

Edgar Filing: ELAN CORP PLC - Form 6-K

ELAN CORP PLC  
Form 6-K  
February 18, 2004

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934

For the month of February, 2004

Commission File Number 001-13896

Elan Corporation, plc  
(Translation of registrant's name into English)

Lincoln House, Lincoln Place, Dublin 2, Ireland  
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F    /X/                                    Form 40-F    / /

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (1):

Yes    / /    No /X/

Note: Regulation S-T Rule 101(b) (1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (7):

Yes    / /    No /X/

Note: Regulation S-T Rule 101(b) (7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the

## Edgar Filing: ELAN CORP PLC - Form 6-K

report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes / /

No /X/

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):

This Report of Foreign Issuer on Form 6-K is incorporated by reference into the Post-Effective Amendments on Forms F-3 and S-8 to Form F-4 Registration Statement of Elan Corporation, plc (Registration No. 333-12756), the Registration Statement on Form F-3 of Elan Corporation, plc and Athena Neuroscience Finance, LLC (Registration No. 333-13130), and the Registration Statements on Form S-8 of Elan Corporation, plc (Registration Nos. 333-13996, 333-12344, 333-11940, 333-09644, 333-09284, 333-09048, 333-08384, 333-07361, 333-07136, 333-14240, 33-27506, 333-100252 and 333-100556).

### EXHIBIT LIST

Exhibit	Description
99.1	Press release dated February 18, 2004 titled: Biogen Idec and Elan announce intention to submit Antegren(R) for approval for multiple sclerosis based on one-year data.
99.2	Press release dated February 18, 2004 titled: Elan reports fourth quarter 2003 and full-year financial results - Elan provides financial guidance for 2004 - Execution momentum continues with key R&D milestones.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Edgar Filing: ELAN CORP PLC - Form 6-K

ELAN CORPORATION, plc

By: /s/ William F. Daniel

-----  
William F. Daniel  
Company Secretary

Date: February 18, 2004

Exhibit 99.1

For More Information Contact:

MEDIA CONTACTS:

Biogen Idec

Elan

Amy Brockelman Ph: 617 914 6524

Anita Kawatra Ph: 212 407 5755

INVESTOR CONTACTS:

Elan

Biogen Idec

Emer Reynolds Ph: 353 1 709 4000

Elizabeth Woo Ph: 617 679 2812

BIOGEN IDEC AND ELAN ANNOUNCE INTENTION TO SUBMIT ANTEGREN(R) FOR APPROVAL  
FOR MULTIPLE SCLEROSIS BASED ON ONE-YEAR DATA

Cambridge, MA, San Diego, CA and Dublin, Ireland (February 18, 2004) - Biogen Idec and Elan Corporation, plc today announced that they expect to submit to the U.S. Food and Drug Administration (FDA) an application for approval of ANTEGREN(R) (natalizumab) as a treatment for multiple sclerosis (MS). The companies expect to submit the filing mid-year 2004.

The decision to file a Biologics License Application (BLA) was made after discussions with the FDA of one-year data from the two ongoing two-year Phase III trials in MS. The companies are committed to completing the two-year trials. To protect the integrity of the trials, the companies are not disclosing the one-year data at this time.

Biogen Idec and Elan are collaborating equally on the development of natalizumab for MS, Crohn's disease, and rheumatoid arthritis.

About the ANTEGREN MS Clinical Trials

The AFFIRM (natalizumab safety and efficacy in relapsing-remitting MS) trial is a two-year, randomized, multi-center, placebo-controlled, double-blind study of approximately 900 patients, evaluating the ability of natalizumab to slow the progression of disability in MS and reduce the rate of clinical relapses. The SENTINEL (safety and efficacy of natalizumab in combination with AVONEX(R) (Interferon beta-1a)) trial is a two-year, randomized, multi-center,

## Edgar Filing: ELAN CORP PLC - Form 6-K

placebo-controlled, double-blind study of approximately 1,200 patients with relapsing-remitting MS, evaluating the effect of the combination of natalizumab and AVONEX compared to treatment with AVONEX alone in slowing the progression of disability and reducing the rate of clinical relapses. Both studies have protocols that included a one-year analysis of the data. The primary endpoints for both Phase III two-year trials in MS are based on the Expanded Disability Status Scale (EDSS) and relapse rates. The pre-specified primary endpoint of the one-year analysis was relapse rates.

### About ANTEGREN (natalizumab)

Natalizumab, a humanized monoclonal antibody, is the first alpha-4 antagonist in the new SAM (selective adhesion molecule) inhibitor class. The drug was designed to selectively inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue as occurs in a variety of inflammatory diseases. To date, approximately 2,800 patients have received natalizumab in clinical studies. In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. Serious adverse events have included infrequent hypersensitivity-like reactions.

### About Biogen Idec

Biogen Idec (NASDAQ: BIIB) creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit <http://www.biogenidec.com>.

### About Elan

Elan Corporation, plc (NYSE: ELN) is focused on the discovery, development, manufacturing, selling and marketing of novel therapeutic products in neurology, severe pain and autoimmune diseases. Elan shares trade on the New York, London and Dublin Stock Exchanges. For additional information about the company, please visit <http://www.elan.com>.

### Safe Harbor/Forward Looking Statements

This press release contains forward-looking statements regarding the companies' intent to file with the FDA for approval of ANTEGREN (natalizumab) and the potential of ANTEGREN as a treatment for MS. These statements are based on the companies' current beliefs and expectations. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that unexpected concerns may arise from additional data or analysis or that regulatory authorities

may require additional information or further studies or that the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic reports of IDEC Pharmaceuticals Company, Biogen, Inc. and Elan Corporation, plc filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

FOR IMMEDIATE RELEASE

Investors:  
Emer Reynolds  
Ph: 353-1-709-4000  
800-252-3526

Media:  
Anita Kawatra  
Ph: 212-407-5755  
800-252-3526

ELAN REPORTS FOURTH QUARTER 2003 AND FULL-YEAR FINANCIAL RESULTS

Elan provides financial guidance for 2004  
Execution momentum continues with key R&D milestones

Dublin, Ireland, February 18, 2004-- Elan Corporation, plc today announced its fourth quarter and full-year 2003 financial results, provided an update on the progress of its product development activities and gave guidance for 2004.

Commenting on the results, Kelly Martin, Elan's President and Chief Executive Officer, said "Elan demonstrated significant progress during the course of 2003 which provides for a strong foundation upon which to build long term value for our shareholders. Our focus on execution and operating discipline has enabled us to simplify our balance sheet, increase liquidity and reduce our overall debt and operating costs while achieving continued revenue growth from retained products and services. Importantly, we never wavered from our commitment to invest in and develop our strategic pipeline within our key therapeutic areas of neurology, autoimmune and severe pain. The expected one-year filing for MS, the recent positive Phase III maintenance results in Antegren for Crohn's disease and the successful Phase III trial for Prialt confirms the potential for our world class science to reach those patients who suffer from these diseases.

Such execution momentum is the result of focus, dedication and the extraordinary efforts of the Elan employees around the world who remain dedicated to positioning us for success and working towards bringing our scientific innovation to patients."

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 2

Financial highlights of the group's performance from continuing operations are set out below. The results of the group's discontinued operations under U.S. GAAP are presented as a separate component of net loss for the current and prior periods. Details of the group's discontinued operations are discussed on page 9.

Fourth Quarter 2003 Financial Highlights - Continuing Operations

- o Total revenue of \$157.5 million compared to \$196.7 million in the fourth quarter of 2002 (excluding exceptional provisions for product returns,

## Edgar Filing: ELAN CORP PLC - Form 6-K

primarily Zanaflex(TM), of \$83.0 million), a decrease of 20%.

- o Revenue from retained products of \$107.8 million compared to \$74.1 million in the fourth quarter of 2002, an increase of 45%.
- o Reduction of 43% in selling, general and administrative expenses in the fourth quarter of 2003 to \$82.5 million from \$144.9 million in the fourth quarter of 2002. Reduction of 38% in research and development expenditure in the fourth quarter of 2003 from \$101.1 million to \$62.9 million.
- o Negative EBITDA of \$34.9 million (before including net losses on divestment of businesses and recovery plan related charges of \$172.2 million) for the fourth quarter of 2003 compared to \$109.7 million in the fourth quarter of 2002. (See "Non-GAAP Financial Information" on page 6).
- o Net investment related losses of \$101.1 million compared to net investment losses of \$318.3 million in the fourth quarter of 2002.
- o Net loss after discontinued operations of \$328.2 million (\$0.88 loss per diluted share) compared to \$688.5 million (\$1.97 loss per diluted share) in the fourth quarter of 2002, a reduction of 52%.
- o Cash and cash equivalents at December 31, 2003, of \$807.5 million compared to \$1,013.9 million at December 31, 2002.

### Full-Year 2003 Financial Highlights - Continuing Operations

- o Total revenue of \$746.0 million compared to \$1,132.5 million for full-year 2002, a decrease of 34%.
- o Revenue from retained products (excluding Zanaflex which went generic in June 2002) of \$398.4 million compared to \$283.3 million in the full-year 2002, an increase of 41%.

### Elan Reports Fourth Quarter and full-year 2003 Financial Results

Page 3

- o Reduction of 30% in selling, general and administrative expenses in 2003 to \$403.8 million from \$575.7 million in the full-year 2002. Reduction of 21% in research and development expenditure in the full-year 2003 from \$368.3 million to \$289.2 million.
- o Negative EBITDA of \$184.6 million (before including net losses on divestment of businesses and recovery plan related charges of \$173.8 million) for the full-year compared to \$116.7 million in the full-year 2002. (See "Non-GAAP Financial Information" on page 6).
- o Net investment related losses of \$38.8 million compared to net investment losses of \$1,460.9 million in the full-year 2002.
- o Net loss after discontinued operations of \$529.4 million (\$1.49 loss per diluted share) compared to \$2,362.3 million (\$6.75 loss per diluted share) for full-year 2002, a decrease of 78%.

### R&D Highlights

- o A Biologics License Application ("BLA") for Antegren for MS is expected to be submitted mid-year to the U.S. Food and Drug Administration ("FDA") by Elan and Biogen Idec.

## Edgar Filing: ELAN CORP PLC - Form 6-K

- Prialt(TM) (ziconotide) achieved a positive outcome on the primary endpoint in its Phase III study for patients with severe chronic pain. Elan expects to file an amendment to its New Drug Application ("NDA") with the FDA in the second quarter of this year.
- Positive data was obtained from the Antegren(TM) (natalizumab) Phase III trial in Crohn's disease, where statistical significance was reached in the primary endpoint of maintenance of response following six months' treatment. A treatment difference of greater than 30 percent was seen for patients taking Antegren as compared to placebo.
- An Investigational New Drug Application ("IND") was filed for Antegren for the treatment of Rheumatoid Arthritis (RA), and a Phase II clinical trial will begin in the first half of the year.
- Reviews of European Marketing Authorisation Applications ("MAA") for Prialt in severe chronic pain and for Zonegran as adjunctive treatment of partial seizures in adults with epilepsy are ongoing.

### Elan Reports Fourth Quarter and full-year 2003 Financial Results

Page 4

#### Recovery Plan Completion

- Announced successful conclusion of the recovery plan with the divestment of certain European businesses and locations.
- Gross consideration received from asset divestitures of \$2.1 billion, ahead of the target announced in July 2002 of \$1.5 billion, and net proceeds of \$0.6 billion from a private ordinary share and convertible notes offering, bringing the total consideration received to \$2.7 billion.
- Standard and Poor's raised Elan's corporate and senior unsecured debt ratings to "B-" with positive outlook from "CCC+"
- Total contracted and potential future payments reduced from \$4.5 billion in 2002 to less than \$2.0 billion at December 31, 2003, of which \$1.1 billion fall due in 2008.
- All of the 55 active business ventures at July 2002 have been terminated, restructured or are now inactive.
- Headcount reduced to less than 2,000 as of today from approximately 4,700 in July 2002 and approximately 2,400 in November 2003.
- Recovery plan related and other significant charges of \$443.2 million in 2003 compared to \$763.6 million in 2002; and net gains on the divestment of businesses of \$267.8 million compared to nil in 2002.

#### Guidance 2004

This guidance does not take into account the additional investment required to position Antegren for a successful potential launch in MS in 2005, which investment in research and development and selling, general and administrative expenses may be significant given the expected filing announced today. We will provide updated guidance to the market at the appropriate time.

- Total revenues in the range of \$575.0 million to \$625.0 million of which approximately 85% will comprise product revenues.

## Edgar Filing: ELAN CORP PLC - Form 6-K

- o Research and development expenses at the level of approximately \$300 million reflecting retention of drug delivery business and increased investment of \$30 million in key programmes.
- o Negative EBITDA, after research and development expenses in the range of \$300 million, in the range of \$150.0 million to \$170.0 million.

Elan Reports Fourth Quarter and full-year 2003 Financial Results

Page 5

Three Months Ended December 31	Unaudited Consolidated US GAAP Income Statement Data		E
2002 US\$m	2003 US\$m		
-----			
Revenue (see p. 9)			
73.1	146.3	Product revenue	
40.6	11.2	Contract revenue	
-----	-----		
113.7	157.5	Total revenue	1
-----			
Operating Expenses (see p. 14)			
101.1	62.9	Research & development	
70.3	71.0	Cost of goods sold	
144.9	82.5	Selling, general & administrative	
(37.7)	-	- Gain on repurchase of LYONs	
-	(23.9)	Net gain on divestment of businesses	
394.9	196.1	Recovery plan and other significant charges	
-----	-----		
673.5	388.6	Total operating expenses	1
-----			
(559.8)	(231.1)	Operating loss	(
-----			
Net Interest and Investment Losses (see p.15)			
(23.8)	(24.0)	Net interest expense	
(2.9)	-	- Business venture funding	
7.6	-	- Investment gains	
(325.9)	(101.1)	Investment losses and other	(1,
-----	-----		
(345.0)	(125.1)	Net interest and investment losses	(1,
-----			
(904.8)	(356.2)	Net loss from continuing operations before tax	(2,
(3.6)	10.0	Taxation	
-----	-----		
(908.4)	(346.2)	Net loss before discontinued operations	(2,
219.9	18.0	Net income from discontinued operations	
-----	-----		
(688.5)	(328.2)	Net loss	(2,



Edgar Filing: ELAN CORP PLC - Form 6-K

=====		=====		=====	
				Weighted average no. of ordinary shares outstanding	
349,825	373,838			(in thousands)	3
				Basic and diluted loss per ordinary share - continuing	
(\$2.60)	(\$0.93)			operations	(
				Basic and diluted earnings per ordinary share - discontinued	
\$0.63	\$0.05			operations	
(\$1.97)	(\$0.88)			Basic and diluted loss per ordinary share - net loss	(

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 6

Unaudited Non-GAAP Financial Information - EBITDA		Three Months		Ended December 31		2002		2003		End		
						US\$m		US\$m		US\$m		
				Non-GAAP Financial Information								
				Reconciliation Schedule								
				EBITDA								
(559.8)	(231.1)			Operating loss								(829.8)
				Depreciation and amortisation included in								
35.7	35.2			operating loss								146.7
(25.8)	(11.2)			Amortised revenue included in total revenue								(242.5)
-----	-----			-----								-----
(549.9)	(207.1)			EBITDA								(925.6)
=====	=====			=====								=====

Three Months		Ended December 31		2002		2003		End		
				US\$m		US\$m		US\$m		
				Non-GAAP Financial Information						
				Reconciliation Schedule						
				EBITDA before net losses/(gains) on						
				divestment of businesses and recovery plan						
				related charges						
(559.8)	(231.1)			Operating loss						(829.8)
				Depreciation and amortisation included in						
35.7	35.2			operating loss						146.7
(25.8)	(11.2)			Amortised revenue included in total revenue						(242.5)
83.0	-			Exceptional product returns - genericisation						83.0
(37.7)	-			Gain on repurchase of LYONs						(37.7)

Edgar Filing: ELAN CORP PLC - Form 6-K

-	(23.9)	Gain on divestment of businesses (net)	-
394.9	196.1	Recovery plan and other significant charges	763.6
-----	-----		-----
(109.7)	(34.9)	EBITDA before net gains on divestment of businesses and recovery plan related charges	(116.7)
=====	=====		=====

To supplement our consolidated financial statements presented on a US GAAP basis, Elan provides readers with EBITDA (Earnings Before Interest, Taxes, Depreciation and Amortisation), a non-GAAP measure of operating results. Elan has also provided EBITDA guidance for 2004 which has been calculated on a consistent basis. EBITDA is defined as operating income/(loss) plus/minus depreciation and amortisation of costs and revenues. EBITDA is not presented as an alternative measure of operating results or cash flow from operations, as determined in accordance with US GAAP. Elan's management uses EBITDA to evaluate the operating performance of Elan and its business and is among the factors considered as a basis for Elan's planning and forecasting for future periods. Elan believes EBITDA is a measure of performance used by some investors, equity analysts and others to make informed investment decisions. EBITDA is used as an analytical indicator of income generated to service debt and to fund capital expenditures. EBITDA does not give effect to cash used for interest payments related to debt service requirements and does not reflect funds available for investment in the business of Elan or for other discretionary purposes. EBITDA, as presented in this press release, may not be comparable to similarly titled measures reported by other companies. A reconciliation of EBITDA to operating income/(loss) is set out in the table above titled "Non-GAAP Financial Information Reconciliation Schedule".

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 7

Unaudited US GAAP Balance Sheet Data

	December 31 2002 US\$m	December 31 2003 US\$m
Assets		
-----		
Current Assets		
Cash and cash equivalents	1,013.9	807.5
Marketable investment securities	450.6	349.4
Held for sale assets (1)	189.5	175.0
Other current assets	299.4	228.0
	-----	-----
	1,953.4	1,559.9
Intangible assets	1,338.8	934.9
Property, plant and equipment	410.1	329.3
Investments and marketable investment securities	313.2	192.9
	-----	-----
Total Assets	4,015.5	3,017.0
	=====	=====

## Edgar Filing: ELAN CORP PLC - Form 6-K

Liabilities and Shareholders' Equity		
Shareholders' equity	826.9	605.0
Accounts payable and accrued liabilities	549.8	364.5
Held for sale liabilities (1)	25.6	27.9
Deferred income	258.2	154.8
Guarantee provision - EPIL II	295.5	344.5
Product acquisition payments	227.2	19.4
6.5% convertible guaranteed notes due 2008	-	460.0
EPIL III notes	390.0	390.0
7.25% senior notes due 2008	650.0	650.0
3.25% zero coupon subordinated exchangeable notes due 2018	792.3	0.9
	-----	-----
Total Liabilities and Shareholders' Equity	4,015.5	3,017.0
	=====	=====

Reconciliation of Movement in Shareholders' Equity	US\$m
At December 31, 2002	826.9
Net loss for the twelve months ended December 31, 2003	(529.4)
Movement on unrealised gains on securities	89.6
Net proceeds of share sale	168.0
Other	49.9
	-----
At December 31, 2003	605.0
	=====

(1) In accordance with SFAS No. 144, Elan has recorded as held for sale the assets and liabilities related to its former European sales and marketing business, San Diego office property and Elan Pharma S.A., a manufacturing and research and development business based in Mezzovia, Switzerland. Each of these divestitures closed during the first quarter 2004.

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 8

Three months Ended December 31,		Unaudited US GAAP Cash Flow Data	
2002 US\$m	2003 US\$m		
(75.6)	(53.0)	Cashflows from operating activities	
(41.2)	(89.5)	Movement on debt interest and tax	
229.9	(52.3)	Working capital movement	
(63.2)	(84.5)	Net purchase of tangible/intangible assets	
0.7	10.1	Net sale of investments	
-	(99.6)	Purchase of Pharma Marketing royalty rights	
-	-	Purchase of Autoimmune royalty rights	
-	-	Sale of EPIL III assets in connection with repayment of	
-	-	EPIL III debt	
443.1	50.7	Net proceeds of business divestments	

## Edgar Filing: ELAN CORP PLC - Form 6-K

(125.9)	179.3 Cashflows from financing activities
367.8	(138.8) Net Cash Movement
646.1	946.3 Cash and cash equivalents at beginning of period
1,013.9	807.5 Cash and cash equivalents at end of period

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 9

In accordance with SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets", Elan has recorded the results and gains or losses on the divestment of its discontinued operations including Elan Transdermal Technologies, Athena Diagnostics, Elan Diagnostics, a manufacturing business in Italy, the pain portfolio of products, Actiq(TM), the dermatology portfolio of products and Abelcet(TM) US/Canada within discontinued operations in the income statement. With the exception of Actiq and Elan Diagnostics, these businesses and assets have been included as discontinued operations during the fourth quarter of 2003 for the first time. Consequently, the revenues and costs of prior quarters reflect this treatment. There is no impact on the net loss in prior quarters. An analysis of the results of the discontinued operations is set out for each quarter of 2002 and 2003 in Appendix 2.

During the course of the recovery plan, Elan sold a number of other assets and businesses (principally the primary care franchise and the European sales and marketing business) which in accordance with SFAS No. 144 are not included in discontinued operations. Elan believes that it has a significant continuing involvement in the operations of these businesses, for example through ongoing supply arrangements or formulation activities.

The analysis below is based on the revenues and costs from continuing operations presented in accordance with U.S. GAAP.

### Revenue

Total revenue decreased 20% to \$157.5 million in the fourth quarter of 2003 from \$196.7 million in the fourth quarter of 2002 (excluding exceptional provisions for product returns, primarily Zanaflex, of \$83.0 million) and decreased by 34% from \$1,132.5 million for the full-year 2002 to \$746.0 million for the full-year 2003. The historical analysis of total revenue is set out in Appendix 1.

Elan's product revenue is analysed between revenue from currently retained products and revenue arising from products that have been divested (including the recent sale of the European sales and marketing business, which closed on February 12, 2004).

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 10

Total revenue can be further analysed as follows:

## Edgar Filing: ELAN CORP PLC - Form 6-K

	Q4 2002 US\$m	Q4 2003 US\$m	Full-Year
<b>(a) Product Revenue</b>			
Revenue from retained products	74.1	107.8	406
Revenue from divested products	76.4	30.0	387
Amortised revenue - Adalat/Avinza	5.6	8.5	7
Pharma Marketing/Autoimmune	-	-	62
Exceptional product returns - genericisation	(83.0)	-	(83.0)
	-----	-----	-----
Total product revenue	73.1	146.3	781
<b>(b) Contract Revenue</b>			
Amortisation of fees	20.2	2.7	234
Research revenue and milestones	20.4	8.5	78
Pharma Marketing/Autoimmune	-	-	37
	-----	-----	-----
Total contract revenue	40.6	11.2	350
	-----	-----	-----
Total Revenue	113.7	157.5	1,132
	-----	-----	-----

### (a) Product Revenue

Total product revenue for the fourth quarter of 2003 was \$146.3 million compared to \$73.1 million in the fourth quarter of 2002, an increase of 100%. Total product revenue for the full-year 2003 was \$647.0 million compared to \$781.8 million for the full-year 2002, a decrease of 17%. The decline in product revenue in 2003 is due mainly to the divestiture of a number of products as part of the recovery plan and the impact of generic competition on sales of Zanaflex, compensated for, in part, by the growth in sales of those products retained.

#### Revenue from retained products

Revenue from retained products was \$107.8 million in the fourth quarter of 2003 compared to \$74.1 million in the fourth quarter of 2002, an increase of 45%. This increase primarily reflects the growth in prescriptions and demand for those retained products.

Sales of Maxipime(TM) and Azactam(TM) in the fourth quarter of 2003 were \$42.3 million and \$154.2 million for the full-year 2003, an increase of 22% and 37% respectively over the comparable periods in 2002, reflecting stronger demand and the negative impact on the sales of these products in the third quarter of 2002 due to a change in Elan's discounting strategy and short term

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 11

supply issues resulting from third party manufacturing constraints. Maxipime audited sales volumes for the fourth quarter of 2003 increased by 12% compared to the same period in 2002. Azactam audited sales volumes for the fourth quarter of 2003 increased by 14.3% compared to the same period in 2002. For the full-year 2003 audited sales volumes increased by 12.3% for Maxipime and 14.1% for Azactam.

Zonegran prescription demand remained strong for the fourth quarter of 2003 and increased by 74.1% over the fourth quarter of 2002 and by 57% for the full-year 2003 compared to the full-year 2002. Zonegran demand continues to grow as a

## Edgar Filing: ELAN CORP PLC - Form 6-K

result of Elan's promotional efforts as well as the increased interest in this product following the approval of the 25mg and 50mg strengths in late 2003. Zonegran recorded revenue of \$19.5 million for the fourth quarter of 2003, an increase of 225% compared to the same period in 2002. Revenues for full-year 2003 at \$80.7 million were 87% higher than full-year 2002 revenues. Sales in 2002 were negatively affected by the change in Elan's discounting strategy.

Frova(TM), which was launched in the second quarter of 2002 by the combined Elan and UCB Pharma, Inc ("UCB") sales forces, generated revenue of \$13.7 million in the fourth quarter of 2003 compared to \$4.0 million in the fourth quarter of 2002. Frova prescription demand remained strong for the fourth quarter of 2003 and increased by 63.2% over the fourth quarter of 2002 and by 264% for the full-year 2003. Revenues for full-year 2003 at \$37.5 million were 235% higher than full-year 2002 revenues of \$11.2 million.

### Revenue from divested products

As previously announced in December 2003, Elan agreed to sell its European sales and marketing business to Medeus Pharma Ltd. The transaction closed on February 12, 2004, resulting in total consideration of approximately \$120 million. On February 17, 2004, Elan also sold a product which is marketed in the UK for approximately \$9 million. Product revenue from these businesses was \$26.0 million in the fourth quarter of 2003 compared to \$22.6 million in the fourth quarter of 2002, and for the full-year 2003 was \$97.9 million compared to \$87.0 million for the full-year 2002.

During 2002 and 2003 Elan sold a number of other products and businesses, principally Skelaxin(TM) and Sonata(TM), which contributed \$4.0 million to product revenue in the fourth quarter

### Elan Reports Fourth Quarter and full-year 2003 Financial Results Page 12

of 2003, \$121.8 million in the full-year 2003, \$53.8 million in the fourth quarter of 2002 and \$300.4 million in the full-year 2002.

### Amortised Product Revenue

The fourth quarter of 2003 includes \$8.5 million of amortised revenue related to the licensing of rights to Elan's generic form of Adalat CC and the restructuring of Elan's Avinza(TM) license agreement with Ligand Pharmaceuticals, Inc. ("Ligand"), compared to \$5.6 million in the fourth quarter of 2002. The remaining unamortised revenue on these products of \$103.2 million will be recognised as revenue over the next four years reflecting Elan's ongoing involvement in the manufacture of these products.

### Pharma Marketing/Autoimmune

During the fourth quarter of 2003, Elan purchased all the royalty rights in respect of Zonegran, Frova and Zanaflex from Pharma Operating Ltd. ("Pharma Operating"), a wholly owned subsidiary of Pharma Marketing Ltd. ("Pharma Marketing") for \$99.6 million. This amount was expensed during the fourth quarter of 2003. As a result, all of Elan's agreements with Pharma Marketing were terminated. This followed the acquisition in the second quarter of 2003 of the royalty rights held by Pharma Operating in respect of Sonata and Prialt for \$196.4 million. No royalties were paid to Pharma Marketing in the fourth quarters of 2003 and 2002. \$43.3 million in royalties were paid to Pharma Marketing in full-year 2003 compared to \$24.1 million in full-year 2002. During full-year 2003 Elan received no co-promotion or contract revenues from Pharma Marketing compared to \$31.3 million during 2002.

## Edgar Filing: ELAN CORP PLC - Form 6-K

During the third quarter of 2002, Elan acquired all the royalty rights held by Autoimmune Research and Development Corp. Ltd ("Autoimmune") and this risk sharing arrangement was terminated. Consequently, no co-promotion or contract revenues were received from Autoimmune during 2003 or the fourth quarter of 2002 compared to \$68.7 million during full-year 2002.

### (b) Contract Revenue

Contract revenue in the fourth quarter of 2003 was \$11.2 million compared to \$40.6 million in the same period of 2002, a decrease of 72%. The amortisation of fees amounted to \$2.7 million

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 13

in the fourth quarter of 2003 compared to \$20.2 million in the fourth quarter of 2002. In the fourth quarter of 2002, \$15.3 million of the \$20.2 million related to the business ventures.

Contract revenue in the full-year 2003 was \$99.0 million compared to \$350.7 million in the full-year 2002. The amortisation of fees amounted to \$49.6 million in the full-year 2003 compared to \$234.7 million in the full-year 2002. Included in the amortisation of fees for 2003 is \$35.2 million related to the business ventures compared to \$203.8 million in 2002.

As part of the recovery plan outlined on July 31, 2002, Elan completed a review of its business venture programme and, as a result all of the business ventures have been terminated, restructured or are now inactive. The reduction in amortised fees during the fourth quarter and full-year 2003 arose primarily from the restructuring and termination of business ventures, which started in 2002. There are no remaining unamortised fees from the business ventures at December 31, 2003.

Research revenues and milestones were \$8.5 million in the fourth quarter of 2003 and \$49.4 million for the full-year 2003 compared to \$20.4 million and \$78.8 million in the comparable periods in 2002. This reduction reflects a lower level of activity in 2003 coupled with the timing of the receipt of milestone payments.

### Gross Profit

The gross profit margin on product revenue was 51% in the fourth quarter of 2003 compared to 4% in the fourth quarter of 2002 due primarily to the inclusion of an exceptional product returns provision in 2002 of \$83.0 million. The gross profit margin on product revenue for full-year 2003 was 54% compared to 63% for the full-year 2002. The reduction in the gross margin in 2003 reflects the change in the mix of product revenues, including the divestment of a number of products and businesses over the period of the recovery plan, under-utilisation of capacity at Elan's manufacturing facility in Athlone and the payment of royalties to Pharma Marketing. No royalties were paid to Pharma Marketing during the fourth quarter of 2003 or 2002. During full-year 2003 royalties of \$43.3 million were paid to Pharma Marketing compared to \$24.1 million for full-year 2002. Royalties paid are charged to cost of sales.

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 14

During the second quarter of 2002, Frova was launched by the combined Elan and

## Edgar Filing: ELAN CORP PLC - Form 6-K

UCB salesforce. Under the terms of these arrangements Elan pays UCB co-promotion fees based on sales of Frova. These co-promotion fees are included in cost of sales and have the impact of reducing the gross margin on revenues from Frova to approximately 25%.

### Operating Expenses

Research and development expenses were \$62.9 million in the fourth quarter of 2003 and \$289.2 million for the full-year 2003 compared to \$101.1 million and \$368.3 million in the comparable periods of 2002. This reduction reflects the refocusing of research and development efforts on key programmes: Antegren, Prialt and the Alzheimer's programmes.

Selling, general and administrative expenses decreased by 43% to \$82.5 million in the fourth quarter of 2003 from \$144.9 million in the fourth quarter of 2002. For the full-year 2003 selling, general and administrative expenses decreased by 30% to \$403.8 million from \$575.7 million in 2002 reflecting the successful implementation of the recovery plan and related cost reduction initiatives.

### Recovery Plan and Other Significant Charges / Gains

During the fourth quarter of 2003 Elan recorded net costs primarily associated with the implementation of the recovery plan of \$196.1 million and \$23.9 million net gains on the divestment of certain businesses. These may be analysed as follows:

	Q4 2002 US\$m	Q4 2003 US\$m	Full-Year US\$m
Write-down of tangible and intangible assets	325.2	54.3	5
Net gain on divestment of businesses	-	(23.9)	
Purchase of royalty rights	-	99.6	
Gain on repurchase of LYONs	(37.7)	-	(3
Severance costs, relocation and exit costs	19.5	12.3	
Costs related to shareholder litigation, SEC investigation and 401k recission offer	19.5	1.8	
EPIL II/III waiver fee	-	16.8	
Other	30.7	11.3	
	357.2	172.2	7

### Elan Reports Fourth Quarter and full-year 2003 Financial Results

Page 15

During the fourth quarter of 2003 Elan recorded impairments of \$54.3 million against tangible and intangible assets, primarily related to Myobloc, based on revised estimates of its future prospects.

The net gain on the divestment of businesses in the fourth quarter of \$23.9 million arises primarily from \$25.0 million milestone payment, pursuant to a previously announced term of the amended agreement between Elan and King Pharmaceuticals, Inc. ("King") that was contingent upon ongoing patent exclusivity for Skelaxin. For the full-year 2003, the net gain on the divestment



## Edgar Filing: ELAN CORP PLC - Form 6-K

of businesses relates principally to the profit of \$264.4 million in relation to the divestment of the primary care franchise to King.

During the fourth quarter of 2003, Elan purchased all the royalty rights in respect of Zonegran, Frova and Zanaflex from Pharma Operating for \$99.6 million. This amount was expensed during the fourth quarter of 2003. This followed the acquisition in the second quarter of 2003 of the royalty rights held by Pharma Operating in respect of Sonata and Prialt for \$196.4 million. This amount was expensed in the second quarter of 2003.

On November 10, 2003, Elan announced that it had successfully completed a private offering of \$460.0 million in aggregate principal amount of 6.5% Guaranteed Convertible Notes due 2008. In connection with this offering a waiver fee of \$16.8 million was paid to the holders of the EPIL II and EPIL III notes.

Although the recovery plan is complete, Elan may incur further charges related to the SEC investigation and shareholder litigation.

### Net Interest and Investment Losses

Net interest and investment losses amounted to \$125.1 million in the fourth quarter of 2003 compared to a loss of \$345.0 million in the fourth quarter of 2002.

In the fourth quarter of 2003, net interest expense amounted to \$24.0 million (full-year 2003: \$95.0 million) compared to \$23.8 million (full-year 2002: \$68.3 million) in the fourth quarter of 2002, reflecting lower interest income earned on cash deposits and other investments, the interest

### Elan Reports Fourth Quarter and full-year 2003 Financial Results Page 16

costs associated with the \$460.0 million convertible notes issued in the fourth quarter of 2003, and offset by lower interest expense due to previously announced Liquid Yield Option Notes ("LYONs") repurchases. The loss on investments in the fourth quarter of 2003 of \$101.1 million included \$14.3 million in relation to the mark-to-market of certain investments, investment impairments of \$47.1 million and an increase in the EPIL II guarantee provision of \$32.5 million.

In addition, certain other publicly quoted investments were marked-to-market and the net increase in value of approximately \$5 million in the quarter has been included in unrealised gains on securities within shareholders' equity.

During the full-year 2003, Elan recorded net investment losses of \$38.8 million compared to \$1,460.9 million during full-year 2002. Investment losses in 2002 resulted from a significant decline in the biotech sector overall, the impact on the value of smaller biotech companies (that make up a significant part of Elan's portfolio) of difficult financing markets and the impact of the business venture restructuring programme initiated in the third quarter of 2002.

### Liquidity

At December 31, 2003, Elan had \$807.5 million in cash and cash equivalents compared with \$1,013.9 million at December 31, 2002 and \$946.3 million at September 30, 2003.

On November 5, 2003, Elan announced that it had successfully completed a private offering of 35 million Ordinary Shares and on November 10, 2003, Elan announced that it had successfully completed a private offering of \$460.0 million in aggregate principal amount of 6.5% Guaranteed Convertible Notes due 2008. The

## Edgar Filing: ELAN CORP PLC - Form 6-K

offerings resulted in aggregate net proceeds (after giving effect to the payment of commissions and concessions and the estimated expenses of the offerings, including a waiver fee of \$16.8 million paid to the holders of the EPIL II and EPIL III notes) of approximately \$595 million. The net proceeds from the offerings were used by Elan's subsidiary, Elan Finance Corporation, Ltd., to repurchase outstanding LYONs, including LYONs surrendered for purchase by the holders on December 14, 2003, pursuant to the indenture under which the LYONs were issued and for the repurchase of royalty rights from Pharma Operating.

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 17

As of December 2003, the major contracted and potential non-operating cash payments relating to Elan's business are:

	2004 US\$m	2005 US\$m	2008 US\$m	T
-----				
Contracted & LYONs				
7.25% Senior Notes (2008)	-	-	650.0	6
6.5% Convertible Notes	-	-	460.0	4
Fixed Product Payments	19.4	-	-	
Contingent Product Payments (1)	-	-	-	
EPIL II (2)	450.0	-	-	4
EPIL III	-	390.0	-	3
3.25% LYONs	-	-	0.9	
	-----			
Total Contracted & LYONs	469.4	390.0	1,110.9	1,9
	-----			
Potential				
Pharma Marketing/Autoimmune (1)	-	-	-	
Product Acquisitions (1)	-	-	-	
	-----			
Total Potential	-	-	-	
	-----			
Total Contracted, Potential & LYONs	469.4	390.0	1,110.9	1,9
	-----			

(1) In order to comply with US GAAP, these amounts are not included on the balance sheet.

(2) In order to comply with US GAAP, \$344.5 million of this amount (2002: \$295.5 million) is provided on the balance sheet.

### Qualifying Special Purpose Entity ("QSPE")

Elan has guaranteed loan notes issued by EPIL II (a QSPE, which is not consolidated under U.S. GAAP) to the extent that the investments held by it are insufficient to repay the loan notes and accrued interest when they fall due. The aggregate principal amount outstanding under the loan notes issued by EPIL II was \$450.0 million at December 31, 2003, and is repayable on June 28, 2004. The investments held by EPIL II will be sold to meet the maturity of the loan

## Edgar Filing: ELAN CORP PLC - Form 6-K

notes.

During the fourth quarter of 2003, Elan increased the provision for its guarantee by \$32.5 million to \$344.5 million, reflecting the net reduction in the value of the investments held by EPIL II during this period after charging interest of \$10.6 million for the quarter. After providing for the estimated investment shortfalls, the carrying values and cash position of EPIL II were as follows:

	US\$m
Investments in public companies	76.3
Investments in private companies	9.0
Cash	20.5
Accrued interest and expenses	(0.3)
	-----
Total assets	105.5
Provision for guarantees	344.5
	-----
Total guaranteed indebtedness	450.0

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 18

This provision has been arrived at based on the estimated value of the investment portfolio at December 31, 2003, using established financial valuation methodologies and consistent with the requirements of U.S. GAAP, and does not reflect any liquidity discount.

### Guidance

Elan is providing guidance as to the potential financial outcome for 2004. As there are many variables which could have a significant impact on this outcome and which are outside the control of Elan, such as strategic product divestments or acquisitions and timing of regulatory filings and approvals, the actual outcome could be significantly different.

This guidance does not take into account the additional investment required to position Antegren for a successful potential launch in MS in 2005, which investment may be significant given the press release of today. Based on today's Antegren press release, Elan expects research and development and selling, general and administrative expenses to increase significantly during 2004 and we will provide updated guidance to the market at the appropriate time.

During 2004, Elan anticipates total revenues in the range of \$575.0 million to \$625.0 million, of which approximately 85% will comprise product revenues. Amortised revenues, mainly in relation to Adalat CC and Avinza, are anticipated to be less than 10% of total revenues. The gross profit percent on revenues is expected to be maintained in the range of 53% to 57%.

Selling, general and administration expenses from continuing operations are expected to reduce by a further 20% to 25% from the \$403.8 million recorded in the full-year 2003. This reduction reflects the implementation of ongoing cost reduction initiatives, together with an increased investment of approximately \$35 million for both pre-launch costs for Prialt and an increased investment in Maxipime following the decision to retain this product.

Research and development expenses are expected to continue at about the same level as in 2003. This includes an increased investment in Antegren, Prialt and

## Edgar Filing: ELAN CORP PLC - Form 6-K

the Alzheimer's programmes of approximately \$30 million. These increased investments are considered critical to make sure Elan has all the necessary data and studies completed to ensure the commercial success of its

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 19

unique and innovative pipeline. Approximately 15% of research and development expenses relate to the drug delivery businesses which Elan decided to retain in December 2003, and these costs are expected to be more than covered by research revenues and milestones from these businesses.

EBITDA for 2004 is expected to be negative and in the range of \$150.0 million to \$170.0 million. Net cash interest and related financing costs are expected to increase from \$95.0 million to approximately \$120 million.

### R&D Update

Elan's research and development activities include the discovery and development of products in the therapeutic areas of neurology, autoimmune diseases and severe pain. Elan is a proven leader in the understanding of the pathology of Alzheimer's disease and in the advancement of potential disease modifying agents. Other neurology research and development efforts include work in the areas of Parkinson's disease, multiple sclerosis (MS) and epilepsy. In autoimmune diseases and severe pain, Elan has late-stage development efforts in Antegren and Prialt.

### Antegren(TM) (natalizumab)

Elan and Biogen Idec, Inc. ("Biogen Idec") are collaborating on the development, manufacturing and commercialisation of Antegren, a humanised monoclonal antibody, and the first in a new class of compounds known as selective adhesion molecule ("SAM") inhibitors. This novel mechanism of action lends itself to potential utility in several disease states, as the drug is designed to selectively inhibit immune cells from leaving the bloodstream and migrating into chronically inflamed tissue, such as the gastrointestinal tract in Crohn's disease, the brain in MS, and the joints in RA.

Elan and Biogen Idec have engaged in four Phase III trials to evaluate the safety and efficacy of Antegren in both Crohn's disease and MS. Combined, these trials have enrolled over 3,000 patients.

Today, Elan and Biogen Idec announced the intention to submit to the FDA an application for

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 20

approval of Antegren as a treatment for MS. The companies expect to submit the filing mid-year 2004. The decision to file a BLA was made after discussions with the FDA of one-year data from the two on-going two-year Phase III trials in MS. The companies are committed to completing the two-year trials. To protect the integrity of the trials, the companies are not disclosing the one-year data at this time.

On January 29, 2004, Elan and Biogen Idec announced positive results from the

## Edgar Filing: ELAN CORP PLC - Form 6-K

Phase III maintenance trial of Antegren in Crohn's disease, known as ENACT-2 (Evaluation of Natalizumab as Continuous Therapy-2). ENACT-2 was designed to evaluate the ability of Antegren to maintain efficacy in Crohn's disease as assessed by the Crohn's Disease Activity Index (CDAI). The trial met the primary endpoint of maintenance of response following six months of treatment in this study. Maintenance of response was defined by a sustained CDAI score of less than 220 as well as no use of rescue intervention throughout the six months of this study. There was a significant treatment difference of greater than 30 percent in favour of Antegren in patients taking the drug compared to those taking placebo.

Antegren was safe and well tolerated in the ENACT-2 trial, and the safety profile remains similar to that seen in previous Antegren studies, with a low incidence of infusion reactions and immunogenicity. There was no notable difference in the overall rate of side effects between Antegren and placebo treatment groups as observed through six months of treatment in ENACT-2.

Elan and Biogen Idec will present the data of the ENACT-1 and ENACT-2 studies to U.S. and European regulatory authorities and determine the regulatory path forward for Antegren in Crohn's disease.

The clinical development programme for Antegren in MS is ongoing with more than 2,000 patients enrolled in two Phase III studies.

In addition to the commitment to develop Antegren for Crohn's disease and MS, an IND was filed with the FDA to evaluate the potential of Antegren for the treatment of RA, and a Phase II trial is on track to be initiated in the first half of this year. Elan and Biogen Idec believe Antegren will provide a meaningful advance for patients with these debilitating diseases.

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 21

### Prialt (ziconotide)

Elan recently announced that the Phase III trial evaluating Prialt in patients with chronic severe pain met its primary endpoint. In the double-blind placebo-controlled trial, patients treated with Prialt displayed a statistically significant improvement at week three in the Visual Analog Scale of Pain Intensity (VASPI) score, as compared to placebo. Based on these positive results, Elan expects to file an amendment to its NDA with the FDA in the second quarter of 2004 and to launch the product no later than the first quarter of 2005. The European MAA was filed and accepted by the European regulatory authority during 2003, and the review of this application is ongoing.

Prialt is an innovative, highly potent intrathecal therapy for severe chronic pain. Prialt is the first in a new class of non-opioid analgesics known as N-type calcium channel blockers. Elan is encouraged by these most recent Phase III results and is hopeful that Prialt may offer a meaningful advance for patients currently suffering with chronic severe pain, many of whom are not adequately treated by available therapies.

### Zonegran (zonisamide)

Zonegran is currently marketed in the United States by Elan and by Dainippon in Japan for the adjunctive treatment of partial seizures in adults with epilepsy. Elan has also filed a MAA with the European regulatory authorities for Zonegran for patients with partial seizures in epilepsy.

### Alzheimer's Programmes

## Edgar Filing: ELAN CORP PLC - Form 6-K

Elan has a broad-based research and development effort in the area of Alzheimer's disease, which is primarily focused in three areas targeting the beta-amyloid peptide. The first two approaches are focused on two distinct enzyme inhibitors that may limit production of beta-amyloid: beta secretase and gamma secretase inhibitors. In the third programme, Elan and Wyeth are utilising an immunotherapeutic approach which may decrease beta amyloid in the brain.

Elan, with Wyeth, re-entered the clinic with our Alzheimer's programme and has an ongoing Phase I study evaluating safety and tolerability of a humanised monoclonal antibody targeted at the A-beta peptide. Preclinical efforts continue with a novel immunotherapeutic A-beta peptide

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 22

conjugate to evaluate the potential for an active immunisation approach in parallel with the passive monoclonal antibody approach.

### About Elan

Elan is focused on the discovery, development, manufacturing, sale and marketing of novel therapeutic products in neurology, severe pain and autoimmune diseases. Elan (NYSE: ELN) shares trade on the New York, London and Dublin Stock Exchanges.

This document contains forward-looking statements about Elan's financial condition, results of operations and business prospects that involve substantial risks and uncertainties. You can identify these statements by the fact that they use words such as "anticipate", "estimate", "project", "envisage", "intend", "plan", "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: Elan's intent to file with the FDA for approval for Antegren for MS; a delay in filing the Antegren BLA for MS; the potential of Antegren as a treatment for MS and Crohn's disease; a delay in filing an amendment to Elan's NDA with respect to Prialt; the potential of Prialt as an intrathecal treatment for severe pain; a delay in the start of the Phase II clinical trial of Antegren for the treatment of RA; Elan's ability to maintain sufficient cash, liquid resources, and investments and other assets capable of being monetised to meet its liquidity requirements; the outcome of the ongoing SEC investigation and the shareholder and other pending litigation; the success of research and development activities and the speed with which regulatory authorisations and product launches may be achieved; competitive developments affecting Elan's current products; the ability to successfully market both new and existing products; difficulties or delays in manufacturing; the ability to meet generic and branded competition after the expiration of Elan's patents; the trend towards managed care and health care cost containment; possible legislation affecting pharmaceutical pricing; exposure to product liability and other types of lawsuits; Elan's ability to protect its intellectual property; interest rate and foreign currency exchange rate fluctuations; governmental laws and regulations affecting domestic and foreign operations, including tax obligations; general changes in U.S. and Irish generally accepted accounting principles; growth in costs and expenses; changes in product mix; the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items. A further list and description of these risks, uncertainties and other matters can be found in Elan's Annual

## Edgar Filing: ELAN CORP PLC - Form 6-K

Report on Form 20-F for the fiscal year ended December 31, 2002, and in its Reports of Foreign Issuer on Form 6-K. Elan assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 23

### Appendix 1

Historic Revenue Analysis (Unaudited)  
Total revenue analysis (US\$m)

	Q4 2002	Full-Year 2002	Q4
Revenue from Retained Products			
U.S. Promoted Products			
Maxipime	25.2	79.2	
Azactam	9.5	33.0	
Zonegran	6.0	43.1	
Myobloc	8.6	19.6	
Frova	4.0	11.2	
	-----	-----	-----
	53.3	186.1	
U.S. Non-promoted Products			
Zanaflex	1.1	123.5	
Other	0.1	4.7	
	-----	-----	-----
	1.2	128.2	
Contract Manufacturing and Royalties	19.6	92.5	
Total Revenue from Retained Products	74.1	406.8	1
Revenue from Divested Products			
Skelaxin	19.9	145.4	
Sonata	20.5	92.5	
European business	22.6	87.0	
Rationalisation programme	13.4	62.5	
	-----	-----	-----
	76.4	387.4	
Co-promotion Fees			
Autoimmune	-	38.8	
Pharma Marketing	-	24.0	
	-----	-----	-----
	-	62.8	
Amortised Revenue - Adalat/Avinza	5.6	7.8	
Exceptional Product Returns - Genericisation	(83.0)	(83.0)	
Total Product Revenue	73.1	781.8	1
Contract Revenue			

## Edgar Filing: ELAN CORP PLC - Form 6-K

Amortisation of fees	20.2	234.7
Research revenue and milestones	20.4	78.8
Pharma Marketing/Autoimmune	-	37.2
Total Contract Revenue	40.6	350.7
Total Revenue	113.7	1,132.5

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 24

### Appendix 2

Discontinued Operations (unaudited)  
Twelve Months Ended December 31, 2003

	Q1 2003 US\$m	Q2 2003 US\$m	Q3 2003 US\$m	Q4 (US\$m)
Product revenue	44.5	29.6	29.8	
Contract revenue	-	0.5	-	
Total revenue	44.5	30.1	29.8	
Research & development	4.2	6.3	1.7	
Cost of goods sold	17.5	14.6	7.4	
Selling, general & administrative	7.8	4.8	7.3	
Loss/(gain) on divestment of businesses (net)	0.8	0.3	5.5	
Recovery plan and other significant charges	0.8	4.7	6.0	
Total operating expenses	31.1	30.7	27.9	
Operating profit / (loss)	13.4	(0.6)	1.9	
Net interest and investment losses	(1.1)	(1.0)	(0.2)	
Net income before tax	12.3	(1.6)	1.7	
Taxation	-	(0.3)	-	
Net income/(loss)	12.3	(1.9)	1.7	

Non- GAAP Financial Information  
EBITDA

Operating profit/(loss)	13.4	(0.6)	1.9
Depreciation & amortisation	4.9	5.6	6.4
Amortised revenue included in total revenue	(10.5)	-	-



Edgar Filing: ELAN CORP PLC - Form 6-K

EBITDA	7.8	5.0	8.3
Loss/(gain) on divestment of businesses (net)	0.8	0.3	5.5
Recovery plan and other significant charges	0.8	4.7	6.0
-----			
EBITDA before net losses/(gains) on divestment of businesses and recovery plan related charges	9.4	10.0	19.8
=====			

Elan Reports Fourth Quarter and full-year 2003 Financial Results  
Page 25

Appendix 2

Discontinued Operations (unaudited) Twelve Months Ended December 31, 2002	Q1 2002 US\$m	Q2 2002 US\$m	Q3 2002 US\$m	Q4 2002 US\$m
Product revenue	79.3	89.2	56.0	90.0
Contract revenue	1.6	1.1	0.5	0.5
-----				
Total revenue	80.9	90.3	56.5	90.5
-----				
Research & development	7.2	6.9	8.5	8.5
Cost of goods sold	31.9	33.4	30.7	29.7
Selling, general & administrative	35.0	36.4	37.6	29.7
Gain on divestment of businesses (net)	-	-	-	(177.0)
Recovery plan and other significant charges/gains	2.7	63.0	119.4	(22.0)
-----				
Total operating expenses	76.8	139.7	196.2	(136.0)
-----				
Operating profit/ (loss)	4.1	(49.4)	(139.7)	23.0
-----				
Net interest and investment (losses)/gains	(1.9)	(1.9)	(2.2)	0.0
-----				
Net income/(loss) before tax	2.2	(51.3)	(141.9)	23.0
Taxation	-	-	(0.2)	(11.0)
-----				
Net income/(loss)	2.2	(51.3)	(142.1)	12.0
=====				
Non-GAAP Financial Information				
EBITDA				
Operating profit/(loss)	4.1	(49.4)	(139.7)	23.0
Depreciation & amortisation	12.3	12.4	15.0	12.3
Amortised revenue included in total revenue	-	-	-	(29.0)
-----				
EBITDA	16.4	(37.0)	(124.7)	21.0

Edgar Filing: ELAN CORP PLC - Form 6-K

Gain on divestment of businesses (net)	-	-	-	(177)
Recovery plan and other significant charges/(gains)	2.7	63.0	119.4	(22)
-----				
EBITDA before net losses/(gains) on divestment of businesses and recovery plan related charges	19.1	26.0	(5.3)	1
=====				