ELAN CORP PLC
Form 20-F
February 24, 2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 20-F

(Mark One)

- o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR(g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

- þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
  For the fiscal year ended: December 31, 2010

OR

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

OR

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

Commission file number: 001-13896

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

Ireland	**Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland**
(Jurisdiction of incorporation or organization)	*(Address of principal executive offices)*

William Daniel, Secretary
Elan Corporation, plc
Treasury Building, Lower Grand Canal Street
Dublin 2, Ireland
011-353-1-709-4000
liam.daniel@elan.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Exchange on Which Registered**
American Depositary Shares (ADSs), representing Ordinary Shares,	New York Stock Exchange
Par value 0.05 each (Ordinary Shares)	New York Stock Exchange
Ordinary Shares	

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

(Title of Class)

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

(Title of Class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report: 585,201,576 Ordinary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o

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

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

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

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

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

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes o No þ

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General

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

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

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

Forward-Looking Statements

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

This Form 20-F contains forward-looking statements about our financial condition, results of operations and estimates, business prospects and products and potential products that involve substantial risks and uncertainties. These statements can be identified by the fact that they use words such as anticipate, estimate, project, target, inte plan, will, believe, expect and other words and terms of similar meaning in connection with any discussion of futur operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: (1) Any negative developments relating to *Tysabri*® (natalizumab), such as safety or efficacy issues (including 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 development and commercialization of additional products; (3) the effects of settlement with the U.S. government relating to marketing practices with respect to our former Zonegran® (zonisamide) product, which will require us to pay $203.5 million in fines and to take other actions that could have a material adverse effect on Elan; (4) 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; (5) whether restrictive covenants in our debt obligations will adversely affect us; (6) our dependence on Johnson & Johnson and Pfizer Inc. (Pfizer) for the development and potential commercialization, and the funding potentially required from us for such development and potential commercialization, of bapineuzumab and any other potential products in the Alzheimer s Immunotherapy Program (AIP); (7) the success of our research and development (R&D) activities and R&D activities in which we retain an interest, including, in particular, whether the Phase 3 clinical trials for bapineuzumab (AAB-001) are successful, and the speed with which regulatory authorizations and product launches may be achieved; (8) Johnson & Johnson is our largest shareholder with an 18.4% interest in our outstanding ordinary

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

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(16) failure to comply with our reporting and payment obligations under Medicaid or other government programs; (17) legislation affecting pharmaceutical pricing and reimbursement, both in the United States and Europe; (18) exposure to product liability risks; (19) 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; (20) the volatility of our stock price; (21) some of our agreements that may discourage or prevent others from acquiring us; (22) governmental laws and regulations affecting domestic and foreign operations, including tax obligations; (23) general changes in U.S. generally accepted accounting principles and IFRS; and (24) the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items. We assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law.

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Part I

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

Not applicable.

Item 2. ***Offer Statistics and Expected Timetable.***

Not applicable.

Item 3. ***Key Information.***

A. Selected Financial Data

The selected financial data set forth below, (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,	**2010**	**2009**	**2008**	**2007**	**2006**
Statement of Operations Data:					
Total revenue	$ 1,169.7	$ 1,113.0	$ 1,000.2	$ 759.4	$ 560.4
Operating income/(loss)	$ (188.6)[1]	$ 31.9[2]	$ (143.5)[3]	$ (265.3)[4]	$ (166.4)[5]
Net loss	$ (324.7)[6]	$ (176.2)[7]	$ (71.0)[8]	$ (405.0)[9]	$ (267.3)[5]
Basic and diluted loss per Ordinary Share[10]	$ (0.56)	$ (0.35)	$ (0.15)	$ (0.86)	$ (0.62)
Other Financial Data:					
Adjusted EBITDA[11]	$ 166.5	$ 96.3	$ 4.3	$ (30.4)	$ (91.1)

At December 31,	**2010**	**2009**	**2008**	**2007**	**2006**
Balance Sheet Data:					
Cash and cash equivalents	$ 422.5	$ 836.5	$ 375.3	$ 423.5	$ 1,510.6
Restricted cash current and non-current	$ 223.1	$ 31.7	$ 35.2	$ 29.6	$ 23.2
Investment securities current	$ 2.0	$ 7.1	$ 30.5	$ 277.6	$ 13.2
Total assets	$ 2,017.5	$ 2,337.8	$ 1,867.6	$ 1,780.8	$ 2,746.3
Debt	$ 1,270.4[12]	$ 1,532.1[13]	$ 1,765.0	$ 1,765.0	$ 2,378.2
Total shareholders equity/(deficit)	$ 194.3	$ 494.2	$ (232.2)	$ (234.7)	$ 85.1
Weighted-average number of shares outstanding basic and diluted	584.9	506.8	473.5	468.3	433.3

(1) *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.

(2) *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.*

(3) *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.*

(4) *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.*

(5) *After other net gains of $20.3 million, primarily relating to an arbitration award of $49.8 million, offset by acquired in-process research and development costs of $22.0 million and severance, restructuring and other costs of $7.5 million; and after a $43.1 million net gain on sale of products and businesses.*

(6) *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.*

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(7) *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.*

(8) *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.*

(9) *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.*

(10) *Basic and diluted net loss per ordinary share is based on the weighted-average number of outstanding Ordinary Shares and the effect of potential dilutive securities including stock options, Restricted Stock Units, warrants and convertible debt securities, unless anti-dilutive.*

(11) *Refer to page 53 for a reconciliation of Adjusted EBITDA to net loss and our reasons for presenting this non-GAAP measure.*

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

(13) *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.

Our current and future revenues depend upon continued sales of our only marketed product *Tysabri*, which represented approximately 73% of our total revenues during 2010. Although we continue 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 or efficacy 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 enter the market 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 certain given the significant restrictions on 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 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*. 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* and efforts at stratifying patients into groups with lower or higher risk for developing PML, including evaluating the potential clinical utility of a JC virus (JCV) antibody assay, may have an adverse impact on prescribing behavior and reduce sales of *Tysabri*.

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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 settled with the U.S. government with respect to its investigation of the marketing practices concerning our former Zonegran product which will require 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 finalized the agreement-in-principle with the U.S. Attorney s Office for the District of Massachusetts to resolve 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. We will pay $203.5 million pursuant to the terms of a global settlement of all U.S. federal and related state Medicaid claims. In addition, we agreed to plead 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 Food and Drug Administration (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.

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, 2010, we had $1,285.0 million of debt falling due in December 2013 ($460.0 million) and October 2016 ($825.0 million). At such date, we had total cash and cash equivalents, restricted cash and cash equivalents, and investments of $453.3 million, excluding an additional $203.7 million held in an escrow account in relation to the Zonegran settlement. Our substantial indebtedness could have important consequences to us. For example, it does or could:

- Increase our vulnerability to general adverse economic and industry conditions;
- Require us to dedicate a substantial portion of our cash flow from operations to payments on indebtedness, thereby reducing the availability of our cash flow to fund R&D, working capital, capital expenditures, acquisitions, investments and other general corporate purposes;
- Limit our flexibility in planning for, or reacting to, changes in our businesses and the markets in which we operate;
- Place us at a competitive disadvantage compared to our competitors that have less debt; and

Limit our ability to borrow additional funds.

We estimate that we have sufficient cash, liquid resources and current assets and investments to meet our liquidity requirements for at least the next 12 months. Our future operating performance will be affected by general economic, financial, competitive, legislative, regulatory and business conditions and other factors, many of which are beyond our control. Even if our future operating performance does meet our expectations, including continuing 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

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force us to curtail programs, sell assets or otherwise take steps to reduce expenses or cease operations. Any of these steps may have a material adverse effect on our prospects.

Restrictive covenants in our debt instruments restrict or prohibit our ability to engage in or enter into a variety of transactions and could adversely affect us.

The agreements governing our outstanding indebtedness contain various restrictive covenants that limit our financial and operating flexibility. The covenants do not require us to maintain or adhere to any specific financial ratio, but do restrict within limits our ability to, among other things:

Incur additional debt;

Create liens;

Enter into transactions with related parties;

Enter into some types of investment transactions;

Engage in some asset sales or sale and leaseback transactions;

Pay dividends or buy back our ordinary shares; and

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

The breach of any of these covenants may result in a default under the applicable agreement, which could result in the indebtedness under the agreement becoming immediately due and payable. Any such acceleration would result in a default under our other indebtedness subject to cross-acceleration provisions. If this were to occur, we might not be able to pay our debts or obtain sufficient funds to refinance them on reasonable terms, or at all. In addition, complying with these covenants may make it more difficult for us to successfully execute our business strategies and compete against companies not subject to similar constraints.

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

On September 17, 2009, Janssen Alzheimer Immunotherapy (Janssen AI), a newly formed subsidiary of Johnson & Johnson, completed the acquisition of substantially all of our assets and rights related to 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. As of December 31, 2010, the remaining balance of the Johnson & Johnson $500.0 million funding commitment was $272.0 million (2009: $451.0 million), which reflects the $179.0 million utilized in 2010 (2009: $49.0 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 will 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 may be called upon to provide funding to Janssen AI commencing in 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. 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

before the initial $500.0 million funding commitment has been spent, Johnson & Johnson is not required to contribute the full $500.0 million. We refer to these transactions as the Johnson & Johnson Transaction in this Form 20-F.

The Johnson & Johnson Transaction resulted in the assignment of our AIP collaboration agreement with Wyeth (which has been acquired by Pfizer) and associated business, which primarily constituted intellectual property, to Janssen AI. While we have a 49.9% interest in Janssen AI, Johnson & Johnson exercises effective control over Janssen AI and consequently over our share of the AIP collaboration. Our financial interest in the AIP collaboration has been reduced from approximately 50% to approximately 25%. The success of the

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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 we are entitled to receive 49.9% of Janssen AI s future profits and certain royalty payments from Janssen AI in respect of sales of bapineuzumab and other potential AIP products. Royalties will generally only arise after Johnson & Johnson has earned profits from the AIP equal to Johnson & Johnson s (up to) $500.0 million investment. Any such payments are dependent on the future commercial success of bapineuzumab and other potential AIP products. If no drug is successfully developed and commercialized, we may not receive any profit or royalty payments from Janssen AI.

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®.

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 safety, future sales of *Tysabri* could be limited.

Generic competitors have challenged existing patent protection for several of the products from which we earn manufacturing or royalty revenue. If these challenges are successful, our manufacturing and royalty revenue will be materially and adversely affected.

Generic 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 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, then our revenues and results of operations may be materially and adversely affected.

If we are unable to secure or enforce patent rights, trade secrets or other intellectual property, then our revenues and potential revenues may be materially reduced.

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and intellectual property protection for new technologies, products and processes. Our success depends in large part on our continued ability to obtain patents for products and technologies, maintain patent protection for both acquired and developed products, preserve our trade secrets,

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obtain and preserve other intellectual property such as trademarks and copyrights, and operate without infringing the proprietary rights of third parties.

The degree of patent protection that will be afforded to technologies, products and processes, including ours, in the United States and in other markets is dependent upon the scope of protection decided upon by patent offices, courts and legislatures in these countries. There is no certainty that our existing patents or, if obtained, future patents, will provide us substantial protection or commercial benefit. In addition, there is no assurance that our patent applications or patent applications licensed from third parties will ultimately be granted or that those patents that have been issued or are issued in the future will prevail in any court challenge. Our competitors may also develop products, including generic 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 product.

Although we believe that we make reasonable efforts to protect our intellectual property rights and to ensure that our proprietary technology does not infringe the rights of other parties, we cannot ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our product or technologies. In addition, third parties may be able to obtain patents that prevent the sale of our product or require us to obtain a license and pay significant fees or royalties in order to continue selling our product.

There has been, and we expect there will continue to be, significant litigation in the industry regarding patents and other intellectual property rights. Litigation and other proceedings concerning patents and other intellectual property rights in which we are involved have been and will continue to be protracted and expensive and could be distracting to our management. Our competitors may sue us or our collaborators as a means of delaying the introduction of products, or to extract royalties against our marketed product *Tysabri*. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents or litigation against our licensors, may be costly and time consuming and could adversely affect us. In addition, litigation has been and may be instituted to determine the validity, scope or non-infringement of patent rights claimed by third parties to be pertinent to the manufacturing, use or sale of our or their products. The outcome of any such litigation could adversely affect the validity and scope of our patents or other intellectual property rights, hinder, delay or prevent the marketing and sale of our product 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.

We do not manufacture *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.

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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. This price regulation leads to inconsistent prices and some third-party trade from markets with lower prices. Such trade-exploiting price differences between countries could undermine our sales in markets with higher prices.

The pharmaceutical industry is subject to anti-kickback, 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 wilfully 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.

In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act (FCPA) prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials 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.

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

The pharmaceutical industry is subject to significant regulation by state, local, national and international governmental regulatory authorities. In the United States, the FDA, 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 our pharmaceutical products, which include drugs, biologics and medical devices. Failure to comply with regulatory requirements at any stage during the regulatory process could result in, among other things, delays in the approval of applications or supplements to approved applications, refusal of a regulatory authority to review pending market approval applications or supplements to approved applications, warning letters, fines, import or export restrictions, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously approved marketing applications or licenses, recommendations by the FDA or other regulatory authorities against governmental contracts, and criminal prosecutions.

We must obtain and maintain approval for 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 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 our 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, events of non-compliance with environmental laws, regulatory enforcement and claims related to personal injury and property damage. If an accident occurred or if we were to discover contamination caused by prior operations, then we could be liable for cleanup, damages or fines, which could have an adverse effect on us.

The environmental laws of many jurisdictions impose actual and potential obligations on us to remediate contaminated sites. These obligations may relate to sites that we currently own or lease, sites that we formerly owned or operated, or sites where waste from our operations was disposed. These environmental remediation obligations could significantly impact our operating results. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to us, and could subject our handling,

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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, 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 product liability claims. We are a defendant in product liability actions related to products that Elan marketed.

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 $190.0 million. Our insurance coverage may not be sufficient to cover fully all potential claims, nor can we guarantee the solvency of any of our insurers.

If our claims experience results in higher rates, or if product liability insurance otherwise becomes costlier because of general economic, market or industry conditions, then we may not be able to maintain product liability

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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 have been named as defendants in putative class actions; an adverse outcome in the class actions could result in a substantial judgment against us.

We and some of our officers and directors have been named as defendants in 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 alleges claims under the U.S. federal securities laws and seeks damages on behalf of all purchasers of our stock during periods ranging between May 21, 2007 and October 21, 2008. The complaints allege that we issued false and misleading public statements concerning the safety and efficacy of bapineuzumab. We have filed a Motion to Dismiss the Consolidated Amended Complaint. 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. Adverse results in these lawsuits 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.

A substantial portion of our operations 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.

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 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 and Development of the Company

Elan Corporation, plc, an Irish public limited company, is a neuroscience-based biotechnology company, listed on the Irish and New York Stock Exchanges, and headquartered in Dublin, Ireland. 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).

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Elan is focused on discovering and developing advanced therapies in neurodegenerative and autoimmune diseases, and in realizing the potential of our scientific discoveries and drug delivery technologies to benefit patients and shareholders. As of December 31, 2010, we employed over 1,200 people and our principal R&D and manufacturing facilities are located in Ireland and the United States.

We have two business units: BioNeurology, focused primarily on neurodegenerative diseases, and Elan Drug Technologies (EDT), a leading drug delivery business. *Tysabri*, a treatment for MS and Crohn s disease that we market in collaboration with Biogen Idec, had over $1.2 billion in global in-market sales in 2010. Almost all of these sales were in relation to the MS indication.

B. Business Overview

Our two principal business areas are BioNeurology and EDT.

BIONEUROLOGY

Elan s BioNeurology business focuses on neurodegenerative diseases, such as Alzheimer s disease and Parkinson s disease; autoimmune diseases, including MS and Crohn s disease and on neo-epitope based targets for treatments across a broad range of therapeutic indications. The following provides information on our key products and initiatives.

Tysabri

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

According to data published in the *New England Journal of Medicine,* after two years *Tysabri* treatment led to a 68% relative reduction in the annualized relapse rate, compared with placebo, and reduced the relative risk of disability progression by 42% to 54%. In post-hoc analyses of the clinical trial data published in *The Lancet Neurology*, 37% of *Tysabri*-treated patients remained free of their MS activity, based on MRI and clinical measures, compared to 7% of placebo-treated patients.

Additional analyses have provided evidence that *Tysabri* is associated with a significant improvement in functional outcome, rather than only slowing or preventing progression of disability, in those living with MS. Patients with a common baseline expanded disability status scale score (an EDSS of 2.0) treated with *Tysabri* showed a significant increase in the probability of sustained improvement in disability; this increase was 69% relative to placebo.

For 2010, *Tysabri* global in-market net sales increased by 16% to $1,230.0 million from $1,059.2 million for 2009. As of the end of December 2010, approximately 56,600 patients were on therapy worldwide, including approximately 27,600 commercial patients in the United States and approximately 28,400 commercial patients in the rest of world (ROW).

Tysabri increases the risk of PML, an opportunistic viral infection of the brain caused by the JCV, that can lead to death or severe disability. The risk of PML increases with longer treatment duration and in patients treated with an immunosuppressant prior to receiving *Tysabri*; these risks appear to be independent of each other. Data beyond four years are limited.

In the United States, Europe and the ROW, provisions 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 *Tysabri* for MS.

A number of diagnostic tools have been considered to potentially identify patients exposed to the JCV and who may be at a higher or lower risk of developing PML. With Biogen Idec, we are developing a two-step enzyme-linked immunosorbent assay (ELISA) to detect anti-JCV antibodies in the sera of patients. A preliminary analysis of this antibody assay was published in the journal *Annals of Neurology* in August 2010 and validation of the clinical utility of the assay as a risk-stratification tool continues. We believe that consideration of a patient s anti-JCV antibody

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status, together with his or her duration of treatment and prior treatments, can provide useful information to a patient and his or her clinician regarding the patient s risk of developing PML. We aim to provide information regarding the relative risk of developing PML to *Tysabri* patients, which should allow for more informed risk-benefit analyses by patients and clinicians.

In December 2010, Elan and Biogen Idec submitted a supplemental Biologics License Application (sBLA) to the FDA and a Type II Variation to the EMA to request review and approval to update the respective *Tysabri* Prescribing Information and Summary of Product Characteristics. The companies are proposing updated product labeling to include anti-JCV antibody status as one potential factor to help stratify the risk of PML in the *Tysabri*-treated population.

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

We have initiated the five year renewal process for *Tysabri* s marketing authorization in the European Union (E.U.). This marketing authorization review by the EMA, in addition to ongoing label discussions with U.S. regulators, includes assessment of the criteria for confirming PML diagnosis, the number of PML cases, the incidence of PML in *Tysabri* patients, the risk factors for PML, as well as an overall assessment of *Tysabri* s benefit-risk profile. Our interactions with E.U. and U.S. regulators could result in modifications to the respective labels or other restrictions for *Tysabri*. Upon completion of the assessment of the *Tysabri* renewal in the European Union, the marketing authorization is expected to be valid for either an unlimited period or for an additional five year term.

We believe the safety data to date continues to support a favorable benefit-risk profile for *Tysabri.* Information about *Tysabri* for the treatment of MS, including important safety information, is available at www.*Tysabri*.com. The contents of this website are not incorporated by reference into this Form 20-F.

We evaluated *Tysabri* as a treatment for Crohn s disease in collaboration with Biogen Idec and subsequently launched *Tysabri* for the treatment of Crohn s disease in the United States in the first quarter of 2008. Complete information about *Tysabri* for the treatment of Crohn s disease, including important safety information, is available at www.*Tysabri*.com.

Science and Discovery

In late 2010, Elan began implementing an initiative to build the next generation of science and discovery for our BioNeurology business.

As part of this initiative, we are deepening our existing focus on Parkinson s disease and have established a Parkinson s disease genetics group. The group s activities will be guided by human genetics associated with Parkinson s disease, and it will have as its foundation research into the fundamental pathways of Parkinson s biology, genetics-based animal models, and structural characterization of genetic targets for drug design. In addition, we have formed an antibody research group, called Neotope, which is focused on creating novel monoclonal antibodies based on neo-epitope targets for the treatment of a broad range of therapeutic indications. Neotope aims to explore specific immunotherapeutic treatment of a number of diseases including Alzheimer s disease, Parkinson s disease, amyloid light chain (AL) amyloidosis and diabetes.

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 the

our key strength.

Alzheimer s Disease Programs

Elan s scientists have been leaders in Alzheimer s disease research for more than 25 years, and insights gained from our work are an important part of the scientific foundation of understanding this disease. We are known and

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respected for our innovative Alzheimer s disease platforms and our commitment to creating new therapeutic opportunities for patients desperately in need of them.

Our Scientific Approach

Our scientific approach to Alzheimer s disease is centered upon our landmark basic research that revealed the fundamental biology that leads to the production and accumulation of a toxic protein, beta amyloid, in the brains of Alzheimer s disease patients. The process by which this protein is generated, aggregates and is ultimately deposited in the brain as plaque is often referred to as the beta amyloid cascade. The formation of beta amyloid plaques is the hallmark pathology of Alzheimer s disease.

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

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

Three Approaches to Disrupting the Beta Amyloid Cascade

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

Preventing aggregation of beta amyloid in the brain (ELND005);

Clearing existing beta amyloid from the brain through immunotherapies targeting beta amyloid (AIP, sold to Janssen AI in 2009); and

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

ELND005, an A 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 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 plaque deposition. Daily oral treatment with this compound has been shown to prevent cognitive decline in a transgenic mouse model of Alzheimer s disease, with reduced amyloid plaque load in the murine brain and increased life span of these animals.

In June 2010, a Phase 2 clinical study (study AD201) was completed and topline results were announced on August 9, 2010. Study AD201 was a Phase 2 placebo-controlled study in 351 patients with mild to moderate Alzheimer s disease who received study drug (250mg twice daily; 1,000mg twice daily; 2,000mg twice daily; or placebo) for up to 18 months. The two higher dose groups were discontinued in December 2009. The study did not achieve significance

on co-primary outcome measures (neuropsychological test battery (NTB) and Alzheimer s Disease Cooperative Study-Activities of Daily Living (ADCS-ADL)). The 250mg twice daily dose demonstrated a biological effect on amyloid-beta protein in the cerebrospinal fluid (CSF), in a subgroup of patients who provided CSF samples. This dose achieved targeted drug levels in the CSF previously associated with therapeutic effects in animal models, and showed some effects on clinical endpoints in an exploratory analysis. After reviewing the final safety data with the study s Independent Safety Monitoring Committee, we concluded that the 250mg twice daily dose has acceptable safety and tolerability. Elan and Transition, after discussions with experts in the field, believe

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the preponderance of evidence from both biomarker and clinical data, supports further clinical development of ELND005. We are continuing to explore pathways forward for the ELND005 asset.

In December 2010, we modified our Collaboration Agreement with Transition and, in connection with this modification, Transition elected to exercise its opt-out right under the original agreement. Under this amendment, we paid Transition $9.0 million in January 2011. Under the modified Collaboration Agreement, Transition will be eligible to receive a further $11.0 million payment upon the commencement of the next ELND005 clinical trial, and will no longer be eligible to receive a $25.0 million milestone payment that would have been due upon the commencement of a Phase 3 trial for ELND005 under the terms of the original agreement. As a consequence of Transition s decision to exercise its opt-out right, it will no longer fund the development or commercialization of ELND005 and has relinquished its 30% ownership of ELND005 to us. Consistent with the terms of the original agreement, following its opt-out decision, Transition will be entitled to receive milestone payments of up to $93.0 million (in addition to the $11.0 million described above), along with tiered royalties ranging from high single digit to the mid teens (subject to offsets) based on net sales of ELND005 should the drug receive the necessary regulatory approvals for commercialization.

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). 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 ROW. The subcutaneous delivery of bapineuzumab is being tested in Phase 2 trials.

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

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

Secretase inhibitors

Beta and gamma secretases are proteases, or enzymes that break down other proteins that clip APP and result in the formation of beta amyloid. This finding is significant because if the clipping of APP could be prevented, the pathology of Alzheimer s disease may be changed. We have been at the forefront of research in this area, publishing extensively since 1989, and have developed and are pursuing advanced discovery programs focused on molecular inhibitors of beta and gamma secretases. In 2010 alone, we had ten publications in this area discussing advances on inhibitors of BACE (for Beta-site of APP Cleaving Enzyme) and gamma and their impact on the disease.

Gamma secretase

Gamma secretase is a multi-protein complex that is required to produce beta amyloid. We have played a critical leadership role characterizing how gamma secretase may affect Alzheimer s disease pathology. Our finding that functional gamma secretase inhibitors appear to reduce beta amyloid levels in the brain, published in the *Journal of Neurochemistry* in 2001, was an important step in this area of Alzheimer s disease research. We continue to progress our gamma secretase discovery program with unique molecules that affect the activity of gamma secretase in a substrate-specific manner.

Our development program for ELND006, a small molecule gamma secretase inhibitor, was halted in October 2010. We continue to concentrate our efforts on gamma secretase inhibitors at earlier stages in our pipeline.

Beta secretase

Beta secretase, sometimes called BACE, is believed to initiate the first step in the formation of beta amyloid, the precursor to plaque development in the brain. Our findings concerning the role beta secretase plays in beta amyloid production, published in *Nature* in 1999, are considered a landmark discovery. Today, we continue to be at the center of understanding the complexities of beta secretase. Our ongoing drug discovery efforts in this area focus on inhibiting beta secretase and its role in the progression of Alzheimer s disease pathology.

Parkinson s Research

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

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.

Our scientists have made significant progress in identifying unusual modified forms of alpha-synuclein in human Parkinson s disease brain tissue. In 2009, our scientists published research in the *Journal of Biological Chemistry* about the discovery of an enzyme that may be involved in the modification of alpha-synuclein. In 2010, we continued to characterize this enzyme and made selective inhibitors to test in animal models of the disease. We also made significant progress on understanding other forms of alpha-synuclein, the role that different forms of synuclein can play in normal and abnormal cellular functions, as well as the pathogenicity of alpha-synuclein in animal models of disease.

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We are also studying parkin, a protein found in the brain that, like alpha-synuclein, has been genetically linked to Parkinson s disease. Parkin may be involved in the elimination of misfolded proteins within neurons, and has demonstrated neuroprotective capabilities in cells. Some familial forms of Parkinson s disease have been linked to mutations in parkin, with more than 50% of early-onset Parkinson s disease being linked to a loss of parkin protein and function in neurons. In 2010, our scientists found novel ways to modulate the activity of parkin in cells and are in the process of determining how parkin can regulate the disease processes of neurodegeneration.

We are also pursuing other genetic targets associated with Parkinson s disease and have formed a dedicated research group to focus on this area.

Neotope

Neotope Biosciences Limited, a wholly-owned subsidiary of Elan Corporation, plc, is a discovery enterprise focused on creating novel antibodies based on neo-epitope targets for treatment of a broad range of therapeutic indications, including Alzheimer s disease, Parkinson s disease, AL amyloidosis and diabetes.

Why Target Neo-Epitopes to Treat Disease?

Several progressively debilitating diseases with poor treatment options and often fatal prognoses are all caused by the mis-folding and accumulation of disease-specific proteins. These protein accumulations, though each unique and due to a different protein, are often referred to as amyloids. Scientists at Neotope have led efforts to discover and develop antibody-based strategies that target several of these disease-causing amyloids.

Neotope Approach[tm]

Neotope s strategy applies our expertise in the generation of novel antibodies that are then screened in specific preclinical disease models to select candidates with therapeutic potential for clinical development. We leverage a global network of collaborators for the relevant disease models and harness their expertise in assessments of preclinical efficacy in the pathway to select and develop antibodies for further human clinical studies. Neotope is working with Boehringer Ingelheim for manufacture of our antibody-based therapeutics in order to accelerate advancement of these programs towards clinical development.

Neotope Targets

Neotope s lead program in preclinical development is a proprietary antibody for treatment of AL amyloidosis. Neotope s portfolio of targets includes tau for treatment of Alzheimer s disease and other tauopathies, alpha-synuclein for treatment of synucleinopathies such as Lewy body dementia or Parkinson s disease and targets for treatment of type 2-diabetes.

Alpha 4 Integrin

Our therapeutic strategy for treating autoimmune and other diseases is to identify mechanisms common to these diseases and develop novel therapeutics that stop the underlying causes of disease. Alpha 4 integrin is a protein expressed by immune cells that allows those cells to leave the bloodstream and invade target tissues. Blocking alpha 4 integrin stops immune cells from entering tissues.

Since first publishing the hypothesis concerning the therapeutic potential of blocking alpha 4 integrin in 1992, leading to the development of *Tysabri*, our scientists have been expanding and refining our understanding of how cells enter tissues. Through this deep understanding, we have developed small molecules that can selectively block particular

alpha 4 integrin interactions.

ELND002

We are continuing to develop ELND002, a novel alpha4 integrin inhibitor for the treatment of MS. Phase 1b/2a clinical trials for ELND002 are ongoing in MS patients and the FDA has granted Fast Track status to develop ELND002 for the treatment of Secondary Progressive MS.

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ELAN DRUG TECHNOLOGIES Over 40 Years of Drug Delivery Leadership

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

Throughout its over 40 year history, EDT has been a leader, bringing forth innovative solutions that have addressed real patient needs, with significant benefits across the pharmaceutical industry. Since its founding in Ireland in 1969, EDT has been focused on developing and applying technologies to unsolved drug formulation challenges. Our two principal drug technology platforms are our Oral Controlled Release (OCR) technologies and our Bioavailability Enhancement Platform which includes our *NanoCrystal*® technology.

Our portfolio includes 25 currently marketed products by EDT licensees and 12 products in clinical development.

Since 2001, 12 products incorporating EDT technologies have been approved and launched in the United States alone. To date, EDT s drug delivery technologies have been commercialized in 36 products around the world, contributing to annual client sales of more than $3.0 billion.

Key Events

In March 2010, our licensee, Acorda Therapeutics Inc. (Acorda), launched Ampyra® following its approval by the FDA in late January 2010 as a treatment to improve walking in patients with MS. Ampyra is marketed and distributed in the United States by Acorda and if approved outside the United States, where it is called Fampyra® (prolonged-release fampridine tablets), will be marketed and distributed by Biogen Idec, Acorda s sub-licensee. Ampyra is the first New Drug Application (NDA) approved by the FDA for a product using EDT s *MXDAS*®(matrix drug absorption system) technology and is the first medicine approved by the FDA indicated to improve walking speed in people with MS. In January 2010, Biogen Idec announced the submission of a Marketing Authorisation Application (MAA) to the EMA for Fampyra. Biogen Idec also announced that it has filed a New Drug Submission (NDS) with Health Canada. In January 2011, the CHMP of the EMA issued a negative opinion, recommending against approval of Fampyra in the European Union. Biogen Idec intends to appeal this opinion and request a re-examination of the decision by the CHMP. Biogen Idec also received a Notice of Deficiency from Health Canada for its application to sell Fampyra in Canada. EDT has the right to manufacture supplies of Ampyra for the global market at its Athlone, Ireland facility.

In 2010, the hydrocodone ER product (ZX002) from our U.S. licensee, Zogenix Inc (Zogenix) progressed in Phase 3 clinical trials. By the end of 2010, the enrollment of the 12-month safety study (Study 802) was completed and the 12-week double-blind, placebo controlled efficacy study was underway with full enrollment expected in early 2011. Pending positive clinical results, Zogenix expects to submit an NDA to the FDA by early 2012. ZX002 is a novel controlled release formulation of hydrocodone, developed by EDT using our *SODAS*® technology and is in clinical trials for the treatment of moderate to severe chronic pain in individuals who require around-the-clock opioid therapy for the control of pain.

In October 2010, we launched our new Manufacturing Services business at the world CPhI trade show. This new development offers clients a broad range of services and expertise integrated to one company, builds on over 40 years experience in drug delivery and provides pharmaceutical clients with process design and development expertise, process improvements as well as improved production methods in scale-up and commercial manufacturing.

Other regulatory advances included approvals for new strengths for Focalin XR® (25mg and 35mg) in the United States, Xeplion® (paliperidone palmitate) being filed by Janssen in the European Union and Morphelan® filed in the

European Union by Elan.

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Advancing Technologies, Improving Medicines

EDT is an established, profitable business unit of Elan that has been applying its skills and knowledge to enhance the performance of dozens of drugs that have subsequently been marketed worldwide. Today, products enabled by EDT technologies are used by more than two million patients each day.

Throughout its 40-plus years in business, EDT has remained committed to using its extensive experience, drug delivery technologies and commercial capabilities to help clients develop innovative products that provide clinically meaningful benefits to patients. Committed to innovation whether in the products developed, advancing our existing technologies or developing new technologies EDT has been driven by some of the best scientific talent in the area of drug delivery formulation. We provide a broad range of creative drug formulation approaches, including formulation development, scale-up and manufacturing. Commercialized technologies include those for poorly water-soluble compounds as well as technology platforms for customized oral release. Since 2001, our technologies have been incorporated and subsequently commercialized in 12 products in the United States. With 12 pipeline products in the clinic, multiple preclinical programs and a strong client base, EDT plans to maintain its position as a leading drug delivery company worldwide.

During 2010, EDT generated $274.1 million (2009: $275.9 million; 2008: $301.6 million) in revenue and operating income of $60.8 million in 2010 (2009: $70.5 million; 2008: $85.8 million). EDT generates revenue from two sources: royalties and manufacturing fees from licensed products; and contract revenues relating to R&D services, license fees and milestones.

Revenues for 2010 were impacted by the expected reduced revenues from Skelaxin® and TriCor® 145 as a result of the cessation of, or significantly decreased, promotional efforts by our clients in respect of these products. A generic form of Skelaxin was approved and launched in April 2010. The decrease in revenue from these products was offset by the launch of Ampyra in the United States.

Typically, EDT receives royalties in the single-digit range as well as manufacturing fees based on cost-plus arrangements where appropriate. More recently, EDT has brought product concepts to a later stage of development before out-licensing and as a result will seek to attain an increasing proportion of revenue.

EDT s Business Strategy

Throughout our 40-plus year history, we have invested in the development of innovative technologies, particularly in OCR platform technologies and technologies for poorly water-soluble compounds. Although revenues declined slightly in 2010, over the medium term we are focused on profitably growing as a drug delivery business, underpinned by our product development capabilities and drug delivery technologies.

Our strategy, based on our comprehensive product development and proprietary technology platforms, involves two complementary elements:

- Working with pharmaceutical companies to develop products through the application of our technologies to their pipeline and marketed products; and

- Selectively developing product candidates based on our proprietary technologies where we originate the product concept and ultimately develop the product to a later stage of development prior to out-licensing or making a decision to continue internal development.

Our drug delivery technologies are key to our future business. Today, we have many patent and patent applications around our key technology and product areas.

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Marketed Products

Twenty-five (25) products incorporating EDT technologies are currently marketed by EDT licensees. EDT receives royalties and, in some cases, manufacturing fees on these products, which include:

Licensee	Product	Indication
Abbott Laboratories	TriCor 145	Cholesterol reduction
Acorda Therapeutics, Inc.	Zanaflex Capsules®	Muscle spasticity
Acorda Therapeutics, Inc.	Ampyra	Walking disability associated with MS
Janssen	Invega® Sustenna®	Schizophrenia
Jazz Pharmaceuticals Inc.	Luvox CR®	SAD[1] and OCD[2]
King Pharmaceuticals, Inc.	Avinza®	Chronic pain
Merck & Co., Inc.	Emend®	Nausea post chemo
Novartis AG	Focalin XR/Ritalin® LA	ADHD[3]
Par Pharmaceutical Co., Inc.	Megace® ES	Cachexia
Pfizer	Rapamune®	Anti-rejection
Victory Pharma	*Naprelan®*	NSAID[4] Pain

(1) *Social Anxiety Disorder*

(2) *Obsessive Compulsive Disorder*

(3) *Attention Deficit Hyperactivity Disorder*

(4) *Non-Steroidal Anti-Inflammatory Drug*

EDT PRODUCT PIPELINE

EDT s pipeline spans a range of therapeutic classes, routes of administration and licensee profiles, as outlined below. In addition, EDT has a large number of projects at the preclinical or formulation development stage.

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Validated Platform of Technologies NanoCrystal Technology and Oral Controlled Release

EDT has a unique platform of validated technologies to offer our clients including OCR, delayed release, and pulsatile release delivery systems as well as technology solutions for poorly water-soluble compounds. We have a complete range of capabilities from formulation development through to commercial-scale manufacture in modern facilities. Our technologies are supported by a robust patent estate.

Proven Innovation for Poorly Water-soluble Compounds NanoCrystal Technology

EDT s proprietary *NanoCrystal* technology is a drug optimization technology applicable to many poorly water-soluble compounds. It is an enabling technology for evaluating new chemical entities exhibiting poor water solubility and a tool for optimizing the performance of established drugs. *NanoCrystal* technology involves reducing drugs to particles in the nanometer size. By reducing particle size, the exposed surface area of the drug is increased and then stabilized to maintain particle size. A drug in *NanoCrystal* form can be incorporated into common dosage forms, including tablets, capsules, inhalation devices, and sterile forms for injection, with the potential for substantial improvements to clinical performance.

Our *NanoCrystal* technology is:

Proven Five licensed products have been launched to date, achieving over $1.9 billion annual in-market sales

Patent Protected More than 1,400 patents/patent applications around the *NanoCrystal* technology in the United States and the ROW. Refer to page 29 for additional information on our *NanoCrystal* technology patents.

Simple, Easy and Effective Optimized and simplified from 20 years of development behind the technology. It is applicable to all dosage forms and has been manufactured at commercial scale since 2001.

The potential benefits of applying the *NanoCrystal* technology for existing and new products include:

Enhancing oral bioavailability;

Increased therapeutic effectiveness;

Reducing/eliminating fed/fasted variability;

Optimizing delivery; and

Increased absorption.

EDT s *NanoCrystal* technology has now been incorporated into five licensed and commercialized products, with more than 30 other compounds at various stages of development.

Oral Controlled Release Technology Platform

OCR technologies provide significant benefits in developing innovative products that may provide meaningful clinical benefits to patients. EDT has developed a range of OCR technologies, which it applies to help overcome many of the technical difficulties that have been encountered in developing OCR products. OCR products are often difficult to formulate, develop and manufacture. As a result, significant experience, expertise and know-how are required to

successfully develop such products.

EDT s OCR technologies are focused on using advanced drug delivery technology and its manufacturing expertise to formulate, develop and manufacture controlled release, oral dosage form pharmaceutical products that improve the release characteristics and efficacy of active drug agents, and also provide improved patient convenience and compliance. The drug delivery technologies employed, coupled with its manufacturing expertise, enable EDT to cost effectively develop value-added products and to enhance product positioning.

EDT s suite of OCR technologies has been incorporated into many commercialized products. EDT s OCR technology platform allows a range of release profiles and dosage forms to be engineered. Customized release

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profiles for oral dosage forms such as extended release, delayed release and pulsatile release have all been successfully developed and commercialized.

A unique platform of validated technologies to offer our clients:

Validated and Commercialized 20 products currently on the market.

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

Patent Protected More than 400 patents/patent applications in the United States and the ROW.

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

Manufacturing, Development and Scale-up Expertise

EDT has a long and established history in the scale-up and manufacture of pharmaceutical dosage forms for pharmaceutical markets worldwide, with multiple products successfully launched in North America, Asia, Europe, Latin America, Australasia and, more recently, India and China. EDT s main production facilities are located in Athlone, Ireland, and Gainesville, Georgia, United States.

With over 40 years experience and innovation, EDT s manufacturing services business provides a range of contract manufacturing services that include analytical development, clinical trial manufacturing, scale-up, product registration support and supply chain management for client products. At present over 30 of the world s leading pharma companies are clients of ours.

Range of Manufacturing Services:

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

270,000 square feet of cGMP facilities between our sites in Ireland and the United States.

Process and analytical equipment, U.S. Drug Enforcement Administration (DEA) controlled site, packaging facilities in United States and Ireland.

Dedicated research, development, scale-up and commercial manufacturing facilities.

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

ENVIRONMENT

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

Government Regulation

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

Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing and marketing of pharmaceutical products. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions. In addition, administrative remedies can

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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. We agreed to pay $203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims and $203.7 million is held in an escrow account at December 31, 2010 to cover the settlement amount. During 2010, we recorded a $206.3 million reserve charge for the settlement, interest and related costs. As part of the agreement, our subsidiary Elan Pharmaceuticals, Inc. (EPI), has agreed to plead guilty to a misdemeanor violation of the FD&C Act and we have 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 civil settlement agreement and the agreed-upon sentence for the misdemeanor plea are subject to approval by the U.S. District Court for the District of Massachusetts. 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 cli