

ALKERMES INC
Form 425
July 28, 2011
Table of Contents

Filed by Elan Corporation, plc

pursuant to Rule 425 of the

Securities Act of 1933 and

deemed filed pursuant to

Rule 14a-12 of the

Securities Exchange Act of 1934

Subject Company: Alkermes, Inc.

Commission File No.: 001-14131

Elan Corporation, plc

Half-Year Financial Report

Six Months Ended 30 June 2011

Table of Contents

Table of Contents

	Page
<u>Chief Executive Officer's Statement</u>	1
<u>Half-Year Management Report</u>	2
<u>Unaudited Condensed Consolidated Half-Year Financial Statements</u>	17
<u>Notes to the Unaudited Condensed Consolidated Half-Year Financial Statements</u>	22
<u>U.S. GAAP Information</u>	42
<u>Responsibility Statement</u>	49
<u>Independent Review Report of KPMG</u>	50

Table of Contents

CHIEF EXECUTIVE OFFICER'S STATEMENT

To Our Shareholders:

During the first half of 2011, Elan delivered significant financial advancement, announced a strategic transaction that will lay the foundation for the Company in the years to come and added to the depth and breadth of our discovery/research activities. Adjusted Earnings Before Interest Tax Depreciation and Amortisation (EBITDA) increased by 49% over the same period in 2010 as overall financial results continue to improve (see page 13 for a reconciliation of Adjusted EBITDA to IFRS net income/(loss)). The significant increase in Adjusted EBITDA principally reflects a continuation in revenue growth coupled with an increase in operating margins being driven by a business structure that allows a portfolio approach to costs and investments against expected timelines, results and overall performance.

Revenue increases for the BioNeurology business were driven by growth of *Tysabri*[®], which recorded in-market sales of \$738.4 million in the first half of 2011, an increase of 25% over the \$589.4 million recorded in the same period of 2010. At the end of June 2011, approximately 61,500 patients were on therapy worldwide, an increase of 15% over the 53,300 (revised) who were on therapy at the end of June 2010.

We continue to work closely with our collaborator on *Tysabri*, Biogen Idec, Inc. (Biogen Idec), as well as the clinical and scientific communities, to create significant understanding in both efficacy and safety of the therapy so it may be best positioned to the maximum clinical benefit of patients. Importantly, in June 2011, the European Commission (EC) approved the inclusion of the anti-JC virus (JCV) antibody status as an additional factor in stratifying patients at risk for developing progressive multifocal leukoencephalopathy (PML) in the survey of Product Characteristics for *Tysabri* in the European Union. In addition, as part of a standard review process, the EC concluded the quality, safety and efficacy of *Tysabri* continue to be adequately demonstrated, and renewed *Tysabri*'s five year marketing authorization in the EU. Elan and Biogen have filed for a similar label update with the U.S. Food and Drug Administration (FDA) and expect to hear a response in the second half of 2011.

In May 2011, we announced the signing of an agreement to merge our Elan Drug Technologies (EDT) business with Alkermes, Inc. (Alkermes), a transaction that we believe provides a clear strategic pathway for Elan while, at the same time, providing significant benefit to our shareholders. The newly formed Alkermes plc will have a diversity of assets, a balance of expertise and will be cash flow positive from an operating point of view upon the closing of the transaction. In consideration for this transaction, we will receive \$500 million in cash and 31.9 million shares of Alkermes plc common stock upon closing of the transaction. We intend to use the proceeds to further reduce our debt and continue to strengthen our balance sheet and overall capital structure. We expect the EDT transaction to close in the third quarter of 2011.

Also in May 2011, we entered a strategic business relationship with Proteostasis Therapeutics, Inc. (Proteostasis) to advance the discovery and development of disease modifying small molecule drugs and diagnostics for the treatment of neurodegenerative disorders and a broad array of dementia related diseases including Alzheimer's disease. This innovative initiative will combine Proteostasis' unique discovery technology, novel targets and compounds that modulate key Proteostasis network pathways with our longstanding strength in proprietary animal models, biology, medicinal chemistry and clinical development. We invested \$20 million into the equity capital of Proteostasis and became a 24% shareholder. We will have the opportunity to invest an additional \$30 million in collaboration funding over five years and retain the right of first negotiation to exclusively license potential compounds.

As part of our on-going effort to engage best in class business partners, we announced a global technical development and manufacturing agreement for antibody based therapeutics with Boehringer Ingelheim. In addition, we formed a global business collaboration with Pharmaceutical Product Development, Inc. (PPD) to focus the advancement and execution of our clinical development portfolio. Both of these important initiatives will allow us to advance our science and therapeutics in a flexible, cost efficient manner and further combine outstanding science with a business model that allows for flexibility, scale and operating leverage.

We look forward to and expect to make continued progress on all aspects of our business. Elan will remain a company that has as its core distinctive science and an ability to translate that science into possible therapies that may offer the opportunity to help millions of patients around the world. In doing so, we expect to create shareholder value over time and through cycles as we dynamically manage a portfolio of science, clinical assets, cash flows, timelines, risks and capital structure to achieve our goal of attaining clear leadership within the industry.

G. Kelly Martin

Chief Executive Officer

Table of Contents

HALF-YEAR MANAGEMENT REPORT

In connection with the proposed merger, Alkermes plc has filed with the Securities and Exchange Commission (SEC) a registration statement that includes a preliminary prospectus regarding the proposed merger and Alkermes, Inc. has filed with the SEC a proxy statement in respect of the proposed merger. The definitive proxy statement/prospectus will be mailed to the stockholders of Alkermes, Inc. INVESTORS ARE URGED TO CAREFULLY READ THE REGISTRATION STATEMENT AND THE PROXY STATEMENT/PROSPECTUS AND OTHER MATERIALS REGARDING THE PROPOSED MERGER BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT ALKERMES, INC. AND EDT AND THE PROPOSED TRANSACTION. Investors may obtain a free copy of the registration statement and the proxy statement/prospectus and other documents containing information about EDT and Alkermes, Inc., without charge, at the SEC's website at www.sec.gov. Copies of the proxy statement/prospectus and the filings with the SEC that will be incorporated by reference in the proxy statement/prospectus can also be obtained, without charge, from Elan's website www.elan.com.

This communication does not constitute an offer to sell, or the solicitation of an offer to sell, or the solicitation of an offer to subscribe for, or buy, any securities, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

Introduction

This Half-Year Financial Report for the six months ended 30 June 2011 meets the reporting requirements pursuant to the Transparency (Directive 2004/109/EC) Regulations 2007 and the related Transparency Rules of the Republic of Ireland's Financial Regulator.

This half-year management report includes the following:

Business overview, including important events that have occurred during the half-year;

Selected financial data;

Principal risks and uncertainties relating to the remaining six months of the year;

Results of operations for continuing and discontinued operations for the first half 2011, compared to the first half of 2010;

Reconciliation of net income/(loss) to Adjusted EBITDA – non-GAAP financial information;

Liquid resources and shareholders' equity;

Cash flows summary;

Debt facilities;

Related party transactions; and

Directors.

Business Overview

Elan Corporation, plc, an Irish public limited company (also referred to hereafter as we, our, us, Elan and the Company), is a neuroscience-biotechnology company, listed on the Irish and New York Stock Exchanges, and headquartered in Dublin, Ireland. We were incorporated as a private limited company in Ireland in December 1969 and became a public limited company in January 1984. Our registered office and principal executive offices are located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland and our telephone number is +353-1-709-4000. As of 30 June 2011, we employed over 1,000 people and our principal research and development (R&D), manufacturing and marketing facilities are located in Ireland and the United States.

Our operations are organised into two business units; BioNeurology and EDT. BioNeurology engages in research, development and commercial activities primarily in the areas of Alzheimer's disease, Parkinson's disease and multiple sclerosis (MS). EDT is an established, profitable, integrated drug delivery business unit of Elan, which has been applying its skills and knowledge in product development and drug delivery technologies to enhance the performance of dozens of drugs that have been marketed worldwide.

Table of Contents

EDT Transaction

On 9 May 2011, Alkermes and Elan announced the execution of a definitive agreement under which Alkermes will merge with EDT in a cash and stock transaction valued at approximately \$960 million as of the date of announcement. Alkermes and EDT will be combined under a new holding company incorporated in Ireland. This newly created company will be named Alkermes plc.

In connection with the transaction, at closing, we will receive \$500 million in cash and 31.9 million ordinary shares of Alkermes plc common stock. Existing shareholders of Alkermes will receive one ordinary share of Alkermes plc in exchange for each share of Alkermes they own at the time of the merger. Alkermes plc shares will be registered in the United States and are expected to trade on the NASDAQ exchange.

On the closing of the transaction, we will hold approximately 25% of the equity of Alkermes plc, with the existing shareholders of Alkermes holding the remaining 75% of the equity. We will account for our equity investment in Alkermes plc as an investment in an associate and expect to record a substantial gain on the disposal of EDT when the transaction closes. We intend to use the net cash proceeds from the transaction to retire debt.

The transaction is subject to approval by Alkermes' stockholders and the satisfaction of customary closing conditions and regulatory approvals. The transaction is expected to close during the third quarter of 2011. We refer to this transaction as the EDT Transaction in this Half-Year Financial Report.

Following the approval of the EDT Transaction by the Board of Elan on 8 May 2011, the EDT business met the criteria to be classified as held for sale and the assets and liabilities of EDT have been classified as held for sale on the half-year balance sheet at 30 June 2011. The results of EDT are presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative amounts have been restated to reflect this classification.

Summary of Operating Performance

Our continuing operations solely relate to the BioNeurology business. Total revenue for the BioNeurology business increased by 12% to \$324.9 million in the first half of 2011, compared to the same period in 2010. The increase was driven by the growth of *Tysabri* revenue where total in-market sales were \$738.4 million in the first half of 2011, an increase of 25% over the \$589.4 million recorded in the same period of 2010, and resulted in recorded *Tysabri* revenue of \$321.7 million (2010: \$250.3 million). The growth in in-market sales reflects increased patient demand across global markets and a higher price in the United States, along with favourable foreign currency movements in the rest of world (ROW). At the end of June 2011, approximately 61,500 patients were on therapy worldwide, including approximately 28,500 commercial patients in the United States and approximately 32,300 commercial patients in ROW, representing an increase of 15% over the 53,300 patients (revised) who were on therapy at the end of June 2010.

For a reconciliation of operating profit/(loss) before other charges to operating profit/(loss), refer to page 8. We believe this reconciliation is meaningful because it provides additional information when analysing certain items. The principal items classified as other charges include transaction costs, severance, restructuring and other costs, facilities charges and net loss on divestment of business.

In July 2010, we announced that we reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts with respect to the previously disclosed U.S. Department of Justice's investigation of sales and marketing practices for ZONEGRA[®], which we divested in 2004. During the first half of 2010, we recorded a \$206.3 million provision charge for the settlement, interest and related costs. The agreement was finalised in December 2010. Consistent with the terms of the agreement-in-principle announced in July 2010, we paid \$203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims. The resolution of the ZONEGRA investigation could give rise to other investigations of litigation by state government entities or private parties.

Excluding other charges, the BioNeurology business recorded an operating profit for the first half of 2011 of \$44.0 million compared to an operating profit, excluding the settlement provision and other charges, of \$7.1 million recorded in the first half of 2010. This improvement reflects the 12% increase in revenue, improved operating margins and a 11% reduction in combined SG&A and R&D expenses (excluding other charges).

Table of Contents

The net income from discontinued operations of \$103.1 million in the first half of 2011 as compared to \$21.1 million in the first half of 2010 relates to the EDT business. The net income from discontinued operations in the first half of 2011 includes legal settlement gains of \$84.5 million, which are further discussed on page 12. Including the net income from continuing and discontinued operations, total net income for the first half of 2011 was \$50.1 million compared to a net loss of \$219.8 million in the same period of 2010.

In the first half of 2011, BioNeurology Adjusted EBITDA increased to \$73.2 million from \$35.9 million for the same period in 2010. The increase principally reflects the increase in revenue, improved operating margins and the reduction in combined SG&A and R&D expenses (excluding other charges). For a reconciliation of net loss to Adjusted EBITDA, refer to page 13.

For additional discussion of the results of operations for the first half of 2011, refer to pages 6 to 12 of this half-year management report.

BioNeurology R&D Update

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

The new SmPC language states that patients who are anti-JCV antibody positive are at an increased risk of developing PML compared to patients who are anti-JCV antibody negative. Recent studies suggest that irrespective of MS treatment, approximately 55% of MS patients are anti-JCV antibody positive. The SmPC language also states that patients who are anti-JCV antibody positive, have received prior immunosuppressant (IS) therapy, and received treatment with *Tysabri* for more than two years have the highest risk of developing PML.

This update to the SmPC was based on analysis of data from Biogen and Elan's quantitative risk stratification algorithm, which was presented at a number of recent major, international medical meetings. In the analysis, patients who were anti-JCV antibody negative were at a lower risk for developing PML. Patients who were anti-JCV antibody positive had varying degrees of risk for developing PML depending on prior IS use and *Tysabri* treatment duration.

In May 2011, we announced a strategic business relationship with Proteostasis to leverage Proteostasis' platform for the discovery and development of disease-modifying, small molecule drugs and diagnostics for the treatment of neurodegenerative disorders such as Parkinson's, Huntington's, MS and amyotrophic lateral sclerosis (ALS), and a broad array of dementia-related diseases including Alzheimer's. This innovative initiative will bring together Proteostasis' unique discovery technology, novel targets and compounds that modulate key Proteostasis Network pathways with our recent scientific advances in Parkinson's disease and long-standing strength in proprietary animal models, biology and medicinal chemistry as well as our current development expertise.

Under the terms of the agreement, we invested \$20 million into the equity capital of Proteostasis and will have an opportunity to provide an additional \$30 million in collaboration funding over five years. As part of the agreement, we became an approximate 24% shareholder in Proteostasis, obtained a right of first negotiation to exclusively license compounds emerging from the combined initiative, and have the right to a seat on the Proteostasis board of directors as well as its scientific advisory board. By mutual agreement, the relationship can be extended for a further five years. Elan's CEO, Kelly Martin, has joined the board of directors of Proteostasis and Elan's chief scientific officer, Dale Schenk, has joined its Scientific Advisory Board.

Neotope Biosciences Limited (Neotope Biosciences) is a wholly owned subsidiary of Elan that was created in 2010. Its focus is on creating novel monoclonal antibodies to neo-epitope amyloid related targets for the treatment of a broad range of therapeutic indications. These indications cover many different diseases from neurodegeneration to cancer to diabetes.

With progress being made in our lead programme against AL amyloidosis, we will begin the process of forming a separate and initially wholly owned subsidiary dedicated to advancing oncology related

Table of Contents

therapeutics. This business structure enables Neotope Biosciences and our Parkinson's Disease Genetics (PDG) group to continue to follow the science, reinforcing our focus, expertise and operating discipline in the broad field of neurology while simultaneously benefiting from possible therapeutic advancements in non-neurology fields.

During the second quarter of 2011, we discontinued our ELND007 gamma secretase programme.

In July 2011, we presented data from the Phase 2 clinical trial of ELND005 (Scyllo-inositol) in mild to moderate Alzheimer's disease patients, at the Alzheimer's Association International Conference 2011.

Poster presentations on the safety and efficacy results of the Phase 2 randomised, placebo-controlled, dose-ranging study of ELND005 in mild to moderate Alzheimer's disease and on the population pharmacokinetic analysis of plasma, cerebrospinal fluid, and brain ELND005 in patients with mild to moderate Alzheimer's disease were presented. An oral presentation on imaging and cerebrospinal fluid biomarker results of a Phase 2 dose-ranging study of ELND005 in mild to moderate Alzheimer's disease was also presented.

Selected Financial Data

The selected financial data set forth below is derived from our unaudited condensed consolidated half-year financial statements (half-year financial statements) in this Half-Year Financial Report and our 2010 Annual Report, and should be read in conjunction with, and is qualified by reference to, our half-year financial statements and related notes thereto.

Six Months Ended 30 June,	2011	2010
Income Statement Data (in \$m, except for per share and number of shares data):		
Continuing operations		
Total revenue	324.9	291.1
Settlement provision charge		206.3
Operating profit/(loss)	32.5	(203.1)
Net loss from continuing operations	(53.0)	(240.9)
Adjusted EBITDA – continuing operations ⁽¹⁾	73.2	35.9
Discontinued operations		
Net income from discontinued operations	103.1	21.1
Adjusted EBITDA – discontinued operations ⁽¹⁾	49.8	46.5
Net income/(loss)	50.1	(219.8)
Adjusted EBITDA ⁽¹⁾	123.0	82.4
Basic earnings/(loss) per Ordinary Share		
From continuing operations	(0.09)	(0.41)
From discontinued operations	0.18	0.04
Basic weighted-average shares outstanding (in millions) – continuing and discontinued operations	586.4	584.6
Diluted earnings/(loss) per Ordinary Share		
From continuing operations	(0.09)	(0.41)
From discontinued operations	0.17	0.04
Diluted weighted-average shares outstanding (in millions) – continuing operations	586.4	584.6
Diluted weighted-average shares outstanding (in millions) – discontinued operations	591.4	587.3
	30 June	31 December
	2011	2010
Balance Sheet Data (in \$m):		
Cash and cash equivalents	491.9	422.5
Restricted cash and cash equivalents – current and non-current	17.6	223.1
Available-for-sale investments – current	1.2	2.0
Assets held for sale	349.4	
Total assets	1,881.3	1,999.1
Liabilities held for sale	23.4	
Long-term debt	1,251.8	1,249.1

Edgar Filing: ALKERMES INC - Form 425

Total shareholders equity	295.4	214.0
---------------------------	-------	-------

⁽¹⁾Refer to page 13 for a reconciliation of Adjusted EBITDA to net income/(loss) and our reasons for presenting this non-GAAP measure.

Table of Contents**Principal Risks and Uncertainties**

Our operating performance in the second half of 2011 is subject to risks and uncertainties. These include, but are not limited to, the following principal items:

In respect of *Tysabri*, at the end of June 2011, approximately 61,500 patients were on therapy worldwide, including approximately 28,500 commercial patients in the United States and approximately 32,300 commercial patients in the ROW, representing an increase of 15% over the 53,300 patients (revised) who were on therapy at the end of June 2010. While we expect sales of *Tysabri* to continue to grow in the second half of 2011, the potential of *Tysabri* may be severely constrained by increases in the incidence of serious adverse events (including deaths) associated with *Tysabri* (in particular, if there are increases in the incidence rate for cases of PML, or by competition from existing or new therapies (in particular, oral therapies approved or filed for U.S. and European approvals);

In May 2011, we announced that we had entered into an agreement with Alkermes to sell our EDT business unit in a cash and stock transaction valued at approximately \$960 million, as of the date of announcement. While we expect the transaction to close in the third quarter of 2011, there are conditions to closing that must be satisfied or waived before the deal can close. There can be no assurance that such conditions will be satisfied or waived and thus there can be no assurance that the transaction will be consummated in the third quarter of 2011 or at all; and

Johnson & Johnson is our largest shareholder with an 18.4% interest in our outstanding Ordinary Shares and is in control of our remaining interest in the Alzheimer's Immunotherapy Program (AIP). Johnson & Johnson's interest in Elan and the AIP may discourage others from seeking to work with or acquire us.

Additionally, the pharmaceutical industry is highly competitive and subject to significant and changing regulation by international, national, state and local government entities; thus we face a number of other risks and uncertainties, which are discussed in more detail in our 2010 Annual Report.

Results of Operations for the Six Months Ended 30 June 2011 and 2010

	2011 \$m	2010 \$m	% increase/ (decrease)
Continuing Operations			
Product revenue	324.9	290.1	12%
Contract revenue		1.0	(100%)
Total revenue	324.9	291.1	12%
Cost of sales	121.8	105.1	16%
Gross profit	203.1	186.0	9%
Selling, general and administrative expenses	73.0	79.4	(8%)
Research and development expenses	97.6	103.4	(6%)
Settlement provision charge		206.3	(100%)
Operating profit/(loss)	32.5	(203.1)	(116%)
Interest expense	59.5	60.7	(2%)
Interest income	(1.4)	(1.7)	(18%)
Investment gains	(2.3)	(13.9)	(83%)
Net loss on investments in associates	25.9		100%

Edgar Filing: ALKERMES INC - Form 425

Net interest and investment gains and losses	81.7	45.1	81%
Loss before tax	(49.2)	(248.2)	(80%)
Income tax expense/(benefit)	3.8	(7.3)	(152%)
Net loss from continuing operations	(53.0)	(240.9)	(78%)
Discontinued Operations			
Net income from discontinued operations	103.1	21.1	389%
Net income/(loss)	50.1	(219.8)	(123%)

Table of Contents**Results of Continuing and Discontinued Operations**

The results of our continuing operations exclude the EDT business and relate to the operations of BioNeurology only. The EDT business is presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative amounts have been restated to reflect this classification. A discussion of the results of the BioNeurology and EDT businesses in the first half of 2011 is set out below.

Operating Review of Continuing Operations BioNeurology**Revenue**

Total revenue from BioNeurology increased 12% to \$324.9 million in the first half of 2011 from \$291.1 million in the same period of 2010. The increase was driven by growth in *Tysabri* sales.

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue:		
<i>Tysabri</i>	321.7	250.3
Maxipime®	0.7	5.4
Azactam®	0.4	27.4
Prialt®		6.2
Royalties	2.1	0.8
Total product revenue	324.9	290.1
Contract revenue		1.0
Total revenue from BioNeurology	324.9	291.1

Tysabri

The *Tysabri* collaboration is a jointly controlled operation in accordance with International Accounting Standards (IAS) 31, *Financial Reporting of Interests in Joint Ventures*, (IAS 31). A jointly controlled operation is an operation of a joint venture (as defined by IAS 31) that involves the use of the assets and other resources of the venturers rather than establishing a corporation, partnership or other entity, or a financial structure that is separate from the venturers themselves. Each venturer uses its own property, plant and equipment and carries its own inventories. It also incurs its own expenses and liabilities and raises its own finance, which represent its own obligations.

The *Tysabri* collaboration operating profit or loss is calculated excluding R&D expenses (we record our share of the total *Tysabri* collaboration R&D expenses within our R&D expenses). In accordance with IAS 31, we recognise as revenue our share of the collaboration profit from the sale of *Tysabri*, plus our directly-incurred collaboration expenses on these sales. Our actual operating profit or loss on *Tysabri* differs from our share of the collaboration operating profit or loss because certain *Tysabri*-related expenses are not shared through the collaboration, and certain unique risks are retained by each party.

Global in-market net sales of *Tysabri* for MS, which we market in collaboration with Biogen Idec, were as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
United States	353.0	280.1
ROW	385.4	309.3

Total <i>Tysabri</i> in-market net sales	738.4	589.4
--	-------	-------

Table of Contents

Tysabri in-market net sales increased 25% to \$738.4 million in the first half of 2011 from \$589.4 million in the same period of 2010. The increase reflects increased patient demand across global markets and a higher price in the United States, along with favourable foreign currency movements in ROW.

The *Tysabri* revenue of \$321.7 million in the first half of 2011 (2010: \$250.3 million) was calculated as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
<i>Tysabri</i> in-market sales	738.4	589.4
Operating expenses incurred by Elan and Biogen Idec (excluding R&D expenses)	(336.9)	(283.1)
<i>Tysabri</i> collaboration operating profit	401.5	306.3
Elan's 50% share of <i>Tysabri</i> collaboration operating profit	200.8	153.2
Elan's directly incurred costs	120.9	97.1
Net <i>Tysabri</i> revenue	321.7	250.3

Other BioNeurology Products

Elan ceased distributing Azactam as of 31 March 2010 and Maxipime as of 30 September 2010. Revenue for Maxipime and Azactam for the first half of 2011 was \$0.7 million and \$0.4 million, respectively, and relates to adjustments to discounts and allowances associated with sales prior to the cessation of distribution. Elan divested its Prialt assets and rights in May 2010 and revenue for the first half of 2010 was \$6.2 million.

Other Charges Reconciliation

The following table shows a reconciliation of BioNeurology operating profit/(loss) before other charges to operating profit/(loss):

	Six Months Ended 30 June 2011			Six Months Ended 30 June 2010		
	Before Other Charges \$m	Other Charges \$m	IFRS \$m	Before Other Charges \$m	Other Charges \$m	IFRS \$m
Product revenue	324.9		324.9	290.1		290.1
Contract revenue				1.0		1.0
Total revenue	324.9		324.9	291.1		291.1
Cost of sales	122.1	(0.3)	121.8	104.8	0.3	105.1
Gross margin	202.8	0.3	203.1	186.3	(0.3)	186.0
Selling, general and administrative expenses	62.0	11.0	73.0	75.9	3.5	79.4
Research and development expenses	96.8	0.8	97.6	103.3	0.1	103.4
Settlement provision charge				206.3		206.3
Operating profit/(loss)	44.0	(11.5)	32.5	(199.2)	(3.9)	(203.1)

Cost of Sales

Edgar Filing: ALKERMES INC - Form 425

BioNeurology cost of sales decreased to \$121.8 million in the first half of 2011 from \$105.1 million in the first half of 2010. Included within cost of sales was an other charges credit of \$0.3 million (2010: \$0.3 million expense), as described in Note 5 to the half-year financial statements. Excluding other charges, the BioNeurology gross margin on revenue was 62% in 2011 and 64% in 2010.

Table of Contents

Included within total cost of sales is \$115.2 million of directly incurred collaboration expenses related to *Tysabri* for 2011 (2010: \$88.4 million), resulting in a reported *Tysabri* gross margin of 64% in 2011 (2010: 65%). The reported *Tysabri* gross margin is impacted by the collaboration profit-sharing, commercial spend and operational arrangements.

Selling, General and Administrative Expenses

BioNeurology selling, general and administrative (SG&A) expenses decreased to \$73.0 million in the first half of 2011 from \$79.4 million in the first half of 2010. Included within SG&A expenses were other charges of \$11.0 million (2010: \$3.5 million), as described in Note 5 to the half-year financial statements. Excluding other charges, SG&A expenses decreased 18% to \$62.0 million in 2011 from \$75.9 million in 2010. The decrease principally reflects lower support costs in the first half of 2011 as a result of the realignment and restructuring of the R&D organisation within BioNeurology in 2010, partially offset by increased commercial spending for *Tysabri*.

Research and Development Expenses

BioNeurology R&D expenses decreased to \$97.6 million in the first half of 2011 from \$103.4 million in the first half of 2010. Included within R&D expenses were other charges of \$0.8 million (2010: \$0.1 million), as described in Note 5 to the half-year financial statements. Excluding other charges, R&D expenses decreased 6% to \$96.8 million in 2011, compared to \$103.3 million in 2010. The decrease primarily relates to the realignment and restructuring of the R&D organisation within Elan's BioNeurology business in 2010, partially offset by increased investment in development activities related to *Tysabri*.

Settlement Provision Charge

In July 2010, we announced that we reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts with respect to the previously disclosed U.S. Department of Justice's investigation of sales and marketing practices for Zonegran, which we divested in 2004. During the first half of 2010, we recorded a \$206.3 million provision charge for the settlement, interest and related costs. The agreement was finalised in December 2010. Consistent with the terms of the agreement-in-principle announced in July 2010, we paid \$203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims. The resolution of the Zonegran investigation could give rise to other investigations of litigation by state government entities or private parties.

Net Interest and Investment Gains and Losses

Net interest and investment gains and losses amounted to a net expense of \$81.7 million for the first half of 2011, compared to a net expense of \$45.1 million for the same period of 2010. The increase in net interest and investment gains and losses is primarily attributable to the net loss on investment in associates of \$25.9 million (2010: \$Nil) in the first half of 2011. For further discussion of investments in associates, refer to Note 8 to the half-year financial statements. In addition, we recorded net investment gains of \$2.3 million in the first half of 2011 (2010: \$13.9 million), relating to the disposal of non-current investments.

Taxation

The income tax expense was \$3.8 million in the first half of 2011, compared to a \$7.3 million benefit in the first half of 2010. The income tax expense for the first half of 2011 includes deferred expense of \$2.1 million (2010: \$8.1 million benefit) primarily related to the deferred tax asset (DTA) recognised in 2008, as the underlying loss carryforwards and other DTAs are utilised to shelter taxable income in the United States.

Table of Contents**Operating Review of Discontinued Operations EDT**

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue	124.4	124.3
Contract revenue	4.4	8.1
Total revenue	128.8	132.4
Cost of sales	49.6	58.9
Gross margin	79.2	73.5
Operating expenses:		
Selling, general and administrative expenses	19.8	20.6
Research and development expenses	37.8	27.1
Gain on legal settlements	(84.5)	
Operating profit	106.1	25.8
Net interest expense	0.4	0.2
Net income before tax	105.7	25.6
Income tax expense	2.6	4.5
Net income from discontinued operations	103.1	21.1

Revenue

Revenue from the EDT business unit decreased to \$128.8 million in 2011 from \$132.4 million in the first half of 2010.

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue:		
Manufacturing revenue and royalties:		
TriCor® 145	24.0	25.0
Ampyra®	22.4	20.8
Focalin XR®/Ritalin LA®	18.2	16.6
Verelan®	13.2	11.9
Skelaxin®		5.2
Other	46.6	44.8
Total product revenue manufacturing revenue and royalties	124.4	124.3
Contract revenue:		
Research revenue	3.9	3.7
Milestone payments	0.5	4.4
Total contract revenue from EDT	4.4	8.1

Edgar Filing: ALKERMES INC - Form 425

Total revenue from EDT	128.8	132.4
------------------------	-------	-------

Manufacturing revenue and royalties comprise revenue earned from products we manufacture for clients and royalties earned principally on sales by clients of products that incorporate our technologies. Except as noted above, no other product accounted for more than 10% of total manufacturing revenue and royalties in the first half of 2011 or the first half of 2010.

Table of Contents

Manufacturing revenue and royalties increased slightly to \$124.4 million in the first half of 2011 from \$124.3 in the first half of 2010.

The increase in manufacturing revenue and royalties in the first half of 2011, compared to the first half 2010, is primarily attributable to increased revenue from Ampyra, Rapamune®, Invega®Sustenna® and Focalin XR/Ritalin LA, partially offset by decreased revenue from Naprelan®, Diltiazem and Skelaxin.

The manufacturing and royalty revenue recorded for Ampyra in the first half of 2010 of \$20.8 million principally reflected shipments to Acorda Therapeutics, Inc. (Acorda) of \$18.9 million in the first quarter of 2010 to satisfy Acorda's initial stocking requirements for the launch of the product as well as build-up of safety stock supply. Elan records revenue upon shipment of Ampyra to Acorda, as this revenue is not contingent upon ultimate sale of the shipped product by Acorda or its customers. Consequently, revenue varies with shipments and is not based directly on in-market sales.

Potential generic competitors have challenged the existing patent protection for several of the products from which we earn manufacturing revenue and royalties. We and our clients defend the parties' intellectual property rights vigorously. However, if these challenges are successful, EDT's manufacturing revenue and royalties will be materially and adversely affected. As a result of the approval and launch of a generic form of Skelaxin in April 2010, EDT's royalty revenue from this product has ended.

Contract Revenue

Contract revenue decreased to \$4.4 million in the first half of 2011 from \$8.1 million for the same period in 2010. The decrease in contract revenue in the first half of 2011 compared to the first half of 2010 was primarily due to the timing of recognition of milestones, partially offset by development fees from clients.

Other Charges Reconciliation

The following table shows a reconciliation of the EDT operating profit before other charges to operating profit:

	Six Months Ended 30 June 2011			Six Months Ended 30 June 2010		
	Before Other Charges \$m	Other Charges \$m	IFRS \$m	Before Other Charges \$m	Other Charges \$m	IFRS \$m
Product revenue	124.4		124.4	124.3		124.3
Contract revenue	4.4		4.4	8.1		8.1
Total revenue	128.8		128.8	132.4		132.4
Cost of sales	49.4	0.2	49.6	58.5	0.4	58.9
Gross margin	79.4	(0.2)	79.2	73.9	(0.4)	73.5
Selling, general and administrative expenses	18.1	1.7	19.8	20.6		20.6
Research and development expenses	24.6	13.2	37.8	27.1		27.1
Gain on legal settlements	(84.5)		(84.5)			
Operating profit	121.2	(15.1)	106.1	26.2	(0.4)	25.8

Cost of Sales

Total EDT cost of sales decreased to \$49.6 million in the first half of 2011 from \$58.9 million in the first half of 2010. Included within cost of sales were other charges of \$0.2 million (2010: \$0.4 million), as described in Note 10 to the half-year financial statements. Excluding other charges, the EDT gross margin on revenue was 62% in 2011 and 56% in 2010. The decrease in cost of sales in the first half of 2011 is primarily due to decreased amortisation expense on the *Verelan* intangible asset, which was fully amortised in December 2010.

Table of Contents

Selling, General and Administrative Expenses

Total EDT SG&A expenses were \$19.8 million in the first half of 2011 from \$20.6 million in the first half of 2010. Included within SG&A expenses were other charges of \$1.7 million (2010: \$Nil), as described in Note 10 to the half-year financial statements. Excluding other charges, SG&A expenses decreased 12% to \$18.1 million in 2011 from \$20.6 million in 2010. The decrease primarily relates to lower legal costs.

Research and Development Expenses

Total EDT R&D expenses were \$37.8 million in the first half of 2011 from \$27.1 million in the first half of 2010. Included within R&D expenses were other charges of \$13.2 million (2010: \$Nil), as described in Note 10 to the half-year financial statements. Excluding other charges, R&D expenses decreased 9% to \$24.6 million in 2011, compared to \$27.1 million in 2010. The decrease is primarily due to timing of R&D spending on proprietary projects.

Gain on Legal Settlements

In May 2011, we entered into an agreement with Alcon Laboratories, Inc. (Alcon) to settle litigation in relation to the application of its *NanoCrystal*[®] technology. As part of the settlement agreement with Alcon, we received \$6.5 million in May 2011 in full and final settlement.

In June 2008, a jury ruled in the U.S. District Court for the District of Delaware that Abraxis (since acquired by Celgene Corporation) had infringed a patent owned by Elan in relation to the application of its *NanoCrystal* technology to Abraxane[®]. We were awarded \$55 million, applying a royalty rate of 6% to sales of Abraxane from 1 January 2005 through 13 June 2008 (the date of the verdict). This award and damages associated with the continuing sales of the Abraxane product were subject to interest. In February 2011, we entered into an agreement with Abraxis to settle this litigation. As part of the settlement agreement with Abraxis, we received \$78.0 million in full and final settlement of the litigation in March 2011. We will not receive future royalties in respect of Abraxane.

Net Interest

Net interest expense of \$0.4 million (2010: \$0.2 million) for the first half of 2011 is primarily related to foreign exchange losses.

Taxation

The income tax expense was \$2.6 million in the first half of 2011, compared to a \$4.5 million expense in the first half of 2010. The income tax expense in the first half of 2011 includes a deferred tax expense of \$2.0 million (2010: \$3.9 million) primarily related to the DTA recognised in 2008, as the underlying loss carryforwards and other DTAs are utilised to shelter taxable income in the United States.

Table of Contents**Reconciliation of Net Income/(Loss) to Adjusted EBITDA Non-GAAP Financial Information**

	Continuing Operations		Discontinued Operations		Total	
	Six Months Ended		Six Months Ended		Six Months Ended	
	30 June		30 June		30 June	
	2011	2010	2011	2010	2011	2010
	\$m	\$m	\$m	\$m	\$m	\$m
Net income/(loss)	(53.0)	(240.9)	103.1	21.1	50.1	(219.8)
Adjustments:						
Interest expense	59.5	60.7	0.4	0.2	59.9	60.9
Interest income	(1.4)	(1.7)			(1.4)	(1.7)
Income tax expense/(benefit)	3.8	(7.3)	2.6	4.5	6.4	(2.8)
Depreciation and amortisation	15.3	15.9	8.6	16.3	23.9	32.2
Amortised fees	(0.3)	(0.2)	(0.2)	(0.2)	(0.5)	(0.4)
EBITDA	23.9	(173.5)	114.5	41.9	138.4	(131.6)
Share-based compensation expense ⁽¹⁾	14.2	13.1	4.7	4.2	18.9	17.3
Gain on legal settlement			(84.5)		(84.5)	
Settlement provision charge		206.3				206.3
Other charges	11.5	3.9	15.1	0.4	26.6	4.3
Net losses on investments in associates	25.9				25.9	
Net investment gains	(2.3)	(13.9)			(2.3)	(13.9)
Adjusted EBITDA	73.2	35.9	49.8	46.5	123.0	82.4

⁽¹⁾ Share-based compensation expense excludes \$0.6 million included in other charges in the first half of 2011 (2010: \$0.2 million credit).

Adjusted EBITDA is a non-GAAP measure of operating results. Elan's management uses this measure to evaluate our operating performance and it is among the factors considered as a basis for our planning and forecasting for future periods. We believe that Adjusted EBITDA is a measure of performance used by some investors, equity analysts and others to make informed investment decisions.

Adjusted EBITDA is defined as net income or loss plus or minus net interest expense, income tax expense, depreciation and amortisation of costs and revenue, share-based compensation, gain on legal settlements, settlement provision charge, other charges or gains, net losses on investments in associates and net investment gains and losses. Adjusted EBITDA is not presented as, and should not be considered an alternative measure of, operating results or cash flows from operations, as determined in accordance with International Financial Reporting Standards (IFRS). A reconciliation of Adjusted EBITDA to net income/(loss) is set out in the table above.

In the first half of 2011, we reported Adjusted EBITDA of \$123.0 million, compared to Adjusted EBITDA of \$82.4 million in the first half of 2010. The improvement reflects the 12% increase in revenue, improved operating margins and the 11% decrease in combined SG&A and R&D expenses (excluding other charges).

Liquid Resources and Shareholders' Equity

Our liquid resources and shareholders' equity were as follows:

	30 June 2011 \$m	31 December 2010 \$m	% increase /(decrease)
Cash and cash equivalents	491.9	422.5	16%
Restricted cash and cash equivalents - current	2.6	208.2 ⁽¹⁾	(99%)

Edgar Filing: ALKERMES INC - Form 425

Available-for-sale investments	current	1.2	2.0	(40%)
Total liquid resources		495.7	632.7	(22%)
Shareholders	equity	295.4	214.0	38%

⁽¹⁾ Current restricted cash included \$203.7 million held in an escrow account in relation to the Zonegran settlement, which was subsequently paid in March 2011.

Table of Contents

We have historically financed our operating and capital resource requirements through cash flows from operations, sales of investment securities and borrowings. We consider all highly liquid deposits with a maturity on acquisition of three months or less to be cash equivalents. Our primary source of funds as at 30 June 2011 consisted of cash and cash equivalents of \$491.9 million, which excludes current restricted cash of \$2.6 million, and current investment securities of \$1.2 million. Cash and cash equivalents primarily consist of bank deposits and holdings in U.S. Treasuries funds.

At 30 June 2011, our shareholders' equity was \$295.4 million, compared to \$214.0 million at 31 December 2010. The increase is primarily due to the net income in the first half of 2011 of \$50.1 million. The net income in the first half of 2011 includes legal settlement gains of \$84.5 million.

Cash Flows Summary**Continuing and Discontinued Operations:**

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Net cash provided by/(used in) operating activities	(100.5)	46.1
Net cash provided by investing activities	167.5	0.1
Net cash provided by financing activities	2.3	0.8
Effect of foreign exchange rate changes on cash	0.1	(0.3)
Net increase in cash and cash equivalents	69.4	46.7
Cash and cash equivalents at beginning of period	422.5	836.5
Cash and cash equivalents at end of period	491.9	883.2

Operating Activities

The components of net cash used in operating activities were as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Adjusted EBITDA	123.0	82.4
Net interest and tax	(58.1)	(56.8)
Gain on legal settlements	84.5	
Other charges	(20.9)	(3.7)
Working capital decrease/(increase)	(22.7)	24.2
Decrease in other liabilities relating to Zonegran settlement	(206.3)	
Net cash provided by/(used in) operating activities	(100.5)	46.1

Net cash used in operating activities was \$100.5 million in the first half of 2011 (2010: \$46.1 million).

The improvement in net cash inflow from Adjusted EBITDA from \$82.4 million in 2010 to \$123.0 million in the first half of 2011 is discussed on page 13.

Edgar Filing: ALKERMES INC - Form 425

Net interest and tax of \$58.1 million in the first half of 2011, was primarily comprised of debt interest expense and was higher than the \$56.8 million incurred in the first half of 2010, as further discussed on page 9 and page 12. The legal settlement gains of \$84.5 million in the first half of 2011 is discussed in Note 10 to the half-year financial statements. The settlement provision charge of \$206.3 million which was paid in the first half of 2011, is discussed in Note 6 to the half-year financial statements. The other net charges of \$20.9 million in the

Table of Contents

first half of 2011 (adjusted to exclude net non-cash other charges of \$5.7 million) was primarily comprised of severance, restructuring charges, and EDT Transaction costs. The other charges of \$3.7 million in the first half of 2010 (adjusted to exclude non-cash other charges of \$0.6 million) was also primarily comprised of severance and restructuring charges.

The working capital increase of \$22.7 million in the first half of 2011 was primarily driven by the increase in trade receivables. This is mainly due to higher revenues from *Tysabri* in the first half of 2011 compared to the first half of 2010.

The working capital decrease of \$24.2 million was primarily due to the reduction in revenues from Azactam and Skelaxin following the launch of generic competitors during the first half of 2010, offset by increased revenues from *Tysabri*.

Investing Activities

Net cash provided by investing activities was \$167.5 million in the first half of 2011. The primary component of cash provided by investing activities is the decrease in restricted cash. The restricted cash and cash equivalents movement includes the \$203.7 million that was held in escrow in relation to the Zonegran settlement. This settlement amount was paid in March 2011. The cash provided by investing activities was partially offset by the purchase of an equity method investment in Proteostasis in the first half of 2011 and the payment of \$9.0 million to Transition Therapeutics, Inc. (Transition) in January 2011 in relation to the modification of our Collaboration Agreement with Transition in December 2010. In connection with this modification, Transition elected to exercise its opt-out right under the original agreement. Under this amendment, we agreed to pay Transition \$9.0 million, which has been capitalised in acquired in process research and development (IPR&D).

Net cash provided by investing activities was \$0.1 million in the first half of 2010. The primary components of cash provided by investing activities were capital expenditures of \$23.8 million offset by investment and business disposal proceeds of \$21.0 million.

Financing Activities

Net cash provided by financing activities totaled \$2.3 million in the first half of 2011 (2010: \$0.8 million), primarily reflecting the net proceeds from employee share issuances.

Discontinued Operations

The operating and investing net cash flows for the first half of 2011 and the first half of 2010 discussed above include the discontinued operations of the EDT business. There were no cash flows from financing activities attributable to EDT in the first half of 2011 or 2010. The net cash flows attributable to EDT are set out below:

	Six Months Ended 30 June	
	2011	2010
	\$m	\$m
Net operating cash inflows	133.4	56.9
Net investing cash outflows	(5.1)	(6.5)
Total net cash inflows	128.3	50.4

Table of Contents**Debt Facilities**

At 30 June 2011, we had outstanding debt of \$1,285.0 million in aggregate principal amount (excluding unamortised financing costs and original issue discount), which consisted of the following:

	Original Maturity	\$m
8.875% Notes	December 2013	449.5
Floating Rate Notes due 2013	December 2013	10.5
8.75% Notes issued October 2009	October 2016	625.0
8.75% Notes issued August 2010	October 2016	200.0
Total		1,285.0

As at 30 June 2011, and as of the date of filing of this Half-Year Financial Report, we were not in violation of any of our debt covenants. For additional information regarding our outstanding debt, please refer to Note 15 to the half-year financial statements.

Related Party Transactions

We have related party relationships with our subsidiaries, associates, directors and executive officers. All transactions with subsidiaries eliminate on consolidation and are not presented in accordance with revised IAS 24, *Related Party Disclosures* (IAS 24).

There were no related party transactions that have taken place in the six months ended 30 June 2011 that materially affected the financial position or the performance of the Company during that period and there were no changes in the related party transactions described in the 2010 Annual Report that could have a material effect on the financial position or performance of the Company in the same period.

Directors

The names and functions of the directors are shown on pages 62 to 65 of our 2010 Annual Report. On 26 May 2011, Jonas Frick retired from the Board.

Table of Contents**UNAUDITED CONDENSED CONSOLIDATED HALF-YEAR INCOME STATEMENT****For the Six Months Ended 30 June**

	Notes	2011 \$m	2010 \$m
Continuing operations			
Product revenue		324.9	290.1
Contract revenue			1.0
Total revenue	3	324.9	291.1
Cost of sales	5	121.8	105.1
Gross profit		203.1	186.0
Selling, general and administrative expenses	5	73.0	79.4
Research and development expenses	5	97.6	103.4
Settlement provision charge	6		206.3
Operating profit/(loss)		32.5	(203.1)
Interest expense	7	59.5	60.7
Interest income	7	(1.4)	(1.7)
Investment gains	7	(2.3)	(13.9)
Net loss on investments in associates	8	25.9	
Net interest and investment gains and losses		81.7	45.1
Net loss before tax		(49.2)	(248.2)
Income tax expense/(benefit)	9	3.8	(7.3)
Net loss from continuing operations		(53.0)	(240.9)
Discontinued operations			
Net income from discontinued operations (net of tax)	10	103.1	21.1
Net income/(loss)		50.1	(219.8)
Basic earnings/(loss) per Ordinary Share			
From continuing operations	11	\$ (0.09)	\$ (0.41)
From discontinued operations	11	\$ 0.18	\$ 0.04
Basic weighted-average shares outstanding (in millions) continuing and discontinued operations	11	586.4	584.6
Diluted earnings/(loss) per Ordinary Share			
From continuing operations	11	\$ (0.09)	\$ (0.41)
From discontinued operations	11	\$ 0.17	\$ 0.04
Diluted weighted-average shares outstanding (in millions) continuing operations	11	586.4	584.6
Diluted weighted-average shares outstanding (in millions) discontinued operations	11	591.4	587.3
The net income/(loss) for the six months ended 30 June 2011 and 30 June 2010 are wholly attributable to the owners of the Parent Company.			
The accompanying notes are an integral part of these unaudited condensed consolidated half-year financial statements.			

Table of Contents

UNAUDITED CONDENSED CONSOLIDATED HALF-YEAR

STATEMENT OF COMPREHENSIVE INCOME

For the Six Months Ended 30 June

	2011 \$m	2010 \$m
Net income/(loss) for the period	50.1	(219.8)
<i>Other comprehensive income:</i>		
Foreign currency translation		(0.2)
Available-for-sale investments	(0.1)	2.2
Net gain on available-for-sale investments transferred to the income statement		(4.8)
Other comprehensive loss for the period	(0.1)	(2.8)
Total comprehensive income/(loss) for the period	50.0	(222.6)

The total comprehensive income/(losses) for the six months ended 30 June 2011 and 30 June 2010 are wholly attributable to the owners of the Parent Company.

Total comprehensive income/(loss) arises from:		
Continuing operations	(53.1)	(243.7)
Discontinued operations	103.1	21.1
Total comprehensive income/(loss) for the period	50.0	(222.6)

The accompanying notes are an integral part of these unaudited condensed consolidated half-year financial statements.

Table of Contents**UNAUDITED CONDENSED CONSOLIDATED HALF-YEAR BALANCE SHEET**

	Notes	30 June 2011 \$m	31 December 2010 ⁽¹⁾ \$m
Non-Current Assets			
Goodwill and other intangible assets	13	147.9	225.7
Property, plant and equipment		77.9	287.5
Investments in associates	8	203.1	209.0
Available-for-sale investments		9.8	8.9
Deferred tax asset	9	345.3	336.7
Restricted cash and cash equivalents		15.0	14.9
Other non-current assets		29.3	34.6
Total Non-Current Assets		828.3	1,117.3
Current Assets			
Inventory	14	20.1	39.0
Accounts receivable		171.4	191.6
Other current assets		13.5	15.4
Income tax prepayment		2.9	3.1
Available-for-sale investments		1.2	2.0
Restricted cash and cash equivalents		2.6	208.2
Cash and cash equivalents		491.9	422.5
Assets held for sale	10	349.4	
Total Current Assets		1,053.0	881.8
Total Assets		1,881.3	1,999.1
Non-Current Liabilities			
Long-term debt	15	1,251.8	1,249.1
Other liabilities	16	35.8	40.1
Income tax payable		14.4	14.2
Total Non-Current Liabilities		1,302.0	1,303.4
Current Liabilities			
Accounts payable		38.5	39.2
Accrued and other liabilities	16	220.3	235.5
Provisions	17	0.7	207.0
Income tax payable		1.0	
Liabilities held for sale	10	23.4	
Total Current Liabilities		283.9	481.7
Total Liabilities		1,585.9	1,785.1
Shareholders Equity			
Share capital		36.0	35.9
Share premium		7,089.5	7,087.3
Share-based compensation reserve		235.8	235.0
Foreign currency translation reserve		(11.2)	(11.2)

Edgar Filing: ALKERMES INC - Form 425

Available-for-sale investment reserve	0.8	0.9
Retained loss	(7,055.5)	(7,133.9)
Total Shareholders Equity	295.4	214.0
Total Shareholders Equity and Liabilities	1,881.3	1,999.1

⁽¹⁾ Amounts as at 31 December 2010 are derived from the 31 December 2010 audited financial statements.

The accompanying notes are an integral part of these unaudited condensed consolidated half-year financial statements.

Table of Contents**UNAUDITED CONDENSED CONSOLIDATED HALF-YEAR****STATEMENT OF CASH FLOWS****For the Six Months Ended 30 June**

	2011	2010
	\$m	\$m
Net income/(loss)	50.1	(219.8)
Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities:		
Depreciation and amortisation	23.9	32.2
Gain on sale of investments	(2.3)	(12.7)
Impairment of property, plant and equipment and intangible assets	5.1	
Settlement provision charge		206.3
Share-based compensation expense	19.5	17.1
Net loss on investments in associates	25.9	
Net loss on divestment of business		0.8
Debt interest expense	59.0	60.2
Interest income	(0.3)	(0.5)
Income tax expense	6.4	(2.8)
Other	(0.5)	(3.0)
	186.8	77.8
Decrease/(increase) in accounts receivable	(32.4)	15.3
Decrease/(increase) in prepayments and other assets	(1.5)	3.0
Decrease in inventory	0.8	17.2
Increase/(decrease) in accounts payable and accrued and other liabilities	8.8	(6.7)
Decrease in other liabilities relating to Zonegran settlement	(206.3)	
Cash provided by operations	(43.8)	106.6
Interest received	0.3	0.7
Interest paid	(56.2)	(59.7)
Income taxes paid	(0.8)	(1.5)
Net cash provided by/(used in) operating activities	(100.5)	46.1
Investing activities		
Decrease in restricted cash	205.5	3.2
Purchase of property, plant and equipment	(10.0)	(22.4)
Purchase of intangible and other assets	(10.1)	(1.4)
Purchase of available-for-sale investments	(0.5)	(0.3)
Proceeds from disposal of current available-for-sale investments		8.3
Proceeds from disposal of non-current available-for-sale investments	2.6	8.0
Purchase of investment in associate	(20.0)	
Proceeds from divestment of business		4.7
Net cash provided by investing activities	167.5	0.1
Financing activities		
Proceeds from issue of share capital	2.3	0.8
Net cash provided by financing activities	2.3	0.8
Effect of foreign exchange rate changes	0.1	(0.3)
Net increase in cash and cash equivalents	69.4	46.7

Edgar Filing: ALKERMES INC - Form 425

Cash and cash equivalents at the beginning of the period	422.5	836.5
Cash and cash equivalents at the end of the period	491.9	883.2

The accompanying notes are an integral part of these unaudited condensed consolidated half-year financial statements.

Table of Contents**UNAUDITED CONDENSED CONSOLIDATED HALF-YEAR STATEMENT****OF CHANGES IN SHAREHOLDERS EQUITY**

	Number of Shares m	Share Capital \$m	Share Premium \$m	Share-Based Compensation Reserve \$m	Foreign Currency Translation Reserve \$m	Available- for-sale Investment Reserve \$m	Retained Loss \$m	Total Amount \$m
Balances at 1 January 2010	583.9	35.8	7,085.6	237.2	(11.1)	5.1	(6,838.2)	514.4
<i>Comprehensive income:</i>								
Net loss							(219.8)	(219.8)
<i>Other comprehensive income/(loss):</i>								
Foreign currency translation					(0.2)			(0.2)
Available-for-sale investments						(2.6)		(2.6)
Total other comprehensive loss								(2.8)
Total comprehensive loss								(222.6)
<i>Transactions with owners of the Company, recognised directly in equity:</i>								
Issue of share capital, net of issue costs	0.9		0.8					0.8
Share-based compensation cost				17.1				17.1
Share-based compensation deferred tax				(7.1)				(7.1)
Transfer of exercised and expired share-based awards				(16.6)			16.6	
Balances at 30 June 2010	584.8	35.8	7,086.4	230.6	(11.3)	2.5	(7,041.4)	302.6
<i>Comprehensive income:</i>								
Net loss							(102.8)	(102.8)
<i>Other comprehensive income/(loss):</i>								
Foreign currency translation					0.1			0.1
Available-for-sale investments						(1.6)		(1.6)
Total other comprehensive loss								(1.5)
Total comprehensive loss								(104.3)
<i>Transactions with owners of the Company, recognised directly in equity:</i>								
Issue of share capital, net of issue costs	0.4	0.1	0.9					1.0
Share-based compensation cost				14.3				14.3
Share-based compensation deferred tax				0.4				0.4
Transfer of exercised and expired share-based awards				(10.3)			10.3	
Balances at 1 January 2011	585.2	35.9	7,087.3	235.0	(11.2)	0.9	(7,133.9)	214.0
<i>Comprehensive income:</i>								
Net income							50.1	50.1
<i>Other comprehensive income/(loss):</i>								
Available-for-sale investments						(0.1)		(0.1)
Total other comprehensive loss								(0.1)
Total comprehensive income								50.0

Edgar Filing: ALKERMES INC - Form 425

Transactions with owners of the Company, recognised directly in equity:

Issue of share capital, net of issue costs	1.8	0.1	2.2	2.3				
Share-based compensation cost				19.5				19.5
Share-based compensation deferred tax				9.6				9.6
Transfer of exercised and expired share-based awards				(28.3)			28.3	
Balance at 30 June 2011	587.0	36.0	7,089.5	235.8	(11.2)	0.8	(7,055.5)	295.4

The accompanying notes are an integral part of these unaudited condensed consolidated half-year financial statements.

Table of Contents

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED

HALF-YEAR FINANCIAL STATEMENTS

1. BASIS OF PREPARATION

These unaudited half-year financial statements, which should be read in conjunction with our 2010 Annual Report, have been prepared by Elan Corporation, plc in accordance with IAS 34, *Interim Financial Reporting* (IAS 34), as adopted by the European Union. In addition, these half-year financial statements have been prepared in accordance with the Transparency (Directive 2004/109/EC) Regulations 2007 and the related Transparency Rules of the Republic of Ireland's Financial Regulator. They do not include all of the information required for full annual financial statements, and should be read in conjunction with our 2010 Annual Report.

These half-year financial statements are presented in U.S. dollars, which is the functional currency of the parent company and the majority of the group companies. They are prepared on the historical cost basis, except for certain financial assets and derivative financial instruments, which are stated at fair value.

The half-year financial statements include the accounts of Elan and all of our subsidiary undertakings. All significant intercompany account balances, transactions, and any unrealised gains and losses or income and expenses arising from intercompany transactions have been eliminated in preparing the half-year financial statements.

Following the approval of the EDT Transaction by the Board of Elan on 8 May 2011, the EDT business met the criteria to be classified as held for sale and the assets and liabilities of the EDT business have been classified as held for sale on the half-year balance sheet at 30 June 2011. The results of EDT are presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative amounts have been restated to reflect this classification.

The preparation of half-year financial statements requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses. Actual results could differ materially from these estimates. In preparing these half-year financial statements, the critical judgements made by management in applying the Company's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the Consolidated Financial Statements as at and for the year ended 31 December 2010, and described on pages 114 to 119 of the 2010 Annual Report.

The comparative amounts included for the year ended 31 December 2010 do not constitute statutory financial statements of Elan within the meaning of Regulation 40 of the European Communities (Companies; Group accounts) Regulations, 1992. Statutory financial statements for the year ended 31 December 2010 have been filed with the Companies' Office. The auditor's report on those financial statements was unqualified and did not contain an emphasis of matter paragraph.

Although profitable in the current half-year, we have incurred significant losses during the last number of fiscal years. However, our directors believe that we have adequate resources to continue in operational existence for the foreseeable future and that it is appropriate to continue to prepare our condensed consolidated half-year financial statements on a going concern basis.

These half-year financial statements were approved by the directors on 25 July 2011.

2. SIGNIFICANT ACCOUNTING POLICIES

The accounting policies applied in these half-year financial statements are consistent with those applied in our Consolidated Financial Statements as at and for the year ended 31 December 2010, as set out on pages 106 to 114 of the 2010 Annual Report, except for the impact of the standards described below.

The following new interpretations and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2011.

Revised IAS 24, *Related Party Disclosures* ;

Edgar Filing: ALKERMES INC - Form 425

IFRIC 19, *Extinguishing Financial Liabilities with Equity Instruments* ;

IFRIC 14 (Amendment), *Prepayments of a Minimum Funding Requirement* ;

Amendment to IAS 32, *Financial instruments: Presentation* , on classification of rights issues.

Table of Contents

The adoption of these amendments to standards and interpretations did not impact on our financial position or results from operations.

3. REVENUE

Revenue from continuing operations for the six months ended 30 June 2011 and 2010 is comprised of BioNeurology revenue only, as the results of the EDT business are presented as a discontinued operation in the half-year financial statements for the first half of 2011 and 2010.

Revenue from the BioNeurology business can be further analysed as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue:		
<i>Tysabri</i>	321.7	250.3
Maxipime	0.7	5.4
Azactam	0.4	27.4
Prialt		6.2
Royalties	2.1	0.8
Total product revenue	324.9	290.1
Contract Revenue		1.0
Total revenue from BioNeurology	324.9	291.1

The *Tysabri* collaboration is a jointly controlled operation in accordance with IAS 31. A jointly controlled operation is an operation of a joint venture (as defined by IAS 31) that involves the use of the assets and other resources of the venturers rather than establishing a corporation, partnership or other entity, or a financial structure that is separate from the venturers themselves. Each venturer uses its own property, plant and equipment and carries its own inventories. It also incurs its own expenses and liabilities and raises its own finance, which represent its own obligations.

The *Tysabri* collaboration operating profit or loss is calculated excluding R&D expenses (we record our share of the total *Tysabri* collaboration R&D expenses within our R&D expenses). In accordance with IAS 31, we recognise as revenue our share of the collaboration profit from the sale of *Tysabri* plus our directly incurred collaboration expenses on these sales, which are primarily comprised of royalties, that we incur and are payable by us to third parties and are reimbursed by the collaboration. Our actual operating profit on *Tysabri* differs from our share of the collaboration operating profit because certain *Tysabri*-related expenses are not shared through the collaboration, and certain unique risks are retained by each party.

Global in-market net sales of *Tysabri* were as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
United States	353.0	280.1
ROW	385.4	309.3
Total <i>Tysabri</i> global in-market net sales	738.4	589.4

Table of Contents

For the first half of 2011, we recorded net *Tysabri* revenue of \$321.7 million which was calculated as follows:

	Six Months Ended 30 June 2011		
	U.S. \$m	ROW \$m	Total \$m
<i>Tysabri</i> in-market sales	353.0	385.4	738.4
Operating expenses incurred by Elan and Biogen Idec (excluding R&D expenses)	(160.5)	(176.4)	(336.9)
<i>Tysabri</i> collaboration operating profit	192.5	209.0	401.5
Elan's 50% share of <i>Tysabri</i> collaboration operating profit	96.3	104.5	200.8
Elan's directly incurred costs	63.9	57.0	120.9
Net <i>Tysabri</i> revenue	160.2	161.5	321.7

For the first half of 2010, we recorded net *Tysabri* revenue of \$250.3 million which was calculated as follows:

	Six Months Ended 30 June 2010		
	U.S. \$m	ROW \$m	Total \$m
<i>Tysabri</i> in-market sales	280.1	309.3	589.4
Operating expenses incurred by Elan and Biogen Idec (excluding R&D expenses)	(138.7)	(144.4)	(283.1)
<i>Tysabri</i> collaboration operating profit	141.4	164.9	306.3
Elan's 50% share of <i>Tysabri</i> collaboration operating profit	70.7	82.5	153.2
Elan's directly incurred costs	53.5	43.6	97.1
Net <i>Tysabri</i> revenue	124.2	126.1	250.3

Please refer to Note 10 for an analysis of revenue from the EDT business for the first half of 2011 and 2010.

4. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker (CODM). Our CODM has been identified as Mr. G. Kelly Martin, chief executive officer. Our business is organized into two business units: BioNeurology and EDT, and our chief executive officer reviews the business from this perspective.

Following the approval of the EDT Transaction by the Board of Elan on 8 May 2011, the assets and liabilities of the EDT business are classified as held for sale on the Elan half-year balance sheet and the results of EDT are presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative amounts have been restated to reflect this classification. The EDT Transaction is expected to close in the third quarter of 2011. Until the close of this transaction, our CODM will continue to review the performance of the business by evaluating the performance of the BioNeurology and EDT business units.

Segment performance is evaluated based on operating profit/(loss) and Adjusted EBITDA. Interest income, interest expense, investments and income tax expense are managed on a group basis. Therefore, these items are not allocated between operating segments for the purposes of the information presented to the CODM, and are accordingly omitted from the measure of segment profit or loss and Adjusted EBITDA.

Edgar Filing: ALKERMES INC - Form 425

BioNeurology engages in research, development and commercial activities primarily in Alzheimer's disease, Parkinson's disease and MS. EDT is an established, profitable, integrated drug delivery business unit of Elan, which has been applying its skills and knowledge in product development and drug delivery technologies to enhance the performance of dozens of drugs that have been marketed worldwide.

Table of Contents

The same accounting principles used for the group as a whole are applied to segment reporting. There has been no change in the basis of segmentation or in the basis of measurement of segment profit or loss in the period. Inter-segment pricing is determined on an arm's length basis.

	BioNeurology		EDT		Total	
	Six Months Ended		Six Months Ended		Six Months Ended	
	30 June		30 June		30 June	
	2011	2010	2011	2010	2011	2010
	\$m	\$m	\$m	\$m	\$m	\$m
Segment revenue						
Segment revenue	324.9	291.1	128.9	133.0	453.8	424.1
Less intersegment sales			(0.1)	(0.6)	(0.1)	(0.6)
Total revenue from external customers	324.9	291.1	128.8	132.4	453.7	423.5
Cost of sales	121.8	105.1	49.6	58.9	171.4	164.0
Gross margin	203.1	186.0	79.2	73.5	282.3	259.5
Operating expenses:						
Selling, general and administrative expenses	73.0	79.4	19.8	20.6	92.8	100.0
Research and development expenses	97.6	103.4	37.8	27.1	135.4	130.5
Gain on legal settlements			(84.5)		(84.5)	
Settlement provision charge		206.3				206.3
Total operating expenses	170.6	389.1	(26.9)	47.7	143.7	436.8
Segment operating profit/(loss)	32.5	(203.1)	106.1	25.8	138.6	(177.3)
Segment Adjusted EBITDA	73.2	35.9	49.8	46.5	123.0	82.4

Reconciliation of segment results to net income/(loss):

	BioNeurology		EDT		Total	
	Six Months Ended		Six Months Ended		Six Months Ended	
	30 June		30 June		30 June	
	2011	2010	2011	2010	2011	2010
	\$m	\$m	\$m	\$m	\$m	\$m
Segment Adjusted EBITDA	73.2	35.9	49.8	46.5	123.0	82.4
Depreciation and amortisation	(15.3)	(15.9)	(8.6)	(16.3)	(23.9)	(32.2)
Amortised fees	0.3	0.2	0.2	0.2	0.5	0.4
Share-based compensation expense ⁽¹⁾	(14.2)	(13.1)	(4.7)	(4.2)	(18.9)	(17.3)
Gain on legal settlements			84.5		84.5	
Settlement provision charge		(206.3)				(206.3)
Other charges	(11.5)	(3.9)	(15.1)	(0.4)	(26.6)	(4.3)
Segment operating profit/(loss)	32.5	(203.1)	106.1	25.8	138.6	(177.3)
Net interest and investment gains and losses					82.1	45.3
Income tax expense/(benefit)					6.4	(2.8)
Net income/(loss)					50.1	(219.8)

Edgar Filing: ALKERMES INC - Form 425

⁽¹⁾ *Share-based compensation expense excludes \$0.6 million included in other charges in the first half of 2011 (2010: \$0.2 million credit).*

The segment total assets for BioNeurology and EDT as at 31 December 2010 of \$1,549.2 million and \$449.9 million, respectively, did not materially change as at 30 June 2011, therefore this segmental disclosure has been omitted in accordance with IAS 34.

Table of Contents**5. OTHER CHARGES**

The principal items classified as other charges include transaction costs, severance, restructuring and other costs, facilities charges and a net loss on divestment of business. We believe that disclosure of significant other charges is meaningful because it provides additional information when analysing certain items.

For the first half of 2011, included within cost of sales, SG&A expenses, and R&D expenses for our continuing operations were total other charges of \$11.5 million (2010: \$3.9 million) consisting of the following:

2011

	Cost of Sales \$m	SG&A \$m	R&D \$m	Total \$m
EDT Transaction costs		6.9		6.9
Severance, restructuring and other costs	(0.3)	1.4	0.8	1.9
Facilities charges		2.7		2.7
Total other charges from continuing operations	(0.3)	11.0	0.8	11.5

2010

	Cost of Sales \$m	SG&A \$m	R&D \$m	Total \$m
Severance, restructuring and other costs	0.3	2.7	0.1	3.1
Net loss on divestment of business		0.8		0.8
Total other charges from continuing operations	0.3	3.5	0.1	3.9

Transaction costs of \$6.9 million were incurred during the first half of 2011 relating to the EDT Transaction.

During the first half of 2011 and 2010, we incurred severance and restructuring charges of \$1.9 million and \$3.1 million, respectively, principally associated with realignment and restructuring of the R&D organisation within the BioNeurology business and a reduction of related support services.

As a direct result of the realignment of the BioNeurology business, we incurred facilities charges of \$2.7 million in the first half of 2011 relating to a consolidation of facilities in South San Francisco.

During the first half of 2010, we divested of our Prialat assets and rights to Azur Pharma International Limited (Azur), which resulted in a net loss of \$0.8 million.

Please refer to Note 10 for an analysis of other charges from the EDT business for the six months ended 30 June 2011 and 30 June 2010.

6. SETTLEMENT PROVISION CHARGE

In July 2010, we announced that we reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts with respect to the previously disclosed U.S. Department of Justice's investigation of sales and marketing practices for Zonegran, which we divested in 2004. During the first half of 2010, we recorded a \$206.3 million provision charge for the settlement, interest and related costs. The agreement was finalised in December 2010. Consistent with the terms of the agreement-in-principle announced in July 2010, we paid \$203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims. The resolution of the Zonegran

investigation could give rise to other investigations of litigation by state government entities or private parties.

Table of Contents**7. NET INTEREST AND INVESTMENT GAINS AND LOSSES**

For the first half of 2011, net interest and investment gains and losses from continuing operations were \$81.7 million (2010: \$45.1 million), consisting of the following:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Interest expense (including amortisation of deferred financing costs):		
Interest on 8.75% Notes issued October 2009	28.6	28.4
Interest on 8.875% Notes	20.6	21.3
Interest on 8.75% Notes issued August 2010	9.5	
Interest on Floating Rate Notes due 2011		7.0
Interest on Floating Rate Notes due 2013	0.3	3.5
Total debt interest expense	59.0	60.2
Other financial charges	0.5	0.5
Interest expense	59.5	60.7
Interest income:		
Interest income	(0.3)	(0.5)
Net foreign exchange gains	(0.9)	(1.2)
Other financial gains	(0.2)	
Interest income	(1.4)	(1.7)
Investment gains:		
Gain on auction rate securities recovery		(7.9)
Gains on disposal of investments	(2.3)	(4.8)
Derivative fair value gains		(1.2)
Investment gains	(2.3)	(13.9)
Net loss on investments in associates (refer to Note 8)	25.9	
Net interest and investment gains and losses	81.7	45.1

8. INVESTMENTS IN ASSOCIATES

	Janssen AI \$m	Proteostasis \$m	Total 30 June 2011 \$m
1 January 2011	209.0		209.0
Addition		20.0	20.0
Net loss on investments in associates	(25.5)	(0.4)	(25.9)
At 30 June 2011	183.5	19.6	203.1

Janssen AI

In September 2009, Janssen AI, a newly formed subsidiary of Johnson & Johnson, acquired substantially all of the assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer Inc. (Pfizer)). Johnson & Johnson also committed to fund up to \$500.0 million towards the further development and commercialisation of the AIP to the extent the funding is required by the collaboration. Any required additional expenditures in respect of Janssen AI's obligations under the AIP collaboration in excess of \$500.0 million 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

Table of Contents

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 \$500.0 million has been drawn down, Johnson & Johnson is not required to contribute the full \$500.0 million.

In consideration for the transfer of these assets and rights, we received a 49.9% equity interest in Janssen AI. In general, we are entitled to a 49.9% share of all net profits generated by Janssen AI beginning from the date Janssen AI becomes net profitable and certain royalty payments upon the commercialisation of products under the AIP collaboration. Johnson & Johnson has also committed to fund up to an initial \$500.0 million towards the further development and commercialisation of the AIP to the extent the funding is required by the collaboration. Our equity interest in Janssen AI is recorded as an investment in associate on the half year balance sheet at 30 June 2011, at a carrying value of \$183.5 million (31 December 2010: \$209.0 million). The carrying value is comprised of our proportionate 49.9% share of Janssen's AIP assets (30 June 2011: \$117.3 million; 31 December 2010: \$117.3 million) and our proportionate 49.9% interest in the Johnson & Johnson contingent funding commitment (30 June 2011: \$66.2 million; 31 December 2010: \$91.7 million).

Our proportionate interest in the Johnson & Johnson contingent funding commitment was remeasured as of 30 June 2011 and 31 December 2010 to reflect changes in the probability that the cash will be spent and thereby give rise to the expected cash flows under the commitment, and to reflect the time value of money. As at 30 June 2011, the range of assumed probabilities applied to the expected cash flows was 95%-57% (31 December 2010: 95%-43%). The range of discount rates applied remained at 1%-1.5% (31 December 2010: 1%-1.5%), which was also the range used for initial recognition. The remeasurement of our proportionate interest in the Johnson & Johnson contingent funding commitment as at 30 June 2011 resulted in an increase in the carrying value of our investment in associate during the first half of 2011 of \$25.2 million (2010: \$41.4 million).

The following table sets forth the computation of the net loss on the investment in Janssen AI for the periods ended 30 June 2011 and 2010:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Net loss reported by Janssen AI	101.7	82.9
Elan's 49.9% proportionate interest of Janssen AI's reported net loss	50.7	41.4
Remeasurement of Elan's 49.9% proportionate interest in Johnson & Johnson funding commitment	(25.2)	(41.4)
Net loss on investment in Janssen AI associate	25.5	

As at 30 June 2011, the remaining unspent amount of the initial Johnson & Johnson \$500.0 million funding commitment was \$173.9 million (31 December 2010: \$272.0 million).

Proteostasis

On 20 May 2011, we entered into a strategic business relationship with Proteostasis to advance Proteostasis' platform for the discovery and development of disease-modifying, small molecule drugs and diagnostics for the treatment of neurodegenerative disorders such as Parkinson's, Huntington's, MS, ALS, and a broad array of dementia-related diseases including Alzheimer's.

Under terms of the agreement, we invested \$20.0 million into equity capital of Proteostasis and became a 24% shareholder. We will have the opportunity to invest an additional \$30 million in collaboration funding over five years and obtained a right of first negotiation to exclusively license potential compounds. Elan CEO, Kelly Martin, has joined the Board of Directors of Proteostasis and Elan Chief Scientific Officer, Dale Schenk, has joined its Scientific Advisory Board.

Table of Contents

Our \$20.0 million equity interest in Proteostasis has been recorded as an investment in an associate on the balance sheet. The net loss recorded on the equity method investment in the first half of 2011 was \$0.4 million, representing our share of the net losses of Proteostasis from the date of acquisition of the equity interest on 20 May through 30 June 2011.

9. INCOME TAX

The total tax expense of \$6.4 million (2010: \$2.8 million benefit) arises from and is presented in the half-year income statement as follows:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Continuing Operations		
Current tax expense	1.7	0.8
Deferred tax expense/(benefit) origination and reversal of timing differences	2.1	(8.1)
Income tax expense/(benefit) continuing operations	3.8	(7.3)
Discontinued Operations		
Current tax expense	0.6	0.6
Deferred tax expense	2.0	3.9
Income tax expense discontinued operations	2.6	4.5
Total Operations		
Current tax expense	2.3	1.4
Deferred tax expense/(benefit) origination and reversal of timing differences	4.1	(4.2)
Total income tax expense/(benefit)	6.4	(2.8)

The total income tax expense for continuing and discontinued operations of \$6.4 million in the first half of 2011 (2010: \$2.8 million benefit) reflects tax at standard rates in the jurisdictions in which we operate, the availability of tax losses and foreign withholding tax. The income tax benefit for the first half of 2010 reflects changes to U.S. net income, in addition to one-off tax benefits, recorded during the period.

The income tax expense in the first half of 2011 includes a deferred tax charge of \$4.1 million (2010: \$4.2 million benefit) primarily as a result of deferred tax expense related to the DTA previously recognised in 2008, as the underlying loss carryforwards and other DTAs are utilised to shelter taxable income in the United States.

	Balance 1 January 2011 \$m	Recognised In Income \$m	Recognised In Equity \$m	Reclassified as held for sale liability \$m	Balance 30 June 2011 \$m
Deferred taxation liabilities	(4.4)			3.1	(1.3)
Deferred taxation assets	341.1	(4.1)	9.6		346.6
Net deferred taxation asset	336.7	(4.1)	9.6	3.1	345.3

10. DISCONTINUED OPERATIONS AND HELD FOR SALE ASSETS AND LIABILITIES

Edgar Filing: ALKERMES INC - Form 425

On 9 May 2011, Alkermes and Elan announced the execution of a definitive agreement under which Alkermes will merge with EDT in a cash and stock transaction valued at approximately \$960 million as of the date of announcement. Alkermes and EDT will be combined under a new holding company incorporated in Ireland. This newly created company will be named Alkermes plc. The EDT Transaction is expected to close in the third quarter of 2011. When the deal closes, we will receive \$500 million in cash and 31.9 million ordinary shares of Alkermes plc common stock. We will hold approximately 25% of the equity of Alkermes plc, with the existing shareholders of Alkermes, holding the remaining 75% of the equity. We will account for our investment in Alkermes plc as an associate investment.

Table of Contents

Non-current assets and liabilities are classified as assets and liabilities held for sale when their carrying amount is to be recovered principally through a sale transaction and a sale is considered highly probable. They are stated at the lower of carrying amount and fair value less costs to sell if their carrying amount is to be recovered principally through a sale transaction rather than through continuing use and a sale is considered highly probable. Intangible assets and property, plant and equipment classified as held for sale are not amortised or depreciated. The results of a component of an entity that either has been disposed of, or is classified as held for sale, and represents a separate major line of business or geographical area of operations and is part of a single co-ordinated plan to dispose of a separate major line of business or geographical area of operations are presented as a discontinued operation in the financial statements.

Following the approval of the EDT Transaction by the Board of Elan on 8 May 2011, the EDT business met the criteria to be classified as held for sale and the assets and liabilities of the EDT business have been classified as held for sale on the half-year balance sheet at 30 June 2011. The results of EDT are presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative amounts have been restated to reflect this classification.

(a) Income statement

The income statement financial information relating to the EDT business for the first half of 2011 and 2010 is set out below.

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue	124.4	124.3
Contract revenue	4.4	8.1
Total revenue	128.8	132.4
Cost of sales	49.6	58.9
Gross margin	79.2	73.5
Operating expenses:		
Selling, general and administrative expenses	19.8	20.6
Research and development expenses	37.8	27.1
Gain on legal settlements	(84.5)	
Operating profit	106.1	25.8
Net interest expense	0.4	0.2
Net income before tax of discontinued operation	105.7	25.6
Income tax expense	2.6	4.5
Net income of discontinued operation	103.1	21.1

(b) Cash flows

There were no cash flows from financing activities attributable to EDT in the first half of 2011 and 2010. The net cash flows attributable to the operating and investing activities of EDT for the first half of 2011 and 2010 are set out below:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Net operating cash inflows	133.4	56.9
Net investing cash outflows	(5.1)	(6.5)

Edgar Filing: ALKERMES INC - Form 425

Total net cash inflows	128.3	50.4
------------------------	-------	------

Table of Contents**(c) Revenue**

Revenue from the EDT business for the first half of 2011 and 2010 is set out below:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Product revenue:		
Manufacturing revenue and royalties:		
TriCor 145	24.0	25.0
Ampyra	22.4	20.8
Focalin XR/Ritalin LA	18.2	16.6
Verelan	13.2	11.9
Skelaxin		5.2
Other	46.6	44.8
Total product revenue manufacturing revenue and royalties	124.4	124.3
Contract revenue:		
Research revenue	3.9	3.7
Milestone payments	0.5	4.4
Total contract revenue	4.4	8.1
Total revenue from the EDT business	128.8	132.4

(d) Other charges

Other charges from the EDT business for the first half of 2011 and 2010 are set out below:

2011

	Cost of Sales \$m	SG&A \$m	R&D \$m	Total \$m
Severance, restructuring and other costs	0.2	1.7	8.1	10.0
Asset impairment charges			5.1	5.1
Total other charges from discontinued operations	0.2	1.7	13.2	15.1

2010

	Cost of Sales \$m	SG&A \$m	R&D \$m	Total \$m
Severance, restructuring and other costs	0.4			0.4
Total other charges from discontinued operations	0.4			0.4

Edgar Filing: ALKERMES INC - Form 425

During the second quarter of 2011, we decided to close our King of Prussia, Pennsylvania site and consequently, EDT recorded a non-cash asset impairment of \$5.1 million and severance and restructuring charges of \$10.0 million for the first half of 2011. It is expected that the closure will take place in the second half of 2011.

Other charges for the first half of 2010 of \$0.4 million relate to severance, restructuring and other costs, arising from the realignment of resources to meet our business structure.

Table of Contents**(e) Legal settlement gains**

In May 2011, we entered into an agreement with Alcon to settle litigation in relation to the application of our *NanoCrystal* technology. As part of the settlement agreement with Alcon, we received \$6.5 million in May 2011 in full and final settlement.

In June 2008, a jury ruled in the U.S. District Court for the District of Delaware that Abraxis (since acquired by Celgene Corporation) had infringed a patent owned by Elan in relation to the application of its *NanoCrystal* technology to Abraxane. We were awarded \$55 million, applying a royalty rate of 6% to sales of Abraxane from 1 January 2005 through 13 June 2008 (the date of the verdict). This award and damages associated with the continuing sales of the Abraxane product were subject to interest. In February 2011, we entered into an agreement with Abraxis to settle this litigation. As part of the settlement agreement with Abraxis, we received \$78.0 million in full and final settlement of the litigation in March 2011. We will not receive future royalties in respect of Abraxane.

(f) Held for sale assets and liabilities

The assets and liabilities related to EDT business have been classified as held for sale following the Elan Board approval of the EDT Transaction. The EDT Transaction is expected to close in the third quarter of 2011. The carrying amounts of the EDT assets were less than the fair value less costs to sell when the assets were reclassified to held for sale and accordingly, no remeasurements of the assets were necessary.

The assets and liabilities of the EDT disposal group classified as held for sale are as follows:

	30 June 2011 \$m
Assets held for sale	
Property, plant and equipment	200.4
Goodwill (note 13)	45.2
Other intangible assets (note 13)	23.4
Inventory	18.1
Other current and non current assets	62.3
Total assets held for sale	349.4
Liabilities held for sale	
Accounts payable	2.1
Deferred tax liability	3.1
Accrued and other liabilities	18.2
Total liabilities held for sale	23.4
Total net assets held for sale	326.0

11. NET EARNINGS/(LOSS) PER SHARE

Basic earnings/(loss) per share is computed by dividing the net income/(loss) for the period available to ordinary shareholders by the weighted average number of Ordinary Shares outstanding during the period. Diluted earnings/(loss) per share is computed by dividing the net income/(loss) for the period by the weighted average number of Ordinary Shares outstanding and, when dilutive, adjusted for the effect of all potentially dilutive shares, including share options and Restricted Stock Units (RSUs).

Table of Contents

The following table sets forth the computation for basic and diluted net loss per share:

	Six Months Ended 30 June	
	2011	2010
Numerator (amounts in \$m):		
Basic and diluted net loss from continuing operations	\$ (53.0)	\$ (240.9)
Basic and diluted net income from discontinued operations	\$ 103.1	\$ 21.1
Basic earnings/(loss) per share		
Denominator (amounts in millions):		
Basic weighted-average shares outstanding (in millions) continuing and discontinued operations	586.4	584.6
Basic earnings/(loss) per share:		
From continuing operations	\$ (0.09)	\$ (0.41)
From discontinued operations	\$ 0.18	\$ 0.04
Diluted earnings/(loss) per share		
Denominator (amounts in millions):		
Diluted weighted-average shares outstanding (in millions) continuing operations	586.4	584.6
Diluted weighted-average shares outstanding (in millions) discontinued operations	591.4	587.3
Diluted earnings/(loss) per share:		
From continuing operations	\$ (0.09)	\$ (0.41)
From discontinued operations	\$ 0.17	\$ 0.04

For the first half of 2011 and 2010, there were no differences in the weighted-average number of Ordinary Shares used for basic and diluted net loss per Ordinary Share from continuing operations as the effect of all potentially dilutive Ordinary Shares outstanding was anti-dilutive. As at 30 June 2011, there were 26.2 million (2010: 24.0 million) share options and RSUs outstanding that could potentially have a dilutive impact in the future but were anti-dilutive in the first half 2011 and 2010.

12. SHARE-BASED COMPENSATION

We grant equity awards from the Long Term Incentive Plan (2006 LTIP), which provides for the issuance of share options, RSUs and other equity awards. The terms and conditions of the equity award plans and equity award activities are disclosed in our 2010 Annual Report.

Share Options

Share options are granted at fixed exercise prices equal to the market value of our shares on the date of grant. We granted approximately 3,224,000 share options on similar terms to employees of Elan and an affiliate during the first half of 2011 (2010: approximately 2,089,000 share options).

Equity-settled share-based payments made to employees have been recognised in the financial statements based on the fair value of the awards measured at the date of grant. Equity-settled share-based payments made to non-employees have been recognised in the financial statements based on the fair value of the awards measured when services are rendered. The fair value of share options is calculated using a binomial option-pricing model, and the fair value of options issued under our employee equity purchase plan, which is described further below, is calculated using the Black-Scholes option-pricing model, taking into consideration the relevant terms and conditions.

Table of Contents

The estimated weighted-average grant date fair values of share options awarded during the first half of 2011 and 2010 were \$3.03 and \$3.90 per share option, respectively. The fair values were estimated using the binomial option-pricing model with the following weighted-average assumptions:

	Six Months Ended 30 June	
	2011	2010
Share price and exercise price	\$ 6.84	\$ 7.05
Risk-free interest rate	1.7%	2.1%
Expected volatility ⁽¹⁾	49.8%	66.0%
Expected dividend yield		
Expected life ⁽²⁾		

⁽¹⁾ The expected volatility was based on the implied volatility of traded options on our shares.

⁽²⁾ The expected lives of options granted in the first half of 2011, as derived from the output of the binomial model, ranged from 4.8 years to 7.5 years (2010: 4.8 years to 7.5 years). The contractual life of the options, which is not later than 10 years from the date of grant, is used as an input into the binomial model.

Restricted Stock Units

As disclosed in our 2010 Annual Report, we grant RSUs to certain employees, directors and consultants of Elan and affiliates under our 2006 LTIP. The terms and conditions of the RSU awards are disclosed in our 2010 Annual Report. We granted approximately 3,301,000 RSUs on similar terms to certain directors and employees of Elan and an affiliate during the first half of 2011 (2010: approximately 2,957,000 RSUs). The fair value of services received in return for the RSUs is measured by reference to the fair value of the underlying shares at grant date, for directors and employees, and as services are rendered for non-employees. The estimated weighted-average grant date fair values of RSUs granted during the first half of 2011 and 2010 were \$6.80 and \$6.87 per unit, respectively.

Employee Equity Purchase Plan

As disclosed in our 2010 Annual Report, we operate an employee equity purchase plan for eligible employees in the United States. The estimated weighted-average grant date fair values of options issued under the U.S. plan during the first half of 2011 and 2010 was \$1.67 and \$2.17 per share, respectively. The estimated fair values were calculated using the following weighted-average inputs into the Black-Scholes option-pricing model:

	Six Months Ended 30 June	
	2011	2010
Share price	\$ 5.73	\$ 6.52
Exercise price	\$ 4.87	\$ 5.54
Risk-free interest rate	0.2%	0.2%
Expected volatility ⁽¹⁾	51.0%	66.0%
Expected dividend yield		
Expected life	6 months	6 months

⁽¹⁾ The expected volatility was based on the implied volatility of traded options on our shares.

Table of Contents**Share-based compensation expense**

We recognised total compensation expense related to equity-settled share-based awards of \$19.5 million during the first half of 2011 (2010: \$17.1 million). The expenses have been recognised in the following line items in the condensed consolidated half-year income statement:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Cost of sales	0.1	0.1
Selling, general and administrative expenses ⁽¹⁾	7.5	6.9
Research and development expenses ⁽²⁾	6.8	5.9
Share based compensation expense continuing operations	14.4	12.9
Share based compensation expense discontinued operation ⁽³⁾	5.1	4.2
Total share based compensation expense	19.5	17.1

⁽¹⁾ SG&A expenses in the first half of 2011 include \$0.2 million (2010: \$Nil) that has been recorded in other charges.

⁽²⁾ R&D expenses include \$0.2 million credit in the first half of 2010 that has been recorded in other charges.

⁽³⁾ Share based compensation expense in the first half of 2011 for discontinued operations includes \$0.4 million (2010:\$Nil) that has been recorded in other charges.

Share-based compensation arose under the following share-based awards:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Share options	12.4	7.2
RSUs	6.8	9.4
Employee equity purchase plan	0.3	0.5
Total	19.5	17.1

Table of Contents**13. GOODWILL AND OTHER INTANGIBLE ASSETS**

	Patents, Licences & Other \$m	Acquired IPR&D \$m	Goodwill \$m	Total \$m
Cost:				
At 1 January 2011	391.9	98.0	45.2	535.1
Additions	1.2			1.2
Transfer to assets held for sale	(152.4)	(41.6)	(45.2)	(239.2)
Disposals	(0.8)			(0.8)
At 30 June 2011	239.9	56.4		296.3
Accumulated amortisation:				
At 1 January 2011	(272.5)	(36.9)		(309.4)
Amortised in year	(8.5)	(1.6)		(10.1)
Impairment	(0.1)			(0.1)
Transfer to assets held for sale	149.1	21.5		170.6
Disposals	0.6			0.6
At 30 June 2011	(131.4)	(17.0)		(148.4)
Net book value:				
30 June 2011	108.5	39.4		147.9
31 December 2010	119.4	61.1	45.2	225.7

The components of the carrying value of patents, licences and acquired IPR&D, which have remaining useful lives between 1 and 10 years, were as follows:

	30 June 2011 \$m	31 December 2010 \$m
<i>Tysabri</i>	118.6	125.9
Other intangible assets	29.3	54.6
Total patents, licences and acquired IPR&D	147.9	180.5

The amortisation charge for total intangible assets is recognised in the following line items of the half-year income statement:

	Six Months Ended 30 June	
	2011 \$m	2010 \$m
Cost of sales	5.6	5.5
Selling, general and administrative expenses	1.3	1.2
Research and development expenses	2.0	2.4

Edgar Filing: ALKERMES INC - Form 425

Amortisation charge	continuing operations	8.9	9.1
Amortisation charge	discontinued operations	1.2	5.9
Total amortisation charge for intangible assets		10.1	15.0

Table of Contents**14. INVENTORY**

Our product inventory consisted of the following:

	30 June 2011 \$m	31 December 2010 \$m
Raw materials		10.0
Work-in-process		6.0
Finished goods	20.1	23.0
Total inventory	20.1	39.0

Inventory with a carrying value of \$18.1 million is included in the assets held for sale at 30 June 2011 (raw materials of \$9.9 million, work-in-process of \$5.5 million and finished goods of \$2.7 million). Please refer to Note 10 for an analysis of the assets and liabilities held for sale at 30 June 2011.

15. LONG-TERM DEBT

	Original Maturity	30 June 2011 \$m	31 December 2010 \$m
8.875% Notes	December 2013	445.8	445.1
Floating Rate Notes due 2013	December 2013	10.4	10.4
8.75% Notes issued October 2009	October 2016	607.2	605.9
8.75% Notes issued August 2010	October 2016	188.4	187.7
Total long-term debt		1,251.8	1,249.1

8.875% Notes

The outstanding principal amount of the 8.875% senior fixed rate notes due 1 December 2013 (8.875% Notes) was \$449.5 million at 30 June 2011 (31 December 2010: \$449.5 million), and has been recorded net of unamortised financing costs of \$3.7 million (31 December 2010: \$4.4 million).

Floating Rate Notes due 2013

The outstanding principal amount of the senior floating rate notes due 1 December 2013 (Floating Rate Notes due 2013) was \$10.5 million at 30 June 2011 (31 December 2010: \$10.5 million), and has been recorded net of unamortised financing costs of \$0.1 million (31 December 2010: \$0.1 million). These notes bear interest at a rate, adjusted quarterly, equal to three-months London Interbank Offer Rate (LIBOR) plus 4.125%.

8.75% Notes issued October 2009

The outstanding principal amount of the 8.75% senior fixed rate notes due 15 October 2016 that were issued in October 2009 (8.75% Notes issued October 2009) was \$625.0 million at 30 June 2011 (31 December 2010: \$625.0 million), and has been recorded net of unamortised financing costs of \$17.8 million (31 December 2010: \$19.1 million).

8.75% Notes issued August 2010

The outstanding principal amount of the 8.75% senior fixed rate notes due 15 October 2016 that were issued in August 2010 (8.75% Notes issued August 2010) was \$200.0 million at 30 June 2011 (31 December 2010: \$200.0 million), and has been recorded net of unamortised

financing costs of \$11.6 million (31 December 2010: \$12.3 million).

Table of Contents**16. ACCRUED AND OTHER LIABILITIES**

Our accrued and other liabilities consisted of the following:

	30 June 2011 \$m	31 December 2010 \$m
Non-current liabilities:		
Deferred rent	17.9	18.8
Other liabilities	17.9	21.3
Non-current liabilities	35.8	40.1
	30 June 2011 \$m	31 December 2010 \$m
Current liabilities:		
Accrued royalties payable	74.1	63.3
Accrued rebates	28.6	22.6
Payroll and related taxes	24.7	40.9
Sales and marketing accruals	21.5	22.0
Accrued interest	18.3	18.3
Restructuring accrual	14.7	12.9
Clinical trial accruals	12.6	13.8
Deferred rent	2.6	3.5
Transition payment		9.0
Other accruals	23.2	29.2
Current liabilities	220.3	235.5

Current liabilities of \$17.3 million and non-current liabilities of \$0.9 million are included in liabilities held for sale at 30 June 2011. Please refer to Note 10 for an analysis of the assets and liabilities held for sale at 30 June 2011.

17. PROVISIONS

At 30 June 2011, we had a provisions balance of \$0.7 million (31 December 2010: \$207.0 million). At 31 December 2010, the provision included a \$206.3 million settlement provision relating to the Zonegran settlement, interest and related costs. For further information, please refer to Notes 6 and 19.

18. FINANCIAL RISK MANAGEMENT*Financial risk factors*

We are exposed to various financial risks arising in the normal course of business. Our financial risk exposures are predominantly related to changes in foreign currency exchange rates and interest rates, as well as the creditworthiness of our counterparties.

The half-year financial statements do not include all financial risk management information and disclosures required in the annual financial statements, and should be read in conjunction with the 2010 Annual Report.

There have been no changes in our risk management policies since year-end.

Table of Contents**Liquidity risk**

Compared to year-end, there was no material change in the contractual undiscounted cash outflows for financial liabilities.

Our liquid resources and shareholders' equity were as follows:

	30 June 2011	31 December 2010
	\$m	\$m
Cash and cash equivalents	491.9	422.5
Restricted cash and cash equivalents – current	2.6	208.2 ⁽¹⁾
Available-for-sale investments – current	1.2	2.0
Total liquid resources	495.7	632.7
Shareholders' equity	295.4	214.0

⁽¹⁾ Current restricted cash included \$203.7 million held in an escrow account in relation to the Zonegran settlement, which was subsequently paid in March 2011.

Fair value estimation

There were no significant changes in the business or economic circumstances during the first half of 2011 that affect the fair value of our financial assets and financial liabilities.

During the first half of 2011, there were no reclassifications of financial assets and no significant transfers between levels of the fair value hierarchy used in measuring the fair value of financial instruments.

19. LITIGATION

We are involved in legal and administrative proceedings, including proceedings with respect to *Tysabri* related product liability claims, that could have a material adverse effect on us.

Zonegran matter

In January 2006, we received a subpoena from the U.S. Department of Justice and the Department of Health and Human Services, Office of Inspector General, asking for documents and materials primarily related to our marketing practices for Zonegran, an antiepileptic prescription medicine that we divested to Eisai Inc. in April 2004.

In December 2010, we finalised our agreement 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. In addition, we pleaded guilty to a misdemeanour violation of the U.S. Food Drug & Cosmetic 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 programmes and the FDA. If we materially fail to comply with the requirements of U.S. federal healthcare programmes or the FDA, or otherwise materially breach the terms of the Corporate Integrity Agreement, such as by a material breach of the compliance programme or reporting obligations of the Corporate Integrity Agreement, severe sanctions could be imposed upon us.

We paid \$203.5 million pursuant to the terms of a global settlement resolving all U.S. federal and related state Medicaid claims in March 2011. This resolution of the Zonegran investigation could give rise to other investigations or litigation by state government entities or private parties.

Patent matters

Edgar Filing: ALKERMES INC - Form 425

In May 2011, we entered into an agreement with Alcon to settle litigation in relation to the application of our *NanoCrystal* technology. As part of the settlement agreement with Alcon, we received \$6.5 million in May 2011 in full and final settlement.

Table of Contents

In June 2008, a jury ruled in the U.S. District Court for the District of Delaware that Abraxis, since acquired by Celgene Corporation, had infringed a patent owned by Elan in relation to the application of its *NanoCrystal* technology to Abraxane. We were awarded \$55 million, applying a royalty rate of 6% to sales of Abraxane from 1 January 2005 through 13 June 2008 (the date of the verdict). This award and damages associated with the continuing sales of the Abraxane product were subject to interest. In February 2011, we entered into an agreement with Abraxis to settle this litigation. As part of the settlement agreement with Abraxis, we received \$78.0 million in March 2011 in full and final settlement. We will not receive future royalties in respect of Abraxane.

Securities matters

In March 2005, we received a letter from the U.S. Securities and Exchange Commission (SEC) stating that the SEC's Division of Enforcement was conducting an informal inquiry into actions and securities trading relating to *Tysabri* events. The SEC's inquiry primarily relates to events surrounding the 28 February 2005 announcement of the decision to voluntarily suspend the marketing and clinical dosing of *Tysabri*. We have provided materials to the SEC in connection with the inquiry but have not received any additional requests for information or interviews relating to the inquiry.

The SEC notified us in January 2009 that the SEC was conducting an informal inquiry primarily relating to the 31 July 2008 announcement concerning the initial two *Tysabri*-related PML cases that occurred subsequent to the resumption of marketing *Tysabri* in 2006. We have provided the SEC with materials in connection with the inquiry.

On 24 September 2009, we received a subpoena from the SEC's New York Regional Office requesting records relating to an investigation captioned In the Matter of Elan Corporation, plc. The subpoena requests records and information relating to the 31 July 2008 announcement of the two *Tysabri*-related PML cases as well as records and information relating to the 29 July 2008 announcement at the International Conference of Alzheimer's Disease concerning the Phase 2 trial data for bapineuzumab. We have provided the SEC with materials in connection with the investigation.

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 as In Re: Elan Corporation Securities Litigation. The plaintiffs Consolidated Amended Complaint was filed on 17 August 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 21 May 2007 and 21 October 2008. The complaints allege that we issued false and misleading public statements concerning the safety and efficacy of bapineuzumab. On 23 July 2010, a securities case was filed in the U.S. District Court for the Southern District of New York. This case has been accepted by the court as a related case to the existing 2008 matter. The 2010 case purports to be filed on behalf of all purchasers of Elan call options during the period from 17 June 2008 to 29 July 2008. We filed a Motion to Dismiss the Consolidated Amended Complaint. On 24 June 2011, the court rejected the plaintiffs' claims during oral argument, and issued a Summary Order granting our Motion to Dismiss the class action complaints. The court provided the plaintiffs with the opportunity to file a single, coordinated brief by 29 July 2011 setting forth grounds for allowing them to amend their complaints. If the court believes that the plaintiffs' brief has merit the court will notify Elan in order to provide Elan an opportunity to file an opposition brief prior to the court ruling whether an amended complaint can be filed.

We and some of our officers and directors have been named as defendants in a securities case filed on 24 June 2010 in the U.S. District Court in the Northern District of California. The complaint alleges that during the June/July 2008 timeframe we disseminated materially false and misleading statements/omissions related to *Tysabri* and bapineuzumab. Plaintiffs allege that they lost collectively approximately \$4.5 million. Our Motion to Dismiss this case was granted on 9 February 2011; however, plaintiffs were given leave to amend and filed an amended complaint on 11 March 2011 and we filed a Motion to Dismiss the amended complaint on 13 May 2011. We expect a hearing on our renewed Motion to Dismiss in the second half of 2011.

We and some of our officers have been named as defendants in a putative class action lawsuit filed in the U.S. District Court for the Southern District of New York on 23 February 2011. The plaintiffs' complaint alleges claims under U.S. federal securities laws and seeks damages on behalf of all purchasers of our stock during the

Table of Contents

period between 2 July 2009 and 5 August 2009. The original complaint filed on 27 April 2011 alleges that we issued false and misleading public statements concerning our September 2009 transaction with Johnson & Johnson. In response to the complaint, on 6 June 2011, we filed a Motion to Dismiss and an accompanying brief. Rather than respond to our filing, plaintiffs filed an amended complaint on 27 June 2011 and we filed a subsequent Motion to Dismiss and accompanying brief on 14 July 2011. Assuming the court schedules an oral hearing regarding our filing to dismiss the action, we expect that such a hearing would occur in the second half of 2011.

Antitrust matters

In 2002 and 2003, 10 actions were filed in the U.S. District Courts (seven in the District of Columbia and three in the Southern District of New York) claiming that we (and others) violated federal and state antitrust laws based on licensing and manufacturing arrangements between Elan, Teva Pharmaceuticals Inc. and Biovail Corporation relating to nifedipine. The complaints sought various forms of remedy, including damages and injunctive relief. The actions were brought by putative classes of direct purchasers, individual direct purchasers, and putative classes of indirect purchasers. On 29 May 2003, the Judicial Panel for Multidistrict Litigation coordinated and consolidated for pre-trial proceedings all pending cases in the U.S. District Court for the District of Columbia. In late 2007, we entered into a settlement agreement with the indirect purchaser class resulting in a dismissal of that segment of the lawsuit. In December 2009, we entered into a separate settlement agreement with the individual opt-out direct purchasers and agreed to pay \$4.6 million to this opt-out direct purchaser class resulting in a dismissal of the second segment of the litigation. In October 2010, we agreed to pay \$12.5 million to settle the third and final piece of this litigation. On 31 January 2011, the U.S. District Court for the District of Columbia approved the settlement and dismissed the case.

Paragraph IV litigation

We and/or our product licensees are involved in various sets of so-called Paragraph IV litigation proceedings in the United States. In the United States, putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file Abbreviated New Drug Applications (ANDAs) and, in doing so, they are not required to include preclinical and clinical data to establish safety and effectiveness of their drug. Instead, they would rely on such data provided by the innovator drug New Drug Application (NDA) holder. However, to benefit from this less costly abbreviated procedure, the ANDA applicant must demonstrate that its drug is generic or bioequivalent to the innovator drug, and, to the extent that patents protect the innovator drug that are listed in the Orange Book, the ANDA applicant must write to the innovator NDA holder and the patent holder (to the extent that the Orange Book-listed patents are not owned by the innovator NDA holder) certifying that their product either does not infringe the innovator's patents and/or that the relevant patents are invalid. The innovator and the patent holder may sue the ANDA applicant within 45 days of receiving the certification and, if so, the FDA may not approve the ANDA for 30 months from the date of certification unless, at some point before the expiry of those 30 months, a court makes a final decision in the ANDA applicant's favour.

We are involved in a number of Paragraph IV suits in respect of seven different products (Tricor, Focalin XR, Avinza[®], Zanaflex[®], Rapamune, Luvox CR[®] and Megace[®] ES) either as plaintiff or as an interested party (where the suit is being taken in the name of one of our licensees). If we are unsuccessful in these and other similar type suits, our or our licensees' products may be subject to generic competition, and our manufacturing revenue and royalties would be materially and adversely affected.

20. RELATED PARTIES

We have related party relationships with our subsidiaries, associates, directors and executive officers. All transactions with subsidiaries eliminate on consolidation and are not presented in accordance with revised IAS 24.

There were no related party transactions that have taken place in the six months ended 30 June 2011 that materially affected the financial position or the performance of the Company during that period and there were no changes in the related party transactions described in the 2010 Annual Report that could have a material effect on the financial position or performance of the Company in the same period.

Table of Contents**U.S. GAAP INFORMATION**

The half-year financial statements of the Company have been prepared in accordance with IFRS, which differs in certain significant respects from accounting principles generally accepted in the United States (U.S. GAAP).

In June 2011, the Staff of the U.S. Securities and Exchange Commission's Division of Corporation Finance informed the Company that it had completed its review of Elan's 2009 Annual Report on Form 20-F. Following comments received from the Staff during this review, we revised our application of equity method accounting to our investment in Janssen AI under U.S. GAAP. Please refer to page 47 for a discussion of the revised accounting model under U.S. GAAP and how this model differs from IFRS. The change in accounting model under U.S. GAAP does not affect the economic rights or obligations under, or any other terms of, the September 2009 transaction with Johnson & Johnson, nor does it result in any adjustment to our historical revenue, Adjusted EBITDA or cash and cash equivalents.

Reconciliation from IFRS to U.S. GAAP**Unaudited Condensed Consolidated Half-Year Income Statement****For the Six Months Ended 30 June 2011**

	(A)	(B)	(C)	(D)	(E)	(F)	(G) & (H)	U.S.
	Tysabri	Other	Taxation	Other Net	Discontinued	Investment in	Pensions	GAAP
	\$m	Intangible	\$m	Charges	Operations	Associate	&	\$m
		Assets	\$m	\$m	\$m	\$m	Other	\$m
		\$m	\$m	\$m	\$m	\$m	\$m	\$m
Continuing operations								
Revenue	324.9	192.8			128.8			646.5
Cost of sales	121.8	154.3		0.1	49.6			325.8
Gross profit	203.1	38.5		(0.1)	79.2			320.7
Selling, general and administrative expenses	73.0	38.5	(1.6)	(12.7)	19.8			117.0
Research and development expenses	97.6			(14.0)	37.8			121.4
Other net gains				26.6	(84.5)			(57.9)
Total operating expenses	170.6	38.5	(1.6)	(0.1)	(26.9)			180.5
Operating profit	32.5	1.6			106.1			140.2
Net interest and investment gains and losses	81.7				0.4	25.7	2.3	110.1
Net income/(loss) before tax	(49.2)	1.6			105.7	(25.7)	(2.3)	30.1
Income tax expense	3.8		2.6		2.6			9.0
Net income/(loss) from continuing operations	(53.0)	1.6	(2.6)		103.1	(25.7)	(2.3)	21.1
Discontinued operations								
Net income from discontinued operations	103.1				(103.1)			
Net income	50.1	1.6	(2.6)			(25.7)	(2.3)	21.1

Table of Contents**Unaudited Condensed Consolidated Half-Year Income Statement****For the Six Months Ended 30 June 2010**

	IFRS \$m	(A) Tysabri \$m	(B) Goodwill \$m	(B) Other Intangible Assets \$m	(D) Other Net Charges \$m	(E) Discontinued Operations \$m	(G) & (H) Other \$m	U.S. GAAP \$m
Continuing operations								
Revenue	291.1	155.9				132.4		579.4
Cost of sales	105.1	122.6		1.2	(0.7)	58.9		287.1
Gross profit	186.0	33.3		(1.2)	0.7	73.5		292.3
Selling, general and administrative expenses	79.4	33.3		(1.9)	(3.5)	20.6	(0.1)	127.8
Research and development expenses	103.4				(0.1)	27.1	(0.1)	130.3
Settlement provision charge	206.3							206.3
Other net charges			0.6	0.2	4.3			5.1
Total operating expenses	389.1	33.3	0.6	(1.7)	0.7	47.7	(0.2)	469.5
Operating loss	(203.1)		(0.6)	0.5		25.8	0.2	(177.2)
Net interest and investment gains and losses	45.1					0.2	(4.6)	40.7
Net loss before tax	(248.2)		(0.6)	0.5		25.6	4.8	(217.9)
Income tax benefit	(7.3)					4.5		(2.8)
Net loss from continuing operations	(240.9)		(0.6)	0.5		21.1	4.8	(215.1)
Discontinued operations								
Net income from discontinued operations	21.1					(21.1)		
Net loss	(219.8)		(0.6)	0.5			4.8	(215.1)

Table of Contents**Unaudited Condensed Consolidated Half-Year Balance Sheet**

At 30 June 2011

	IFRS \$m	(B) Goodwill \$m	(B) Other Intangible Assets \$m	(C) Taxation \$m	(G) Pension \$m	(E) Investment in Associate \$m	(H) Other \$m	U.S. GAAP \$m
Non-Current Assets								
Goodwill and other intangible assets	147.9	207.4	(39.4)					315.9
Property, plant and equipment	77.9							77.9
Investment in associate	203.1					(25.7)		177.4
Available-for-sale investments	9.8						(0.2)	9.6
Deferred tax asset	345.3			(190.5)				154.8
Restricted cash and cash equivalents	15.0							15.0
Other non-current assets	29.3				(10.0)		19.6	38.9
Total Non-Current Assets	828.3	207.4	(39.4)	(190.5)	(10.0)	(25.7)	19.4	789.5
Current Assets								
Inventory	20.1							20.1
Accounts receivable	171.4							171.4
Other current assets	13.5							13.5
Deferred tax asset				37.7				37.7
Income tax prepayment	2.9			(2.9)				
Available-for-sale investments	1.2							1.2
Restricted cash and cash equivalents	2.6							2.6
Cash and cash equivalents	491.9							491.9
Assets held for sale	349.4	4.5	(20.1)					333.8
Total Current Assets	1,053.0	4.5	(20.1)	34.8				1,072.2
Total Assets	1,881.3	211.9	(59.5)	(155.7)	(10.0)	(25.7)	19.4	1,861.7
Non-Current Liabilities								
Long-term debt	1,251.8						19.6	1,271.4
Other liabilities	35.8				15.5			51.3
Income tax payable	14.4			(1.9)				12.5
Total Non-Current Liabilities	1,302.0			(1.9)	15.5		19.6	1,335.2
Current Liabilities								
Accounts payable	38.5							38.5
Accrued and other liabilities	220.3						0.7	221.0
Provisions	0.7						(0.7)	
Income tax payable	1.0			(1.0)				
Liabilities held for sale	23.4							23.4
Total Current Liabilities	283.9			(1.0)				282.9
Total Liabilities	1,585.9			(2.9)	15.5		19.6	1,618.1

Edgar Filing: ALKERMES INC - Form 425

Shareholders Equity									
Total Shareholders	Equity	295.4	211.9	(59.5)	(152.8)	(25.5)	(25.7)	(0.2)	243.6
Total Shareholders	Equity and Liabilities	1,881.3	211.9	(59.5)	(155.7)	(10.0)	(25.7)	19.4	1,861.7

Table of Contents**Audited Consolidated Balance Sheet**

At 31 December 2010

	IFRS \$m	(B) Goodwill \$m	(B) Other Intangible Assets \$m	(C) Taxation \$m	(G) Pension \$m	(H) Other \$m	U.S. GAAP \$m
Non-Current Assets							
Goodwill and other intangible assets	225.7	211.9	(61.1)				376.5
Property, plant and equipment	287.5						287.5
Investment in associate	209.0						209.0
Available-for-sale investments	8.9					0.5	9.4
Deferred tax asset	336.7			(182.4)			154.3
Restricted cash and cash equivalents	14.9						14.9
Other non-current assets	34.6				(10.5)	21.3	45.4
Total Non-Current Assets	1,117.3	211.9	(61.1)	(182.4)	(10.5)	21.8	1,097.0
Current Assets							
Inventory	39.0						39.0
Accounts receivable	191.6						191.6
Other current assets	15.4						15.4
Deferred tax asset				41.8			41.8
Income tax prepayment	3.1			(3.1)			
Available-for-sale investments	2.0						2.0
Restricted cash and cash equivalents	208.2						208.2
Cash and cash equivalents	422.5						422.5
Total Current Assets	881.8			38.7			920.5
Total Assets	1,999.1	211.9	(61.1)	(143.7)	(10.5)	21.8	2,017.5
Non-Current Liabilities							
Long-term debt	1,249.1					21.3	1,270.4
Other liabilities	40.1				19.9		60.0
Income tax payable	14.2			(3.1)			11.1
Total Non-Current Liabilities	1,303.4			(3.1)	19.9	21.3	1,341.5
Current Liabilities							
Accounts payable	39.2						39.2
Accrued and other liabilities	235.5					207.0	442.5
Provisions	207.0					(207.0)	
Total Current Liabilities	481.7						481.7
Total Liabilities	1,785.1			(3.1)	19.9	21.3	1,823.2
Shareholders Equity							
Total Shareholders Equity	214.0	211.9	(61.1)	(140.6)	(30.4)	0.5	194.3

Edgar Filing: ALKERMES INC - Form 425

Total Shareholders Equity and Liabilities	1,999.1	211.9	(61.1)	(143.7)	(10.5)	21.8	2,017.5
---	---------	-------	--------	---------	--------	------	---------

The principal differences between IFRS as adopted by the European Union and U.S. GAAP, as they apply to our financial statements, are as follows:

(A) *Tysabri*

Tysabri was developed and is now being marketed in collaboration with Biogen Idec. In general, subject to certain limitations imposed by the parties, we share with Biogen Idec most development and commercialisation costs. Biogen Idec is responsible for manufacturing the product. In the United States, we purchase *Tysabri* from

Table of Contents

Biogen Idec and are responsible for distribution. Under U.S. GAAP, we record as revenue the net sales of *Tysabri* in the U.S. market. We purchase product from Biogen Idec as required at a price that includes the cost of manufacturing plus Biogen Idec's gross profit on *Tysabri*, and this cost, together with royalties payable to other third parties, is included in cost of sales. Outside of the United States, Biogen Idec is responsible for distribution and, under U.S. GAAP, we record as revenue our share of the profit or loss on EU sales of *Tysabri* plus our directly incurred expenses on these sales.

Under IFRS, the *Tysabri* collaboration is a jointly controlled operation in accordance with IAS 31. A jointly controlled operation is an operation of a joint venture (as defined in IAS 31) that involves the use of the assets and other resources of the venturers rather than establishing a corporation, partnership or other entity, or a financial structure that is separate from the venturers themselves. Each venturer uses its own property, plant and equipment and carries its own inventories. It also incurs its own expenses and liabilities and raises its own finance, which represent its own obligations. Under IFRS, to account for our share of the *Tysabri* jointly controlled operation, we record our directly incurred expenses within operating expenses and we recognise as revenue our share of the collaboration profit from the sale of *Tysabri*, plus our directly incurred collaboration expenses related to these sales, which are primarily comprised of royalties, that we incur and are payable by us to third parties and are reimbursed by the collaboration.

There are no reconciling differences to total net income/(loss) or shareholders' equity between IFRS and U.S. GAAP related to *Tysabri*. However, the amounts recorded for revenue and operating expenses related to the U.S. market differ under both standards due to the differing accounting principles for *Tysabri* sales. As described above, under U.S. GAAP we record as revenue the net sales of *Tysabri* in the U.S. market, whereas under IFRS we record as revenue our share of the collaboration profit on these sales plus our directly incurred collaboration expenses related to these sales. There are no differences between IFRS and U.S. GAAP for the amounts recorded related to sales outside of the United States.

(B) Goodwill and other intangible assets

The carrying value of goodwill is lower under IFRS than under U.S. GAAP, while conversely the carrying value of our other intangible assets is higher under IFRS than under U.S. GAAP, because of differences in our historical Irish generally accepted accounting principles (Irish GAAP) accounting for business combinations which have carried into our IFRS financial statements as part of the transitional arrangements. The higher carrying value for intangible assets other than goodwill gives rise to a higher amortisation charge under IFRS than under U.S. GAAP. Goodwill is not amortised under either IFRS or U.S. GAAP, but instead is subject to regular (at least annual) impairment testing.

The principal reason for a higher carrying value of intangible assets other than goodwill under IFRS is that under U.S. GAAP, the fair value of acquired IPR&D is expensed upon acquisition, whereas under Irish GAAP and IFRS, these amounts are capitalised as intangible assets.

In addition, a number of differences arose in the manner in which goodwill was previously written off when businesses were sold under Irish GAAP and U.S. GAAP, which caused the net carrying value of goodwill to be lower under IFRS than U.S. GAAP at 30 June 2011 and 31 December 2010. Under Irish GAAP, the goodwill arising from acquisition was written off on disposal, whereas under U.S. GAAP, the goodwill write-off on disposal was calculated proportionately based on the relative fair value of the disposed business to the total fair value of the reporting unit. Similarly, under U.S. GAAP a portion of the BioNeurology goodwill was allocated to the Prialt business upon its divestment to Azur in 2010 and to the AIP upon the divestment of that business to Janssen AI in 2009 (because of these historic Irish GAAP differences, there is no carrying value for BioNeurology goodwill under IFRS), thus resulting in a lower gain (or higher loss) on divestment of these businesses under U.S. GAAP compared to IFRS. The carrying amount of goodwill allocated to the EDT business and included as a held for sale asset at 30 June 2011 is also lower under IFRS compared to U.S. GAAP; \$45.2 million under IFRS compared to \$49.7 million under U.S. GAAP. As we did not restate our historical business combinations in accordance with IFRS 3, *Business Combinations*, as permitted by IFRS 1, *First-time Adoption of International Financial Reporting Standards*, these differences remain in effect between U.S. GAAP and IFRS.

Table of Contents***(C) Taxation***

There are different rules under IFRS and U.S. GAAP in relation to the recognition of DTAs associated with share-based compensation. DTAs are only recognised under either GAAP in relation to jurisdictions where tax deductions are available to the employer for equity grants given to employees (relevant employee equity awards). For example, such tax deductions are available in the United States but in general not in Ireland. Under U.S. GAAP, a DTA may be recognised for relevant employee equity awards only to the extent that a compensation expense has previously been recorded in relation to those awards. In contrast, under IFRS, a DTA may be recognised in relation to the tax effect of the full intrinsic value at the balance sheet date of all relevant employee equity awards expected to be exercised, regardless of whether or not a compensation expense has previously been recognised for those awards. Accordingly, the total DTA recognised under IFRS is substantially higher than under U.S. GAAP.

(D) Other net charges

The principal items classified as other charges include transaction costs, severance, restructuring and other costs, facilities and other asset impairment charges and legal settlements and awards. These items have been treated consistently from period to period. We believe that disclosure of significant other charges is meaningful because it provides additional information in relation to analysing certain items. Under IFRS, other net charges are recorded within their respective income statement line items. Under U.S. GAAP, they are recorded as a separate line item in the consolidated income statement.

(E) Discontinued operations

In connection with the EDT Transaction, at closing, we will receive \$500 million in cash and 31.9 million ordinary shares of Alkermes plc common stock. We will hold approximately 25% of the equity of Alkermes plc, with the existing shareholders of Alkermes, holding the remaining 75% of the equity. We will account for our investment in Alkermes plc as an associate (equity method investment) under both IFRS and U.S. GAAP.

Under IFRS, the results of EDT are presented as a discontinued operation in the half-year income statement for the first half of 2011 and the comparative income statement figures have been restated. Under U.S. GAAP, EDT is not classified as a discontinued operation because of Elan's continuing involvement in the business through its 25% equity interest.

The assets and liabilities of EDT are classified as held for sale at 30 June 2011 under both IFRS and U.S. GAAP. The carrying value of the assets held for sale under IFRS is \$349.4 million compared to \$333.8 million under U.S. GAAP; which is attributable to the higher carrying value of intangible assets under IFRS, as explained above, that have been transferred to held for sale.

(F) Investment in associate undertaking

As part of the transaction whereby Janssen AI, a subsidiary of Johnson & Johnson, acquired substantially all of our assets and rights related to our AIP collaboration with Wyeth (which has been acquired by Pfizer), we received a 49.9% equity investment in Janssen AI. Johnson & Johnson also committed to fund up to an initial \$500.0 million towards the further development and commercialisation of the AIP to the extent the funding is required by the collaboration.

Under both IFRS and U.S. GAAP, we have recorded our investment in Janssen AI as an investment in an associate (equity method investment) on the balance sheet as we have the ability to exercise significant influence, but not control or joint control, over the investee. The investment was recognised initially based on the estimated fair value of the investment acquired, representing our proportionate 49.9% share of Janssen AI's AIP assets along with the fair value of our proportionate interest in the Johnson & Johnson contingent funding commitment, and is subsequently accounted for using the equity method.

Under both U.S. GAAP and IFRS, investors are required to recognise their share of post-acquisition changes in net assets of an investee. This is applied under IFRS by remeasuring our proportionate interest in the

Table of Contents

Johnson & Johnson funding commitment, which had an initial carrying value of \$117.7 million, at each reporting date during the period that the funding of Janssen AI is being provided exclusively by Johnson & Johnson to reflect any changes in the expected cash flows and this remeasurement, along with the recognition of our proportionate share of the other changes in the net assets of Janssen AI, will result in changes in the carrying value of the investment in associate that will be reflected in the income statement.

Under U.S. GAAP, the \$117.7 million initial carrying value of the Johnson & Johnson contingent funding commitment asset is being amortised to the income statement on a pro rata basis; based on the actual amount of Janssen AI losses that are solely funded by Johnson & Johnson in each period as compared to the total \$500.0 million, which is the total amount we estimate will be solely funded by Johnson & Johnson. Similar to the IFRS accounting model, in the event that the entire \$500.0 million contingent funding commitment is spent, the maximum net losses that would be recorded by Elan over the period of the expenditure is \$117.7 million. The U.S. GAAP application of equity method accounting results in a different timing of amortisation of the \$117.7 million, with greater amounts applicable to earlier periods than under IFRS.

Under IFRS, the net loss recorded on the Janssen AI investment for the first half of 2011 was \$25.5 million (2010: \$Nil) compared to a net loss of \$51.2 million under U.S. GAAP (2010: \$9.6 million). The net loss of \$51.2 million under U.S. GAAP for the first half of 2011 included a charge of \$26.7 million (2010: \$Nil) to correct an immaterial error in prior periods that arose as a result of revising the application of equity method accounting to the investment in Janssen AI under U.S. GAAP. The remaining \$24.5 million net loss on equity method investment for Janssen AI for first half of 2011 (2010: \$9.6 million) relates to the amortisation of the contingent funding commitment applicable to this period.

(G) Pensions

Under both IFRS and U.S. GAAP, actuarial gains and losses relating to defined benefit plans arise as a result of two factors: (a) experience adjustments due to differences between the previous actuarial assumptions and actual outcomes; and (b) changes in actuarial assumptions. At a minimum, actuarial gains and losses are required to be recognised in the income statement when the cumulative unrecognised amount thereof at the beginning of the period exceeds a corridor, which is 10% of the greater of the present value of the obligation and the fair value of the assets. Under both IFRS and U.S. GAAP, we amortise actuarial gains and losses in excess of the corridor on a straight-line basis over the expected remaining working lives of the employees in the plans.

Under IFRS, the unamortised net actuarial losses relating to our defined benefit plans that were not recognised in the income statement are classified as assets. Under U.S. GAAP, these unamortised net actuarial losses are recognised directly in shareholders' equity. At 30 June 2011, the defined benefit plans had a total unfunded status (excess of the projected benefit obligations over the fair value of the plans' assets) of \$15.5 million (31 December 2010: \$19.9 million) and total unamortised net actuarial losses of \$25.5 million (31 December 2010: \$30.4 million) based on the foreign exchange rate at the balance sheet date. Under IFRS, the unfunded status is netted off against the unamortised net actuarial losses resulting in a net pension asset of \$10.0 million and \$10.5 million at 30 June 2011 and 31 December 2010, respectively. Under U.S. GAAP, the unfunded status is recognised as a long-term liability on the balance sheet, and the unamortised net actuarial losses are recognised as a reduction to shareholders' equity. Consequently, a reconciling difference of \$25.5 million to shareholders' equity arises at 30 June 2011 (31 December 2010: \$30.4 million), reflecting this difference in classification of the unamortised net actuarial losses between IFRS (assets) and U.S. GAAP (shareholders' equity).

(H) Other

The primary components of the other reconciling items in the balance sheet relate to provisions and unamortised financing costs. Under IFRS, provisions are disclosed separately on the balance sheet whereas under U.S. GAAP, these reserves are included within accrued and other liabilities. Under IFRS, deferred transaction costs are netted off against the aggregate principal amount of the related debt in liabilities whereas under U.S. GAAP, these deferred costs are presented as assets in the balance sheet.

Table of Contents

RESPONSIBILITY STATEMENT

For the six months ended 30 June 2011

Each of the directors, whose names and functions are listed on pages 62 to 65 of our Annual Report, except for changes noted on page 16 of this Half-Year Financial Report, confirm that, to the best of each person's knowledge and belief:

- 1) The condensed unaudited consolidated half-year financial statements, comprising the condensed consolidated half-year income statement, the condensed consolidated half-year statement of comprehensive income, the condensed consolidated half-year balance sheet, the condensed consolidated half-year statement of cash flows and the condensed consolidated half-year statement of changes in shareholders' equity and the related explanatory notes thereto, have been prepared in accordance with IAS 34 as adopted by the European Union.

- 2) The half-year management report includes a fair review of the information required by:
 - (i) *Regulation 8(2) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being an indication of important events that have occurred during the six months ended 30 June 2011 and their impact on the condensed consolidated half-year financial statements; and a description of the principal risks and uncertainties for the six months ending 31 December 2011; and

 - (ii) *Regulation 8(3) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being related party transactions that have taken place in the six months ended 30 June 2011 and that have materially affected the financial position or performance of the Company during that period; and any changes in the related party transactions described in the 2010 Annual Report that could do so.

On behalf of the board,

Robert A. Ingram

Chairman

25 July 2011

G. Kelly Martin

Chief Executive Officer

25 July 2011

Table of Contents

INDEPENDENT REVIEW REPORT OF KPMG TO ELAN CORPORATION, PLC

Introduction

We have been engaged by Elan Corporation, plc (the Company) to review the condensed consolidated half-year financial statements for the six months ended 30 June 2011 which comprise the condensed consolidated half-year income statement, the condensed consolidated half-year statement of comprehensive income, the condensed consolidated half-year balance sheet, the condensed consolidated half-year statement of cash flows, the condensed consolidated half-year statement of changes in shareholders' equity and the related explanatory notes thereto. We have read the other information contained in the Half-Year Financial Report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed consolidated half-year financial statements.

This report is made solely to the Company in accordance with the terms of our engagement to assist the Company in meeting the requirements of the Transparency (Directive 2004/109/EC) Regulations 2007 and the Transparency Rules of the Republic of Ireland's Financial Regulator. Our review has been undertaken so that we might state to the Company those matters we are required to state to it in this report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company for our review work, for this report, or for the conclusions we have reached.

Directors' responsibilities

The Half-Year Financial Report, including the condensed consolidated half-year financial statements contained therein, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the Half-Year Financial Report in accordance with the Transparency (Directive 2004/109/EC) Regulations 2007 and the Transparency Rules of the Republic of Ireland's Financial Regulator.

As disclosed in note 1 – basis of preparation, the annual consolidated financial statements of the Company are prepared in accordance with International Financial Reporting Standards as adopted by the European Union (EU). The condensed consolidated half-year financial statements included in this Half-Year Financial Report have been prepared in accordance with IAS 34, *Interim Financial Reporting*, as adopted by the EU.

Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed consolidated half-year financial statements in the Half-Year Financial Report, based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the Auditing Practices Board for use in Ireland and the UK. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated half-year financial statements in the Half-Year Financial Report for the six months ended 30 June 2011 are not prepared, in all material respects, in accordance with IAS 34 as adopted by the EU, the Transparency (Directive 2004/109/EC) Regulations 2007 and the Transparency Rules of the Republic of Ireland's Financial Regulator.

Ruaidhri Gibbons

For and on behalf of

KPMG

Chartered Accountants, Statutory Audit Firm

Dublin, Ireland

25 July 2011