

# CONSOLIDATED FINANCIAL REPORT For the Third Quarter of Fiscal 2010 (the Fiscal Year Ending March 31, 2011, Japan Standard)

February 1, 2011

Eisai Co., Ltd. Stock exchange listings: Tokyo, Osaka

TSE Code: 4523 URL <a href="http://www.eisai.co.jp">http://www.eisai.co.jp</a>

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Vice President,

**Corporate Communications** 

Expected date of quarterly report submission: February 10, 2011

Expected date of dividend payment commencement: -

Preparation of quarterly supplementary explanatory material: Yes Quarterly results briefing held: Yes

(Figures are rounded down to the nearest million yen unless otherwise stated)

## 1. Consolidated Financial Results for the Third Quarter of Fiscal 2010 (April 1, 2010 to December 31, 2010)

#### (1) Consolidated Operating Results (cumulative)

(Percentage figures show year-on-year change)

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	Net sales	Operating income	Ordinary income	Net income	
	(¥ million)	(¥ million)	(¥ million)	(¥ million)	
3Q fiscal 2010	613,859 +1.6	109,434 +28.7	102,734 +28.3	67,371 +24.9	

	(¥)	(¥)
3Q fiscal 2010		

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Dividend per share

#### **Performance by Segment**

(Net sales for each segment include only sales to external customers.)

#### **Japan Pharmaceuticals Business**

- Net sales totaled ¥269,136 million (up 6.5% year on year), with segment profit of ¥116,596 million (up 7.3% year on year).
- Sales of Aricept increased to ¥80,405 million (up 10.8% year on year), and sales of Pariet increased to ¥48,750 million (up 13.2% year on year).

#### **United States Pharmaceuticals Business**

- Net sales totaled ¥257,966 million (down 0.7% year on year; up 6.9% on a U.S. dollar-denominated basis), with segment profit of ¥85,146 million (up 14.7% year on year).
- Sales of Aricept came to ¥143,840 million (up 4.0% year on year; up 12.1% on a U.S. dollar-denominated basis), and sales of Aciphex came to ¥51,323 million (down 16.2% year on year; down 9.7% on a U.S. dollar-denominated basis)
- ' **Aricept 23 mg tablet**, a higher dose formulation for the treatment of moderate-to-severe Alzheimer's disease, was launched in August 2010. Sales of the new product accounted for ¥4,039 million of the total sales of **Aricept**.
- Greenstone LLC., a subsidiary of U.S. based Pfizer Inc., launched **Aricept AG** (Authorized Generic: a generic product sold under license from the manufacturer of an original drug). **Sales of Aricept AG** and related business income, including revenue generated from this affiliation, accounted for ¥11,881 million of the total sales of **Aricept**.
- Halaven, a novel anticancer agent indicated for the treatment of patients with metastatic breast cancer who have previously been treated with at least two chemotherapeutic regimens including an anthracycline and a taxane, was launched in November 2010. Sales of Halaven totaled ¥399 million.

Sales of Aricept came to ¥5,065 million (up 4.7% year on year), and sales of Pariet came to ¥3,686 million (down 0.4% year on year).

### **New Markets Pharmaceuticals Business**

- Net sales totaled ¥730 million (up 28.0% year on year), with a segment loss of ¥413 million.
- Sales of Aricept (brand name in India: Aricep) came to ¥105 million (up 21.3% year on year), and sales of Pariet (brand name in India: Parit) came to ¥213 million (up 49.9% year on year).
- (2) Third Quarter Financial Highlights (October 1, 2010 December 31, 2010)
  - ' Consolidated net sales

- additional twice-daily dosage and administration for the treatment of reflux esophagitis patients who are unable to obtain satisfactory relief with conventional proton pump inhibitor treatment.
- In January 2011, the **botulinum toxin type B neuromuscular-blocking agent Nerbloc** obtained approval in Japan for the treatment of cervical dystonia.
- In June 2010, the application submitted for the **proton pump inhibitor Aciphex Extended-Release 50 mg** formulation was accepted for review in the U.S. The application submitted in Europe for the **Pariet Extended-Release 50 mg** formulation was also accepted for review in September 2010.
- In June 2010, an application seeking approval of a new granule formulation of the oral **anticoagulant Warfarin** was submitted in Japan.
- In July 2010, the application submitted for a new oral suspension (40mg/mL) formulation of the **anti-epileptic agent Banzel** was accepted for review in the U.S.
- In August 2010, an application seeking approval of an additional indication of the **fully human anti-TNFalpha monoclonal antibody Humira** for the treatment of juvenile idiopathic arthritis was submitted in Japan.
- In September 2010, an application seeking approval of additional dosage and administration of the oral **anticoagulant Warfarin** in pediatric patients was submitted in Japan.
- In October 2010, the application submitted for a new oral suspension formulation of the **anti-epileptic agent Inovelon** was accepted for review in Europe.
- In November 2010, an application seeking approval of **SEP-190** as a treatment for insomnia was submitted in Japan.
- In November 2010, an application seeking approval of additional dosage and administration of the **calcium channel blocker Vasolan** for the treatment of arrhythmia in pediatric patients was submitted in Japan.

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## **Status of Major Alliances and Agreements**

In June 2010, Eisai's U.S. subsidiary Eisai Inc. concluded an exclusive license

subject of a co-promotion agreement between Eisai Co., Ltd. and Pfizer Japan Inc. In October 2010, Pfizer received approval to replace the indication of postherpetic neuralgia with the new and broader indication of peripheral neuropathic pain. In December 2010, an internet portal site "Toutsu.jp" (<a href="http://toutsu.jp">http://toutsu.jp</a>) was launched to provide the general public with easy-to-understand information on neural pain.

In April 2010, Eisai established the

- counter allergy medication for the relief of rhinitis and skin-related allergic symptoms caused by hay fever and other allergies, was launched in Japan.
- In January 2011, Eisai commenced fully-fledged operations at its new Chinese pharmaceutical trading subsidiary Eisai (Suzhou) Trading Co., Ltd.
- In January 2011, Eisai's Indian subsidiary Eisai Pharmaceuticals India Pvt. Ltd. signed a Public-Private Partnership (PPP) agreement with Apollo Hospitals (India's largest healthcare provider) and HelpAge India (India's largest patient advocacy group) aimed at improving access to medicines in India. Under the PPP agreement, the three parties will develop and implement a program to educate, screen, diagnose, treat and

#### (4) Qualitative Information Concerning Financial Position

#### Assets, Liabilities and Equity

- **Total assets** as of the end of this period amounted to ¥1,054,223 million (down ¥47,686 million from the end of the previous fiscal year). Major decreases included decreases in intangible assets due to the decrease in assets of foreign subsidiaries as a result of yen conversion.
- **Total liabilities** as of the end of this period amounted to ¥651,290 million (down ¥28,879 million from the end of the previous fiscal year).
- Total equity as of the end of this period amounted to ¥402,933 million (down ¥18,806 million from the end of the previous fiscal year). The shareholders' equity ratio was 37.6% (down 0.1 percentage points from the end of the previous fiscal year).

#### Cash Flow (April 1, 2010 to December 31, 2010)

- Net cash provided by operating activities for the nine month period ended December 31, 2010 amounted to ¥105,086 million (up ¥45,769 million from the same period of the previous fiscal year). More specifically, income before income taxes and minority interests was ¥101,433 million; depreciation and amortization was ¥32,751 million; increase in notes and accounts receivable-trade was ¥15,003 million; and income taxes-paid was ¥18,585 million.
- Net cash used in investing activities amounted to ¥34,437 million (up ¥6,634 million from the same period of the previous fiscal year). Of this amount, ¥10,037 million was used for purchases of property, plant and equipment

## (5) Basic Policy on Profit Appropriation and Dividend Forecast for Fiscal 2010 (the Fiscal year ending March 31, 2011)

Eisai Co., Ltd. is devoted to providing sustainable and stable dividends based on its consolidated financial performance along with the Dividend on Equity ratio (DOE) and cash income.

DOE encompasses both the Dividend Payout Ratio (DPR), which measures the extent to which profits are distributed to shareholders in the form of dividends, and Return on Equity (ROE), which measures how effectively the Company uses the money invested by shareholders to generate profits.

Cash income expresses the Company's ability to generate cash. Cash income is used in order to improve the financial standing of the Company, i.e. investment in future growth and business development, dividend payments, repayment of borrowings, and other expenditures. The Company considers that a well-balanced allocation of cash income for these applications over a medium term is important.

From this standpoint, the Company considers it well-balanced and appropriate to take DOE and cash income, in addition to consolidated financial results, into consideration in a comprehensive manner in mid-term assessments of shareholder return. In addition, acquisition of treasury stock will be carried out flexibly on a timely basis.

Eisai Co., Ltd. is a company with a committees system and, to facilitate a flexible dividend policy as specified in the Company's Articles of Incorporation, dividend payments are to be determined by a resolution of the Board of Directors.

Based on the Company's dividend policy to provide shareholders with sustainable and stable dividends, the Company intends to set the fiscal year-end dividend at ¥80 per share (same amount as the same perde shareholders with susanlcar-end 4-5.8(vi)8.1(d0C¥dEdn2(l0 0 -1.41s)7.7)C1P1803 5w(

## (6) Consolidated Financial Results Forecast for Fiscal 2010 (April 1, 2010 to March 31, 2011)

### **Consolidated Forecast**

The full fiscal year consolidated forecast has been revised as follows from that previously announced in October 2010.

	Revised Forecast		ed Forecast Previous Forecast		Increase/ (Decrease)	Rate of Changes
	(A)	(%)	(B)	(%)	(A-B)	(%)
Net sales	¥770,000 mil.	-4.1	¥795,000 mil.	-1.0	(¥25,000 mil.)	-3.1

Operating income \$\frac{116,000 \text{ mil.} +34.2}{\text{ +34.2}}\$\$ \$\frac{\text{ +34.2}}{\text{ -0.0}}\$\$

## (Reference)

### **Non-consolidated Financial Forecast**

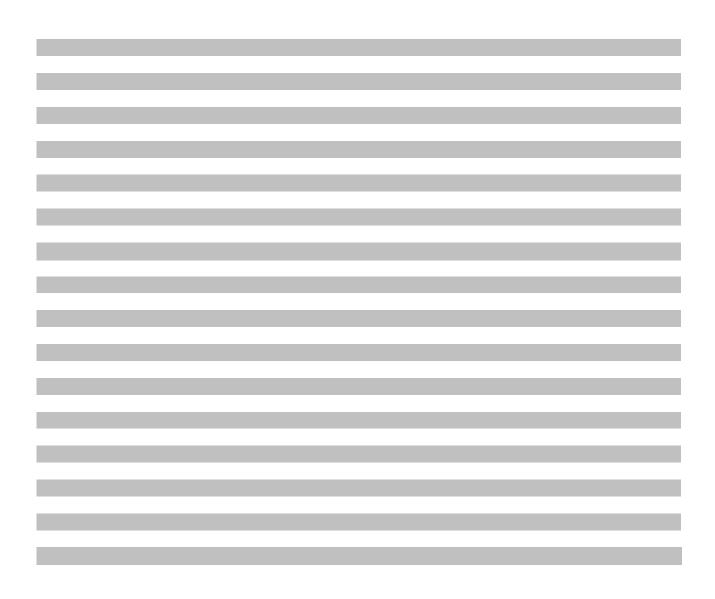
The full fiscal year non-consolidated forecast has been revised as follows from that previously announced in October 2010.

	Revised Forecast	Previous Forecast	Increase/ (Decrease)	
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## 2. Other Information

- (1) Application of the Simplified Accounting Method and Special Accounting Treatment
  - 1) Simplified accounting method

## 3. Consolidated Financial Statements(1) Consolidated Balance Sheets



LIABILITIES		
Current liabilities:		
Notes and accounts payable-trade	22,429	20,314
Short-term borrowings	8,000	24,000
Bonds and debentures (Current-portion)	39,999	
Accounts payable-other	53,410	67,913
Accrued expenses	48,810	59,65
Income tax payable	25,082	6,55
Reserve for sales rebates	29,654	32,72
Other reserves	551	556
Other	12,018	8,523
Total current liabilities	239,956	220,244
Non-current liabilities:		
Bonds and debentures	79,991	119,98
Long-term borrowings	258,894	265,824

## (2) Consolidated Statements of Income (Nine month period from April 1 to December 31)

Net sales	604,489	613,859
Cost of sales	121,487	127,305
Gross profit	483,002	486,553
Provision for sales returns-net	61	14
Gross profit after deducting sales returns-net	482,941	486,539
Selling, general and administrative expenses	397,880	377,104
Operating income	85,061	109,434
Non-operating income		
Interest income	959	752
Dividend income	848	917
Other	221	210
Total non-operating income	2,029	1,880
Non-operating expenses		
Interest expense	5,775	5,608
Foreign exchange loss	594	2,738
Other	650	233
Total non-operating expenses	7,020	8,580
Ordinary income	80,069	102,734
Special gain		
Gain on sales of fixed assets	12	33
Gain on sales of investment securities	-	46
Reversal of provision for doubtful accounts	-	142
Other	34	2
Total special gain	46	225
Special loss		
Loss on disposal of fixed assets	361	279
Loss on impairment of long-lived assets	-	305
Loss on devaluation of investment securities	-	277
Loss associated with the adoption of Accounting Standard for		

## (Three month period from October 1 to December 31)

(millions of yen)

## (3) Consolidated Statements of Cash Flows (Nine month period from April 1 to December 31)

		(millions of yen)
	April 1, 2009 -	April 1, 2010 -
	December 31, 2009	December 31, 2010
Operating activities:		
Income before income taxes and minority interests	79,747	101,433
Depreciation and amortization	36,797	32,751
Amortization of goodwill	6,402	5,913
Other loss (gain)-net	4,400	4,573
Increase (decrease) in notes and accounts receivable-trade	(28,212)	(15,003)
Increase (decrease) in inventories	(3,037)	(5,781)
Increase (decrease) in trade payables	555	4,497
Increase (decrease) in other current liabilities	8,330	(4,857)
Increase (decrease) in reserve for sales rebates	4,005	1,058
Other-net	4,559	2,904
Sub-total	113,548	127,489
Interest and dividends received	1,711	1,537
Interest paid	(5,630)	(5,354)
Income taxes paid	(50,312)	(18,585)
Net cash provided by operating activities	59,317	105,086
Investing activities:		
Purchases of property, plant and equipment	(16,363)	(10,037)
Purchases of intangible assets	(7,072)	(4,702)
Purchases of investment securities	(5,186)	(2,972)
Proceeds from sales and redemptions of investment securities	8,174	4,536

#### (4) Going Concern

None

#### (5) Segment Information

1) Overview of reporting segments

The Eisai Group defines its reporting segments as follows: units that comprise the Group for which it can obtain independent financial information; and units for which top management undertakes a periodic review in order to determine the allocation of management resources and to evaluate performance.

The Group's Pharmaceuticals business encompasses operations in five regions worldwide: Japan, the United States, Europe, Asia (including China) and New Markets (India, Middle East, etc), each of which pursues strategies tailored to the specific characteristics of each region or market. In the Pharmaceuticals business, the Group is mainly engaged in the manufacture and sale of prescription drugs.

The Group's segments consist of the Pharmaceuticals and Other businesses, and the Pharmaceuticals business of each region is identified as a reporting segment.

2) Information concerning sales, profit (loss) by reporting segment

Nine month period ended December 31, 2010 (April 1, 2010 to December 31, 2010)

(millions of yen)

Reporting Segment (millions of year)

Three month period ended December 31, 2010 (October 1, 2010 to December 31, 2010)

(millions of yen)

Note: "Other" is a business segment not included in reporting segments. Pharmaceutical raw materials and machinery businesses are included in this segment.

### (7) Notes to Consolidated Financial Statements

(Notes to Consolidated Statements of Income)

April 1, 2009-December 31, 2009

April 1, 2010-December 31, 2010

\*1. The main contents of selling, general and administrative expenses are as follows:

Promotional expenses \$\ \text{\frac{\pmatrix}{152,945}} \text{ mil.}\$
Research and development expenses \$\ \text{\frac{\pmatrix}{116,815}} \text{ mil.}\$
Salaries and bonuses \$\ \text{\frac{\pmatrix}{447,669}} \text{ mil.}\$

\*1. The main contents of selling, general and administrative expenses are as follows: Promot7 Tw[and4f.74 T(1of s)-3.4(e)8u 'rd' '1, 20

#### Contents

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1.	Consolidated Financial Highlights	 1
2.	Consolidated Statements of Income	 3
3.	Consolidated Statements of Cash Flows	 4
4.	Financial Results by Business Segment	 5
5.	Consolidated Balance Sheets	 10
6.	Changes in Consolidated Quarterly Results	 12
7.	Non-Consolidated Financial Highlights	 16
8.	Major Events	 18
9.	Major R&D Pipeline	 21

<sup>\*</sup> Revisions have been made to the full-year consolidated forecast announced previously. The revised parts are underlined.

#### **Currency Exchange Rates**

	US	EU	UK	China
	(¥/USD)	(¥/EUR)	(¥/GBP)	(¥/RMB)
(Apr. 2009 - Dec. 2009) Nine Months Average Rate	93.56	132.99	150.41	13.69
(Dec. 31, 2009) Third Quarter End Rate	92.10	132.00	146.53	13.49
(Apr. 2009 - Mar. 2010) Fiscal Year Average Rate	92.84	131.15	148.25	13.57
(Mar. 31, 2010) Fiscal Year End Rate	93.04	124.92	140.40	13.63
(Apr. 2010 - Dec. 2010) Nine Months Average Rate	86.84	113.30	133.53	12.85
(Dec. 31, 2010) Third Quarter End Rate	81.49	107.90	126.48	12.30
Mar. 31, 2011) Fourth Quarter Rate (forecast)	<u>82.00</u>	<u>110.00</u>	130.00	12.50

#### **About Indications in this Reference Data**

Eisai believes that cash generating ability is the most intrinsic element determining the true value of a company. Upon this basic concept, in order to reflect our true earnings capacity, we focus on disclosing "cash income" and "cash EPS," which are not affected by non-cash profit-and-loss items, such as depreciation of property, plant and equipment, amortization of goodwill, loss on impairment (including loss on devaluation of investment securities), and in-process R&D expenses.

#### Cash income

Cash income is the total amount of cash available for investment in future growth and business development, dividend payments, repayment of borrowings, and other expenditures. We consider cash income as an indicator to assess corporate growth potential and strategies.

Cash income = Net income + Depreciation of PP&E and amortization of intangible assets + In-process R&D expenses + Amortization of goodwill + Loss on impairment of long-lived assets (including loss on devaluation of investment securities)

#### Cash income per share (Cash EPS)

Cash EPS = Cash income / Number of shares issued and outstanding at the end of the year after deducting treasury stocks

#### Segment information

Details concerning performance by segment are provided in accordance with the "Revised Accounting Standard for Disclosures about Segments of an Enterprise and Related Information" (Accounting Standards Board of Japan (ASBJ) Statement No. 17 released on March 27, 2009) and the "Guidance on Accounting Standard for Disclosures about Segments of an Enterprise and Related Information" (ASBJ Guidance No. 20 released on March 21, 2008), which were adopted effective from the first quarter of the fiscal year ending March 31, 2011. In addition, indices that compare data with the same period of the previous fiscal year are provided for reference purposes only.

<sup>\*</sup> All amounts are rounded to their nearest specified unit.

<sup>\*</sup> The exchange rates used in the reference data are noted in the table below.

<sup>\*</sup> All amounts of overseas profit and loss are converted into yen based on the average exchange rates for the periods shown in the table below.

## 1. Consolidated Financial Highlights

1) Income Statement Data

(billions of ven)

1) meeme etatement bata	(billions of yen)					
	Nine r	Nine months ended Dec 31				
	FY2009	FY2010	YOY	FY2009	FY2010	
			%		est.	
Net sales	604.5	613.9	101.6	803.2	<u>770.0</u>	
Cost of sales	121.5	127.3	104.7	160.7	<u>165.0</u>	
R&D expenses	116.8	106.2	90.9	179.1	<u>143.0</u>	
SG&A expenses	281.1	270.9	96.4	376.9	<u>346.0</u>	
Operating income	85.1	109.4	128.7	86.4	116.0	
Ordinary income	80.1	102.7	128.3	79.7	107.0	
Net income	53.9	67.4	124.9	40.3	70.0	
Cash income	97.1	106.6	109.8	126.4	121.0	
			Diff.			
Dividend per share (DPS, yen)	-	-	-	150.0	150.0	
Earnings per share (EPS, yen)	189.3	236.4	47.2	141.6	245.7	
Cash income per share (Cash EPS, yen)	340.9	374.2	33.3	443.7	424.7	

<sup>\* &</sup>quot;Cost of sales" includes "Provision for (reversal of) sales returns-net."

2) Cash Flow Data

(billions of yen)

	(2				
	Nine r	Nine months ended Dec 31			
	FY2009	FY2010	Diff.	FY2009	
Net cash provided by (used in) operating activities	59.3	105.1	45.8	107.9	
Net cash used in investing activities	(27.8)	(34.4)	(6.6)	(69.8)	
Net cash provided by (used in) financing activities	(14.7)	(59.7)	(45.0)	(49.2)	
Cash and cash equivalents at end of period	142.7	113.6	(29.1)	115.1	
Free cash flow	35.7	90.5	54.8	52.9	

<sup>\* &</sup>quot;Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (incl. acquisition and others)"

3) Balance Sheet Data

of Balance Greet Bata		lollila)	is or yerr)
		<u>2010</u>	
	Mar 31	Dec 31	Diff.
Total assets	1101.9	1,054.2	(47.7)
Liabilities	680.2	651.3	(28.9)
Bonds and debentures	120.0	120.0	0.0
Borrowings	289.8	266.9	(22.9)
Equity	421.7	402.9	(18.8)
Shareholders' equity	415.9	396.9	(19.1)
Shareholders' equity ratio to total assets (%)	37.7	37.6	(0.1)
Liabilities ratio Net DER/times)	0.6	0.5	(0.1)

<sup>\* &</sup>quot;Liabilities ratio Net DER)" = ("Interest-bearing debt" ("Borrowings" + "Bonds and debentures") - "Cash and cash in banks" -

<sup>&</sup>quot;Short-term investments" / "Shareholders' equity"

4) Capital Expenditures and Depreciation/Amortization

(billions of yen)

	Nine mor	Nine months ended Dec 31			
	FY2009	FY2010	Diff.	FY2009	
Capital expenditures	19.0	13.9	(5.1)	28.7	
Property, plant and equipment	14.9	9.1	(5.8)	22.9	
Intangible assets	4.1	4.8	0.7	5.8	
Depreciation and amortization	36.8	32.8	(4.0)	48.9	

<sup>\* &</sup>quot;Depreciation and amortization" includes amortization of "Intangible assets."

### 5) Financial Results by Business Segment

(1) Consolidated Net Sales by Reporting Segment

(billions of yen)

	Nine mor	Nine months ended Dec 31			
	FY2009	FY2010	YOY		
			%		
Japan pharmaceuticals business	252.6	269.1	106.5		
US pharmaceuticals business	259.9	258.0	99.3		
Europe pharmaceuticals business	37.9	33.4	88.0		
Asia pharmaceuticals business	23.0	23.5	102.1		
New markets pharmaceuticals business	0.6	0.7	128.0		
Other	30.4	29.2	95.8		
Consolidated net sales	604.5	613.9	101.6		

<sup>\*</sup> Net sales to external customers for each segment.

(2) Consolidated Operating Income by Reporting Segment

	Nine months ended Dec 31			
	FY2009	FY2010	YOY	
			%	
Japan pharmaceuticals business	108.6	116.6	107.3	
US pharmaceuticals business	74.3	85.1	114.7	
Europe pharmaceuticals business	5.3	3.5	66.6	
Asia pharmaceuticals business	5.8	4.2	73.3	
New markets pharmaceuticals business	(0.2)	(0.4)	-	
Other profit	13.2	13.0	98.2	
R&D expenses	116.8	106.2	90.9	
Non-allocated SG&A expenses	5.2	6.5	125.7	
Operating income	85.1	109.4	128.7	

<sup>\*</sup>The Group's Pharmaceuticals business is classified into five segments comprising Japan, the United States, Europe, Asia and New Markets (India, Middle East, etc). Steps are taken to pursue strategies and plans that take into account the specific characteristics and attributes of each region or market. In the Pharmaceuticals business, the Group is mainly engaged in the manufacture and sale of prescription drugs.

R&D expenses are not allocated to any segment as the Group manages such expense on a global basis. Similarly, management cost of the Group headquarters and other are not allocated to any segment as this is the cost covering Group-wide operations.

## 2. Consolidated Statements of Income

	FY2009	Sales %	FY2010	Sales %	YOY %	Diff.	FY2009	Sales %
Net sales	604.5	100.0	613.9	100.0	101.6	9.4	803.2	100.0
Cost of sales	121.5	20.1	127.3	20.7	104.7	5.8	160.7	20.0
Gross profit	482.9	79.9	486.5	79.3	100.7	3.6	642.4	80.0
R&D expenses	116.8	19.3	106.2	17.3	90.9	(10.6)	179.1	22.3
SG&A expenses	281.1	46.5	270.9	44.1	96.4	(10.1)	376.9	46.9
Personnel expenses	62.6	10.4	61.8	10.1	98.7	(0.8)	83.4	10.4
Marketing and promotion expenses	174.9	28.9	168.2	27.4	96.1	(6.8)	234.0	29.1
Administrative expenses and others	43.5	7.2	40.9	6.7	94.1	(2.6)	59.5	7.4
Operating income	85.1	14.1	109.4	17.8	128.7	24.4	86.4	10.8
Non-operating income	2.0	0.3	1.9	0.3		(0.1)	2.4	0.3
Non-operating expense	7.0	1.2	8.6	1.4		1.6	9.1	1.1
Ordinary income	80.1	13.2	102.7	16.7	128.3	22.7	79.7	9.9
Special gain	0.0	0.0	0.2	0.0		0.2	0.1	0.0
Special loss	0.4	0.1	1.5	0.2		1.2	5.5	0.7
Income before income taxes and minority interests	79.7	13.2	101.4	16.5	127.2	21.7	74.3	9.2
Income taxes-current	27.5	4.6	37.5	6.1		10.0	26.8	3.3
Income taxes-deferred	(2.1)	(0.3)	(3.7)	(0.6)		(1.6)	6.6	8.0
Minority interests in net income	0.4	0.1	0.3	0.1		(0.1)	0.5	0.1
Net income	53.9	8.9	67.4	11.0	124.9	13.5	40.3	5.0
* "Cost of Sales" includes "Provision for (reversal of) sale	s returns-net."							
Cash income								
Net income	53.9	8.9	67.4	11.0	124.9	13.5	40.3	5.0
Depreciation of PP&E and amortization of intangible assets	22.4		19.5				29.8	
Amortization of intangible assets obtained by acquisition	14.4		13.2				19.1	
In-process R&D expenses	-		-				23.9	
Amortization of goodwill	6.4		5.9				8.5	
Loss on impairment of long-lived assets (including loss on devaluation of investment securities)	-		0.6				4.9	
4.9e35ts								

## 3. Consolidated Statements of Cash Flows

	FY2009	FY2010	Diff.
Income before income taxes and minority interests	79.7	101.4	21.7
Depreciation and amortization	36.8	32.8	(4.0)
Decrease (increase) in notes and accounts receivable, trade payables and inventories	(30.7)	(16.3)	14.4
Increase (decrease) in accounts payable-other/accrued expenses etc.	8.3	(4.9)	(13.2)
Other	19.4	14.4	(4.9)
[Sub-total]	113.5	127.5	13.9

## 4. Financial Results by Business Segment

## 1) Japan Pharmaceuticals Business

	FY2009	FY2010	YOY FY20	
Net sales	252.6	269.1	% 106.5	est.
Segment profit	108.6	116.6	107.3	
Net sales in Japan		0.40.0		
Pharmaceuticals	228.0	240.3	105.4	

2) U.S. Pharmaceuticals Business

		Nine mo	nths ended [	Dec 31
		FY2009	FY2010	YOY
				%
Net sales	Billions JPY	259.9	258.0	99.3
				<106.9>
Segment profit	Billions JPY	74.3	85.1	114.7
U.S. ethical drugs (Eisai)				
Anti-Alzheimer's agent	Billions JPY	138.3	143.8	104.0
Aricept	[Millions USD]	[1,478]	[1,656]	<112.1>
Proton pump inhibitor	Billions JPY	61.3	51.3	83.8
Aciphex	[Millions USD]	[655]	[591]	<90.3>
Antiemetic agent	Billions JPY	27.7	26.5	95.9
Aloxi	[Millions USD]	[296]	[305]	<103.3>
DNA hypomethylating agent	Billions JPY	11.6	12.2	105.0
Dacogen	[Millions USD]	[124]	[141]	<113.1>
Injectable anti-clotting agent	Billions JPY	9.9	12.5	126.2
Fragmin	[Millions USD]	[106]	[144]	<135.9>
Anticancer agent	Billions JPY	_	0.4	_
Halaven	[Millions USD]		[5]	

<sup>\*</sup> Sales of Aricept 23mg in total sales of Aricept in FY2010 (April 1, 2010 to December 31, 2010) are ¥4.0 billion (47millions USD.)

Sales of AG (Authorized Generic: a generic product sold under license from the manufacturer of an original drug) are ¥11.9 billion (137millions USD.)

### 3) Europe Pharmaceuticals Business

		Nine mo	Nine months ended Dec 31			
		FY2009	FY2010	YOY		
				%		
Net sales	Billions JPY	37.9	33.4	88.0		
				<102.2>		
Segment profit	Billions JPY	5.3	3.5	66.6		
Europe ethical drugs (Eisai)						
Anti-Alzheimer's agent	Billions JPY	21.7	18.2	83.8		
Aricept				<97.4>		
Proton pump inhibitor	Billions JPY	6.2	5.1	81.4		
Pariet	Dimons of 1	0.2	0.1	<93.8>		
Anti-epileptic drug	Billions JPY	3.4	3.2	95.7		
Zonegran				<110.8>		

<sup>\*</sup> Indices showed in parentheses "<>" compare data with the same period of the previous fiscal year on a constant currency basis.

## 4) Asia Pharmaceuticals Business

		Nine months ended Dec 31		
		FY2009	FY2010	YOY
				%
Net sales	Billions JPY	23.0	23.5	102.1
				<105.8>
Segment profit	Billions JPY	5.8	4.2	73.3
Asia ethical drugs (Eisai)				
Peripheral neuropathy treatment	Billions JPY	6.1	5.2	84.9
Methycobal				<89.5>
Anti-Alzheimer's agent	Billions JPY	4.8	5.1	104.7
Aricept				<107.0>
Proton pump inhibitor	Billions JPY	3.7	3.7	99.6
Pariet				<102.3>
Fully-human monoclonal anti-TNFalpha antibody	Billions JPY	1.6	2.4	151.0
Humira				<154.7>
Liver Disease/Allergic Disease Agents	Billions JPY	2.2	2.2	98.9
Stronger Neo-Minophagen C and Glycyron Tablets				<105.4>

## <Reference> China Pharmaceuticals Business

		Nine months ended Dec 31			
		FY2009	FY2010	YOY	
				%	
Net sales	Billions JPY	11.3	10.5	92.7	
				<98.7>	
China ethical drugs (Eisai)					
Peripheral neuropathy treatment	Billions JPY	5.3	4.3	82.2	
Methycobal	[Millions RMB]	[387]	[339]	<87.6>	
Liver Disease/Allergic Disease Agents	Billions JPY	2.2	2.2	98.9	
Stronger Neo-Minophagen C and Glycyron Tablets	[Millions RMB]	[160]	[169]	<105.4>	
Proton pump inhibitor	Billions JPY	0.8	1.1	134.3	
Pariet	[Millions RMB]	[58]	[83]	<143.1>	
Anti-Alzheimer's agent	Billions JPY	0.9	0.9	92.9	
Aricept	[Millions RMB]	[67]	[66]	<99.0>	

## 5) New Markets Pharmaceuticals Business

	Nine months ended Dec 31			
	FY2009	FY2010	YOY	
			%	
Billions JPY	0.6	0.7	128.0	
			<131.9>	
Billions JPY	(0.2)	(0.4)	_	
Billions JPY	0.1	0.1	121.3	
			<124.4>	
Billions JPY	0.1	0.2	149.9	
			<153.7>	
	Billions JPY Billions JPY	Billions JPY 0.6  Billions JPY (0.2)  Billions JPY 0.1	FY2009         FY2010           Billions JPY         0.6         0.7           Billions JPY         (0.2)         (0.4)           Billions JPY         0.1         0.1	

<sup>\*</sup> Indices showed in parentheses "<>" compare data with the same period of the previous fiscal year on a constant currency basis.

## 6) Sales of Major Products (Eisai)

## (1) Aricept (Anti-Alzheimer's agent)

		Nine months ended Dec 31			<u>Full</u>
		FY2009	FY2010	YOY %	FY2009
Japan	Billions JPY	72.6	80.4	110.8	93.6
U.S.	Billions JPY	138.3	143.8	104.0	194.7
	[Millions USD]	[1,478]	[1,656]	<112.1>	[2,097]
Europe Total	Billions JPY	21.7	18.2	83.8	27.9
				<97.4>	
UK	Billions JPY	4.0	4.5	113.4	5.3
	[Millions GBP]	[27]	[34]	<127.7>	[36]
France	Billions JPY	10.9	8.8	80.6	14.3
	[Millions EUR]	[82]	[78]	<94.6>	[109]
Germany	Billions JPY	6.8	4.9	71.4	8.3
	[Millions EUR]	[51]	[43]	<83.9>	[63]
Asia	Billions JPY	4.8	5.1	104.7	6.6
				<107.0>	
China	Billions JPY	0.9	0.9	92.9	1.4
	[Millions RMB]	[67]	[66]	<99.0>	[106]
New markets	Billions JPY	0.1	0.1	121.3	0.1
				<124.4>	
Total	Billions JPY	237.6	247.6	104.2	322.8

<sup>\*</sup> Sales of Aricept 23mg in total sales of Aricept in FY2010 (April 1, 2010 to December 31, 2010) are ¥4.0 billion (47millions USD.)

(2) Aciphex/Pariet (Proton pump inhibitor)

		Nine mor	<u>Full</u>		
		FY2009	FY2010	YOY	FY2009
	D:II: ID:/	40.0	40.0	%	50.0
Japan	Billions JPY	43.0	48.8	113.2	53.8
U.S.	Billions JPY	61.3	51.3	83.8	81.0
	[Millions USD]	[655]	[591]	<90.3>	[872]
Europe Total	Billions JPY	6.2	5.1	81.4	8.2
				<93.8>	
UK	Billions JPY	1.8	1.3	72.7	2.2
	[Millions GBP]	[12]	[10]	<81.9>	[15]
Germany	Billions JPY	1.2	1.1	94.8	1.6
	[Millions EUR]	[9]	[10]	<111.3>	[12]
Italy	Billions JPY	2.7	2.1	76.1	3.6
	[Millions EUR]	[20]	[18]	<89.4>	[28]
Asia	Billions JPY	3.7	3.7	99.6	4.8
				<102.3>	
China	Billions JPY	0.8	1.1	134.3	1.1
	[Millions RMB]	[58]	[83]	<143.1>	[80]
New markets	Billions JPY	0.1	0.2	149.9	0.2
				<153.7>	
Total	Billions JPY	114.4	109.0	95.3	148.0

<sup>\*</sup> Sales forecast for the year ending Mar. 31, 2011 is ¥137.0 billion.

Sales of AG (Authorized Generic: a generic product sold under license from the manufacturer of an original drug) are ¥11.9 billion (USD \$137 million).

 $<sup>^{\</sup>star}$  Sales forecast for the year ending Mar. 31, 2011 is  $\ensuremath{\mbox{\sc Y}}\underline{294.0}$  billion.

<sup>\*</sup> Indices showed in parentheses "<>" compare data with the same period of the previous fiscal year on a constant currency basis.

(3) Oncology Related Products

		Nine mor	ec 31	<u>Full</u>	
		FY2009	FY2010	YOY	FY2009
				%	
Aloxi (Antiemetic agent)					
U.S.	Billions JPY	27.7	26.5	95.9	38.3
	[Millions USD]	[296]	[305]	<103.3>	[413]
Dacogen (DNA Hypomethylating agent)					
U.S.	Billions JPY	11.6	12.2	105.0	15.4
	[Millions USD]	[124]	[141]	<113.1>	[166]
Fragmin (Injectable anti-clotting agent)					-
U.S.	Billions JPY	9.9	12.5	126.2	14.5
	[Millions USD]	[106]	[144]	<135.9>	[156]
Halaven (Anticancer agent)					
U.S.	Billions JPY	-	0.4	-	-
	[Millions USD]		[5]		
Other	Billions JPY	8.6	8.0	93.1	11.6
Total	Billions JPY	57.8	59.7	103.2	79.9

(4) Humira (Fully-human monoclonal anti-TNFalpha antibody )

		Nine months ended Dec 31			<u>Full</u>
		FY2009	FY2010	YOY	FY2009
				%	
Japan	Billions JPY	4.8	9.5	195.9	6.6
Asia	Billions JPY	1.6	2.4	151.0	2.3
				<154.7>	
Total	Billions JPY	6.4	11.9	184.7	8.9

<sup>\*</sup> Indices showed in parentheses "<>" compare data with the same period of the previous fiscal year on a constant currency basis.

7) Overseas Sales	(billions of yer				
	Nine mo	<u>Full</u>			
	FY2009	FY2010	YOY	FY2009	
			%		
Overseas sales	340.1	331.5	97.5	465.5	
Overseas sales (%)	56.3	54.0	-	58.0	
<reference></reference>					
Overseas sales by geographical area	324.2	316.6	97.7	443.4	
Overseas sales (%) by geographical area	53.6	51.6	-	55.2	

<sup>\*</sup> Net sales to external customers for each segment.

<sup>\* &</sup>quot;Overseas sales by geographical area" is amount of overseas subsidiary companys' sales.

# 5. Consolidated Balance Sheets

1) Consolidated Balance Sheet	(billio	(billions of yen)				
		<u>20</u>	<u>10</u>		YOY	Diff.
	Mar 31	%	Dec 31	%	%	
Cash and cash in banks	69.6		88.2			18.5
Notes and accounts receivable-trade	207.2		213.1			5.9
Short-term investments	83.8		87.7			3.9
Inventories	67.6		68.7			1.1
Deferred tax assets	32.5		38.7			6.3
Other	19.6		18.0			(1.6)
Allowance for doubtful receivables	(0.2)		(0.1)			0.2
Total current assets	480.0	43.6	514.3	48.8	107.1	34.2
Buildings and structures-net	86.5		84.4			(2.2)
Other	70.1		62.6			(7.6)
Total property, plant and equipment-net	156.6	14.2	146.9	13.9	93.8	(9.7)
Goodwill	152.8		127.8			(25.0)
Sales rights	109.7		84.9			(24.8)
Core technology	51.0		42.7			(8.3)
Other	12.4		12.0			(0.4)
Total Intangible assets	325.9	29.6	267.4	25.4	82.0	(58.5)
Investment securities	64.8		57.5			(7.3)
Deferred tax assets	63.6		61.1			(2.5)
Other	11.3		7.3			(4.0)
Allowance for doubtful accounts	(0.3)		(0.2)			0.1
Total investments and other assets	139.3	12.6	125.7	11.9	90.2	(13.7)
Total fixed assets	621.9	56.4	540.0	51.2	86.8	(81.9)
Total assets	1,101.9	100.0	1,054.2	100.0	95.7	(47.7)

### Notes

Total assets

Decrease resulting from conversion of overseas subsidiaries' assets into yen in accordance with fluctuations in exchange rates.

Decrease resulting from amortization of Intangible assets.

2) Consolidated Balance Sheets < Liabilities and Equity>

(billions of yen) YOY Diff.

## 6. Changes in Consolidated Quarterly Results

1) Income Statement Data

(billions of yen)

		FY2009				FY2010		
	1st	2nd	3rd	4th	1st	2nd	3rd	
	Quarter							
Net sales	194.7	200.3	209.5	198.7	204.5	207.8	201.6	
Cost of sales	38.3	40.6	42.6	39.2	43.5	40.6	43.2	
R&D expenses	39.4	41.3	36.1	62.3	36.0	37.8	32.3	
SG&A expenses	92.8	93.5	94.8	95.9	92.1	95.0	83.8	
Operating income	24.1	25.0	35.9	1.3	32.8	34.4	42.2	
Ordinary income (decrease)	23.2	22.0	34.9	(0.4)	30.2	32.0	40.6	
Net income (decrease)	16.3	14.6	23.0	(13.6)	18.8	21.2	27.4	
Cash income	30.7	29.1	37.3	29.3	32.6	34.2	39.9	
Earnings per share (decrease) (EPS, yen)	57.4	51.2	80.7	(47.7)	65.9	74.3	96.2	
Cash income per share (Cash EPS, yen)	107.7	102.1	131.1	102.8	114.4	119.9	139.9	

<sup>\* &</sup>quot;Cost of Sales" includes "Provision for (reversal of) sales returns-net."

2) Cash Flow Data

(billions of yen)

	(Billions of York								
		<u>FY2009</u>				FY2010			
	1st	2nd	3rd	4th	1st	2nd	3rd		
	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter	Quarter		
Net cash provided by (used in) operating activities	(0.5)	32.8	27.1	48.6	28.2	56.5	20.5		
Net cash used in investing activities	(12.9)	(9.8)	(5.2)	(42.0)	(5.1)	(21.8)	(7.6)		
Net cash provided by (used in) financing activities	(12.3)	(3.3)	0.8	(34.5)	(31.1)	(12.3)	(16.3)		
Cash and cash equivalents at the end of period	105.2	118.4	142.7	115.1	101.4	119.6	113.6		
Free cash flow	(10.7)	26.5	19.9	17.2	23.9	52.6	14.0		

<sup>\* &</sup>quot;Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (incl. acquisition and others)"

### 3) Balance Sheet Data

(billions of yen)

	Jun 30	Sep 30	Dec 31	Mar 31	Jun 30	Sep 30	Dec 31
Total assets	1,127.4	1,109.9	1,140.3	1101.9	1,065.5	1,064.2	1,054.2
Liabilities	697.0	686.4	708.3	680.2	667.4	659.6	651.3
Bonds and debentures	120.9	120.9	120.0	120.0	120.0	120.0	120.0
Borrowings	307.2	300.1	323.5	289.8	279.1	264.3	266.9
Equity	430.4	423.5	432.0	421.7	398.1	404.6	402.9
Shareholders' equity	425.1	418.1	426.4	415.9	392.3	398.7	396.9
Shareholders' equity ratio to total assets (%)	37.7	37.7	37.4	37.7	36.8	37.5	37.6
Liabilities ratio Net DER/times)	0.7	0.7	0.6	0.6	0.6	0.5	0.5

## 4) Capital Expenditures and Depreciation/Amortization

(billions of yen)

	1st	2nd	3rd	4th	1st	2nd	3rd
	Quarter						
Capital expenditures	5.8	7.2	6.0	9.7	3.5	3.7	6.7
Property, plant and equipment	4.8	5.9	4.2	8.0	2.5	2.8	3.9
Intangible assets	1.0	1.3	1.8	1.7	1.0	0.9	2.8

### 5) Sales of Major Products (Eisai)

(1) Aricept

			FY20	09			FY2010	
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
Japan	Billions JPY	23.4	22.3	26.9	21.0	25.3	25.6	29.5
U.S.	Billions JPY [Millions USD]	42.7 [438]	50.1 [533]	45.5 [507]	56.4 [619]	50.2 [545]	55.9 [647]	37.8 [464]
Europe	Billions JPY	7.2	7.1	7.5	6.1	5.8	5.8	6.6
UK	Billions JPY [Millions GBP]	1.5 [10]	1.3 [9]	1.2 [8]	1.3 [9]	1.7 [13]	1.5 [11]	1.4 [10]
France	Billions JPY [Millions EUR]	3.5 [27]	3.6 [27]	3.8 [29]	3.3 [27]	2.8 [24]	2.8 [25]	3.2 [28]
Germany	Billions JPY [Millions EUR]	2.1 [16]	2.2 [16]	2.5 [19]	1.5 [12]	1.2 [10]	1.6 [14]	2.1 [18]
Asia	Billions JPY	1.6	1.6	1.6	1.8	1.7	1.8	1.6
China	Billions JPY [Millions RMB]	0.2 [14]	0.4 [27]	0.3 [26]	0.5 [38]	0.3 [22]	0.3 [27]	0.2 [17]
New markets	Billions JPY	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	Billions JPY	74.8	81.2	81.5	85.3	82.9	89.1	75.6

(2) Aciphex/Pariet

			<u>FY2009</u>				FY2010	
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
Japan	Billions JPY	13.4	12.8	16.9	10.7	15.1	14.8	18.9
U.S.	Billions JPY [Millions USD]	19.8 [203]	20.6 [220]	20.8 [231]	19.7 [217]	17.0 [185]	17.0 [198]	17.3 [209]
Europe	Billions JPY	2.1	2.0	2.1	2.0	1.8	1.9	1.4
UK	Billions JPY [Millions GBP]	0.6 [4]	0.6 [4]	0.6 [4]	0.5 [3]	0.5 [4]	0.4 [3]	0.3 [3]
Germany	Billions JPY [Millions EUR]	0.4 [3]	0.4 [3]	0.4 [3]	0.4 [3]	0.4 [4]	0.6 [5]	0.1 [1]
Italy	Billions JPY [Millions EUR]	0.9 [7]	0.9 [7]	0.9 [7]	0.9 [7]	0.6 [5]	0.7 [6]	0.7 [7]
Asia	Billions JPY	1.4	1.1	1.2	1.1	1.3	1.3	1.1
China	Billions JPY [Millions RMB]	0.4 [26]	0.2 [12]	0.3 [20]	0.3 [22]	0.4 [26]	0.5 [37]	0.2 [19]
New markets	Billions JPY	0.0	0.0	0.0	0.1	0.1	0.1	0.1
Total	Billions JPY	36.7	36.6	41.1	33.6	35.3	35.1	38.7

(3) Oncology Related Products

(0) 0110010	y itelated i roddett		FY20	na	Ī		FY2010	
		1st	2nd	<u>00</u> 3rd	4th	104	2nd	3rd
		Quarter	Quarter	Quarter	Quarter	1st Quarter	Quarter	Quarter
Aloxi								
U.S.	Billions JPY	9.5	9.5	8.7	10.6	8.8	8.5	9.2
	[Millions USD]	[97]	[101]	[97]	[117]	[96]	[99]	[111]
Dacogen								
U.S.	Billions JPY	4.2	3.7	3.8	3.8	4.3	4.1	3.8
	[Millions USD]	[43]	[40]	[42]	[42]	[47]	[47]	[46]
Fragmin								
U.S.	Billions JPY	3.2	3.1	3.7	4.6	4.3	4.2	3.9
	[Millions USD]	[33]	[33]	[41]	[50]	[47]	[49]	[48]
Halaven								
U.S.	Billions JPY	-	-	-	-	-	-	0.4
	[Millions USD]							[5]
Other	Billions JPY	2.9	3.0	2.7	3.0	2.8	2.4	2.8
Total	Billions JPY	19.7	19.3	18.8	22.0	20.3	19.2	20.2

(4) Humira

			FY2009				<u>FY2010</u>		
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	
Japan	Billions JPY	1.2	1.6	2.0	1.8	2.6	3.0	3.8	
Asia	Billions JPY	0.5	0.5	0.6	0.7	0.8	0.8	0.8	
Total	Billions JPY	1.7	2.1	2.6	2.5	3.5	3.8	4.5	

### 7. Non-Consolidated Financial Highlights

### 1) Non-Consolidated Financial Highlights

(1) Income Statement Data

(billions of yen)

	Nine mo	nths ended D	ec 31	<u>Full</u>		
	FY2009	FY2010	YOY	FY2009	FY2010	
			%		est.	
Net sales	335.8	361.4	107.6	444.7	<u>470.0</u>	
Cost of sales	63.8	69.7	109.4	82.3	90.0	
R&D expenses	109.5	91.8	83.9	145.3	<u>124.0</u>	
SG&A expenses	95.1	96.9	102.0	123.9	<u>134.0</u>	
Operating income	67.5	102.9	152.5	93.3	<u>122.0</u>	
Ordinary income	64.0	97.6	152.5	88.6	<u>114.5</u>	
Net income	45.4	67.0	147.4	57.3	<u>79.0</u>	

<sup>\* &</sup>quot;Cost of sales" includes "Provision for (reversal of) sales returns-net."

(2) Cash Flow Data

(billions of yen)

	Nine mor	Nine months ended Dec 31				
	FY2009	FY2010	Diff.	FY2009		
Net cash provided by (used in) operating activities	37.8	89.4	51.6	71.5		
Net cash used in investing activities	(16.5)	(28.8)	(12.3)	(31.3)		
Net cash provided by (used in) financing activities	(13.5)	(59.5)	(45.9)	(38.7)		
Cash and cash equivalents at end of period	18.0	12.7	(5.2)	11.7		
Free cash flow	29.6	81.2	51.6	58.3		

<sup>\* &</sup>quot;Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (incl. acquisition and others)"

(3) Balance Sheet Data

(billions of yen)

		<u>2010</u>				
	Mar 31	Dec 31	Diff.			
Total assets	951.1	978.8	27.7			
Liabilities	449.8	456.7	7.0			
Bonds and debentures	120.0	120.0	0.0			
Borrowings	234.0	218.0	(16.0)			
Equity	501.3	522.0	20.7			
Shareholders' equity	500.6	521.2	20.6			
Shareholders' equity ratio to total assets (%)	52.6	53.2	0.6			

### 2) Net Sales by Business Segment

2) Net Sales by Business Segment			(billi	ons of yen)
	Nine months ended Dec 31		<u>Full</u>	
	FY2009	FY2010	YOY	FY2009
			%	
Net sales	335.8	361.4	107.6	444.7
Ethical drugs	228.0	240.2	105.4	
Consumer health care products and other	14.5	15.4	106.6	
Industrial property rights and other	57.0	62.7	110.1	
Exports of pharmaceuticals	35.1	41.9	119.3	
Other	1.2	1.2	95.0	

August
Announced that a Phase III study with AMPA receptor antagonist perampanel (E2007) conducted in patients with epilepsy met its primary endpoint <announced on August 24>
Submitted an application for additional indication of Humira, a fully human anti-TNF-alpha monoclonal antibody, for the treatment of juvenile idiopathic arthritis in Japan <announced on August 30>
Received notification from the U.S. FDA about an extension to the review period of the new drug application for investigational anticancer agent eribulin mesylate (E7389) <announced on August 30>
September
Commenced the first clinical study of BAN2401, a novel monoclonal antibody targeting the neurotoxic protofibrils believed to cause Alzheimer's disease, in the U.S. <announced on September 2>
Launched the rapid acting secretagogue Glufast in China <announced on September 3>
Launched Symbenda (bendamustine hydrochloride) in Singapore for the treatment of low-grade non-Hodgkin's lymphoma and chronic lymphatic leukemia <announced on September 7>

Date November Description

## Major R&D Pipeline

### 1) R&D Pipeline (Japan, United States, Europe)

### **R&D Pipeline List**

Product Name/Research Code	Additional Indication, etc.	Development Stage	Therapeutic Area
New Approval			
Tambocor (Tachyarrhythmia in pediatric patients)	AI, ADA	(Japan) approved	Vascular and Immunological Reaction
Pariet (Non-erosive gastroesophageal reflux disease)	AI, ADA	(Japan) approved	Gastrointestinal Disorders
Pariet (Concomitant therapy for eradication of Helicobacter pylori)	Al	(Japan) approved	Gastrointestinal Disorders
Aricept (Higher dose 23 mg tablet)	ADA, AF	(US) approved	Neurology
Zonegran (Orally disintegrating tablets)	AF	(Europe) approved	Neurology
Humira (Crohn's disease)	Al	(Japan) approved	Vascular and Immunological Reaction
Humira (Ankylosing spondylitis)	Al	(Japan) approved	Vascular and Immunological Reaction
Halaven (Breast cancer)		(US) approved	Oncology and Supportive Care
Pariet (Reflux esophagitis)	ADA	(Japan) approved	Gastrointestinal Disorders
Nerbloc (Cervical dystonia)		(Japan) approved	Neurology

Under Review/Preparing for Submission

T-614 (Rheumatoid arthritis)		(Japan) PIII	Vascular and Immunological Reaction
Aricept (Lewy body dementia)	Al	(Japan) PIII	Neurology
Zonegran (Pediatric epilepsy)	Al	(EU) PIII	Neurology
Zonegran (Monotherapy for epilepsy)	Al	(EU) PIII	Neurology
Humira (Inhibition of structural damage of joints)	Al	(Japan) PIII	Vascular and Immunological Reaction
E0302 (Amyotrophic lateral sclerosis (ALS))	Al	(Japan) PII/III	Neurology
AS-3201 (Diabetic neuropathy)		(US/EU) PII/III	Neurology
Humira (Ulcerative colitis)	Al		

Humira (Ulcerative colitis)

Development progress from October 2010 onwards



#### Research Code: E7850 Generic Name: irofulven (Anticancer agent/DNA synthesis inhibitor)

Description: Expected to exhibit an anticancer effect against various solid tumors by inhibiting DNA synthesis.			
Prostate cancer, etc.	US: PII	Inj.	

#### Research Code: E5501/AKR-501 (Treatment for thrombocytopenia/thrombopoietin receptor agonist)

Description: An oral thrombopoietin receptor agonist that increases platelet production. Expected to exhibit effects against conditions that are associated with thrombocytopenia.			
Idiopathic thrombocytopenic purpura (ITP)	US: PII	Submission Target FY2012	Oral
Thrombocytopenia associated with liver disease (TLD)	US: PII		Oral

#### Research Code: **E6014** Generic name: **glutamine** (Oral mucositis/glutamine oral suspension)

	, s	. ,	
Description: A topical, oral glutamine suspens	ion for the treatment of chemotherap	y-induced mucositis.	
Oral mucositis	US: PIII		Oral
Oral mucositis	US. PIII		Susp.

#### Product Name: Ontak Research Code: E7272 Generic name: denileukin diftitox

(Anticancer agent/interleukin-2 diphtheria toxin fusion protein)

Description: A fusion protein that combines the interleukin-2 (IL-2) receptor binding domain with diphtheria toxins. It specifically binds to IL-2 receptors on the cell surface, causing diphtheria toxins that have entered cells to inhibit protein synthesis. The agent is already approved in the United States as a treatment for CD25 (a component of the IL-2 receptor) positive cutaneous T-cell lymphoma.

Additional Indications: Melanoma US: PII Inj.

#### Research Code: **E7040** (Embolic bead/medical device)

Description: A hydrophilic microspherical particle produced from a polyvinyl alcohol polymer. An embolic bead that is injected through a catheter to physically and selectively embolize targeted blood vessels. Microscopic and uniformly spherical in shape, it allows for precise embolization of targeted vessels based on vascular diameter and tumor size.

Transcatheter arterial embolization (TAE) in

Development progress from October 2010 onwards

ç Submission target changed from the previous announcement

Migraine prophylaxis	US: PII	Oral

Research Code: AS-3201 Generic name: ranirestat (Treatment for diabetic complications/aldose reductase inhibitor)

Description: An aldose reductase inhibitor that is believed to reduce intracellular accumulation of sorbitol. Currently being investigated as a potential treatment for diabetic neuropathy, one of the most common diabetic complications.

US: PII/III

Diabetic neuropathy

Oral

Product Name: Zonegran Research Code: E2090 Generic name: zonisamide (Anti-epileptic agent)

Description: Believed to exhibit a broad anti-epileptic (i)- $6.8(l)1.2(e)8(l)1.2(584\ 657f8lhl\ (i)-6d3(t))-72ep)7.5(i)-6.8(l)1.253(i)-6d:npih8(l)1.253(i)-0(0ve)-7it2(e)7.8(l)1.253(i)-6d:npih8(l)1.253(i)-6$ 

EU: PII/III

Development progress from October 2010 onwards

ç Submission target changed from the previous announcement

Additional Indications: Inhibition of structural damage of joints	Japan: PIII	Submission Target FY2011	lnj.
Additional Indications: Ulcerative colitis	Japan: PII/III	Submission Target FY2011	lnj.

#### Research Code: E5564 Generic name: eritoran (Severe sepsis/endotoxin antagonist)

Description: Exhibits endotoxin antagonist e caused by endotoxins.	effects that inhibit isolation of inflammatory cytokines. Suppresses vari	ious clinical conditions
	Global	
ç Severe sepsis	Development	lnj.
	Program: PIII	

<sup>•</sup> The further development plan for E5564 will be determined in accordance with the data obtained through the Phase III trials.

#### Research Code: **E5555** (Thrombin receptor antagonist)

	,	
Description: Selectively binds to the thrombin rece	eptor (PAR-1) and inhibits platelet aggregation and vasc	ular smooth muscle cell
proliferation by suppressing thrombin-mediated cellu	ular activation.	
	US: PII	
Acute coronary syndrome	EU: PII	Oral
	Japan: PII	
	US: PII	
Atherothrombosis	EU: PII	Oral
	Japan: PII	

#### Research Code: E6201 (Novel MEK-1/MEKK-1 kinase inhibitor)

Description: A novel MEK-1/MEKK-1 kinase inhi	oitor. Expected to inhibit inflammatory cellular	signaling as well as overgrowth of
epidermal cells in patients with psoriasis.		
Descripcio	US: PII	Taniaal
Psoriasis	EU: PII	Topical

#### Research Code: **T-614** Generic name: **iguratimod** (Rheumatoid arthritis)

Description: Suppresses inflammato	ry cytokine production ar	nd immunoglobulin pro	oduction. Expected to exhibit	effects against
rheumatoid arthritis.				
Rheumatoid arthritis		Japan: PIII	Submission Target FY20	11 Oral

#### Product Name: **Tambocor** Generic name: **flecainide** (Anti-arrhythmic agent)

Description: Suppresses tachyarrhythmia by blocking cardiac sodium channels. The agent was approved for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal superventricular tachycardia, ventricular tachycardia) in pediatric patients, in addition to the existing indication for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter and ventricular tachycardia) in adults.

Additional Indication, Dosage & Administration:	Japan: approved (May 2010)	Oral
Tachyarrhythmia in pediatric patients	Japan. approved (May 2010)	Olai

#### Product Name: Warfarin Generic name: warfarin potassium (Oral anticoagulant)

Description: Exhibits anticoagulant effects by antagonizing vitamin K and inhibiting the production of blood clotting factors. Widely used for the treatment and prevention of thromboembolisms in adults. An application seeking approval for pediatric dosage and administration was submitted in Japan after a special committee for the use of unapproved and off-label drugs for which there is a high medical need, operating under the Japanese Ministry of Health, Labour and Welfare, designated the agent as a drug that can prov

Development progress from October 2010 onwards

ç Submission target changed from the previous announcement

Product Name: Vasolan Generic name: verapamil (Calcium channel blocking antiarrhythmic agent)

Description: Slows cardiac excitation and regulates tachyarrhythmia by blocking calcium channels. Also exhibits coronary dilating and peripheral vasodilator action and is widely used as a treatment for ischemic heart disease and tachyarrhythmia in adults. An application seeking approval for pediatric dosage and administration was submitted in Japan after a special committee for the use of unapproved and off-label drugs for which there is a high medical need, operating under the Japanese Ministry of Health, Labour and Welfare,

Development progress from October 2010 onwards

ç Submission target changed from the previous announcement

### 2) R&D Pipeline (Asia)

Product Name: **Glufast** Generic name: **mitiglinide** (Rapid-acting insulin secretagogue agent)

	Description: By selectively binding	to sulfonylurea receptors in pancreatic beta cells, it accelerates	insulin release,	resulting in	the
reduction of blood glucose. (In-licensed from Kissei Pharmaceutical Co., Ltd.)					
	Type 2 diabetes mellitus	approved: Thailand, Philippines		(	Oral
		under review: Indonesia Malaysia			

#### Product Name: **Gasmotin** Generic name: **mosapride** (Gastroprokinetic agent)

Description: A selective serotonin 5-HT <sub>4</sub> receptor agonist that exhibits gastroprokinetic and gastric evacuation effects by enhan		
acetylcholine release. (In-licensed from Dainippon Sumitomo Pharma Co., Ltd.)		
	currently marketed: Thailand	
Gastroprokinetic agent	approved: Philippines, Vietnam	Oral
	under review: Malaysia, Myanmar, Laos	

### Generic name: **clevudine** (Anti-chronic hepatitis B agent)

Description: An antiviral drug that exerts an anti-HBV effect by inhibiting DNA polymerase. (In-licensed from Bukwang Pharmaceutic	al
Co., Ltd.)	
currently marketed: Philippines (Product Name: Revovir)	ral

Development progress from October 2010 onwards
 Submission target changed from the previous announcement