zonisamide) product, which required us to pay $203.5 million in fines and to take other actions that could have a material adverse effect on Elan; (13) failure to comply with anti-kickback, bribery and false claims laws in the United States and elsewhere; (14) extensive government regulation; (15) risks from potential environmental liabilities; (16) failure to comply with our reporting and payment obligations under Medicaid or other government programs; (17) exposure to product liability risks, in particular with respect to *Tysabri*; (18) an adverse effect that could result from the putative class action lawsuits alleging we disseminated false and misleading statements related to bapineuzumab and the outcome of our other pending or future litigation; (19) our business is exposed to the volatility of currency exchange rates and the risks of a partial or total collapse of the euro; and (20) some of our agreements that may discourage or prevent others from acquiring us and Johnson & Johnson is our largest shareholder with an 18.2% interest in our outstanding Ordinary Shares and is largely in control of our remaining interest in the AIP, which may discourage others from seeking to work with or acquire us. 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, (in millions, except per share data), 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,	2011	2010	2009	2008	2007
Statement of Operations Data:					
Total revenue	$ 1,246.0	$ 1,169.7	$ 1,113.0	$ 1,000.2	$ 759.4
Operating income/(loss)	$ 840.2[1]	$ (188.6)[2]	$ 31.9[3]	$ (143.5)[4]	$ (265.3)[5]
Net income/(loss)	$ 560.5[6]	$ (324.7)[7]	$ (176.2)[8]	$ (71.0)[9]	$ (405.0)[10]
Basic income/(loss) per Ordinary Share[11]	$ 0.95	$ (0.56)	$ (0.35)	$ (0.15)	$ (0.86)
Diluted income/(loss) per Ordinary Share[11]	$ 0.94	$ (0.56)	$ (0.35)	$ (0.15)	$ (0.86)
Basic weighted-average number of shares outstanding	587.6	584.9	506.8	473.5	468.3
Diluted weighted-average number of shares outstanding	593.5	584.9	506.8	473.5	468.3
Other Financial Data:					
Adjusted EBITDA[12]	$ 213.0	$ 166.5	$ 96.3	$ 4.3	$ (30.4)
Pro forma Adjusted EBITDA[13]	$ 146.7	$ 62.7	$ (20.9)	$ (125.5)	$ (157.1)

At December 31,	2011	2010	2009	2008	2007
Balance Sheet Data:					
Cash and cash equivalents	$ 271.7	$ 422.5	$ 836.5	$ 375.3	$ 423.5
Restricted cash current and non-current	$ 16.3	$ 223.1	$ 31.7	$ 35.2	$ 29.6
Investment securities current	$ 0.3	$ 2.0	$ 7.1	$ 30.5	$ 277.6
Total assets	$ 1,753.8	$ 2,017.5	$ 2,337.8	$ 1,867.6	$ 1,780.8
Debt	$ 615.0[14]	$ 1,270.4[15]	$ 1,532.1[16]	$ 1,765.0	$ 1,765.0
Total shareholders equity/(deficit)	$ 801.8	$ 194.3	$ 494.2	$ (232.2)	$ (234.7)

(1) *After a net gain on divestment of business of $652.9 million; and after other net gains of $42.2 million, primarily relating to legal settlement gains of $84.5 million, offset by severance, restructuring and other costs of $20.4 million, and facilities and other asset impairment charges of $21.9 million.*

(2) *After a settlement reserve charge of $206.3 million; other net charges of $56.3 million, primarily relating to severance, restructuring and other costs of $19.6 million, facilities and other asset impairment charges of $16.7 million, net loss on divestment of the Prialt business of $1.5 million, a legal settlement of $12.5 million, net acquired in-process research and development costs of $6.0 million; and after a net gain on divestment of business of $1.0 million.*

(3) *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 $29.0 million, facilities and other asset impairment charges of $16.1 million, acquired in-process research and development costs of $5.0 million, reduced by net legal awards of $13.4 million.*

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(4) *After other net charges of $34.2 million, primarily relating to severance, restructuring and other costs of $21.2 million, the write-off of deferred transaction costs of $7.5 million, a legal settlement of $4.7 million and facilities and other asset impairment charges of $0.8 million.*

(5) *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.*

(6) *After a net gain on divestment of business of $652.9 million; after other net gains of $42.2 million, primarily relating to legal settlement gains of $84.5 million, offset by severance, restructuring and other costs of $20.4 million, facilities and other asset impairment charges of $21.9 million; after a net loss on equity method investments of $81.8 million; after a net charge on debt retirement of $47.0 million; and after a tax charge of $40.0 million relating to the write-down of U.S. state deferred tax assets.*

(7) *After a settlement reserve charge of $206.3 million; other net charges of $56.3 million, primarily relating to severance, restructuring and other costs of $19.6 million, facilities and other asset impairment charges of $16.7 million, net loss on divestment of the Prialt business of $1.5 million, a legal settlement of $12.5 million, net acquired in-process research and development costs of $6.0 million; after a net gain on divestment of business of $1.0 million; after a net loss on equity method investment of $26.0 million; and after a net charge on debt retirement of $3.0 million.*

(8) *After a net gain on divestment of business of $108.7 million; 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 $29.0 million, facilities and other asset impairment charges of $16.1 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.*

(9) *After other net charges of $34.2 million, primarily relating to severance, restructuring and other costs of $21.2 million, the write-off of deferred transaction costs of $7.5 million, a legal settlement of $4.7 million, facilities and other asset impairment charges of $0.8 million; and after a tax credit of $236.6 million, which resulted from the release of a deferred tax asset valuation allowance.*

(10) *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.*

(11) *Basic and diluted net income/(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.*

(12) *Refer to pages 50 and 51 for a reconciliation of net income/(loss) to Adjusted EBITDA and page 49 for our reasons for presenting this non-GAAP measure.*

(13) *Refer to pages 50 and 51 for a reconciliation of net income/(loss) to pro forma Adjusted EBITDA and to pages 38 and 49 for our reasons for presenting this pro forma non-GAAP financial information.*

(14) *Net of unamortized original issue discount of $9.5 million.*

(15) *Net of unamortized original issue discount of $14.6 million.*

(16) *Net of unamortized original issue discount of $7.9 million.*

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.

We are substantially dependent on revenues from Tysabri.

Sales of our only marketed product *Tysabri* represented approximately 85% of our total revenues and approximately 100% of our pro forma revenues (see page 38 for a reconciliation Elan s total GAAP revenues to

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pro forma Elan revenues) during 2011. The Elan Drug Technologies (EDT) business, which we sold to Alkermes, Inc. on September 16, 2011, accounted for approximately 14% of our total revenues in 2011. Although we continue to seek to discover and develop additional products for commercial introduction, we may be substantially dependent on sales from *Tysabri* for many years. Any negative developments relating to *Tysabri,* such as safety, efficacy or reimbursement issues, the introduction or greater acceptance of competing products, including biosimilars, or adverse regulatory or legislative developments may reduce our revenues and adversely affect our results of operations. New competing products for use in multiple sclerosis (MS) are beginning to (or will soon) enter the market, including BG-12 which our collaborator, Biogen Idec has in late stage development, and if they have a similar or more attractive profile in terms of efficacy, convenience or safety, future sales of *Tysabri* could be limited, which would reduce our revenues.

Tysabri s sales growth cannot be assured given the significant restrictions on its use and the significant safety warnings in the label, including the risk of developing PML, a serious brain infection. The risk of developing PML increases with prior immunosuppressant (IS) use, which may cause patients who have previously received immunosuppressants or their physicians to refrain from using or prescribing *Tysabri*. The risk of developing PML also increases with longer treatment duration, with limited experience beyond four years. This may cause prescribing physicians or patients to suspend treatment with *Tysabri*. In addition, the risk of developing PML is heightened when a patient has anti-JC virus (JCV) antibodies. In January 2012, the U.S. Food and Drug Administration (FDA) approved a product label change for *Tysabri* that identifies anti-JCV antibody status as a risk factor for PML. This risk had already been incorporated into the European label for *Tysabri* in June 2011. Physicians have discontinued treatment and are likely to continue to discontinue treatment with *Tysabri* in patients who test positive for JCV antibodies. Increased incidences of PML could limit sales growth, prompt regulatory review, require significant changes to the label or result in market withdrawal. Additional regulatory restrictions on the use of *Tysabri* or safety-related label changes, including enhanced risk management programs, whether as a result of additional cases of PML or otherwise, may significantly reduce expected revenues and require significant expense and management time to address the associated legal and regulatory issues. In addition, ongoing or future clinical trials involving *Tysabri,* efforts at stratifying patients into groups with lower or higher risk for developing PML and the commercial availability of the JCV antibody assay may have an adverse impact on prescribing behavior and reduce sales of *Tysabri*. Further, the utility of the JCV antibody assay may be diminished as a result of the assay s false negative rate and because a patient who tests negative for JCV antibodies may be infected by the JCV after testing.

Our long-term success depends upon the successful development and commercialization of other product candidates.

Our long-term viability and growth will depend upon the successful discovery, development and commercialization of other products from our R&D activities, including bapineuzumab, which is being developed by Johnson & Johnson and Pfizer and in which we retain an approximate 25% economic interest. Product development and commercialization are very expensive and involve a high degree of risk. Only a small number of R&D programs result in the commercialization of a product. Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, product candidates may not receive marketing approval if regulatory authorities disagree with our view of the data or require additional studies.

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, 2011, we had $624.5 million of debt falling due in October 2016 (2010: $1,285.0 million, comprised of $460.0 million that was due in December 2013 and $825.0 million due in October 2016). At such date, we had total cash and cash equivalents, restricted cash and cash equivalents and investments of $298.1 million (2010: $453.3 million). Our substantial indebtedness could have important adverse consequences to us. For example, it does or could:

- Increase our vulnerability to general adverse economic and industry conditions;

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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 (including our funding commitments to Janssen Alzheimer Immunotherapy (Janssen AI) for the AIP), 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 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 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 AI, a newly formed subsidiary of Johnson & Johnson, completed the acquisition of substantially all of our assets and rights related to the 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 at the time. Johnson & Johnson also committed to fund up to $500.0 million towards the further development and commercialization of AIP to the extent the funding is required by the collaboration. In the event that either an AIP product reaches market and Janssen AI is in a positive operating cash flow position, or the AIP is terminated

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before the initial $500.0 million funding commitment has been spent, Johnson & Johnson is not required to contribute the full $500.0 million. As of December 31, 2011, the remaining unspent amount of the Johnson & Johnson $500.0 million funding commitment was $57.6 million (2010: $272.0 million), which reflects the $214.4 million utilized in 2011 (2010: $179.0 million). Any required additional expenditures in respect of Janssen AI s obligations under the AIP collaboration in excess of the initial $500.0 million funding commitment is required to be funded by Elan and Johnson & Johnson in proportion to their respective shareholdings up to a maximum additional commitment of $400.0 million in total. Based on current spend levels, we anticipate that we will be called upon to provide funding to Janssen AI commencing in the second quarter of 2012. In the event that further funding is required beyond the $400.0 million, such funding will be on terms determined by the board of Janssen AI, with Johnson & Johnson and Elan having a right of first offer to provide additional funding. If we fail to provide our share of the $400.0 million commitment or any additional funding that is required for the development of the AIP, and if Johnson & Johnson elects to fund such an amount, our interest in Janssen AI could, at the option of Johnson & Johnson, be commensurately reduced. 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% equity interest in Janssen AI, Johnson & Johnson exercises effective control over Janssen AI and consequently over our share of the AIP collaboration. As a result of the Johnson & Johnson Transaction, our financial interest in the AIP collaboration has been reduced from approximately 50% to approximately 25%. The success of the AIP collaboration 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 successful development and commercialization of bapineuzumab and other potential AIP products.

Under the terms of the Johnson & Johnson Transaction, in general, we are entitled to a 49.9% share of all net profits generated by Janssen AI beginning from the date Janssen AI becomes net profitable, 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 Johnson & Johnson s (up to) $500.0 million initial investment. Any such payments are dependent on the future commercial success of bapineuzumab and other potential AIP products. If no drug is successfully developed and commercialized, we may not receive any profit or royalty payments from Janssen AI.

Almost all of our investments are shares of Alkermes plc which we are restricted in transferring or disposing.

We own approximately 25% of the outstanding shares of Alkermes plc, which acquired our EDT business on September 16, 2011. The transfer or disposition of these shares is restricted by securities law and by contract. We do not know when or whether we will be able to dispose of these Alkermes plc shares, or, if we can dispose of these shares, what value we will receive for these Alkermes plc shares. If the value of Alkermes plc shares should fall substantially before we can dispose of our holdings of Alkermes plc shares, then the market value of our investment in Alkermes plc shares will be commensurately reduced.

Our 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 us. We also compete with smaller research companies and generic and biosimilar drug manufacturers. In addition, our collaborator on *Tysabri*, Biogen Idec, markets a competing MS therapy, Avonex® and has another potentially competitive MS therapy (BG-12) in late stage development.

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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 or biosimilar products. The price of pharmaceutical products typically declines as competition increases. *Tysabri* sales may be very sensitive to additional new competing products (in particular, from oral therapies approved or filed for U.S. and European approvals or under development). If these products have a similar or more attractive overall profile in terms of efficacy, convenience and/or safety, future sales of *Tysabri* could be adversely impacted.

Generic and biosimilar 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 less for a competing version of a product. Managed care organizations (MCOs) 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 or biosimilar products may rapidly and significantly reduce, or slow the growth in, the sales and profitability of any 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 or biosimilar versions of products, has had and may have a material and adverse effect on our revenues and results of operations.

Our competitive position depends, in part, upon our continuing ability to discover, acquire and develop innovative, cost-effective new products, as well as new indications and product improvements, and to protect all of this with patents and other intellectual property rights. We also compete on the basis of price and product differentiation. 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 obtain 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 in our industry and obtaining regulatory approvals, it is very important to obtain patent and other intellectual property protection for new technologies, products and processes. Our success depends in large part on our continued ability to obtain patents for 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 valid and enforceable proprietary rights of third parties.

The degree of patent protection that will be afforded to technologies, products and processes, including ours, in the United States and in other markets is dependent upon the scope of protection provided 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 with 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 or biosimilar 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 valid and enforceable 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 product or technologies. In addition, third parties may be able to obtain patents that prevent the sale or use 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 and business operations. Our competitors have sued and may sue us or our collaborators as a means of delaying the introduction of products, or to extract royalties against a marketed product. Any litigation, interference proceedings, re-examinations or oppositions against us or our licensors, may

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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 there are significant delays in the manufacture or supply of Tysabri or in the supply of raw materials for Tysabri, then sales of Tysabri could be materially and adversely affected.

Biogen Idec manufactures *Tysabri.* Our dependence upon Biogen Idec for the manufacture of *Tysabri* may result in unforeseen delays or other problems beyond our control. For example, if Biogen Idec is not in compliance with current good manufacturing practices (cGMP) or other applicable regulatory requirements, then the supply of *Tysabri* could be materially and adversely affected. If Biogen Idec experiences delays or difficulties in producing *Tysabri*, then sales of *Tysabri* could be materially and adversely affected. Biogen Idec requires supplies of raw materials for the manufacture of *Tysabri*. Biogen Idec does not have dual sourcing of all required raw materials. The inability to obtain sufficient quantities of required raw materials could materially and adversely affect the supply of *Tysabri*.

We are subject to pricing pressures and uncertainties regarding healthcare reimbursement and reform.

In the United States, many pharmaceutical products and biologics are subject to increasing pricing pressures. Our ability to commercialize products successfully depends, in part, upon the extent to which healthcare providers are reimbursed by third-party payers, such as governmental agencies, including the Centers for Medicare and Medicaid Services, private health insurers and other organizations, such as health maintenance organizations (HMOs), for the cost of such products and related treatments. In addition, if healthcare providers do not view current or future Medicare reimbursements for our products favorably, then they may not prescribe our products. Third party payers are increasingly challenging the pricing of pharmaceutical products by, among other things, limiting the pharmaceutical products that are on their formulary lists. As a result, competition among pharmaceutical companies to place their products on these formulary lists has reduced product prices. If reasonable reimbursement for our products is unavailable or if significant downward pricing pressures in the industry occur, then we could be materially and adversely affected.

The Obama Administration and the Congress in the United States have significantly changed U.S. healthcare law and regulation, which may change the manner by which drugs and biologics are developed, marketed and purchased. In addition, MCOs, 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. Many countries are seeking to reduce their public expenditures on healthcare. These efforts may result in patient access restrictions, increased pressure on drug pricing, including denial of price increases, prospective and retrospective price decreases and increased mandatory discounts or rebates. For instance, a revenue reserve of $14.1 million was recorded in 2011 on *Tysabri* in-market sales in Italy, arising from a disagreement between Biogen Idec and the Italian Medicines Agency on a contract interpretation of a limit established by the agency in 2007. The revenue reserve is discussed further on page 40. The sovereign debt crisis in Europe and elsewhere may accelerate efforts by governments to cut public expenditures on healthcare. These efforts may negatively impact *Tysabri*.

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We settled with the U.S. government with respect to its investigation of the marketing practices concerning our former Zonegran product which required us to pay $203.5 million in criminal and civil fines and penalties and take other actions that could have a material adverse effect on us.

In December 2010, we resolved all aspects of the U.S. Department of Justice s investigation of sales and marketing practices for Zonegran, an antiepileptic prescription medicine that we divested in 2004. In the first quarter of 2011, we paid $203.5 million pursuant to the terms of a global settlement of all U.S. federal and related state Medicaid claims. In addition, we pleaded guilty to a misdemeanor violation of the U.S. Federal Food Drug & Cosmetic Act (FD&C Act) and entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services to promote our compliance with the requirements of U.S. federal healthcare programs and the FDA. If we materially fail to comply with the requirements of U.S. federal healthcare programs or the FDA, or otherwise materially breach the terms of the Corporate Integrity Agreement, such as by a material breach of the compliance program or reporting obligations of the Corporate Integrity Agreement, severe sanctions could be imposed upon us. This resolution of the Zonegran investigation could give rise to other investigations or litigation by state government entities or private parties.

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

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, bribery 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, we and other pharmaceutical companies have settled charges under the federal False Claims Act, and related state laws, relating to off-label promotion. We are now operating under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services to promote our compliance with the requirements of U.S. federal healthcare programs and the FDA. If we materially fail to comply with the requirements of U.S. federal healthcare programs or the FDA, or otherwise materially breach the terms of the Corporate Integrity Agreement, such as by a material breach of the compliance program or reporting obligations of the Corporate Integrity Agreement, severe sanctions could be imposed upon us. 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.

The Foreign Corrupt Practices Act (FCPA) and the United Kingdom Bribery Act (U.K. Bribery Act) prohibits companies and their representatives from offering, promising, authorizing or making payments to foreign officials (and some private individuals under the U.K. Bribery Act) for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we interact with may meet the

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definition of a foreign government official for purposes of the FCPA. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, the imposition of civil or criminal sanctions and the prosecution of executives overseeing our international operations.

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

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

We must obtain and maintain approval for 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, including regulations issued by the EMA for the European Union. Any finding by the FDA, the EMA 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, the EMA or other regulatory agency could also affect our ability to obtain new approvals until such issues are resolved. The FDA, the EMA and other regulatory authorities conduct scheduled periodic regulatory inspections of facilities to ensure compliance with cGMP regulations. Any determination by the FDA, the EMA 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 product supply.

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 and result in 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.

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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 a product that is 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.

For manufacturers 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 (PHS) 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 PHS, 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 *Tysabri*, which is covered by Medicare Part B (primarily injectable or infused products). We submit ASP information for *Tysabri* 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 *Tysabri*. 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, in particular with respect to Tysabri, which could cost us material amounts of money.

Risks relating to product liability claims are inherent in the development, manufacturing and marketing of products. Any person who is injured while using our product, or products that we are responsible for, may have a product liability claim against us. Since we distribute a product to a wide number of end users, the risk of such claims could be material. Persons who participate in our clinical trials may also bring liability claims. We are a defendant in product liability actions related to products that Elan marketed. In addition, we are defendants in

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product liability lawsuits arising out of serious adverse events, including deaths, that occurred in patients taking *Tysabri*. We expect additional product liability lawsuits related to *Tysabri* usage to be filed. While we intend to vigorously defend these lawsuits, we cannot predict how these cases will be resolved. Adverse results in one or more of these cases could result in substantial monetary judgments against us.

Excluding any self-insured arrangements, we 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 $140.0 million. Our current 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 product 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 were 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 were named as defendants in five putative class action lawsuits filed in the U.S. District Court for the Southern District of New York in 2008. The cases have been consolidated. The plaintiffs Consolidated Amended Complaint was filed on August 17, 2009, and alleged claims under the U.S. federal securities laws and sought damages on behalf of all purchasers of our stock during periods ranging between May 21, 2007 and October 21, 2008. The complaint alleged that we issued false and misleading public statements concerning the safety and efficacy of bapineuzumab. In July 2010, a second securities case was filed in the U.S. District Court for the Southern District of New York, as a related case to the existing 2008 matter, by purchasers of Elan call options during the period of June and July 2008. These cases have been dismissed with prejudice by the trial court, but an appeal has been filed to the 2nd Circuit by the plaintiffs in the related case. Adverse results in this lawsuit or in any litigation to which we are a party could have a material adverse affect on us.

Our sales and operations are subject to the risks of fluctuations in currency exchange rates and to the risk of a partial or total collapse of the euro.

Our headquarters are in Ireland and three of the major markets for *Tysabri* are Germany, France and Italy. As a result, changes in the exchange rate between the U.S. dollar and the euro can have significant effects on our results of operations. In addition, the partial or total collapse of the euro would cause severe and adverse consequences to sales of *Tysabri* in Europe and to reimbursements for sales of *Tysabri* in Europe.

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;

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;

The Corporate Integrity Agreement that we entered into with the U.S. government with respect to the settlement of the Zonegran matter contains provisions that may require any acquirer to assume the

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obligations imposed by the Corporate Integrity Agreement, which may limit our attractiveness to a potential acquirer; 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 & Development of the Company

Elan Corporation, plc, an Irish public limited company, is a leading neuroscience-based biotechnology company, listed on the New York and Irish Stock Exchanges, and headquartered in Dublin, Ireland. Elan was 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: 011-353-1-709-4000).

Elan is focused on discovering and developing advanced therapies in neurodegenerative and autoimmune diseases, and in realizing the potential of our scientific discoveries to benefit patients and shareholders. As of December 31, 2011, we employed over 400 people. Our principal R&D facilities are located in the United States.

Tysabri, a treatment for MS and Crohn s disease that we market and distribute with Biogen Idec, had over $1.5 billion in global in-market sales in 2011. Almost all of those sales were in relation to the MS indication.

On September 16, 2011, we completed the sale of our EDT business to Alkermes, Inc. EDT and Alkermes, Inc. were combined under a new holding company incorporated in Ireland named Alkermes plc. In connection with the transaction, we received $500.0 million in cash and 31.9 million ordinary shares of Alkermes plc. As of December 31, 2011, we held approximately 25% of the equity of Alkermes plc. For additional information on this transaction, refer to Note 5 to the Consolidated Financial Statements.

For information on our principal expenditures on property, plants and equipment, see Item 4D. Property, Plant & Equipment. For information on our significant investments in R&D, see Item 5C. Research and Development, Patents and Licenses, etc. For information on our significant investments in other companies, refer to Note 9 to the Consolidated Financial Statements.

B. Business Overview

Elan s business focuses on neurodegenerative diseases, such as Alzheimer s disease and Parkinson s disease; autoimmune diseases, including MS and Crohn s disease and neo-epitope based targets for treatments across a broad range of therapeutic indications.

We made significant changes during 2011, which resulted in a more refined focus on neuroscience. Facilitated by the sale of our EDT business, we reduced the total principal amount of our debt by 51%. We achieved revenue growth of over 19% on a pro forma basis (see page 38 for a reconciliation of Elan s total GAAP revenues to pro forma Elan revenues) and remained disciplined on cost. Finally, we made progress on *Tysabri*, particularly in relation to the awareness of the benefits and risks associated with taking this drug.

Tysabri

Tysabri, an alpha-4 integrin inhibitor invented by Elan scientists and available since 2006, continues to be a successful therapy for MS, a neurological disorder involving central nervous system dysfunction among adults.

Tysabri is approved in more than 65 countries. *Tysabri* is approved in the United States as a monotherapy for relapsing forms of MS, generally for patients who have had an inadequate response to, or are unable to tolerate, an alternative MS therapy. In the European Union, it is approved for highly active relapsing-remitting MS (RRMS) in adult patients who have failed to respond to beta interferon or have rapidly evolving, severe RRMS.

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Tysabri has advanced the treatment of MS patients with its established efficacy. Data from the Phase 3 AFFIRM trial, which was published in the *New England Journal of Medicine*, showed that after two years, *Tysabri* treatment led to a 68% relative reduction ($p<0.001$) in the annualized relapse rate when compared with placebo and reduced the relative risk of disability progression by 42% to 54% ($p<0.001$).

We continue to work closely with our collaborator on *Tysabri*, Biogen Idec, as well as the clinical and scientific communities, to generate significant understanding in both efficacy and safety of the therapy so it may be positioned for the clinical benefit of patients.

As of December 31, 2011, there were approximately 64,400 patients on *Tysabri* therapy worldwide, compared to 57,200 patients as of December 31, 2010, which represents an increase of 13%. In 2011, global in-market sales of *Tysabri* exceeded $1.5 billion and constituted approximately 12% of the global MS market by value.

Tysabri increases the risk of PML, an opportunistic viral infection of the brain which usually leads to death or severe disability. Infection by the JCV is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. Recent studies suggest that irrespective of MS treatment, approximately 55% of MS patients are anti-JCV antibody positive. Factors that increase the risk of PML are presence of anti-JCV antibodies, prior IS use, and longer *Tysabri* treatment duration. Patients who have all three risk factors have the highest risk of developing PML. Other serious adverse events that have occurred in *Tysabri*-treated patients include hypersensitivity reactions (for example, anaphylaxis) and infections, including opportunistic and other atypical infections. Clinically significant liver injury has also been reported in the post-marketing setting.

In the United States, Europe and in other countries, programs are in place to inform patients of the risks associated with *Tysabri* therapy, including PML, and to enhance collection of post-marketing data on the safety and utilization of *Tysabr*i for MS. In 2011, we made significant progress in better understanding the risk of PML associated with *Tysabri* and in building awareness of *Tysabri* s benefit/risk profile.

Tysabri label updates provide a more informed benefit/risk analysis

Europe

In June 2011, the European Commission (EC) approved the inclusion of the anti-JCV antibody status as an additional factor in stratifying patients at risk for developing PML in the Summary of Product Characteristics (SmPC) for *Tysabri* in the European Union. In addition, as part of a standard review process, the EC concluded the quality, safety and efficacy of *Tysabri* continues to be adequately demonstrated, and renewed *Tysabri* s five year marketing authorization in the EU.

The new SmPC language states that patients who are anti-JCV antibody positive are at an increased risk of developing PML compared to patients who are anti-JCV antibody negative. The SmPC language also states that patients who are anti-JCV antibody positive, have received prior IS therapy, and have received treatment with *Tysabri* for more than two years have the highest risk of developing PML.

This update to the SmPC was based on analysis of data from Biogen Idec s and Elan s quantitative risk stratification algorithm, which was presented at a number of major international medical meetings. The analysis showed that patients who were anti-JCV antibody negative were at a lower risk for developing PML. Patients who were anti-JCV antibody positive had varying degrees of risk for developing PML, depending on prior IS use and *Tysabri* treatment duration. The revised SmPC will enable a more informed benefit vs risk discussion between patients and physicians, ultimately better stratifying the risk for those on or considering *Tysabri* as an appropriate therapy.

United States

We also made progress to stratify PML risk for MS patients in the United States. In January 2012, the FDA approved an update to the Prescribing Information for *Tysabri* to include anti-JCV antibody status as a factor to

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help stratify the risk of PML in the *Tysabri*-treated population. The inclusion of anti-JCV antibody status as a risk factor along with prior IS use and treatment duration enables the identification of differing levels of risk and provides the information patients and physicians need to make a more informed treatment decision.

We developed a two-step enzyme-linked immunosorbent assay (ELISA) called STRATIFY JCV with Biogen Idec. The assay detects anti-JCV antibodies in the blood of patients, and is widely commercially available in Europe. In January 2012, the FDA cleared the assay for commercial use in the United States. As of December 31, 2011, over 80,000 tests had been administered using the assay.

Advancement with *Tysabri* risk stratification in 2011 exceeded our expectations, and is facilitating a more personalized approach to treatment selection.

Tysabri is marketed and distributed by Elan and Biogen Idec. For full prescribing information and more information about *Tysabri,* please visit www.elan.com or www.biogenidec.com. Information about *Tysabri* treatment for MS, including important safety information, is available at www.Tysabri.com.

Tysabri for Secondary Progressive Multiple Sclerosis

In 2011, Elan and Biogen Idec initiated patient enrollment in ASCEND, a Phase 3 trial to test the effectiveness of *Tysabri* treatment on the reduction of disability progression in subjects with secondary progressive MS.

Science, Discovery and Translational Medicine

We started an initiative in 2010 to build the next generation of science and discovery, which continues today and is facilitated by our new business structure.

As part of this initiative, we established the Parkinson s disease genetics (PDG) group which researches fundamental pathways of Parkinson s biology, genetics-based animal models, and structural characterization of genetic targets for drug design. A separate research group, which is called Neotope, is focused on creating novel monoclonal antibodies based on neo-epitope targets for the treatment of a broad range of therapeutic indications.

We plan to continue to make measured and disciplined investment in our Alzheimer s disease and MS pipelines and to continue to utilize external collaborations and relationships to enhance our focus on scientific discovery, which is our key strength.

Alzheimer s Disease Programs

Our Scientific Approach

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 research and our commitment to creating new therapeutic opportunities for patients desperately in need of them.

Our scientific approach to treating Alzheimer s disease has focused principally on beta amyloid. The process by which this protein is generated, aggregates and is ultimately deposited in the brain 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, also known as Abeta, is a small part of a larger protein called the amyloid precursor protein (APP). Beta amyloid is formed when certain enzymes called secretases clip (or cleave) APP. It is becoming increasingly clear that once beta amyloid is released, it exists in multiple physical forms with distinct functional activities. It is believed that the toxic effects of these forms may be involved in the complex cognitive, functional and behavioral deficits characteristic of Alzheimer s disease.

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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 (intravenous and subcutaneous delivery) 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).

As part of the Johnson & Johnson Transaction in 2009, Janssen AI, a subsidiary of Johnson & Johnson, acquired substantially all of our assets and rights related to the AIP collaboration. Under the terms of this transaction, Johnson & Johnson provided an initial $500 million funding to Janssen AI and we have a 49.9% shareholding in Janssen AI. In general, we are entitled to a 49.9% share of all net profits generated by Janssen AI beginning from the date Janssen AI becomes net profitable and certain royalty payments upon the commercialization of products under the AIP collaboration. As of December 31, 2011, the remaining unspent amount of the $500.0 million funding commitment was $57.6 million. Based on current spend levels, we expect that we will be called upon to provide funding to Janssen AI commencing in the second quarter of 2012.

In January 2011, Johnson & Johnson and Pfizer reported that enrollment was completed for the North American Phase 3 trials and sub-studies of bapineuzumab. 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. Johnson & Johnson now anticipates that the North American bapineuzumab Phase 3 trials will be completed in 2012 and Phase 3 rest of world trials will be completed in 2014.

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ELND005, an Aß aggregation inhibitor

In 2006, we entered into an exclusive, worldwide collaboration with Transition Therapeutics, Inc. (Transition) for the joint development and commercialization of a novel therapeutic agent for Alzheimer s disease. The small molecule ELND005 (Scyllo-inositol) 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 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 or reducing plaque deposition.

In December 2010, we modified our Collaboration Agreement with Transition and as a result, Transition is no longer funding any continuing development or commercialization of ELND005 and has relinquished its 30% ownership of ELND005 to Elan. Under the modified agreement, we paid Transition $9.0 million in January 2011. While Transition is still eligible to receive a further $11.0 million payment upon the commencement of the next ELND005 clinical trial, it is no longer eligible to receive a $25.0 million milestone that would have been due upon the commencement of a Phase 3 trial for ELND005, under the terms of the original agreement.

In July 2011, Elan presented data from the Phase 2 clinical trial of ELND005 in mild to moderate Alzheimer s disease patients at the Alzheimer s Association International Conference 2011. Poster presentations on the safety and efficacy results of the Phase 2 randomized, placebo-controlled, dose-ranging study of ELND005 in mild to moderate Alzheimer s disease and on the population pharmacokinetic analysis of plasma, cerebrospinal fluid (CSF) and brain ELND005 in patients with mild to moderate Alzheimer s disease were presented. An oral presentation on imaging and cerebrospinal fluid biomarker results of a Phase 2 dose-ranging study of ELND005 in mild to moderate Alzheimer s disease was also presented.

In November 2011, ELND005 was featured during four oral presentations and on two posters, at the 4th Conference on Clinical Trials on Alzheimer s disease, where new analyses were presented from the Phase 2 Alzheimer s disease study. The presentations focused on treatment effects at earlier stages of the disease, using validated composite cognitive endpoints. These results support the general direction of the field for earlier intervention. In addition, data on ELND005 s role in reducing the emergence of neuropsychiatric symptoms in Alzheimer s patients was highlighted. The results of the Phase 2 clinical study data of ELND005 in mild to moderate Alzheimer s disease were published in *Neurology*, the peer-reviewed journal, in September 2011.

ELND005 may have additional applications in psychiatric indications such as bipolar disorder. Our goal is to initiate a proof of concept Phase 2 study in bipolar disorder in 2012, post-completion of discussions with therapeutic area experts and regulators.

In November 2011, we entered into a manufacturing agreement for the supply of the active pharmaceutical ingredient for ELND005 with Lonza Group AG.

Parkinson s Disease Genetics

Parkinson s disease is a slowly progressive disease of the nervous system and the second most common degenerative neurological disorder after Alzheimer s disease. In general, it affects one in 100 people over the age of 60, though people younger than this also live with the disease.

Elan s discovery approach, through our dedicated PDG group, is guided by our expertise in Alzheimer s disease research. The goal of our discovery efforts is to pursue a number of genetically validated targets that could prevent the neurodegenerative cascade associated with the Parkinson s disease and other neurological disorders.

Like many other neurodegenerative disorders, Parkinson s disease involves the formation and accumulation of misfolded proteins in the brain. Alpha-synuclein is a protein genetically linked to Parkinson s disease abnormal aggregates of alpha-synuclein, including fibrils and inclusions known as Lewy bodies, occur in degenerating neurons in brain regions controlling movement and can involve other regions of the brain as well. Alterations in alpha-synuclein are believed to play a critical role in Parkinson s disease.

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Our scientists are examining the different forms of alpha-synuclein and the role that they can play in normal and abnormal cellular functions, as well as the pathogenicity of alpha-synuclein in animal models of disease.

Parkin is 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 scientists continue the process of determining how parkin can regulate the processes of neurodegeneration.

In addition to our dedicated internal research group, in 2011, we expanded our collaborative effort with the University of Cambridge, and also began working with Proteostasis Therapeutics, Inc. (Proteostasis) to help us advance more quickly from the laboratory to the clinic.

Neotope Biosciences Limited

Neotope Biosciences Limited (Neotope) is our wholly owned subsidiary that focuses on the discovery and development of antibodies to neo-epitope related targets for the potential treatment of a broad range of indications including amyloidosis, diabetes, cancer and macular degeneration. Neotope s strategy is to apply its expertise in generating novel therapeutic antibodies working with a broad range of collaborators in specific disease models, to select candidates for further clinical development.

Approach

An epitope is the molecular target recognized by an antibody. A neo-epitope is formed upon a modification of a protein. Of particular interest are sites on proteins that become accessible only after modification, such as cleavage or other covalent modifications (for example, phosphorylation) or by misfolding into an abnormal shape. The neo-epitopes targeted by Neotope may occur as part of a disease-associated pathological process. For each neo-epitope target, Neotope is developing novel, specific monoclonal antibodies for the potential treatment of patients having a disease associated with the neo-epitope.

Programs

Neotope s portfolio of targets includes alpha-synuclein for the potential treatment of synucleinopathies, such as Lewy body dementia and Parkinson s disease, tau for Alzheimer s disease and other tauopathies. We also have a program for type 2-diabetes. Additional discovery efforts target other disease indications such as age-related macular degeneration and cancer.

Onclave Therapeutics Limited

Our wholly owned subsidiary Onclave Therapeutics Limited (Onclave) was formed to develop assets originating from Elan that have potential application in oncology related diseases. Onclave s lead program, NEOD001, which originated from Neotope, is being investigated for the potential treatment of AL amyloidosis, a fatal disease involving abnormal accumulation of amyloid in organs and tissue. In 2011, Onclave filed for orphan drug designation of NEOD001. Onclave s pipeline includes additional novel compounds with potential relevance in diverse cancer indications.

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Scientific Collaborations and Relationships

Cambridge-Elan Centre Parkinson s and Alzheimer s Disease Research

In November 2011, we launched a collaboration with the University of Cambridge, England, the Cambridge-Elan Centre for Research Innovation and Drug Discovery (Cambridge-Elan Centre). The goal of the Cambridge-Elan Centre is to discover novel compounds capable of altering the behavior of proteins associated with neurodegenerative disorders that can be developed into new treatments.

The Cambridge-Elan Centre will bring together Elan s more than two decades of experience in Alzheimer s research and our knowledge of biology and model systems with the University of Cambridge s pioneering contributions in the development of biophysical approaches to study the molecular basis of protein misfolding and aggregation, and their links to disease. This ten-year agreement paves the way for a long-term collaboration between the University of Cambridge and Elan.

Dublin Neurological Institute (DNI)

In November 2011, we entered into a sponsorship agreement with the DNI to provide financial support over a five year term for an initiative to support improved access and quality of neurological patient care in Ireland. The total financial support amount pledged by us to the DNI is 1.5 million.

University College Dublin (UCD)

In December 2011, we announced an initiative with UCD to support leadership in the global biotechnology industry, including the establishment of Europe s first interdisciplinary Chair in the Business of Biotechnology . The initiative is expected to run for at least seven years and will include a contribution in excess of 3 million from Elan.

Proteostasis

We entered into a strategic business relationship with Proteostasis in May 2011. Our $20.0 million equity interest in Proteostasis represented approximately 24% of the equity of Proteostasis at the time of the investment and has been recorded as an equity method investment on our Consolidated Balance Sheet. The net loss recorded on the equity method investment in 2011 was $2.7 million.

Proteostasis has expertise in protein turnover and biological pathways, central to diseases associated with neurodegeneration, and is a complementary fit for our vision and scientific direction in Parkinson s disease. It is anticipated that the collaborative agreement will enable discovery and development of disease-modifying small molecule drugs and diagnostics for the treatment of neurodegenerative disorders such as Parkinson s disease, Huntington s disease, MS and amyotrophic lateral sclerosis (ALS), and a broad array of dementia-related diseases including Alzheimer s.

ENVIRONMENT

The U.S. market is our most important market. Refer to Note 4 to the Consolidated Financial Statements for an analysis of revenue by geographic region. For this reason, the factors discussed below, such as Government Regulation and Product Approval, place emphasis on requirements in the United States.

Government Regulation

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

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

In addition, the U.S. Centers for Disease Control and Prevention regulate select biologics and toxins. This includes registration and inspection of facilities involved in the transfer or receipt of select agents. Select agents are subject to specific regulations for packaging, labeling and transport. Non-compliance with applicable requirements could result in criminal penalties and the disallowance of research and manufacturing of clinical products. Exemptions are provided for select agents used for a legitimate medical purpose or for biomedical research, such as toxins for medical use and vaccines.

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

In December 2010, we resolved all aspects of the U.S. Department of Justice s investigation of sales and marketing practices for Zonegran, an antiepileptic prescription medicine that we divested in 2004. In March 2011, we paid $203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims. As part of the agreement, our subsidiary Elan Pharmaceuticals, Inc. (EPI), pleaded guilty to a misdemeanor violation of the FD&C Act, and we entered into a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services to promote our compliance with the requirements of U.S. federal healthcare programs and the FDA. If we materially fail to comply with the requirements of U.S. federal healthcare programs or the FDA, or otherwise materially breach the terms of the Corporate Integrity Agreement, such as by a material breach of the compliance program or reporting obligations of the Corporate Integrity Agreement, severe sanctions could be imposed upon us. The resolution of the Zonegran investigation could give rise to other investigations or litigation by state government entities or private parties.

Product Approval

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

The clinical trial process can take three to ten years or more to complete, and there can be no assurance that the data collected will demonstrate that the product is safe or effective or, in the case of a biologic product, pure and potent, or will provide sufficient data to support FDA approval of the product. The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a license application such as a new drug application (NDA) or a Biologics License Application (BLA). In certain cases, an Abbreviated New Drug Application (ANDA) can be filed in lieu of filing an NDA.

There can be no marketing in the United States of any drug, biologic or device for which a marketing application is required until the application is approved by the FDA. Until an application is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA.

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Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval. The packaging and labeling of all products developed by us are also subject to FDA approval and ongoing regulation.

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable regulatory authorities in other countries outside the United States must be obtained prior to the marketing of the product in those countries. The approval procedure varies from country to country. It can involve additional testing and the time required can differ from that required for FDA approval. Although there are procedures for unified filings for E.U. countries, in general, most other countries have their own procedures and requirements.

Once a product has been approved, significant legal and regulatory requirements apply in order to market a product. In the United States, these include, among other things, requirements related to adverse event and other reporting, product advertising and promotion, and ongoing adherence to cGMP requirements, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Further, Elan s Corporate Integrity Agreement regulates certain aspects of current, and future, development and marketing of Elan products.

The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. We are also subject to Section 6002 of the Affordable Care Act (ACA), commonly known as the Physician Payment Sunshine Act (Sunshine Act) which regulates disclosure of payments to certain healthcare professionals and providers.

The FCPA and U.K. Bribery Act prohibit companies and their representatives from offering, promising, authorizing or making payments to foreign officials (and certain private individuals under the U.K. Bribery Act) for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we interact with may meet the definition of a foreign government official for purposes of the FCPA. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, the imposition of civil or criminal sanctions and the prosecution of executives overseeing our international operations.

Patents and Intellectual Property Rights

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

Tysabri is covered by issued patents and pending patent applications in the United States and other countries. A primary U.S. patent covering the humanized antibody expires in 2017. Additional U.S. patents and patent applications of Elan and/or our collaborator Biogen Idec covering (i) methods of use, including the use of *Tysabri* to treat MS, irritable bowel disease and a variety of other indications and (ii) methods of manufacturing *Tysabri*, generally expire between 2012 and 2023. Outside the United States, patents and pending patent applications covering *Tysabri*, methods of using *Tysabri* and methods of manufacturing *Tysabri* generally expire between 2014 and 2023. Patents in the United States and outside the United States may be granted additional patent term due to various mechanisms for obtaining patent term extensions. In addition to the noted patents, we and Biogen Idec have additional patents and pending patent applications covering various aspects of *Tysabri* that may confer additional patent protection.

In addition to our *Tysabri* collaboration with Biogen Idec, we have entered into licenses covering intellectual property related to *Tysabri*. We pay royalties under these licenses based upon the level of *Tysabri* sales. We may be required to enter into additional licenses related to *Tysabri* intellectual property. If these licenses are not available, or are not available on reasonable terms, we may be materially and adversely affected.

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Competition

The pharmaceutical industry is highly competitive. Our principal pharmaceutical competitors consist of major international companies, many of which are larger and have greater financial resources, technical staff, manufacturing, R&D and marketing capabilities than we have. We also compete with smaller research companies and generic drug and biosimilar manufacturers.

Tysabri, a treatment for relapsing forms of MS, competes primarily with Avonex marketed by our collaborator Biogen Idec, Betaseron® marketed by Berlex (an affiliate of Bayer Schering Pharma AG) in the United States and sold under the name Betaferon® by Bayer Schering Pharma in Europe, Rebif® marketed by Merck Serono and Pfizer in the United States and by Merck Serono in Europe, Copaxone® marketed by Teva Neurosciences, Inc. in the United States and co-promoted by Teva and Sanofi-Aventis in Europe and Novartis AG s Gilenya , an oral treatment for relapsing MS. Additional oral treatments for MS are awaiting regulatory approval or are under development, including BG-12, which is being developed by Biogen Idec. Many companies are working to develop new therapies or alternative formulations of products for MS that, if successfully developed, would compete with *Tysabri*.

A drug may be subject to competition from alternative therapies during the period of patent protection or regulatory exclusivity and, thereafter, it may be subject to further competition from generic products or biosimilars. Governmental and other pressures toward the dispensing of generic products or biosimilars may rapidly and significantly reduce, slow or reverse the growth in sales and profitability of any product not protected by patents or regulatory exclusivity, and may adversely affect our future results and financial condition. The launch of competitive products, including generic or biosimilar versions of our products, has had and may have a material adverse effect on our revenues and results of operations.

Our competitive position depends, in part, upon our continuing ability to discover, acquire and develop innovative, cost-effective new products, as well as new indications and product improvements protected by patents and other intellectual property rights. We also compete on the basis of price and product differentiation. If we fail to maintain our competitive position, our business, financial condition and results of operations may be materially and adversely affected.

Distribution

We sell *Tysabri* primarily to drug wholesalers. Our revenue reflects, in part, the demand from these wholesalers to meet the in-market consumption of *Tysabri* and to reflect the level of inventory that *Tysabri* wholesalers carry. Changes in the level of inventory can directly impact our revenue and could result in our revenue not reflecting in-market consumption of *Tysabri*.

Product Supply

Supplies are generally available in quantities adequate to meet the needs of our business. We are dependent on Biogen Idec to manufacture *Tysabri*. An inability to obtain product supply could have a material adverse impact on our business, financial condition and results of operations.

Employees

As of December 31, 2011, we had 412 employees worldwide, of whom 226 were engaged in R&D activities and the remainder worked in selling, marketing, general and administrative areas.

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C. Organizational Structure

At December 31, 2011, we had the following principal subsidiary undertakings:

Company	Nature of Business	Group Share %	Registered Office & Country of Incorporation
Athena Neurosciences, Inc.	Holding company	100	180 Oyster Point Blvd., South San Francisco, CA, USA
Crimagua Ltd.	Holding company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Holdings Ltd.	Holding company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan International Services Ltd.	Financial services company	100	Juniper House, 30 Oleander Hill, Smiths, FL-08, Bermuda
Elan Pharma International Ltd.	R&D, sale and distribution of pharmaceutical products, management services and financial services	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Pharmaceuticals, Inc.	R&D and sale of pharmaceutical products	100	180 Oyster Point Blvd., South San Francisco, CA, USA
Elan Science One Ltd.	Holding company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Elan Science Three Ltd.	Holding company	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Keavy Finance Ltd.	Dormant	100	Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland
Monksland Holdings BV	Holding company	100	Claude Debussylaan 24, 1082 MD, Amsterdam

D. Property, Plants and Equipment

We consider that our properties are in good operating condition and that our equipment has been well maintained.

For additional information, refer to Note 18 to the Consolidated Financial Statements, which discloses amounts invested in land and buildings and plant and equipment; Note 28 to the Consolidated Financial Statements, which discloses future minimum rental commitments; Note 29 to the Consolidated Financial Statements, which discloses capital commitments for the purchase of property, plant and equipment; and Item 5B. Liquidity and Capital Resources, which discloses our capital expenditures.

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

Location and Ownership Interest	Use	Size (Sq. Ft.)
Leased: South San Francisco, CA, USA	R&D, sales and administration	441,000[1]
Leased: King of Prussia, PA, USA	Former R&D and manufacturing facility	113,000[2]
Leased: Dublin, Ireland	Corporate administration	41,000

(1) *Approximately 66,636 square feet of laboratory and office space in South San Francisco, which was no longer being utilized by our R&D, sales and administrative functions is sublet to Janssen AI and is included in the 441,000 square feet noted above.*

(2) *The EDT facility in King of Prussia was closed in 2011. Approximately 25,000 square feet of this space was sublet in February 2012.*

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Item 4A. ***Unresolved Staff Comments.***
Not applicable.

Item 5. ***Operating and Financial Review and Prospects.***
The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements, the accompanying notes thereto and other financial information, appearing in Item 18. Consolidated Financial Statements.

Our Consolidated Financial Statements contained in this Form 20-F have been prepared on the basis of U.S. GAAP. In addition to the Consolidated Financial Statements contained in this Form 20-F, we also prepare separate Consolidated Financial Statements, included in our Annual Report, in accordance with IFRS, which differ in certain significant respects from U.S. GAAP. The Annual Report under IFRS is a separate document from this Form 20-F.

This financial review primarily discusses:

Current operations;

Critical accounting policies;

Recently issued accounting pronouncements;

Results of operations for the year ended December 31, 2011, compared to 2010 and 2009; and

Liquidity and capital resources.

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

CURRENT OPERATIONS

Elan is a neuroscience-based biotechnology company engaged in research, development and commercial activities primarily in the areas of Alzheimer s disease, Parkinson s disease and MS. For additional information on our current operations, refer to Item 4B. Business Overview.

CRITICAL ACCOUNTING POLICIES

The Consolidated Financial Statements include certain estimates based on management s best judgments. Estimates are used in determining items such as the carrying amounts of long-lived assets, our equity method investments, revenue recognition, estimating sales discounts and allowances, the fair value of share-based compensation, and the accounting for contingencies and income taxes, among other items. Because of the uncertainties inherent in such estimates, actual results may differ materially from these estimates.

Goodwill, Other Intangible Assets, Tangible Fixed Assets and Impairment

Total goodwill and other intangible assets amounted to $309.9 million at December 31, 2011 (2010: $376.5 million) and our property, plant and equipment had a carrying amount at December 31, 2011 of $83.2 million (2010: $287.5 million).

Goodwill is not amortized, but instead is reviewed for impairment at least annually.

Intangible assets with estimable useful lives are amortized on a straight-line basis over their respective estimated useful lives to their estimated residual values and, as with other long-lived assets such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset be tested for possible impairment, we compare undiscounted cash flows expected to be generated by an asset to the carrying amount of the asset. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. We

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determine fair value using the income approach based on the present value of expected cash flows. Our cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. If we were to use different estimates, particularly with respect to the likelihood of R&D success, the likelihood and date of commencement of generic competition or the impact of any reorganization or change of business focus, then a material impairment charge could arise. We believe that we have used reasonable estimates in assessing the carrying amounts of our intangible assets. The results of certain impairment tests on intangible assets with estimable useful lives are discussed below.

We review our goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. The goodwill impairment test is a two-step process and is performed at the reporting-unit level. A reporting unit is the same as, or one level below, an operating segment. Following the divestment of EDT on September 16, 2011, Elan is comprised of a single reporting unit.

We first assess qualitative factors to determine whether it is necessary to perform the two-step goodwill impairment test. The qualitative factors assessed include, but are not limited to, macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, other relevant events affecting the reporting unit and the share price performance of the Company. If, after assessing the relevant qualitative factors, we determine that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill, then the first and second steps of the goodwill impairment test are not performed. If, after assessing the relevant qualitative factors, we determine that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill, then the first step of the goodwill impairment test is performed.

Under the first step, we compare the fair value of each reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and step two does not need to be performed. If the carrying amount of a reporting unit exceeds its fair value, the second step of the goodwill impairment test would be performed to measure the amount of impairment charge, if any. The second step compares the implied fair value of the reporting-unit goodwill with the carrying amount of that goodwill, and any excess of the carrying amount over the implied fair value is recognized as an impairment charge. The implied fair value of goodwill is determined, by allocating the fair value of a reporting unit to individual assets and liabilities. The excess of the fair value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. In evaluating goodwill for impairment, we determine the fair values of the reporting units using the income approach, based on the present value of expected cash flows.

On September 16, 2011, Alkermes plc and Elan announced the completion of the merger between Alkermes, Inc. and EDT. As part of this transaction, we disposed of goodwill of $49.7 million which was allocated to the EDT reporting unit. We also disposed of patents, licenses, intellectual property and other intangible assets related to EDT with a net book value of $3.3 million and property, plant and equipment with a net book value of $202.0 million related to EDT.

We complete the annual goodwill impairment review on September 30 of each year. For the 2011 fiscal year annual goodwill impairment review, we assessed the relevant qualitative factors post-divestment of the EDT business and determined that it was not more likely than not that the fair value of the reporting unit was less than its carrying amount, including goodwill, so the first and second steps of the goodwill impairment test were not performed.

We performed the first step of the goodwill impairment test in 2010 and 2009 and the result of our tests did not indicate any impairment in either year. In addition, we performed a goodwill impairment test immediately subsequent to the disposal of the Prialt® business in May 2010 and the result of our tests did not indicate any impairment.

There were no material impairment charges relating to intangible assets in 2011 or 2010. In December 2009, we recorded an impairment charge of $30.6 million within other net charges in the Consolidated Statement of Operations relating to the Prialt intangible asset, thus reducing the carrying value of the intangible asset to

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$14.6 million. During 2010, we divested our Prialt assets and rights to Azur Pharma International Limited (Azur). We recorded a net loss of $1.5 million on this divestment. For additional information on goodwill and other intangible assets, refer to Note 19 to the Consolidated Financial Statements.

During 2011, we recorded a non-cash asset impairment charge of $10.0 million relating to property, plant and equipment, within other net charges in the Consolidated Statement of Operations which arose from the consolidation of our facilities in South San Francisco and the closure of EDT s King of Prussia, Pennsylvania, site.

In 2010, we recorded a non-cash asset impairment charge of $11.0 million related to a consolidation of facilities in South San Francisco as a direct result of a realignment of the BioNeurology business. Following the transfer of our AIP manufacturing rights as part of the sale of the AIP business to Janssen AI in 2009, we re-evaluated our longer term biologics manufacturing and fill-finish requirements, and consequently recorded a non-cash asset impairment charge, included as part of the net gain on divestment of business, related to these activities of $41.2 million. The assets relating to biologics manufacturing were written off in full.

Equity Method Investments

Janssen AI

As part of the transaction whereby Janssen AI, a subsidiary of Johnson & Johnson, acquired substantially all of our assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer), we received a 49.9% equity investment in Janssen AI. Johnson & Johnson also committed to fund up to an initial $500.0 million towards the further development and commercialization of the AIP to the extent the funding is required by the collaboration. We have recorded our investment in Janssen AI as an equity method investment on the Consolidated Balance Sheet as we have the ability to exercise significant influence, but not control, over the investee. The investment was initially recognized based on the estimated fair value of the investment acquired, representing the fair value of our proportionate 49.9% share of Janssen AI s total net assets at inception, which were comprised of the AIP assets and the asset created by the Johnson & Johnson contingent funding commitment.

As of December 31, 2011, the carrying value of our Janssen AI equity method investment of $130.6 million (2010: $209.0 million) was approximately $185 million (2010: $120 million) below our share of Janssen AI s reported book value of its net assets. This difference relates to the lower estimated value of Janssen AI s AIP assets when the equity method investment was initially recorded and the asset created by the Johnson & Johnson contingent funding commitment. In relation to the AIP assets, in the event that an AIP product reaches market, our proportionate share of Janssen AI s reported results will be adjusted over the estimated remaining useful lives of those assets to recognize the difference in the carrying values. In relation to the Johnson & Johnson contingent funding commitment asset, the differences in the carrying values is being amortized to the Consolidated Statement of Operations on a pro rata basis; based on the actual amount of Janssen AI losses that are solely funded by Johnson & Johnson in each period as compared to the total $500 million, which is the total amount we estimate will be solely funded by Johnson & Johnson.

During 2011, we recorded amortization expense of $50.9 million (2010: $26.0 million; 2009: $Nil) related to the basis differences between the cost of our equity method investment and the amount of our underlying equity in Janssen AI s reported net assets.

Under the equity method, investors are required to recognize their share of the earnings or losses of an investee in the periods for which they are reported in the financial statements of the investee as this is normally considered an appropriate means of recognizing increases or decreases in the economic resources underlying the investments. However, Johnson & Johnson has committed to wholly fund up to an initial $500.0 million of development and commercialization expenses by Janssen AI so the recognition by Elan of a share of Janssen AI losses that are solely funded by Johnson & Johnson s $500.0 million commitment would result in an inappropriate decrease in Elan s share of the economic resources underlying the investment in Janssen AI. Accordingly, until the $500.0 million funding commitment is fully utilized, we have applied the hypothetical liquidation at book value (HLBV) method to determine how an increase or decrease in net assets of Janssen AI affects Elan s interest in the net assets of Janssen AI on a period by period basis. Under the HLBV method, an

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investor determines its share of the earnings or losses of an investee by determining the difference between its claim on the investee s book value at the end and beginning of the period. After adjusting for the basis differences described above, Elan s claim on Janssen AI s book value as of December 31, 2011 was $117.3 million (2010: $117.3 million).

The net loss on the Janssen AI equity method investment for the year ended December 31, 2011 of $78.4 million (2010: $26.0 million; 2009: $Nil) was comprised of amortization expense of $50.9 million (2010: $26.0 million; $2009: $Nil) related to the basis differences described above and $27.5 million (2010: $Nil; 2009: $Nil) to correct an immaterial error from prior periods relating to our accounting for our equity method investment in Janssen AI.

As of December 31, 2011, the remaining unspent amount of the initial $500.0 million funding commitment was $57.6 million (2010: $272.0 million).

Alkermes plc and Proteostasis

We have recorded our investments in Alkermes plc and Proteostasis as equity method investments on the Consolidated Balance Sheet as we have the ability to exercise significant influence, but not control, over the investees. The investments were initially recognized based on the estimated fair value of the investment acquired. The carrying amount of the Alkermes equity method investment is approximately $300 million higher than our share of the book value of the net assets of Alkermes plc. Based on our preliminary assessment of the fair value of the net assets of Alkermes plc on the date of the transaction, this difference principally relates to identifiable intangible assets and goodwill attributable to the Alkermes Inc. business prior to its acquisition of EDT. Under the equity method, we recognize our share of the earnings or losses of our investees, adjusted for the amortization of basis differences, in the Consolidated Statement of Operations with a corresponding increase or decrease in the carrying amount of the investments on the Consolidated Balance Sheet. We recognize our share of the earnings or losses of Proteostasis in the same periods for which they are reported in the financial statements of the investee; and we recognize our share of the earnings or losses of Alkermes plc on a one-quarter time lag, as Alkermes plc s financial information is generally not publicly available when our quarterly and annual results are reported.

Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Up-front fees received by us are deferred and amortized when there is a significant continuing involvement by us (such as an ongoing product manufacturing contract or joint development activities) after an asset disposal. We defer and amortize up-front license fees to the income statement over the performance period. The performance period is the period over which we expect to provide services to the licensee as determined by the contract provisions. Accounting for milestone payments depends on the facts and circumstances of each contract. We apply the milestone method in accounting for substantive milestone payments under contracts that include R&D deliverables. A milestone is considered substantive if consideration earned from achievement of the milestone (1) is commensurate with either the vendor s performance to achieve the milestone or the enhancement of the value of the delivered item, (2) relates solely to past performance, and (3) is reasonable in comparison to all of the deliverables and payment terms in the arrangement. If a milestone is considered substantive the consideration is recognized as revenue in the period in which the milestone is achieved. It is expected that the substantive milestone method will be appropriate for most contracts. If we determine the substantive milestone method is not appropriate, we apply the proportional performance method to the relevant contract. This method recognizes as revenue the percentage of cumulative non-refundable cash payments earned under the contract, based on the percentage of costs incurred to date compared to the total costs expected under the contract.

Sales Discounts and Allowances

We recognize revenue on a gross revenue basis (except for *Tysabri* revenue outside of the United States) and make various deductions to arrive at net revenue as reported in the Consolidated Statements of Operations. These adjustments are referred to as sales discounts and allowances and are described in detail below. Sales discounts and allowances include charge-backs, managed healthcare rebates and other contract discounts,

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Medicaid rebates, cash and other discounts, sales returns and other adjustments. Estimating these sales discounts and allowances is complex and involves significant estimates and judgments, and we use information from both internal and external sources, including our historical experience, to generate reasonable and reliable estimates. We believe that we have used reasonable judgments in assessing our estimates, and this is borne out by our historical experience. At December 31, 2011, we had total provisions of $45.5 million for sales discounts and allowances, of which approximately 97%, 2% and 1% related to *Tysabri*, Maxipime® and Azactam®, respectively. We have almost six years of experience for *Tysabri* and we ceased distributing Maxipime on September 30, 2010 and Azactam on March 31, 2010, after more than 10 years experience with both products.

We do not conduct our sales using the consignment model. All of our product sales transactions are based on normal and customary terms whereby title to the product and substantially all of the risks and rewards transfer to the customer upon either shipment or delivery. Furthermore, we do not have an incentive program that would compensate a wholesaler for the costs of holding inventory above normal inventory levels, thereby encouraging wholesalers to hold excess inventory.

An analysis of the separate components of our revenue is set out in Item 5A. Operating Results, and in Note 3 to the Consolidated Financial Statements. The table below summarizes our sales discounts and allowances to adjust gross revenue to net revenue for each significant category (in millions).

	2011	2010	2009
Gross revenue subject to discounts and allowances	$ 936.6	$ 762.2	$ 698.9
Net *Tysabri* ROW revenue	317.6	258.3	215.8
Manufacturing revenue and royalties	170.7	263.0	258.9
Contract revenue	9.9	13.7	18.7
Gross revenue	$ 1,434.8	$ 1,297.2	$ 1,192.3
Sales discounts and allowances:			
Charge-backs	$ (116.4)	$ (71.2)	$ (39.7)
Medicaid rebates	(26.6)	(20.4)	(7.1)
Cash discounts	(25.5)	(18.7)	(16.7)
Managed healthcare rebates and other contract discounts	(7.4)	(3.9)	(1.2)
Sales returns	(0.7)	(2.0)	(4.2)
Other adjustments	(12.2)	(11.3)	(10.4)
Total sales discounts and allowances	$ (188.8)	$ (127.5)	$ (79.3)
Net revenue subject to discounts and allowances	747.8	634.7	619.6
Net *Tysabri* ROW revenue	317.6	258.3	215.8
Manufacturing revenue and royalties	170.7	263.0	258.9
Contract revenue	9.9	13.7	18.7
Net revenue	$ 1,246.0	$ 1,169.7	$ 1,113.0

Total sales discounts and allowances were 20.2% of gross revenue subject to discounts and allowances in 2011, 16.7% in 2010 and 11.3% in 2009, as detailed in the rollforward below and as further explained in the following paragraphs.

Charge-backs as a percentage of gross revenue subject to discounts and allowances were 12.4% in 2011, 9.3% in 2010 and 5.7% in 2009. The increases in 2011 and 2010 are due to the expansion of the 340(b) PHS program and the increase in the minimum discount extended to our 340(b) customers, both of which resulted from the U.S. healthcare reform legislation enacted through the Patient Protection Affordable Care Act (PPACA) in 2010. The increases are also attributable to increases in the discounts due to the changes in *Tysabri s* wholesaler acquisition cost price.

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The Medicaid rebates as a percentage of gross revenue subject to discounts and allowances were 2.8% in 2011, 2.7% in 2010 and 1.0% in 2009. The increases in 2011 and 2010 are primarily due to the extension of Medicaid rebates to drugs supplied to enrollees of Medicaid MCOs, the increase in the rebate due to wholesaler acquisition cost price changes in *Tysabri* and the increase in 2010 of the U.S. base Medicaid rebate from 15.1% to 23.1%. Both the increase in the U.S. base Medicaid rebate to 23.1% and the extension of the Medicaid rebates to drugs supplied to enrollees of MCOs were introduced by the U.S. healthcare reform legislation.

Cash and other discounts as a percentage of gross revenue subject to discounts and allowances were 2.7% in 2011, 2.5% 2010 and 2.4% in 2009. Cash and other discounts include cash discounts, generally at 2% of the sales price, as an incentive for prompt payment by customers in the United States.

The managed healthcare rebates and other contract discounts as a percentage of gross revenue subject to discounts and allowances were 0.8% in 2011, 0.5% in 2010 and 0.2% 2009. The increase is primarily attributable to the increase in the number of qualified patients that are eligible for the *Tysabri* patient co-pay assistance program.

Sales returns as a percentage of gross revenue subject to discounts and allowances were 0.1% in 2011, 0.3% in 2010 and 0.6% in 2009. The decrease from 0.3% in 2010 to 0.1% in 2011 is primarily attributable to the changes in the product mix during 2010.

The following table sets forth the activities and ending balances of each significant category of adjustments for the sales discounts and allowances (in millions):

	Charge-Backs	Medicaid Rebates	Cash and other Discounts	Managed Healthcare Rebates and Other Contract Discounts	Sales Returns	Other Adjustments	Total
Balance at December 31, 2009	$ 5.6	$ 8.9	$ 2.0	$ 0.6	$ 7.8	$ 1.6	$ 26.5
Provision related to sales made in current period	71.2	20.4	18.7	3.9	2.4	11.3	127.9
Provision related to sales made in prior periods					(0.4)		(0.4)
Returns and payments	(69.6)	(10.8)	(17.9)	(3.9)	(3.5)	(10.4)	(116.1)
Balance at December 31, 2010	$ 7.2	$ 18.5	$ 2.8	$ 0.6	$ 6.3	$ 2.5	$ 37.9
Provision related to sales made in current period	116.4	26.6	25.5	7.4	2.4	12.2	190.5
Provision related to sales made in prior periods					(1.7)		(1.7)
Returns and payments	(117.3)	(17.2)	(25.3)	(6.6)	(1.9)	(12.9)	(181.2)
Balance at December 31, 2011	$ 6.3	$ 27.9	$ 3.0	$ 1.4	$ 5.1	$ 1.8	$ 45.5

(a) Charge-backs

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

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accounts receivable and revenue periodically throughout each year to reflect actual and future estimated experience.

As described above, there are a number of factors involved in estimating the accrual for charge-backs, but the principal factor relates to our estimate of the levels of inventory in the wholesale distribution channel. At December 31, 2011, *Tysabri*, represented approximately 99.7% of the total charge-backs accrual balance of $6.3 million. If we were to increase our estimated level of inventory in the wholesale distribution channel by one month s worth of demand for *Tysabri,* the accrual for charge-backs would increase by approximately $12.1 million. We believe that our estimate of the levels of inventory for *Tysabri,* in the wholesale distribution channel is reasonable because it is based upon multiple sources of information, including data received from all of the major wholesalers with respect to their inventory levels and sell-through to customers, third-party market research data, and our internal information.

(b) Medicaid rebates

In the United States, we are required by law to participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating state and local government entities. Discounts and rebates provided through these other qualifying federal and state government programs are included in our Medicaid rebate accrual and are considered Medicaid rebates for the purposes of this discussion. We account for Medicaid rebates by establishing an accrual in an amount equal to our estimate of Medicaid rebate claims attributable to a sale. We determine our estimate of the Medicaid rebates accrual primarily based on our estimates of Medicaid claims, Medicaid payments, claims processing lag time, inventory in the distribution channel as well as legal interpretations of the applicable laws related to the Medicaid and qualifying federal and state government programs, and any new information regarding changes in the Medicaid programs regulations and guidelines that would impact the amount of the rebates on a product-by-product basis. We consider outstanding Medicaid claims, Medicaid payments, claims processing lag time and estimated levels of inventory in the distribution channel and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience. At December 31, 2011, *Tysabri* represented approximately 98.8% of the total Medicaid rebates accrual balance of $27.9 million.

(c) Cash and other discounts

Cash and other discounts include cash discounts, generally at 2% of the sales price, as an incentive for prompt payment by customers in the United States. We account for cash and other discounts by reducing accounts receivable by the full amount of the discounts. We consider factors such as the payment performance of each customer and adjust the accrual and revenue periodically throughout each year to reflect actual experience and future estimates.

(d) Managed healthcare rebates and other contract discounts

We offer rebates and discounts to managed healthcare organizations in the United States. We account for managed healthcare rebates and other contract discounts by establishing an accrual equal to our estimate of the amount attributable to a sale. We determine our estimate of this accrual primarily based on historical experience on a product-by-product and program basis and current contract prices. We consider the sales performance of products subject to managed healthcare rebates and other contract discounts, processing claim lag time and estimated levels of inventory in the distribution channel and adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

(e) Sales returns

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

Our sales returns accrual is estimated principally based on historical experience, the estimated shelf life of inventory in the distribution channel, price increases and our return goods policy (goods may only be returned six

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months prior to expiration date and for up to 12 months after expiration date). We also take into account product recalls and introductions of generic products. All of these factors are used to adjust the accrual and revenue periodically throughout each year to reflect actual and future estimated experience.

In the event of a product recall, product discontinuance or introduction of a generic product, we consider a number of factors, including the estimated level of inventory in the distribution channel that could potentially be returned, historical experience, estimates of the severity of generic product impact, estimates of continuing demand and our return goods policy. We consider the reasons for, and impact of, such actions and adjust the sales returns accrual and revenue as appropriate.

As described above, there are a number of factors involved in estimating this accrual, but the principal factor relates to our estimate of the shelf life of inventory in the distribution channel. We believe, based upon both the estimated shelf life and also our historical sales returns experience, that the vast majority of this inventory will be sold prior to the expiration dates, and accordingly believe that our sales returns accrual is appropriate. At December 31, 2011, 80.2% of the total sales returns accrual balance of $5.1 million related to *Tysabri*.

During 2011, we recorded adjustments of $1.7 million (2010: $0.4 million) to decrease the sales returns accrual related to sales made in prior periods.

(f) Other adjustments

In addition to the sales discounts and allowances described above, we make other sales adjustments primarily related to estimated obligations for credits to be granted to wholesalers under wholesaler service agreements we have entered into with many of our pharmaceutical wholesale distributors in the United States. Under these agreements, the wholesale distributors have agreed, in return for certain fees, to comply with various contractually defined inventory management practices and to perform certain activities such as providing weekly information with respect to inventory levels of product on hand and the amount of out-movement of product. As a result, we, along with our wholesale distributors, are able to manage product flow and inventory levels in a way that more closely follows trends in prescriptions. We generally account for these other sales discounts and allowances by establishing an accrual in an amount equal to our estimate of the adjustments attributable to the sale. We generally determine our estimates of the accruals for these other adjustments primarily based on contractual agreements and other relevant factors, and adjust the accruals and revenue periodically throughout each year to reflect actual experience.

(g) Use of information from external sources

We use information from external sources to identify prescription trends and patient demand, including inventory pipeline data from three major drug wholesalers in the United States. The inventory information received from these wholesalers is a product of their record-keeping process and excludes inventory held by intermediaries to whom they sell, such as retailers and hospitals. We also receive information from IMS Health, a supplier of market research to the pharmaceutical industry, which we use to project the prescription demand-based sales for our pharmaceutical products. Our estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information is itself in the form of estimates, and reflect other limitations, including lags between the date as of which third-party information is generated and the date on which we receive such information.

Share-Based Compensation

Share-based compensation expense for all equity-settled awards made to employees and directors is measured and recognized based on estimated grant date fair values. These awards include employee stock options, restricted stock units (RSUs) and stock purchases related to our employee equity purchase plan (EEPP). Share-based compensation cost for RSUs awarded to employees and directors is measured based on the closing fair market value of the Company s shares on the date of grant. Share-based compensation cost for stock options awarded to employees and directors and shares issued under the EEPP is estimated at the grant date based on

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each option s fair value as calculated using an option-pricing model. The value of awards expected to vest is recognized as an expense over the requisite service periods. In 2011, we recognized $35.3 million (2010 and 2009: $31.5 million) relating to equity-settled share-based compensation.

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

Estimating the fair value of share-based awards at grant or vest date using an option-pricing model, such as the binomial model, is affected by our share price as well as assumptions regarding a number of complex variables. These variables include, but are not limited to, the expected share price volatility over the term of the awards, risk-free interest rates, and actual and projected employee exercise behaviors. If factors change and/or we employ different assumptions in estimating the fair value of share-based awards in future periods, the compensation expense that we record for future grants may differ significantly from what we have recorded in the Consolidated Financial Statements. However, we believe we have used reasonable assumptions to estimate the fair value of our share-based awards.

For additional information on our share-based compensation, refer to Note 26 to the Consolidated Financial Statements.

Contingencies Relating to Actual or Potential Administrative and Legal Proceedings

We are currently involved in legal and administrative proceedings relating to securities matters, patent matters, product liability matters and other matters, some of which are described in Note 30 to the Consolidated Financial Statements. We assess the likelihood of any adverse outcomes to contingencies, including legal matters, as well as potential ranges of probable losses. We record accruals for such contingencies when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If an unfavorable outcome is probable, but the amount of the loss cannot be reasonably estimated, we estimate the range of probable loss and accrue the most probable loss within the range. If no amount within the range is deemed more probable, we accrue the minimum amount within the range. If neither a range of loss nor a minimum amount of loss is estimable, then appropriate disclosure is provided, but no amounts are accrued. As of December 31, 2011, we had accrued $0.7 million (2010: $207.0 million), representing our estimates of liability and costs for the resolution of these matters.

In March 2011, we paid $203.5 million relating to the agreement-in-principle announced in July 2010, which was finalized with the U.S. Attorney s Office for the District of Massachusetts in December 2010 to resolve all aspects of the U.S. Department of Justice s investigation of sales and marketing practices for Zonegran (zonisamide), an antiepileptic prescription medicine that we divested in 2004. At December 31, 2010, we held $203.7 million in an escrow account to cover the settlement amount and during 2010, we recorded a $206.3 million reserve charge for the settlement, interest and related costs. This resolution of the Zonegran investigation could give rise to other investigations or litigation by state government entities or private parties.

We developed estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances known to us. The factors that we consider in developing our legal contingency accrual include the merits and jurisdiction of the litigation, the nature and number of other similar current and past litigation cases, the nature of the product and assessment of the science subject to the litigation, and the likelihood of settlement and state of settlement discussions, if any. We believe that the legal contingency accrual that we have established is appropriate based on current factors and circumstances. However, it is possible that other people applying reasonable judgment to the same facts and circumstances could develop a different liability amount. The nature of these matters is highly uncertain and subject to change. As a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our estimates, depending on the outcome of these matters.

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Income Taxes

We account for income tax expense based on income before taxes using the asset and liability method. Deferred tax assets (DTAs) and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. DTAs are recognized for the expected future tax consequences, for all deductible temporary differences and operating loss and tax credit carryforwards. A valuation allowance is required for DTAs if, based on available evidence, it is more likely than not that all or some of the asset will not be realized due to the inability to generate sufficient future taxable income.

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

We recognize the tax benefit from an uncertain tax position only if it is more likely than not the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. We account for interest and penalties related to unrecognized tax benefits in income tax expense.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2011-08, Intangibles Goodwill and Other: Testing Goodwill for impairment (Topic 350) , which gives entities the option to first assess qualitative factors to determine whether it is more likely than not (that is, a likelihood of more than 50%) that the fair value of the reporting unit is less than its carrying amount, including goodwill. If, after assessing the relevant qualitative factors, we determine that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill, then the first and second steps of the goodwill impairment test are not performed. If, after assessing the relevant qualitative factors, we determine that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill, then the first step of the goodwill impairment test is performed. Previous guidance under Topic 350 required an entity to test goodwill for impairment, on at least an annual basis, by comparing the fair value of a reporting unit with its carrying amount, including goodwill (step one). If the fair value of a reporting unit is less than its carrying amount, then the second step of the test must be performed to measure the amount of the impairment loss, if any. The amendment in this update is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, but early adoption is permitted. We have early adopted the amendment for the 2011 fiscal year annual goodwill impairment review and after assessing the relevant qualitative factors, we determined that it was not more likely than not that the fair value of the reporting unit was less than its carrying amount, including goodwill, so the first and second steps of the goodwill impairment test were not performed.

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs , which results in common fair value measurement and disclosure requirements in U.S. GAAP and IFRS. The amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. Some of the amendments clarify the FASB s intent about the application of existing fair value measurement requirements while other amendments change a particular principle

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or requirement for measuring fair value or for disclosing information about fair value measurements. The amendments are effective for fiscal years beginning after December 15, 2011. We do not expect that the adoption of ASU 2011-04 will have an impact on our consolidated financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income , to improve the comparability, consistency, and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income/(loss) (OCI). To increase the prominence of items reported in OCI and to facilitate convergence of U.S. GAAP and IFRS, the FASB decided to eliminate the option to present components of OCI as part of the statement of changes in shareholders equity. The amendments require that all non-owner changes in shareholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total OCI, the components of OCI, and the total of comprehensive income. The amendments are effective for fiscal years beginning after December 15, 2011. We do not expect that the adoption of ASU 2011-05 will have an impact on our consolidated financial position, results of operations or cash flows.

A. RESULTS OF OPERATIONS

2011 Compared to 2010 and 2009 (in millions, except per share amounts)

				% Increase/(Decrease)	
	2011	**2010**	**2009**	**2011/2010**	**2010/2009**
Product revenue	$ 1,236.1	$ 1,156.0	$ 1,094.3	7%	6%
Contract revenue	9.9	13.7	18.7	(28)%	(27)%
Total revenue	1,246.0	1,169.7	1,113.0	7%	5%
Cost of sales	639.7	583.3	560.7	10%	4%
Gross margin	606.3	586.4	552.3	3%	6%
Operating expenses:					
Selling, general and administrative expenses	228.7	254.7	268.2	(10)%	(5)%
Research and development expenses	232.5	258.7	293.6	(10)%	(12)%
Net gain on divestment of business	(652.9)	(1.0)	(108.7)	65190%	(99)%
Other net (gains)/charges	(42.2)	56.3	67.3	(175)%	(16)%
Settlement reserve charge		206.3		(100)%	100%
Total operating (gains)/expenses	(233.9)	775.0	520.4	(130)%	49%
Operating income/(loss)	840.2	(188.6)	31.9	(545)%	(691)%
Net interest and investment gains and losses:					
Net interest expense	105.9	117.8	137.9	(10)%	(15)%
Net loss on equity method investments	81.8	26.0		215%	100%
Net charge on debt retirement	47.0	3.0	24.4	1467%	(88)%
Net investment gains	(2.6)	(12.8)	(0.6)	(80)%	2033%
Net interest and investment gains and losses	232.1	134.0	161.7	73%	(17)%
Net income/(loss) before income taxes	608.1	(322.6)	(129.8)	(288)%	149%
Provision for income taxes	47.6	2.1	46.4	2167%	(95)%
Net income/(loss)	$ 560.5	$ (324.7)	$ (176.2)	(273)%	84%
Basic net income/(loss) per Ordinary Share	$ 0.95	$ (0.56)	$ (0.35)	(270)%	60%

Diluted net income/(loss) per Ordinary Share	$ 0.94	$ (0.56)	$ (0.35)	(268)%	60%

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Pro Forma Reconciliation Non-GAAP Financial Information

The table above shows the historical results of operations for Elan for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009, including the EDT business unit that was divested on September 16, 2011. In order to provide a more meaningful discussion of these results of operations, we have presented the analysis of Elan s results in its two constituent parts. Firstly, we have presented and discussed on page 39 the results of operations for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009, on a pro forma basis to exclude the results of EDT; and secondly, we have presented and discussed on page 51 the results of operations for the EDT business unit for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009. The pro forma Elan revenue and operating income/(loss) as presented on page 39 are consistent with the segment results for the BioNeurology business unit for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009. The EDT revenue and operating income as presented on page 51 are consistent with the segment results for the EDT business unit for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009.

The following table shows a reconciliation from the Elan results of operations to the pro forma Elan results of operations for each of the years ended December 31, 2011, December 31, 2010 and December 31, 2009 (in millions):

	GAAP Elan 2011	Pro Forma Adjustments to Exclude EDT 2011	Pro Forma Elan 2011	GAAP Elan 2010	Pro Forma Adjustments to Exclude EDT 2010	Pro Forma Elan 2010	GAAP Elan 2009	Pro Forma Adjustments to Exclude EDT 2009	Pro Forma Elan 2009
Product revenue	$ 1,236.1	$ (168.0)	$ 1,068.1	$ 1,156.0	$ (261.4)	$ 894.6	$ 1,094.3	$ (257.2)	$ 837.1
Contract revenue	9.9	(9.9)		13.7	(12.7)	1.0	18.7	(18.7)	
Total revenue	1,246.0	(177.9)	1,068.1	1,169.7	(274.1)	895.6	1,113.0	(275.9)	837.1
Cost of sales	639.7	(67.0)	572.7	583.3	(118.4)	464.9	560.7	(116.3)	444.4
Gross margin	606.3	(110.9)	495.4	586.4	(155.7)	430.7	552.3	(159.6)	392.7
Operating expenses:									
Selling, general and administrative expenses	228.7	(23.8)	204.9	254.7	(38.9)	215.8	268.2	(35.9)	232.3
Research and development expenses	232.5	(34.3)	198.2	258.7	(53.7)	205.0	293.6	(47.5)	246.1
Net gain on divestment of business	(652.9)		(652.9)	(1.0)		(1.0)	(108.7)		(108.7)
Other net (gains)/charges	(42.2)	68.1	25.9	56.3	(2.3)	54.0	67.3	(5.7)	61.6
Settlement reserve charge				206.3		206.3			
Total operating (gains)/expenses	(233.9)	10.0	(223.9)	775.0	(94.9)	680.1	520.4	(89.1)	431.3
Operating income/(loss)	840.2	(120.9)	719.3	(188.6)	(60.8)	(249.4)	31.9	(70.5)	(38.6)
Net interest and investment gains and losses:									
Net interest expense	105.9	(1.0)	104.9	117.8	0.6	118.4	137.9	(1.8)	136.1
Net loss on equity method investment	81.8		81.8	26.0		26.0			
Net charge on debt retirement	47.0		47.0	3.0		3.0	24.4		24.4
Net investment gains	(2.6)		(2.6)	(12.8)		(12.8)	(0.6)		(0.6)
Net interest and investment gains and losses	232.1	(1.0)	231.1	134.0	0.6	134.6	161.7	(1.8)	159.9
Net income/(loss) before income taxes	608.1	(119.9)	488.2	(322.6)	(61.4)	(384.0)	(129.8)	(68.7)	(198.5)
Provision for/(benefit from) income taxes	47.6	(4.2)	43.4	2.1	(9.1)	(7.0)	46.4	(18.0)	