

**CONSOLIDATED FINANCIAL REPORT**  
**For the Third Quarter of Fiscal 2012**  
**(Fiscal Year Ending March 31, 2013, Japan GAAP)**

February 1, 2013

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>
Representative: Haruo Naito, President & CEO	
Contact: Yutaka Tsuchiya	Telephone: +81-3-3817-5120
Executive Vice President (Representative Corporate Officer), Public Relations	
Expected date of quarterly report submission:	February 13, 2013
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 2012**  
**(April 1, 2012 to December 31, 2012)**

(1) Consolidated Operating Results (cumulative)

(Percentage figures show year-on-year change.)

	Net sales		Operating income		Ordinary income		Net income	
	(¥ million)	%	(¥ million)	%	(¥ million)	%	(¥ million)	%
3Q Fiscal 2012	431,553	(14.5)	54,125	(34.2)	50,224	(35.5)	34,011	(30.9)
3Q Fiscal 2011	504,800	(17.8)	82,215	(24.9)	77,897	(24.2)	49,191	(27.0)

(Note) Comprehensive income: 3Q Fiscal 2012 ¥51,112 million [109.6%] 3Q Fiscal 2011 ¥24,383 million [2.1%]

	Basic earnings per share	Diluted earnings per share
	(¥)	(¥)
3Q Fiscal 2012	119.34	119.31
3Q Fiscal 2011	172.62	172.61

(2) Consolidated Financial Positions

	Total assets	Equity	Shareholders' equity ratio	Shareholders' equity per share
	(¥ million)	(¥ million)	%	(¥)
As of December 31, 2012	968,245	429,984	43.9	1,491.73
As of March 31, 2012	1,004,660	423,427	41.5	1,462.53

(Reference) Shareholders' equity

As of December 31, 2012 ¥425,168 million As of March 31, 2012 ¥416,793 million

## 2. Dividends

	Dividend per share				
	1Q end	2Q end	3Q end	Year-end	Total
	(¥)	(¥)	(¥)	(¥)	(¥)
Fiscal 2011	-	70.00	-	80.00	150.00
Fiscal 2012	-	70.00	-		
Fiscal 2012 (forecast)				80.00	150.00

(Note) Revisions to the latest dividend forecast: None

## 3. Consolidated Financial Forecasts for Fiscal 2012

(April 1, 2012 to March 31, 2013)

(Percentage figures show year-on-year change.)

	Net sales		Operating income		Ordinary income		Net income		Basic earnings per share
	(¥ million)	%	(¥ million)	%	(¥ million)	%	(¥ million)	%	(¥)
Full fiscal year	573,500	(11.5)	71,500	(25.3)	66,500	(26.1)	47,000	(19.7)	164.91

(Note) Revisions to the latest financial forecasts: Yes

### \* Explanatory Notes

- (1) Changes in number of significant subsidiaries\* during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

Increase: -, Decrease: -

\* Subsidiaries that meet the following criteria:

- The subsidiary's sales or purchases from the parent company represent 10% or more of the sales or purchases of the parent company
- The subsidiary's net assets are equal to or more than 30% of the net assets of the parent company
- The amount of common stock is equal to or more than 10% of that of the parent company

- (2) Application of special accounting treatment in preparation of consolidated quarterly financial statements: None

- (3) Changes in accounting policies, accounting estimates and restatements:
- Changes in accounting policies in connection with revisions to accounting standards: None
  - Changes in accounting policies other than 1): None
  - Changes in accounting estimates: None
  - Restatements: None

- (4) Number of shares issued (common stock):
- Number of shares issued as of the end of the reporting period (including treasury stock):  
3Q Fiscal 2012: 296,566,949 shares Fiscal 2011: 296,566,949 shares
  - Number of treasury stock shares as of the end of the reporting period:  
3Q Fiscal 2012: 11,550,576 shares Fiscal 2011: 11,585,988 shares
  - Average number of shares outstanding (cumulative):  
3Q Fiscal 2012: 284,993,471 shares 3Q Fiscal 2011: 284,964,960 shares

\* Disclosure concerning the implementation status of quarterly review procedures:

This quarterly financial report is exempt from quarterly audit procedures as stipulated under the Financial Instruments and Exchange Act of Japan. At the time of this quarterly financial report's disclosure, quarterly financial statement audit procedures have not been completed as stipulated under the Financial Instruments and Exchange Act of Japan.

\* Explanation concerning the appropriate use of results forecasts and other special instructions:

(Disclaimer Regarding Forward-Looking Statements)

Materials and information provided in this financial disclosure may contain "forward looking statements" based on expectations, forecasts, estimates, business goals and assumptions that are subject to risks and uncertainties as of the publication date of these materials. Accordingly, actual outcomes and results may differ materially from these statements depending on a number of important factors. Please refer to page 12 for details with regard to the assumptions and other related matters concerning consolidated financial results forecasts.

(Methods for obtaining supplementary materials and content of financial results disclosure)

Supplementary materials are attached to this financial report. The Company plans to hold a financial results disclosure presentation for institutional investors and securities analysts on Friday, February 1, 2013. The printed materials distributed at the disclosure presentation will be made available on the Company's website after the event

## Supplementary Materials

### Table of Contents

(Page)

1. Qualitative Information Concerning Consolidated Financial Results (April 1, 2012 to December 31, 2012)	
1) Qualitative Information Concerning Consolidated Operating Results (April 1, 2012 to December 31, 2012).....	2
2) Research & Development Pipeline, Alliances, and Other Events .....	5
3) Qualitative Information Concerning Consolidated Financial Position.....	10
4) Profit Appropriation Basic Policy and Dividend Forecast for the End of Fiscal 2012 .....	11
5) Qualitative Information Concerning Consolidated Financial Forecasts for Fiscal 2012 (April 1, 2012 to March 31, 2013) .....	12
2. Explanatory Notes in Financial Results Summary	
1) Changes in Number of Significant Subsidiaries During the Period .....	13
2) Application of Special Accounting Treatment in Preparation of Consolidated Quarterly Financial Statements .....	13
3) Changes in Accounting Policies, Accounting Estimates and Restatements .....	13
3. Consolidated Financial Statements	
1) Consolidated Balance Sheets.....	14
2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income.....	16
3) Consolidated Statements of Cash Flows.....	18
4) Going Concern.....	19
5) Note Regarding Significant Changes in the Amount of Shareholders' Equity.....	19
6) Segment Information .....	19
7) Significant Subsequent Events .....	21

# 1. Qualitative Information Concerning Consolidated Financial Results (April 1, 2012 to December 31, 2012)

## 1) Qualitative Information Concerning Consolidated Operating Results (April 1, 2012 to December 31, 2012)

### [Sales and Income]

- Eisai Co., Ltd. (“the Company”) and its consolidated subsidiaries (collectively referred to as “the Group”) recorded the following consolidated financial results for the quarter ended December 31, 2012:

Net sales:	¥431,553 million (down 14.5% year on year)
Operating income:	¥54,125 million (down 34.2% year on year)
Ordinary income:	¥50,224 million (down 35.5% year on year)
Net income:	¥34,011 million (down 30.9% year on year)
- Although new products such as Halaven (a novel anticancer agent) and Humira (a fully human anti-TNF- $\alpha$  monoclonal antibody) showed a steady increase in sales, total consolidated net sales decreased year on year due to a decline in sales of Aricept (an anti-Alzheimer’s agent) and Pariet (a proton pump inhibitor, U.S. brand name: Aciphex) that resulted from the impact of intensified market competition and National Health Insurance (NHI) drug price revisions in Japan. Specifically, sales of Pariet and Aricept decreased to ¥82,056 million (down 16.4% year on year) and ¥73,554 million (down 40.4% year on year) respectively, while sales of oncology-related products increased to ¥73,824 million (up 6.8% year on year) due to steady growth in sales of Halaven. As a result, the ratio of oncology-related product sales to the Group’s total consolidated net sales rose to 17.1% from 13.7%, the ratio recorded in the same period of the previous fiscal year. Sales of epilepsy franchise products grew by double digits to ¥11,702 million (up 16.9% year on year), aided in part by the launch in September 2012 of Fycompa (an AMPA receptor antagonist) in Europe.
- Operating income, ordinary income and net income decreased due to the impact of lower net sales, in spite of continuous efforts to further improve efficiency in selling, general and administrative expenses that include a reduction in alliance fees paid to promotion partners and a reduction in personnel expenses and other expenses associated with structural reform carried out to date.
- As a result of declined net income, basic earnings per share came to ¥119.34, a decrease of ¥53.28 per share from the same period of the previous fiscal year.
- ¥51,112 million (up 109.6% year on year) was recorded in comprehensive income, after adding/deducting minority interests and other comprehensive income (loss) to/from net income, due to the impact of foreign currency translation adjustment.

### [Cash Income]

- The Group uses cash income as a managerial index to express its ability to generate cash.
- Cash income is the total amount of cash available for investment in future growth, shareholder return and repayment of borrowings. The Group considers cash income as an indicator to assess corporate growth potential and strategies.

- Net income was ¥34,011 million; depreciation of property, plant and equipment and amortization of intangible assets was ¥31,713 million; amortization of goodwill was ¥5,657 million; and loss on impairment of long-lived assets (including loss on devaluation of investment securities) was ¥1,506 million.
- As a result, cash income was ¥72,889 million (down 14.9% year on year), with cash income per share of ¥255.76 (down ¥44.88 per share from the same period of the previous fiscal year).

\* Cash income = Net income (loss) + depreciation of PP&E and amortization of intangible assets + in-process R&D expenses + amortization of goodwill + loss on impairment of long-lived assets (incl. loss on devaluation of investment securities)

\* Cash income per share = Cash income / average number of outstanding shares for the period (after deduction of treasury stock)

## [Performance by Segment]

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

The Group's segments comprise the Pharmaceuticals and Other businesses, with the Pharmaceuticals Business of each geographical region being identified as a reporting segment. Effective from the fiscal year ending March 31, 2013, the Group has designated four new reporting segments as follows: East Asia (Japan, China, South Korea, Taiwan and Hong Kong); Americas (North, Central and South America); EMEA (Europe, the Middle East and Africa) and Indo-Pacific (South Asia, ASEAN countries and Oceania). In line with these changes, figures contained in this report for the fiscal year ended March 31, 2012 are based on the new reporting segments.

### <East Asia Pharmaceuticals Business>

- Net sales totaled ¥274,628 million (down 13.0% year on year; down 13.2% year on year excluding the impact of the exchange rate), with segment profit of ¥111,042 million (down 18.4% year on year). Of this amount, ¥250,036 million (down 15.0% year on year) was recorded by the Japan Pharmaceuticals Business. Sales in China expanded significantly to ¥15,831 million (up 22.0% year on year).
- Sales of Aricept came to ¥60,633 million (down 36.5% year on year), while sales of Pariet came to ¥40,583 million (down 18.6% year on year). Sales of Humira came to ¥21,577 million (up 19.9% year on year), while sales of Halaven came to ¥4,127 million (up 126.5% year on year).
- The Japan Prescription Drugs Business experienced a decline in sales of Aricept (¥56,031 million, down 38.6% year on year) and Pariet (¥38,557 million, down 19.3% year on year) due to the impact of the NHI drug price revisions and intensified market competition. Sales of Halaven came to ¥4,126 million (up 126.4% year on year). In regard to Lyrica, a pain treatment (peripheral neuropathic pain, fibromyalgia) that the Company is co-promoting in Japan with Pfizer Japan Inc., co-promotion income totaled ¥10,317 million (up 22.7% year on year).
- In Japan, the Company launched the insomnia treatment Lunesta in April 2012, the anti-rheumatic agent Careram in September 2012, and the anticancer agent Gliadel Implant in January 2013.
- In Japan, the Company terminated the co-promotion of Aricept with Pfizer Japan Inc. and, as

a result, assumed sole promotion on January 1, 2013.

<Americas Pharmaceuticals Business>

- Net sales totaled ¥114,460 million (down 4.5% year on year; down 5.6% year on year excluding the impact of the exchange rate), with segment profit of ¥25,689 million (up 4.1% year on year).
- Sales of Aciphex came to ¥37,820 million (down 11.9% year on year), sales of Aricept came to ¥9,339 million (down 0.8% year on year), while sales of Halaven came to ¥8,538 million (up 8.7% year on year).
- In the United States, marketing approval for the antiobesity agent Belviq was received in June 2012 and launch preparations are underway.

<EMEA Pharmaceuticals Business>

- Net sales totaled ¥18,876 million (down 44.5% year on year; down 40.7% year on year excluding the impact of the exchange rate), with segment profit of ¥1,305 million (down 75.1% year on year).
- Sales of Pariet and Aricept came to ¥2,425 million (down 40.8% year on year) and ¥2,295 million (down 86.6% year on year), respectively, due to the expiration of both composition of matter patents. Sales of Halaven came to ¥3,649 million (up 215.9% year on year).
- The number of countries in which Fycompa is available has expanded to six since the drug's initial launch in September 2012 in the United Kingdom; the drug has contributed to the growth of the Group's epilepsy franchise in Europe.
- In Russia, marketing approval for Zonegran (an antiepileptic agent), Halaven and Exalief (eslicarbazepine acetate, brand name in Europe: Zebinix) were received in June, July and October of 2012, respectively, and launch preparations for these products are underway.

<Indo-Pacific Pharmaceuticals Business>

- Net sales totaled ¥5,100 million (up 0.03% year on year; up 2.1% year on year excluding the impact of the exchange rate), with segment profit of ¥1,223 million (down 9.6% year on year).
- Sales of Aricept came to ¥1,285 million (down 1.3% year on year) and sales of Pariet came to ¥1,227 million (down 4.4% year on year), while sales of Halaven came to ¥48 million (up 34.9% year on year).

## 2) Research & Development Pipeline, Alliances, and Other Events

### [Status of Ongoing Research & Development Pipelines]

- The anticancer agent Halaven (eribulin mesylate) obtained approval as a treatment for breast cancer sequentially around the world and, as of January 2013, the agent is approved in 44 countries worldwide. A Phase III study to investigate the agent as a potential treatment for sarcoma is underway in the United States, Europe and Asia, while a Phase II study is ongoing in Japan. A Phase III study in non-small cell lung cancer is also being conducted in the United States, Europe and Asia including Japan. Based on the study results obtained from a Phase III study in the United States and Europe that evaluated Halaven as a potential second-line chemotherapy for the treatment of breast cancer, the Group is currently preparing for submission of applications seeking approval for additional indication in Europe. The development plan in the United States is under consideration.
- The AMPA-type glutamate receptor antagonist Fycompa (perampanel) was approved by the European Commission (EC) in July 2012 and received approval from the U.S. Food and Drug Administration (U.S. FDA) in October 2012 as an adjunctive therapy for the treatment of partial-onset seizures in epilepsy patients age 12 years and older; as of January 2013, the agent is approved in 31 countries worldwide. A Phase III study for the indication is also currently underway in Asia including Japan and China. A Phase III study investigating the agent as a potential adjunctive therapy for generalized seizures in patients with epilepsy is ongoing in the United States, Europe and Asia including Japan. Furthermore, a Phase II study in the United States and Europe is being conducted on the agent as a potential therapy for partial-onset epilepsy in pediatric patients. In December 2012, the U.S. FDA granted Orphan Drug Status to the agent as a treatment for Lennox-Gastaut syndrome (LGS).
- In April 2012, the Company received notification from Japan's Ministry of Health, Labour and Welfare (MHLW) that the condition for approval of Humira (adalimumab), a fully human anti-TNF- $\alpha$  monoclonal antibody, had been lifted, referring to a drug use-results survey (all-case surveillance) for plaque psoriasis and psoriasis arthropica. In August 2012, the Company received approval for the additional indication of inhibition of structural damage of joints in patients with rheumatoid arthritis (RA). In principle, the use of Humira is limited to patients with RA who have had an inadequate response to conventional therapy. However, the approval of this indication enables the drug to be administered to patients with rapid progression of structural damage even if they have not received prior treatment with anti-rheumatic drugs. In addition, in October 2012, the Company received further notification from the MHLW that the condition for approval of Humira had been lifted, referring to a drug use-results survey (all-case surveillance) for Crohn's disease.
- In May 2012, the Company's pharmaceutical manufacturing and sales subsidiary Sannova Co., Ltd. received approval for an additional indication and additional dosage and administration of its vitamin K<sub>2</sub> syrup formulation, Kaytwo Syrup 0.2% (menatetrenone), for the prevention of vitamin K deficiency hemorrhage in neonates and infants.
- In June 2012, the Company received approval from the European Medicines Agency (EMA)

to extend the use of the antiepileptic agent Zonegran (zonisamide) as monotherapy for the treatment of partial-onset seizures in adults with newly diagnosed epilepsy. Zonegran was also approved in Russia as an adjunctive therapy in the treatment of adult epilepsy patients with partial-onset seizures.

- In June 2012, the anti-rheumatic agent Careram (iguratimod) was approved for the treatment of RA.
- In May 2012, the Company submitted a marketing authorization application seeking approval in Japan for two types of new triple formulation packs (combination packs) for *Helicobacter pylori* eradication that include its proton pump inhibitor Pariet (rabeprazole sodium) as well as amoxicillin hydrate and either clarithromycin for primary eradication or metronidazole for secondary eradication. In August 2012, the Company submitted a public knowledge-based application seeking approval in Japan for *Helicobacter pylori* gastritis as an additional indication for *Helicobacter pylori* eradication by concomitant therapy that includes amoxicillin hydrate and either clarithromycin or metronidazole.
- In June 2012, an application seeking approval to market the antiepileptic agent Zonegran for the treatment of partial-onset seizures in pediatric patients with epilepsy age six years and older was accepted for review in the EU.
- In August 2012, the Company submitted a marketing authorization application for the antiepileptic agent E2080 (rufinamide) in Japan seeking approval to market the agent as an adjunctive therapy in the treatment of LGS.
- In November 2012, the U.S. FDA accepted for review Eisai's New Drug Application (NDA) for a new sprinkle capsule formulation (5 mg and 10 mg) of the proton pump inhibitor Aciphex (generic name: rabeprazole sodium) for the healing and maintenance of healing of gastroesophageal reflux disease (GERD) and symptom improvement of GERD in children age 1 to 11. This NDA was granted Priority Review by the U.S. FDA, with an action date (proposed review deadline) of March 27, 2013. In addition, in December 2012, pediatric clinical data of the agent met the U.S. FDA's Written Request requirements for pediatric exclusivity, with Eisai gaining an additional six months of U.S. market exclusivity for Aciphex, which expires on November 8, 2013.
- A Phase II study to investigate the anticancer agent MORAb-004 (humanized anti-endosialin monoclonal antibody) as a potential treatment for sarcoma was initiated and is underway in the United States and Europe.
- A Phase II study to investigate the anticancer agent E7016 (poly [ADP-ribose] polymerase inhibitor) as a potential treatment for melanoma was initiated and is underway in the United States.
- A Phase III study of the embolic bead E7040 for transcatheter arterial embolization (TAE) of hypervascular tumors was initiated and is underway in Japan.
- The Company received orphan drug designation for its anticancer agent E7080 (lenvatinib mesylate, a multikinase inhibitor) for the treatment of thyroid cancer from MHLW in August 2012 in Japan and from U.S. FDA in December 2012 in the United States. A Phase III study to investigate the agent as a potential treatment for hepatocellular carcinoma was initiated



aiming for submission of applications in the U.S., Europe and Asia including Japan and China. A new Phase II study of the agent for non-small cell lung cancer was initiated in the United States, Europe and Asia including Japan.

- A Phase II study to investigate an anti-Alzheimer's disease agent BAN2401 (a humanized anti-A $\beta$  protofibril monoclonal antibody) was initiated in the United States and Europe.
- A Phase III study to investigate the anticancer agent MORAb-003 (farletuzumab, a humanized folate receptor- $\alpha$  monoclonal antibody) aiming for submission of applications seeking approval in the United States, Europe and Asia including Japan as treatment of platinum-sensitive epithelial ovarian cancer in first relapse was completed. The findings included in the preliminary report indicate that the agent failed to achieve the pre-defined statistically significant difference in the primary endpoint (progression-free survival: PFS). However, the agent prolonged PFS in certain subgroups. A new development strategy will be determined after conducting detailed analysis and consultations with external experts and the relevant regulatory authorities.

#### [Status of Major Alliances and Agreements]

- In April 2012, the Company amended the section of its license agreement with Teikoku Pharma USA, Inc. (U.S., TPU) pertaining to exclusive overseas (excluding Japan) marketing rights for the Aricept transdermal patch system. The contractual revision allows TPU to be solely responsible for making all decisions regarding future development activities for the Aricept transdermal patch system, while the Company now has the option to obtain exclusive worldwide marketing rights. This amendment was made in response to TPU's decision in April 2012 to withdraw the New Drug Application (NDA) submitted to the U.S. FDA following receipt of a Complete Response Letter (CRL) in April 2011. On the other hand, the development of a once-daily transdermal formulation of Aricept for the Japanese market is ongoing in accordance with an exclusive license agreement concluded with Teikoku Seiyaku Co., Ltd. (Kagawa) in February 2011.
- In April 2012, Eisai Europe Limited, the Company's U.K. subsidiary, entered into an agreement with PharmaSwiss S.A. (Switzerland), a division of Valeant Pharmaceuticals International, Inc. (Canada), to promote and distribute the anticancer agent Halaven in Central and Eastern European (CEE) countries.
- In April 2012, the Company's U.S. research subsidiary H3 Biomedicine Inc. entered into a collaboration agreement with Horizon Discovery Limited (U.K.), a leading provider of research tools to support the development of personalized medicines, to identify and validate a panel of novel cancer drug targets.
- In June 2012, Lyrica Capsules, the peripheral neuropathic pain treatment for which the Company has concluded a co-promotion agreement with Pfizer Japan Inc. in terms of sales in Japan, was approved for the additional indication of pain associated with fibromyalgia.
- In June 2012, the antiobesity agent Belviq (lorcaserin hydrochloride), for which the Company's U.S. subsidiary Eisai Inc. concluded a license agreement with Arena Pharmaceuticals GmbH (Arena), the Swiss subsidiary of U.S.-based Arena Pharmaceuticals, Inc., concerning exclusive U.S. commercialization rights, received approval from the U.S.

FDA as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater, or 27 kg/m<sup>2</sup> or greater in the presence of at least one weight-related comorbid condition. In addition, all rights pertaining to the New Drug Application (NDA) (rights as the marketing authorization holder) in the United States for Belviq have been transferred to Eisai Inc. from Arena Pharmaceuticals, Inc. as of July 2012. In May 2012, Eisai Inc. and Arena Pharmaceuticals GmbH agreed to expand the existing Belviq commercialization agreement to include 20 countries throughout Americas, including Mexico, Brazil, and Canada.

- In July 2012, the Company's U.S. subsidiary Eisai Inc. entered into a research collaboration with the U.S. company Verastem, Inc. for the generation of Wnt signal inhibitors that target cancer stem cells.
- In September 2012, the Company entered into a partnership agreement to supply the Sabin Vaccine Institute (U.S.) with the vaccine adjuvant E6020 and all relevant information pertaining to the compound to support the development of vaccines for two neglected tropical diseases (Chagas disease and leishmaniasis).
- In September 2012, the Company entered into an option agreement with Santen Pharmaceutical Co., Ltd. (Osaka) under which the Company grants Santen rights of evaluation and first negotiation for Eisai-owned compounds in the field of ophthalmology.
- In October 2012, the Company entered into a global agreement with the Fundação Oswaldo Cruz (Brazil) aimed at collaborations to develop new medicines and vaccines for malaria and neglected tropical diseases. For the first collaboration under the agreement, studies will be conducted on the development of a medicine for cerebral malaria using E6446 and analogs, which are Toll-like receptor 9 (TLR9) antagonists.
- In December 2012, the Company and University College London (U.K.) entered into an agreement to establish a joint research group to work together to investigate innovative new ways of treating neurological diseases such as Alzheimer's, Parkinson's and other related disorders.
- In December 2012, the Company's U.S. subsidiary Eisai Inc. entered into an agreement to divest U.S. rights for its Gliadel Wafer (carmustine intracranial implant wafer), an anticancer agent, to Arbor Pharmaceuticals, Inc. The Eisai Group will retain all rights to Gliadel outside the United States and will continue to manufacture Gliadel at its facility in Baltimore, the United States as well as serve as the exclusive supplier of Gliadel for the global market, including in the United States and Japan.
- Novartis Pharma K.K. (Tokyo) and the Company terminated their co-promotion agreement for three therapies for chronic obstructive pulmonary disease (COPD) effective December 31, 2012, as a result of a review of sales strategies for the products and after negotiations between the two companies. The three therapies are Onbrez (indacaterol maleate) and Seebri (glycopyrronium bromide), which are both manufactured and marketed by Novartis Pharma K.K., and the investigational drug QVA149 (fixed-dose combination of indacaterol maleate and glycopyrronium bromide), which has been filed for approval by Novartis Pharma K.K.
- In December 2012, the Company signed an agreement with Epizyme, Inc. (U.S.) and Roche

Molecular Systems Inc. (U.S.) to collaborate on the development of a companion diagnostic to identify genetic mutations in the epigenetic enzyme EZH2.

[Other Events]

- In April 2012, the Company established a regional office in Dubai to serve as a base for full-fledged future business development in the Middle East and North Africa. Prior to the establishment of this new office, the Company closed its regional office in Bahrain.
- In April 2012, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) published official technology appraisal guidance that does not recommend the Company's anticancer agent Halaven as a treatment for patients with locally advanced or metastatic breast cancer. This guidance was issued despite an appeal by the Company in response to the final appraisal determination on Halaven published by NICE. Patients in England can still access Halaven via the Government's Cancer Drugs Fund (a special fund that pays for cancer drugs that have not been approved by NICE).
- In April 2012, the German Federal Joint Committee (G-BA), the supreme decision-making body for the self-governing medical system in Germany, determined that Halaven has additional benefit over comparative treatments defined by the G-BA for women who have already had extensive prior treatment for locally advanced or metastatic breast cancer.
- In July 2012, the Company's research and development subsidiary KAN Research Institute (KAN), Inc., currently located within the Kobe Biomedical Innovation Cluster, received official approval from the city of Kobe to take part in a special international strategic development project being implemented within the Kansai International Strategic Innovation Zone and therefore the Company decided to relocate to a new research facility within the Zone in order to strengthen KAN's research infrastructure and increase the scale of its research.
- In August 2012, the Company's U.S. subsidiary Morphotek, Inc. established a new pilot manufacturing plant for the production of antibodies to support its early-stage clinical trials in the U.S. state of Pennsylvania where Morphotek is located.
- In October 2012, the Eisai Group's production management structure underwent a transformation that saw the Group shift from the structure it had been using to date that was based on manufacturing sites, to a new globally integrated unit-based structure organized by product family. By transitioning to the new structure, Eisai aims to create a production structure that clearly defines and assigns end-to-end accountability for all products by identifying the true needs of patients and provides products that will deliver optimal patient satisfaction. In consideration of Eisai's product portfolio and technology strategies, the new structure comprises five product family-based Demand Chain Units (DCUs) and two Core Function Units (CFUs), with each unit autonomously managing their respective activities. Within each DCU, a "Product Champion" is also assigned to every product. Product Champions are accountable for all production activities related to their assigned product or products, from procurement of raw materials to production, packaging and distribution, taking ownership of these activities to ensure that each DCU delivers products that provide customer satisfaction. Meanwhile, the CFUs carry out functions common across all units, including quality assurance and managing contract manufacturing of products, providing

expertise in these areas to support the activities of the DCUs. Additionally, a Demand Chain Headquarters was established to carry out strategic planning, organizational and talent management and risk management functions to optimize synergies across the entire Eisai Demand Chain Systems organization while maintaining the autonomy of each unit.

- The Group transformed its in vitro diagnostics development function, aiming to strengthen its overall product creation structure to reflect a focus on personalized medicine. In June 2012, with the aim of achieving early developments in in vitro diagnostics, including companion diagnostics, the Group merged the Company's Biomarker Personalized Medicine Core Function Unit (BPM CFU), which is in charge of biomarker research, with diagnostics business subsidiary EIDIA Co., Ltd.'s diagnostics research and development function, thereby establishing within the BPM CFU a new in vitro diagnostics research organization called the Diagnostic Development Department. Furthermore, in October 2012, the Group decided to dissolve diagnostics research and development subsidiary Palma Bee'Z Research Institute Co., Ltd. and absorb that function into the newly established Diagnostic Development Department, effective March 31, 2013.
- In December 2012, Scotland's health technology assessment (HTA) body, the Scottish Medicines Consortium, approved Eisai's AMPA receptor antagonist Fycompa as a second-line adjunctive treatment in patients with refractory partial-onset epilepsy under National Health Service Scotland.
- In December 2012, the Company's U.S. subsidiary Eisai Inc. entered into a strategic manufacturing alliance with Biogen Idec Inc. (U.S.) to bolster the manufacturing capabilities of both companies through the joint utilization of Eisai Inc.'s manufacturing facility in North Carolina, the United States.

### **3) Qualitative Information Concerning Consolidated Financial Position**

[Assets, Liabilities and Equity]

- Total assets as of the end of this period amounted to ¥968,245 million (down ¥36,415 million from the end of the previous fiscal year). This decrease in total assets was attributed to a decrease in cash and cash in banks due to repayment of long-term borrowings (current portion).
- Total liabilities as of the end of this period amounted to ¥538,260 million (down ¥42,971 million from the end of the previous fiscal year). This decrease in total liabilities was attributed to repayment of long-term borrowings (current portion).
- Total equity as of the end of this period amounted to ¥429,984 million (up ¥6,556 million from the end of the previous fiscal year). The shareholders' equity ratio was 43.9% (up 2.4 percentage points from the end of the previous fiscal year). The net debt-to-equity ratio (Net DER) as of the end of this period was 0.35 times (down 0.02 points from the end of the previous fiscal year).

(Note) Debt-to-equity ratio (Net DER): (interest-bearing debts (borrowings + bonds and debentures) - cash and cash in banks - short-term investments) / shareholders' equity

#### [Cash Flows]

- Net cash provided by operating activities amounted to ¥53,465 million (down ¥1,384 million from the same period of the previous fiscal year). More specifically, income before income taxes and minority interests was ¥51,531 million; depreciation and amortization was ¥31,713 million; and income taxes paid decreased by ¥12,419 million to ¥24,671 million from the same period of the previous fiscal year.
- Net cash provided by investing activities amounted to ¥20,943 million (up ¥10,776 million from the same period of the previous fiscal year). Net decrease in time deposits (exceeding three months) came to ¥29,063 million.
- Net cash used in financing activities amounted to ¥60,832 million (up ¥4,154 million from the same period of the previous fiscal year). This was mainly due to repayment of long-term borrowings amounting to ¥40,000 million and cash dividends paid totaling ¥42,748 million.
- As a result, cash and cash equivalents as of the end of this period stood at ¥133,290 million (up ¥20,722 million from the end of the previous fiscal year).

#### **4) Profit Appropriation Basic Policy and Dividend Forecast for the End of Fiscal 2012**

The Company 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 for shareholder return, investment in future growth and repayment of borrowings and other operations to improve the financial standing of the Company. Eisai is committed to prioritizing stable dividend payments and investment in future growth, and considers it important to allocate cash income appropriately and flexibly according to changes in financial conditions.

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 year-end dividend for fiscal year 2012 at ¥80 per share (same amount as the previous year) as previously projected. With the interim (the second quarter-end) dividend of ¥70 per share, Eisai intends to set the total dividend for the year at ¥150 per share (same amount as the previous year).

## 5) Qualitative Information Concerning Consolidated Financial Forecasts for Fiscal 2012

(April 1, 2012 to March 31, 2013)

[Consolidated Forecasts]

The full fiscal year consolidated forecasts have been revised as follows from the forecasts previously announced in May 2012, in light of the consolidated financial results for the quarter ended December 31, 2012.

	Revised forecast		Previous forecast		Increase/ Decrease	Rate of change (%)
	(A)	(%)	(B)	(%)	(A-B)	
Net sales	¥573,500 mil.	(11.5%)	¥610,000 mil.	(5.9%)	(¥36,500 mil.)	(6.0%)
Operating income	¥71,500 mil.	(25.3%)	¥87,000 mil.	(9.1%)	(¥15,500 mil.)	(17.8%)
Ordinary income	¥66,500 mil.	(26.1%)	¥82,000 mil.	(8.9%)	(¥15,500 mil.)	(18.9%)
Net income	¥47,000 mil.	(19.7%)	¥59,000 mil.	0.8%	(¥12,000 mil.)	(20.3%)

Notes: \*Forecasted annual earnings per share (full year): ¥164.91  
(Assumptions for the 4th quarter) 1 USD=¥88, 1 EUR =¥117, 1 GBP =¥142

### <Net Sales>

- Full year net sales is forecasted at ¥573,500 million (down ¥36,500 million from the previous forecast) in light of the most recent results for the Japan Pharmaceutical Business.
- Full year global net sales for Aricept are forecasted at ¥97,000 million (down ¥15,000 million from the previous forecast) in light of the most recent levels of sales in Japan. Similarly, full year global net sales for Halaven are forecasted at ¥24,000 million (down ¥4,500 million from the previous forecast) in consideration of most recent results in Japan and the United States, while full year global net sales for oncology-related products are forecasted to reach ¥100,000 million. Furthermore, the full year global net sales forecast for Pariet/Aciphex remains unchanged at ¥108,500 million as its sales progress is consistent with the previous forecast.

### <Income>

- In the face of decreased gross profits resulting in lower net sales, the Group continues to make progress with its measures to improve efficiency Group-wide and aggressively invest in research and development and new product launches. As a result, the forecasts for operating income, ordinary income, and net income have been lowered to ¥71,500 million (down ¥15,500 million from the previous forecast), ¥66,500 million (down ¥15,500 million from the previous forecast) and ¥47,000 million (down ¥12,000 million from the previous forecast), respectively.
- Cash income, which the Group uses to express its ability to generate cash, is forecasted at ¥100,000 million (down ¥7,500 million from the previous forecast). Furthermore, the forecast for the total dividend for the year remains unchanged at ¥150 per share (same amount as the previous year).

[Forecasts and Risk Factors]

- Materials and information provided in this financial disclosure may contain “forward-looking statements” based on current expectations, forecasts, estimates, business goals and assumptions that are subject to risks and uncertainties, and actual outcomes and results could differ materially from these statements depending on a number of important factors. Risks and uncertainties include general industry and market conditions, as well as general domestic and international economic conditions such as interest rates and currency exchange fluctuations.
- Risks that could cause significant fluctuations in the consolidated results of the Group or have a material effect on investment decisions include: risks related to overseas operations; uncertainty of new drug developments; risks related to dependence on specific products; risks in alliances with other companies; impact of measures to contain medical costs; risks with respect to generic drug products; risks related to intellectual property; risks of occurrences of side effects; regulatory risks; risks relating to lawsuits; plant closure/shutdown; risks concerning the safety and quality of raw materials; risks associated with outsourcing; environmental risks; risks concerning IT security and information management; risks related to financial markets and currency movement; risks concerning internal control systems; and disaster-related risks. These risks, however, have been evaluated and forecasted as of the disclosure date of this financial report.

For further details on the abovementioned risks, please refer to the “Risk Factors” section of the Annual Securities Report.

## **2. Explanatory Notes in Financial Results Summary**

### **1) Changes in Number of Significant Subsidiaries During the Period**

Not applicable

### **2) Application of Special Accounting Treatment in Preparation of Consolidated Quarterly Financial Statements**

Not applicable

### **3) Changes in Accounting Policies, Accounting Estimates and Restatements**

Not applicable

### 3. Consolidated Financial Statements

#### 1) Consolidated Balance Sheets

(millions of yen)

	March 31, 2012	December 31, 2012
<b>Assets</b>		
Current assets		
Cash and cash in banks	104,444	70,028
Notes and accounts receivable—trade	197,166	180,263
Short-term investments	83,737	110,331
Merchandise and finished goods	43,108	51,841
Work-in-process	18,283	18,921
Raw materials and supplies	13,804	14,642
Deferred tax assets	42,479	42,659
Other	22,974	22,463
Allowance for doubtful receivables	(163)	(134)
Total current assets	525,835	511,018
Non-current assets		
Property, plant and equipment		
Buildings and structures—net	85,580	83,884
Other—net	57,998	55,182
Total property, plant and equipment	143,578	139,067
Intangible assets		
Goodwill	119,054	119,282
Sales rights	65,338	55,286
Core technology	40,492	41,003
Other	13,755	12,841
Total intangible assets	238,640	228,414
Investments and other assets		
Investment securities	39,079	37,894
Deferred tax assets	45,101	45,723
Other	12,586	6,280
Allowance for doubtful accounts	(163)	(152)
Total investments and other assets	96,605	89,745
Total non-current assets	478,824	457,226
Total assets	1,004,660	968,245



(millions of yen)

	March 31, 2012	December 31, 2012
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable—trade	26,205	24,297
Short-term borrowings	6,000	3,566
Long-term borrowings (current portion)	40,000	17,316
Commercial papers	-	24,996
Bonds and debentures (current portion)	-	49,999
Accounts payable—other	41,540	37,756
Accrued expenses	56,021	44,151
Income taxes payable	11,289	5,918
Reserve for sales rebates	16,473	14,245
Other reserves	681	459
Other	9,718	8,560
Total current liabilities	207,932	231,267
Long-term liabilities		
Bonds and debentures	79,994	29,997
Long-term borrowings	219,314	204,632
Deferred tax liabilities	23,019	18,828
Liability for retirement benefits	31,385	25,726
Retirement allowance for directors	600	691
Other	18,986	27,116
Total long-term liabilities	373,300	306,993
Total liabilities	581,232	538,260
<b>Equity</b>		
Shareholders' equity		
Common stock	44,985	44,985
Capital surplus	56,898	56,885
Retained earnings	464,176	455,440
Treasury stock	(39,422)	(39,301)
Total shareholders' equity	526,638	518,009
Accumulated other comprehensive income (loss)		
Valuation difference on available-for-sale securities	1,241	837
Deferred gain (loss) on derivatives under hedge accounting	(1,054)	(1,063)
Foreign currency translation adjustments	(110,032)	(92,614)
Total accumulated other comprehensive income (loss)	(109,844)	(92,840)
Stock options	990	1,069
Minority interests	5,643	3,745
Total equity	423,427	429,984
Total liabilities and equity	1,004,660	968,245

## 2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

### (Consolidated Statements of Income)

(millions of yen)

	April 1, 2011 – December 31, 2011	April 1, 2012– December 31, 2012
Net sales	504,800	431,553
Cost of sales	129,221	128,144
Gross profit	375,578	303,408
Provision for sales returns	95	-
Reversal of provision for sales returns	-	4
Gross profit—net	375,483	303,413
Selling, general and administrative expenses	293,268	249,287
Operating income	82,215	54,125
Non-operating income		
Interest income	541	752
Dividend income	831	715
Other	269	210
Total non-operating income	1,643	1,677
Non-operating expenses		
Interest expense	5,256	5,018
Foreign exchange loss	520	227
Other	184	332
Total non-operating expenses	5,960	5,579
Ordinary income	77,897	50,224
Special gains		
Gain on sales of fixed assets	21	570
Gain on sales of investment securities	483	147
Gain on negative goodwill	-	1,960
Gain on contribution of securities to retirement benefit trust	1,881	-
Other	2	214
Total special gains	2,387	2,892
Special losses		
Loss on disposal of fixed assets	69	78
Loss on impairment of long-lived assets	-	1,256
Loss on devaluation of investment securities	206	250
Other	8	0
Total special losses	284	1,585
Income before income taxes and minority interests	80,001	51,531
Income taxes—current	21,491	23,049
Income taxes—deferred	9,034	(5,748)
Total income taxes	30,526	17,301
Income before minority interests	49,474	34,230
Minority interests in income	283	218
Net income	49,191	34,011

**(Consolidated Statements of Comprehensive Income)**

(millions of yen)

	April 1, 2011– December 31, 2011	April 1, 2012– December 31, 2012
Income before minority interests	49,474	34,230
Other comprehensive income (loss)		
Valuation difference on available-for-sale securities	(2,351)	(418)
Deferred gain (loss) on derivatives under hedge accounting	(310)	(9)
Foreign currency translation adjustments	(22,429)	17,310
Total other comprehensive income (loss)	(25,091)	16,882
Comprehensive Income (loss)	24,383	51,112
(Breakdown)		
Comprehensive income (loss) attributable to shareholders of the parent company	24,360	51,016
Comprehensive income (loss) attributable to minority interests	22	96

### 3) Consolidated Statements of Cash Flows

(millions of yen)

	April 1, 2011– December 31, 2011	April 1, 2012– December 31, 2012
<b>Operating activities</b>		
Income before income taxes and minority interests	80,001	51,531
Depreciation and amortization	30,915	31,713
Amortization of goodwill	5,357	5,657
Gain on negative goodwill	-	(1,960)
Other loss (gain)	1,807	4,365
Decrease (increase) in notes and accounts receivable—trade	(22,636)	19,275
Decrease (increase) in inventories	(3,315)	(8,264)
Increase (decrease) in trade payables	3,360	(2,197)
Increase (decrease) in other current liabilities	(5,229)	(18,789)
Increase (decrease) in reserve for sales rebates	(7,595)	(2,873)
Other	12,952	3,245
<b>Sub-total</b>	<b>95,618</b>	<b>81,703</b>
Interest and dividends received	1,398	1,277
Interest paid	(5,075)	(4,842)
Income taxes paid	(37,090)	(24,671)
<b>Net cash provided by (used in) operating activities</b>	<b>54,850</b>	<b>53,465</b>
<b>Investing activities</b>		
Purchases of property, plant and equipment	(7,805)	(6,976)
Purchases of intangible assets	(4,249)	(8,472)
Purchases of short-term investments and investment securities	(4,327)	(3,118)
Proceeds from sales and redemptions of short-term investments and investment securities	19,421	3,538
Proceeds from sales of investment in consolidated subsidiaries in the previous fiscal year	-	6,084
Net decrease (increase) in time deposits exceeding three months	6,493	29,063
Other	633	825
<b>Net cash provided by (used in) investing activities</b>	<b>10,166</b>	<b>20,943</b>
<b>Financing activities</b>		
Net increase (decrease) in short-term borrowings	27,000	(2,438)
Net increase (decrease) in commercial papers	-	24,996
Repayment of long-term borrowings	-	(40,000)
Redemptions of bonds and debentures	(40,000)	-
Dividends paid	(42,744)	(42,748)
Other	(932)	(641)
<b>Net cash provided by (used in) financing activities</b>	<b>(56,677)</b>	<b>(60,832)</b>
Foreign currency translation adjustments on cash and cash equivalents	(6,198)	7,145
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>2,141</b>	<b>20,722</b>
Cash and cash equivalents at beginning of period	102,800	112,567
<b>Cash and cash equivalents at end of period</b>	<b>104,942</b>	<b>133,290</b>

#### 4) Going Concern

Not applicable

#### 5) Note Regarding Significant Changes in the Amount of Shareholders' Equity

Not applicable

#### 6) Segment Information

Effective from the first quarter of this fiscal year, the Group has changed the designation of its reporting segments. (For details, please see "Information concerning changes to reporting segments, etc." on page 20.)

I. Third quarter of the previous fiscal year (April 1, 2011 to December 31, 2011)

Information concerning sales and profit (loss) for the third quarter of the previous fiscal year based on the new reporting segments is as follows:

##### (1) Information concerning sales and profit (loss) by reporting segment

(millions of yen)

	Reporting Segment <sup>1</sup>					Other <sup>2</sup>	Total
	Pharmaceuticals Business						
	East Asia	Americas	EMEA	Indo-Pacific	Sub-total		
Net sales to external customers	315,695	119,801	34,026	5,098	474,621	30,178	504,800
Segment profit	136,163	24,670	5,241	1,352	167,427	14,821	182,248

(Notes) 1 Reporting segments comprise the following countries and regions:

1. East Asia: Japan, China, South Korea, Taiwan and Hong Kong
2. Americas: North, Central and South America
3. EMEA: Europe, the Middle East and Africa
4. Indo-Pacific: South Asia, ASEAN countries and Oceania

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

##### (2) Amounts and main components of difference between reporting segment total and consolidated statements of income (items concerning difference adjustment)

(millions of yen)

Profit Items	Amount
Total reporting segment profit	167,427
Profit included in "Other"	14,821
R&D expenses <sup>1</sup>	(93,887)
Group headquarters management costs and other expenses <sup>2</sup>	(6,145)
Operating income as reported in the Consolidated Statements of Income	82,215

(Notes) 1 R&D expenses are not allocated to any particular segment as the Group manages such expenses on a global basis.

2 Group headquarters management costs and other expenses are not allocated to any particular segment as these are the costs covering Group-wide operations.

- (3) Information concerning loss on impairment of long-lived assets and goodwill by reporting segment  
Not applicable

II. Third quarter of this fiscal year (April 1, 2012 to December 31, 2012)

(1) Information concerning sales and profit (loss) by reporting segment

(millions of yen)

	Reporting Segment <sup>1</sup>					Other <sup>2</sup>	Total
	Pharmaceuticals Business						
	East Asia	Americas	EMEA	Indo-Pacific	Sub-total		
Net sales to external customers	274,628	114,460	18,876	5,100	413,065	18,487	431,553
Segment profit	111,042	25,689	1,305	1,223	139,260	9,177	148,438

(Notes) 1 Reporting segments comprise the following countries and regions:

1. East Asia: Japan, China, South Korea, Taiwan and Hong Kong
2. Americas: North, Central and South America
3. EMEA: Europe, the Middle East and Africa
4. Indo-Pacific: South Asia, ASEAN countries and Oceania

- 2 "Other" is a business segment not included in reporting segments. Pharmaceutical raw materials business is included in this segment.

(2) Amounts and main components of difference between reporting segment total and consolidated statements of income (items concerning difference adjustment)

(millions of yen)

Profit Items	Amount
Total reporting segment profit	139,260
Profit included in "Other"	9,177
R&D expenses <sup>1</sup>	(87,243)
Group headquarters management costs and other expenses <sup>2</sup>	(7,069)
Operating income as reported in the Consolidated Statements of Income	54,125

(Notes) 1 R&D expenses are not allocated to any particular segment as the Group manages such expense on a global basis.

- 2 Group headquarters management costs and other expenses are not allocated to any particular segment as these are the costs covering Group-wide operations.

(3) Information concerning changes to reporting segments, etc.

The Group's segments comprise the Pharmaceuticals and Other businesses, with the Pharmaceuticals Business of each geographical region being identified as a reporting segment.

Previously, the Group's Pharmaceuticals Business was divided into the following four regions - East Asia (Japan, China, South Korea, Taiwan and Hong Kong), the United States, Europe, and New Markets & ASEAN (Brazil, Mexico, Russia, Canada, Australia, India, the Middle East, Southeast Asia, etc.) - however, effective from the first quarter of this fiscal year, the Group has redesignated the countries overseen by each region with the aim of delegating management oversight responsibilities for new markets such as Canada, Mexico and Brazil directly to individual regions. The newly designated regions comprise East Asia (Japan, China, South Korea, Taiwan and Hong Kong), Americas (North, Central and South America), EMEA (Europe, the Middle East and Africa), and Indo-Pacific (South Asia, ASEAN countries and Oceania).

In line with this regional restructuring, the Group has changed the designation of its reporting segments, with changes also being reflected in segment information for the third quarter of the

previous fiscal year (April 1, 2011 to December 31, 2011).

(4) Information concerning loss on impairment of long-lived assets and goodwill by reporting segment

(Significant loss on impairment of long-lived assets)

The Americas Pharmaceutical Business recognized a loss on impairment of long-lived assets in relation to exclusivity rights (sales rights) to some of its prescription pharmaceutical products. As a result, loss on impairment of long-lived assets for the third quarter of this year amounted to ¥1,256 million.

(Significant gain on negative goodwill)

The Indo-Pacific Pharmaceutical Business recognized negative goodwill following the Company's consolidated subsidiary Eisai Asia Regional Services Pte. Ltd. acquiring additional stock of the latter's own subsidiary Eisai (Thailand) Marketing Co., Ltd. As a result, gain on negative goodwill due to this event for the third quarter of this year amounted to ¥1,960 million.

**7) Significant Subsequent Events**

Not applicable



# 2012.12

# Reference Data

Third Quarter Ended December 31 2012

February 1, 2013

For Inquiry:

Eisai Co., Ltd.

Public Relations / Investor Relations

TEL 81-3-3817-5120 FAX 81-3-3811-3077

<http://www.eisai.co.jp/eir/>



### **Forward-looking Statements and Risk Factors**

Materials and information provided in this financial disclosure may contain “forward-looking statements” based on current expectations, forecasts, estimates, business goals and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations.

Risks that may cause significant fluctuations in the consolidated results of the Eisai Group or have a material effect on investment decisions are described below. These are risk factors that have been identified and assessed as of the disclosure date of the Financial Report.

Risk factors associated with our business include, but are not limited to, challenges arising in overseas operations, uncertainties in new drug development, as well as risks related to dependency on specific products, strategic alliances with partner companies, medical cost-containment measures, generic drug products, intellectual property, possible occurrence of side effects, laws and regulations, litigation, closure or shutdown of production plants, safety and quality of raw materials, outsourcing, environmental issues, IT security and information management, financial market conditions and currency movement, internal control systems, and disasters.

## Contents

1. Consolidated Financial Highlights	-----	1
2. Consolidated Statements of Income	-----	3
3. Consolidated Statements of Cash Flows	-----	5
4. Financial Results by Business Segment	-----	6
5. Sales Forecasts by Reporting Segment	-----	11
6. Consolidated Balance Sheets	-----	12
7. Changes in Consolidated Quarterly Results	-----	14
8. Non-consolidated Financial Highlights	-----	18
9. Major News Releases	-----	19
10. Major R&D Pipeline	-----	22

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

\* All amounts are rounded to the nearest specified unit.

\* The exchange rates used in the reference data are noted in the table below.

\* All overseas profit and loss amounts have been converted into yen based on the average exchange rates for the periods shown in the table below.

### Currency Exchange Rates

	US (JPY/USD)	EU (JPY/EUR)	UK (JPY/GBP)	China (JPY/RMB)
(Apr. 2011 - Dec. 2011) Nine Months Average Rate	79.01	110.63	126.77	12.30
(Dec. 31, 2011) Third Quarter End Rate	77.74	100.71	119.81	12.31
(Apr. 2011 - Mar. 2012) Fiscal Year Average Rate	79.08	108.97	126.22	12.36
(Mar. 31, 2012) Fiscal Year End Rate	82.19	109.80	131.34	13.06
(Apr. 2012 - Dec. 2012) Nine Months Average Rate	79.99	102.17	127.12	12.70
(Dec. 31, 2012) Third Quarter End Rate	86.58	114.71	139.52	13.91
Fiscal Year Ending March 31, 2013 Fourth Quarter Forecast Rate	<u>88.00</u>	<u>117.00</u>	<u>142.00</u>	<u>14.20</u>

### About Indicators in This Reference Data

Eisai believes that cash-generating ability is the most intrinsic element determining the true value of a company. Based upon this belief, in order to reflect our true earnings capacity, we focus on disclosing "cash income" and "cash EPS," which are affected by non-cash profit-and-loss items, such as depreciation of property, plant and equipment, amortization of goodwill, loss on impairment of long-lived assets (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, 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 / Average number of outstanding shares for the period (after deduction of treasury stock)

#### Segment information

The Eisai Group's segments comprise the pharmaceuticals and other businesses, with the pharmaceuticals business of each region being identified as a reporting segment. Effective from the fiscal year ending March 31, 2013, the Group has designated four regions as new reporting segments for its pharmaceuticals business: East Asia (Japan, China, South Korea, Taiwan and Hong Kong), the Americas (North, Central and South America), EMEA (Europe, the Middle East and Africa) and the Indo-Pacific (South Asia, ASEAN countries and Oceania). In line with this change, figures listed in this report for each segment for the fiscal year ended March 31, 2012 are based on the new reporting segments.

# 1. Consolidated Financial Highlights

## 1) Income Statement Data

(billions of yen)

	Nine months ended Dec. 31			Full year	
	FY2011	FY2012	YOY %	FY2011	FY2012 est.
Net sales	504.8	431.6	85.5	648.0	573.5
Cost of sales	129.3	128.1	99.1	173.4	172.4
R&D expenses	93.9	87.2	92.9	125.1	118.0
SG&A expenses	199.4	162.0	81.3	253.7	211.6
Operating income	82.2	54.1	65.8	95.7	71.5
Ordinary income	77.9	50.2	64.5	90.0	66.5
Net income	49.2	34.0	69.1	58.5	47.0
Cash income	85.7	72.9	85.1	107.7	100.0
Comprehensive Income	24.4	51.1	209.6	55.6	-
			Diff.		
Dividend per share (DPS, yen)	-	-	-	150.0	150.0
Earnings per share (EPS, yen)	172.6	119.3	(53.3)	205.3	164.9
Cash income per share (Cash EPS, yen)	300.6	255.8	(44.9)	377.8	350.9

\* "Cost of sales" includes "Provision for (reversal of) sales returns—net."

## 2) Cash Flow Statement Data

(billions of yen)

	Nine months ended Dec. 31			Full year
	FY2011	FY2012	Diff.	FY2011
Net cash provided by (used in) operating activities	54.9	53.5	(1.4)	90.6
Net cash provided by (used in) investing activities	10.2	20.9	10.8	(2.6)
Net cash provided by (used in) financing activities	(56.7)	(60.8)	(4.2)	(78.0)
Cash and cash equivalents at end of period	104.9	133.3	28.3	112.6
Free cash flow	43.1	38.9	(4.1)	71.4

\* "Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (cash basis)"

## 3) Balance Sheet Data

(billions of yen)

	2012		Diff.
	March 31	Dec. 31	
Total assets	1,004.7	968.2	(36.4)
Liabilities	581.2	538.3	(43.0)
Borrowings	265.3	225.5	(39.8)
Commercial paper	-	25.0	25.0
Bonds and debentures	80.0	80.0	0.0
Equity	423.4	430.0	6.6
Shareholders' equity	416.8	425.2	8.4
Shareholders' equity ratio (%)	41.5	43.9	2.4
Liabilities ratio (Net DER/times)	0.38	0.35	(0.02)

\* "Liabilities ratio (Net DER)" = ("Interest-bearing debt" ("Borrowings" + "Bonds and debentures") - "Cash and cash in banks" - "Short-term investments") / "Shareholders' equity"

#### 4) Capital Expenditures and Depreciation/Amortization

(billions of yen)

	Nine months ended Dec. 31			Full year
	FY2011	FY2012	Diff.	FY2011
Capital expenditures	11.7	15.0	3.2	20.7
Property, plant and equipment	7.1	5.1	(2.0)	12.7
Intangible assets	4.7	9.9	5.2	8.0
Depreciation and amortization	30.9	31.7	0.8	41.7

\* "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 months ended Dec. 31			Full year
	FY2011	FY2012	YOY %	FY2011
East Asia pharmaceuticals business	315.7	274.6	87.0	400.4
Japan pharmaceuticals business	294.3	250.0	85.0	372.6
Americas pharmaceuticals business	119.8	114.5	95.5	157.5
U.S. pharmaceuticals business	119.8	114.2	95.4	157.4
EMEA pharmaceuticals business	34.0	18.9	55.5	42.7
Indo-Pacific pharmaceuticals business	5.1	5.1	100.0	6.7
Other	30.2	18.5	61.3	40.7
Consolidated net sales	504.8	431.6	85.5	648.0

\* Net sales to external customers for each segment.

##### (2) Consolidated Operating Income by Reporting Segment

(billions of yen)

	Nine months ended Dec. 31		
	FY2011	FY2012	YOY %
East Asia pharmaceuticals business	136.2	111.0	81.6
Japan pharmaceuticals business	131.9	106.2	80.5
Americas pharmaceuticals business	24.7	25.7	104.1
EMEA pharmaceuticals business	5.2	1.3	24.9
Indo-Pacific pharmaceuticals business	1.4	1.2	90.4
Other	14.8	9.2	61.9
R&D expenses	93.9	87.2	92.9
Non-allocated SG&A expenses	6.1	7.1	115.0
Consolidated Operating income	82.2	54.1	65.8

\* The Group's segments comprise the pharmaceuticals and other businesses, with the pharmaceuticals business of each region being identified as a reporting segment.

\* The Eisai Group's pharmaceuticals business is classified into segments comprising East Asia (Japan, China, South Korea, Taiwan and Hong Kong), the Americas (North, Central and South America), EMEA (Europe, the Middle East and Africa) and the Indo-Pacific (South Asia, ASEAN countries and Oceania), with steps being taken to develop and implement strategies tailored to the specific characteristics of each region or market.

In the pharmaceuticals business, the Group is primarily engaged in the manufacture and sale of prescription drugs.

R&D expenses have not been allocated to any segment as the Group manages such expenses on a global basis.

Similarly, Group headquarters management costs and other expenses have not been allocated to any segment as these are the costs covering Group-wide operations.

## 2. Consolidated Statements of Income

	(billions of yen)							
	FY2011	Nine months ended Dec. 31					Full year	
		Sales %	FY2012	Sales %	YOY %	Diff.	FY2011	Sales %
Net sales	504.8	100.0	431.6	100.0	85.5	(73.2)	648.0	100.0
Cost of sales	129.3	25.6	128.1	29.7	99.1	(1.2)	173.4	26.8
Gross profit	375.5	74.4	303.4	70.3	80.8	(72.1)	474.6	73.2
R&D expenses	93.9	18.6	87.2	20.2	92.9	(6.6)	125.1	19.3
SG&A expenses	199.4	39.5	162.0	37.5	81.3	(37.3)	253.7	39.1
Personnel expenses	57.6	11.4	50.8	11.8	88.2	(6.8)	74.5	11.5
Selling expenses	102.2	20.2	76.9	17.8	75.3	(25.3)	127.1	19.6
Administrative and other expenses	39.5	7.8	34.3	7.9	86.7	(5.3)	52.1	8.0
Operating income	82.2	16.3	54.1	12.5	65.8	(28.1)	95.7	14.8
Non-operating income	1.6	0.3	1.7	0.4		0.0	2.0	0.3
Non-operating expenses	6.0	1.2	5.6	1.3		(0.4)	7.7	1.2
Ordinary income	77.9	15.4	50.2	11.6	64.5	(27.7)	90.0	13.9
Special gain	2.4	0.5	2.9	0.7		0.5	6.3	1.0
Special loss	0.3	0.1	1.6	0.4		1.3	1.7	0.3
Income before income taxes and minority interests	80.0	15.8	51.5	11.9	64.4	(28.5)	94.6	14.6
Income taxes—current	21.5	4.3	23.0	5.3		1.6	28.6	4.4
Income taxes—deferred	9.0	1.8	(5.7)	(1.3)		(14.8)	7.1	1.1
Income before minority interests	49.5	9.8	34.2	7.9	69.2	(15.2)	58.9	9.1
Minority interests in income	0.3	0.1	0.2	0.1		(0.1)	0.4	0.1
Net income	49.2	9.7	34.0	7.9	69.1	(15.2)	58.5	9.0

\* "Cost of sales" includes "Provision for (reversal of) sales returns—net."

### Cash income

Net income	49.2	9.7	34.0	7.9	69.1	(15.2)	58.5	9.0
Depreciation of PP&E and amortization of intangible assets	18.9		18.5				25.7	
Amortization of intangible assets obtained through acquisition	12.0		13.2				16.0	
Amortization of goodwill	5.4		5.7				7.0	
Loss on impairment of long-lived assets (including loss on devaluation of investment securities)	0.2		1.5				0.5	
Cash income	85.7	17.0	72.9	16.9	85.1	(12.8)	107.7	16.6

### Notes

Net sales	Decrease in sales of Aricept [- ¥49.8 billion] Decrease in sales of Pariet/Aciphex [- ¥16.1 billion] Increase in sales of Halaven [+ ¥5.5 billion] Increase in sales of Humira [+ ¥3.6 billion]
Cost of sales to net sales <Reason for increase>	Impact of NHI drug price revisions in Japan and change in product mix due to decrease in net sales of Aricept in Japan and Europe
R&D expenses <Reason for decrease>	Completion of large-scale clinical trials, etc.
SG&A expenses <Reason for decrease>	Decrease in alliance fees paid to promotion partners Decrease in personnel expenses Increase in efficiency of SG&A expenses Group-wide
Special gain/loss	Gain on negative goodwill due to capital increase by allocation of new shares of a consolidated subsidiary to its parent company as underwriter, loss of impairment on long-lived assets, etc.

**Consolidated Statements of Comprehensive Income**

(billions of yen)

	Nine months ended Dec. 31			Diff.	Full year FY2011
	FY2011	FY2012	YOY %		
Income before minority interests	49.5	34.2	69.2	(15.2)	58.9
Other comprehensive income (loss)	(25.1)	16.9	-	42.0	(3.3)
Valuation difference on available-for-sale securities	(2.4)	(0.4)	-	1.9	1.1
Deferred gain (loss) on derivatives under hedge accounting	(0.3)	(0.0)	-	0.3	(0.2)
Foreign currency translation adjustments	(22.4)	17.3	-	39.7	(4.2)
Comprehensive income (loss)	24.4	51.1	209.6	26.7	55.6
(Breakdown)					
Comprehensive income (loss) attributable to shareholders of the parent company	24.4	51.0	209.4	26.7	55.3
Comprehensive income (loss) attributable to minority interests	0.0	0.1	432.4	0.1	0.3

### 3. Consolidated Statements of Cash Flows

	(billions of yen)		
	<u>Nine months ended Dec. 31</u>		
	FY2011	FY2012	Diff.
Income before income taxes and minority interests	80.0	51.5	(28.5)
Depreciation and amortization / Amortization of goodwill	36.3	37.4	1.1
Gain on negative goodwill	-	(2.0)	(2.0)
Decrease (increase) in notes and accounts receivable—trade, trade payables and inventories	(22.6)	8.8	31.4
Increase (decrease) in accounts payable—other / Accrued expenses, etc.	(5.2)	(18.8)	(13.6)
Other	7.2	4.7	(2.4)
[Sub-total]	95.6	81.7	(13.9)
Interest received (paid), etc.	(3.7)	(3.6)	0.1
Income taxes paid	(37.1)	(24.7)	12.4
<b>Net cash provided by (used in) operating activities</b>	<b>54.9</b>	<b>53.5</b>	<b>(1.4)</b>
Capital expenditures (cash basis)	(11.8)	(14.6)	(2.8)
Purchases of securities / Proceeds from sales and redemption of securities	15.1	0.4	(14.7)
Proceeds from sales of investment in consolidated subsidiaries in the previous fiscal year	-	6.1	6.1
Net increase (decrease) in time deposits exceeding three months	6.5	29.1	22.6
Other	0.4	(0.1)	(0.4)
<b>Net cash provided by (used in) investing activities</b>	<b>10.2</b>	<b>20.9</b>	<b>10.8</b>
Net increase (decrease) in short-term borrowings	27.0	(2.4)	(29.4)
Net increase (decrease) in commercial paper	-	25.0	25.0
Repayment of long-term borrowings	-	(40.0)	(40.0)
Redemptions of bonds and debentures	(40.0)	-	40.0
Dividends paid	(42.7)	(42.7)	(0.0)
Other—net	(0.9)	(0.6)	0.3
<b>Net cash provided by (used in) financing activities</b>	<b>(56.7)</b>	<b>(60.8)</b>	<b>(4.2)</b>
Foreign currency translation adjustments on cash and cash equivalents	(6.2)	7.1	13.3
Net increase (decrease) in cash and cash equivalents	2.1	20.7	18.6
Cash and cash equivalents at the beginning of period	102.8	112.6	9.8
Cash and cash equivalents at the end of period	104.9	133.3	28.3
<b>Free cash flow</b>	<b>43.1</b>	<b>38.9</b>	<b>(4.1)</b>

\* "Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (cash basis)"

#### Notes

##### **Net cash provided by (used in) operating activities**

Decrease in income taxes paid due to an decrease in taxable income in the previous year

##### **Net cash provided by (used in) investing activities**

Increase from reversal of time deposits exceeding three months as the fund source for repayment of long-term borrowings

##### **Net cash provided by (used in) financing activities**

Cash dividends paid and repayment of long-term borrowings

## 4. Financial Results by Business Segment

### 1) East Asia Pharmaceuticals Business

(billions of yen)

(Japan, China, South Korea, Taiwan and Hong Kong)	Nine months ended Dec. 31			Full year
	FY2011	FY2012	YOY %	FY2011
Net sales	315.7	274.6	87.0 <86.8>	400.4
Segment profit	136.2	111.0	81.6	167.4

### East Asia Net Sales Breakdown

<b>Net sales in Japan</b>	294.3	250.0	85.0	372.6
Prescription drugs	263.9	216.4	82.0	331.2
Consumer healthcare products, etc.	15.9	15.8	99.5	21.7
Generic drugs (Elmed Eisai Co., Ltd.)	10.1	13.5	133.7	13.7
Diagnostic products (EIDIA Co., Ltd.)	4.4	4.3	97.5	6.0

### Japan prescription drugs - major products (Eisai)

Anti-Alzheimer's agent	91.2	56.0	61.4	108.3
Aricept				
Proton pump inhibitor	47.8	38.6	80.7	60.9
Pariet				
Peripheral neuropathy treatment	23.4	20.1	85.9	30.0
Methycobal				
Fully human anti-TNF- $\alpha$ monoclonal antibody	15.4	18.1	118.0	20.5
Humira				
Pain treatment (peripheral neuropathic pain, fibromyalgia)	8.4	10.3	122.7	11.3
Lyrica (co-promotion income)				
Oral anticoagulant	7.6	7.7	101.9	9.9
Warfarin				
Osteoporosis treatment	8.8	6.9	78.8	11.0
Actonel				
Gastritis / gastric ulcer treatment	7.9	6.0	76.6	10.0
Selbex				
Anticancer agent	1.8	4.1	226.4	3.1
Halaven				

### Japan consumer healthcare products - major product groups (Eisai)

Vitamin B2 preparation ("Chocola BB Plus," etc.)	8.5	8.6	101.1	11.3
Chocola BB Group				

### Net sales in China

Billions JPY	13.0	15.8	122.0 <118.2>	16.9
--------------	------	------	------------------	------

### China prescription drugs - major products

Peripheral neuropathy treatment	Billions JPY	5.7	6.8	118.5	7.5
Methycobal	[Millions RMB]	[465]	[534]	<114.8>	[605]
Liver disease / Allergic disease agents	Billions JPY	2.8	3.4	123.8	3.7
Stronger Neo-Minophagen C and Glycyron Tablets	[Millions RMB]	[226]	[271]	<119.9>	[303]
Anti-Alzheimer's agent	Billions JPY	1.3	1.6	124.5	1.6
Aricept	[Millions RMB]	[106]	[127]	<120.6>	[131]
Proton pump inhibitor	Billions JPY	0.8	1.0	125.4	1.2
Pariet	[Millions RMB]	[67]	[82]	<121.5>	[95]

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



## 2) Americas Pharmaceuticals Business (North, Central and South America)

		Nine months ended Dec. 31		
		FY2011	FY2012	YOY %
Net sales	Billions JPY	119.8	114.5	95.5 <94.4>
Segment profit	Billions JPY	24.7	25.7	104.1
<b>Americas prescription drugs - major products</b>				
Proton pump inhibitor Aciphex	Billions JPY [Millions USD]	42.9 [543]	37.8 [473]	88.1 <87.0>
Antiemetic agent Aloxi	Billions JPY	25.9	27.1	105.0 <103.7>
U.S. prescription drugs	Billions JPY [Millions USD]	25.9 [327]	27.1 [339]	105.0 <103.7>
DNA methylation inhibitor Dacogen	Billions JPY [Millions USD]	12.8 [162]	13.5 [169]	105.6 <104.3>
Anti-Alzheimer's agent Aricept	Billions JPY [Millions USD]	9.4 [119]	9.3 [117]	99.2 <98.0>
Anticancer agent Halaven	Billions JPY	7.9	8.5	108.7 <107.3>
U.S. prescription drugs	Billions JPY [Millions USD]	7.9 [99]	8.5 [106]	108.2 <106.9>
Injectable anticoagulant Fragmin	Billions JPY [Millions USD]	10.8 [137]	7.8 [97]	71.8 <70.9>

\* Sales of Aricept 23 mg tablet out of total sales of Aricept for FY2012 (April 1, 2012 to December 31, 2012) totaled ¥4.5 billion (U.S.\$56 million).

\* The U.S. is the only country where Eisai markets Aricept, Aciphex, Dacogen and Fragmin independently.

## 3) EMEA Pharmaceuticals Business (Europe, the Middle East and Africa)

		Nine months ended Dec. 31		
		FY2011	FY2012	YOY %
Net sales	Billions JPY	34.0	18.9	55.5 <59.3>
Segment profit	Billions JPY	5.2	1.3	24.9
<b>EMEA prescription drugs - major products</b>				
Anticancer agent Halaven	Billions JPY	1.2	3.6	315.9 <336.3>
Antiepileptic agent Zonegran	Billions JPY	3.4	3.4	98.6 <105.4>
Proton pump inhibitor Pariet	Billions JPY	4.1	2.4	59.2 <63.0>
Anti-Alzheimer's agent Aricept	Billions JPY	17.1	2.3	13.4 <14.5>

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

#### 4) Indo-Pacific Pharmaceuticals Business (South Asia, ASEAN countries and Oceania)

		Nine months ended Dec. 31		
		FY2011	FY2012	YOY %
Net sales	Billions JPY	5.1	5.1	100.0 <102.1>
Segment profit	Billions JPY	1.4	1.2	90.4
<b>Indo-Pacific prescription drugs - major products</b>				
Anti-Alzheimer's agent Aricept	Billions JPY	1.3	1.3	98.7 <100.5>
Proton pump inhibitor Pariet	Billions JPY	1.3	1.2	95.6 <98.4>
Peripheral neuropathy treatment Methycobal	Billions JPY	0.6	0.7	111.6 <112.9>
Anticancer agent Halaven	Billions JPY	0.0	0.0	134.9 <132.4>

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

## 5) Sales of Major Products

### (1) Oncology-Related Products

		Nine months ended Dec. 31			Full year
		FY2011	FY2012	YOY %	FY2011
<b>Total</b>	Billions JPY	69.1	73.8	106.8 <106.2>	93.1
Halaven (Anticancer agent)	Billions JPY	10.9	16.4	150.5 <151.7>	16.0
East Asia	Billions JPY	1.8	4.1	226.5 <226.5>	3.1
Japan prescription drugs	Billions JPY	1.8	4.1	226.4	3.1
Americas	Billions JPY	7.9	8.5	108.7 <107.3>	10.9
U.S. prescription drugs	Billions JPY [Millions USD]	7.9 [99]	8.5 [106]	108.2 <106.9>	10.9 [137]
EMEA	Billions JPY	1.2	3.6	315.9 <336.3>	2.0
Indo-Pacific	Billions JPY	0.0	0.0	134.9 <132.4>	0.0
Aloxi (Antiemetic agent)	Billions JPY	25.9	27.1	105.0 <103.7>	34.5
U.S. prescription drugs	Billions JPY [Millions USD]	25.9 [327]	27.1 [339]	105.0 <103.7>	34.5 [436]
Dacogen (DNA methylation inhibitor)	Billions JPY [Millions USD]	12.8 [162]	13.5 [169]	105.6 <104.3>	17.3 [219]
Fragmin (Injectable anticoagulant)	Billions JPY [Millions USD]	10.8 [137]	7.8 [97]	71.8 <70.9>	13.9 [176]
Treakisym / Symbenda (Anticancer agent)	Billions JPY	2.5	2.7	109.5 <109.5>	3.2
Other	Billions JPY	6.3	6.3	100.2 <100.7>	8.2

\* The U.S. is the only country where Eisai markets Dacogen and Fragmin independently.

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

		Nine months ended Dec. 31			Full year
		FY2011	FY2012	YOY %	FY2011
<b>Total</b>	Billions JPY	123.4	73.6	59.6 <59.7>	147.1
East Asia	Billions JPY	95.6	60.6	63.5 <63.4>	113.8
Japan prescription drugs	Billions JPY	91.2	56.0	61.4	108.3
Americas	Billions JPY [Millions USD]	9.4 [119]	9.3 [117]	99.2 <98.0>	11.4 [144]
EMEA	Billions JPY	17.1	2.3	13.4 <14.5>	20.1
Indo-Pacific	Billions JPY	1.3	1.3	98.7 <100.5>	1.7

\* Sales of Aricept 23 mg tablet out of total sales of Aricept for FY2012 (April 1, 2012 to December 31, 2012) totaled ¥4.5 billion (U.S.\$56 million).

\* The U.S. is the only country in the Americas where Eisai markets Aricept independently.

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

### (3) Aciphex/Pariet (Proton pump inhibitor)

		Nine months ended Dec. 31			Full year
		FY2011	FY2012	YOY %	FY2011
<b>Total</b>	Billions JPY	98.2	82.1	83.6 <83.3>	126.4
East Asia	Billions JPY	49.9	40.6	81.4 <81.3>	63.6
Japan prescription drugs	Billions JPY	47.8	38.6	80.7	60.9
Americas	Billions JPY [Millions USD]	42.9 [543]	37.8 [473]	88.1 <87.0>	55.9 [707]
EMEA	Billions JPY	4.1	2.4	59.2 <63.0>	5.2
Indo-Pacific	Billions JPY	1.3	1.2	95.6 <98.4>	1.7

\* The U.S. is the only country in the Americas where Eisai markets Aciphex independently.

### (4) Humira (Fully human anti-TNF- $\alpha$ monoclonal antibody)

		Nine months ended Dec. 31			Full year
		FY2011	FY2012	YOY %	FY2011
<b>Total</b>	Billions JPY	18.0	21.6	119.9 <119.9>	24.0
East Asia	Billions JPY	18.0	21.6	119.9 <119.9>	24.0
Japan prescription drugs	Billions JPY	15.4	18.1	118.0	20.5

### 6) Overseas Sales

(billions of yen)

	Nine months ended Dec. 31			Full year
	FY2011	FY2012	YOY %	FY2011
Overseas sales	198.6	172.0	86.6	258.3
Overseas sales (% of total sales)	39.3	39.9	-	39.9

\* Net sales to external customers for each segment.

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

## 5. Sales Forecasts by Reporting Segment (FY2012)

	(billions of yen)		
	Nine months ended Dec. 31	Full year	
	FY2012	FY2011	FY2012 est.
<b>East Asia</b>	274.6	400.4	<u>359.5</u>
<b>Japan</b>	250.0	372.6	<u>328.5</u>
<b>Prescription drugs</b>	216.4	331.2	<u>281.0</u>
Anti-Alzheimer's agent			
Aricept	56.0	108.3	<u>75.0</u>
Proton pump inhibitor			
Pariet	38.6	60.9	<u>50.0</u>
Peripheral neuropathy treatment			
Methycobal	20.1	30.0	<u>26.0</u>
Fully human anti-TNF- $\alpha$ monoclonal antibody			
Humira	18.1	20.5	<u>24.0</u>
Oral anticoagulant			
Warfarin	7.7	9.9	10.0
Osteoporosis treatment			
Actonel	6.9	11.0	10.0
Anticancer agent			
Halaven	4.1	3.1	<u>6.0</u>
<b>Consumer healthcare products, etc.</b>	15.8	21.7	22.0
Vitamin B <sub>2</sub> preparation ("Chocola BB Plus", etc.)			
Chocola BB Group	8.6	11.3	12.0
<b>Generic drugs (Elmed Eisai Co., Ltd.)</b>	13.5	13.7	19.0
<b>Diagnostics (EIDIA Co., Ltd.)</b>	4.3	6.0	6.5
<b>China</b>	15.8	16.9	<u>21.0</u>
<b>Americas</b>	114.5	157.5	<u>157.0</u>
<b>U.S.</b>	114.2	157.4	<u>156.0</u>
<b>EMEA</b>	18.9	42.7	<u>26.0</u>
<b>Indo-Pacific</b>	5.1	6.7	<u>7.5</u>
<b>Other</b>	18.5	40.7	<u>23.5</u>
<b>Consolidated net sales</b>	431.6	648.0	<u>573.5</u>

\* Sales amounts by new reporting segments for FY2011 are provided for reference purposes only.

\* FY2012 sales forecast for Aricept is ¥97.0 billion.

\* FY2012 sales forecast for Pariet/Aciphex is ¥108.5 billion.

\* FY2012 sales forecast for Halaven is ¥24.0 billion.

## 6. Consolidated Balance Sheets

### 1) Consolidated Balance Sheets <Assets>

	(billions of yen)					
	March 31,		Dec. 31,		YOY	Diff.
	2012	%	2012	%	%	
<b>Total current assets</b>	525.8	52.3	511.0	52.8	97.2	(14.8)
Cash and cash in banks	104.4		70.0			(34.4)
Notes and accounts receivable—trade	197.2		180.3			(16.9)
Short-term investments	83.7		110.3			26.6
Inventories	75.2		85.4			10.2
Deferred tax assets	42.5		42.7			0.2
Other	23.0		22.5			(0.5)
Allowance for doubtful receivables	(0.2)		(0.1)			0.0
<b>Total non-current assets</b>	478.8	47.7	457.2	47.2	95.5	(21.6)
Total property, plant and equipment	143.6	14.3	139.1	14.4	96.9	(4.5)
Buildings and structures—net	85.6		83.9			(1.7)
Other—net	58.0		55.2			(2.8)
Total Intangible assets	238.6	23.8	228.4	23.6	95.7	(10.2)
Goodwill	119.1		119.3			0.2
Sales rights	65.3		55.3			(10.1)
Core technology	40.5		41.0			0.5
Other	13.8		12.8			(0.9)
Total investments and other assets	96.6	9.6	89.7	9.3	92.9	(6.9)
Investment securities	39.1		37.9			(1.2)
Deferred tax assets	45.1		45.7			0.6
Other	12.6		6.3			(6.3)
Allowance for doubtful receivables	(0.2)		(0.2)			0.0
<b>Total assets</b>	1,004.7	100.0	968.2	100.0	96.4	(36.4)

#### Notes

##### Total assets

Decrease in cash and cash in banks due to repayment of long-term borrowings of ¥40.0 billion

## 2) Consolidated Balance Sheets <Liabilities and Equity>

(billions of yen)

	March 31, 2012	%	Dec. 31, 2012	%	YOY %	Diff.
<b>Total current liabilities</b>	207.9	20.7	231.3	23.9	111.2	23.3
Notes payable—trade and accounts payable—trade	26.2		24.3			(1.9)
Short-term borrowings	6.0		3.6			(2.4)
Long-term borrowings (current portion)	40.0		17.3			(22.7)
Commercial paper	-		25.0			25.0
Bonds and debentures (current portion)	-		50.0			50.0
Accounts payable—other / Accrued expenses	97.6		81.9			(15.7)
Income tax payable	11.3		5.9			(5.4)
Reserve for sales rebates	16.5		14.2			(2.2)
Other	10.4		9.0			(1.4)
<b>Total non-current liabilities</b>	373.3	37.2	307.0	31.7	82.2	(66.3)
Bonds and debentures	80.0		30.0			(50.0)
Long-term borrowings	219.3		204.6			(14.7)
Deferred tax liabilities	23.0		18.8			(4.2)
Liability for retirement benefits	31.4		25.7			(5.7)
Other	19.6		27.8			8.2
<b>Total liabilities</b>	581.2	57.9	538.3	55.6	92.6	(43.0)
<b>Total shareholders' equity</b>	526.6	52.4	518.0	53.5	98.4	(8.6)
Common stock	45.0		45.0			-
Capital surplus	56.9		56.9			(0.0)
Retained earnings	464.2		455.4			(8.7)
Treasury stock	(39.4)		(39.3)			0.1
<b>Total accumulated other comprehensive income (loss)</b>	(109.8)	(10.9)	(92.8)	(9.6)	84.5	17.0
Valuation difference on available-for-sale securities	1.2		0.8			(0.4)
Deferred gain (loss) on derivatives under hedge accounting	(1.1)		(1.1)			(0.0)
Foreign currency translation adjustments	(110.0)		(92.6)			17.4
Stock options	1.0	0.1	1.1	0.1	108.0	0.1
Minority interests	5.6	0.6	3.7	0.4	66.4	(1.9)
<b>Total equity</b>	423.4	42.1	430.0	44.4	101.5	6.6
<b>Total liabilities and equity</b>	1,004.7	100.0	968.2	100.0	96.4	(36.4)

### Notes

#### Total liabilities

Decrease in liabilities due to repayment of long-term borrowings of ¥40.0 billion

#### Total equity <Reason for Increase>

Increase in yen equivalent amount of equity of overseas subsidiaries due to yen depreciation

## 7. Changes in Consolidated Quarterly Results

### 1) Income Statement Data

	(billions of yen)							
	FY2011				FY2012			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	
Net sales	167.3	163.7	173.8	143.2	146.9	141.6	143.1	
Cost of sales	43.0	42.7	43.6	44.1	43.2	41.8	43.2	
R&D expenses	33.7	29.2	31.0	31.3	28.4	29.1	29.8	
SG&A expenses	68.4	63.6	67.4	54.3	56.2	52.5	53.3	
Operating income	22.2	28.2	31.8	13.5	19.1	18.2	16.8	
Ordinary income	21.2	26.2	30.6	12.1	17.9	16.6	15.7	
Net income	13.5	19.8	15.9	9.3	11.9	12.6	9.5	
Cash income	25.9	31.8	28.0	22.0	24.3	25.9	22.8	
Comprehensive Income	4.7	1.5	18.2	31.3	(1.1)	8.5	43.7	
Earnings per share (EPS, yen)	47.4	69.6	55.7	32.7	41.7	44.2	33.4	
Cash income per share (Cash EPS, yen)	90.8	111.6	98.3	77.2	85.1	90.8	79.9	

\* "Cost of sales" includes "Provision for (reversal of) sales returns—net."

### 2) Cash Flow Segment Data

	(billions of yen)							
	FY2011				FY2012			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	
Net cash provided by (used in) operating activities	7.8	28.6	18.5	35.8	28.3	8.6	16.6	
Net cash provided by (used in) investing activities	28.2	(16.2)	(1.9)	(12.7)	7.2	24.2	(10.4)	
Net cash provided by (used in) financing activities	(63.1)	(0.3)	6.8	(21.3)	(20.6)	(42.6)	2.3	
Cash and cash equivalents at the end of period	73.9	81.2	104.9	112.6	123.3	112.3	133.3	
Free cash flow	4.2	24.5	14.4	28.3	22.3	3.3	13.4	

\* "Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (cash basis)"

### 3) Balance Sheet Data

	(billions of yen)							
	FY2011				FY2012			
	June 30	Sep.30	Dec.31	March 31	June 30	Sep.30	Dec.31	
Total assets	959.6	943.2	970.5	1,004.7	977.2	921.9	968.2	
Liabilities	567.2	549.4	578.4	581.2	577.7	515.8	538.3	
Borrowings	258.4	256.0	283.6	265.3	266.1	222.6	225.5	
Commercial paper	-	-	-	-	-	-	25.0	
Bonds and debentures	80.0	80.0	80.0	80.0	80.0	80.0	80.0	
Equity	392.3	393.9	392.1	423.4	399.5	406.1	430.0	
Shareholders' equity	386.1	387.7	385.8	416.8	392.9	401.4	425.2	
Shareholders' equity ratio (%)	40.2	41.1	39.8	41.5	40.2	43.5	43.9	
Liabilities ratio (Net DER/times)	0.56	0.47	0.49	0.38	0.39	0.38	0.35	

\* "Liabilities ratio (Net DER)" = ("Interest-bearing debt" ("Borrowings" + "Bonds and debentures") - "Cash and cash in banks" - "Short-term investments") / "Shareholders' equity"



**4) Capital Expenditures and Depreciation/Amortization**

(billions of yen)

	FY2011				FY2012		
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
Capital expenditures	2.7	4.2	4.8	9.0	7.0	4.4	3.6
Property, plant and equipment	1.8	2.7	2.6	5.6	1.3	2.2	1.5
Intangible assets	0.9	1.6	2.2	3.3	5.6	2.2	2.0
Depreciation and amortization	10.5	10.2	10.2	10.8	10.2	10.6	10.9

\* "Depreciation and amortization" includes amortization of "Intangible assets."

## 5) Sales of Major Products

### (1) Oncology-Related Products

		FY2011				FY2012		
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
<b>Total</b>	Billions JPY	24.0	22.3	22.8	24.0	25.2	23.3	25.3
Halaven	Billions JPY	2.6	3.6	4.6	5.1	5.5	5.3	5.6
East Asia	Billions JPY	-	0.6	1.2	1.3	1.3	1.4	1.4
Japan prescription drugs	Billions JPY	-	0.6	1.2	1.3	1.3	1.4	1.4
Americas	Billions JPY	2.5	2.6	2.8	3.0	3.1	2.7	2.7
U.S. prescription drugs	Billions JPY	2.5	2.6	2.8	3.0	3.1	2.7	2.7
	[Millions USD]	[31]	[33]	[35]	[38]	[39]	[34]	[34]
EMEA	Billions JPY	0.1	0.4	0.6	0.8	1.0	1.2	1.4
Indo-Pacific	Billions JPY	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Aloxi	Billions JPY	9.7	8.6	7.6	8.6	9.5	8.4	9.3
U.S. prescription drugs	Billions JPY	9.7	8.6	7.6	8.6	9.5	8.4	9.3
	[Millions USD]	[118]	[111]	[98]	[109]	[119]	[107]	[114]
Dacogen	Billions JPY	4.9	3.6	4.3	4.5	4.4	4.4	4.8
	[Millions USD]	[60]	[46]	[56]	[57]	[55]	[55]	[59]
Fragmin	Billions JPY	3.5	3.7	3.5	3.1	2.9	2.5	2.4
	[Millions USD]	[43]	[48]	[46]	[40]	[36]	[32]	[30]
Treakisym / Symbenda	Billions JPY	0.8	0.8	0.8	0.7	0.9	0.9	0.9
Other	Billions JPY	2.5	1.9	1.9	1.9	2.0	1.9	2.4

\* The U.S. is the only country where Eisai markets Dacogen and Fragmin independently.

### (2) Aricept

		FY2011				FY2012		
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
<b>Total</b>	Billions JPY	42.0	39.3	42.0	23.7	27.3	26.2	20.1
East Asia	Billions JPY	30.0	30.4	35.2	18.3	23.3	20.1	17.3
Japan prescription drugs	Billions JPY	28.5	29.0	33.7	17.1	21.7	18.6	15.7
Americas	Billions JPY	4.7	2.6	2.1	2.0	2.4	5.1	1.9
	[Millions USD]	[57]	[35]	[27]	[25]	[30]	[64]	[23]
EMEA	Billions JPY	6.8	5.9	4.4	3.0	1.2	0.6	0.5
Indo-Pacific	Billions JPY	0.5	0.4	0.4	0.4	0.4	0.4	0.4

\* The U.S. is the only country in the Americas where Eisai markets Aricept independently.

### (3) Aciphex/Pariet

		<u>FY2011</u>				<u>FY2012</u>		
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
<b>Total</b>	Billions JPY	33.2	30.1	34.9	28.2	28.5	24.8	28.8
East Asia	Billions JPY	15.5	15.6	18.8	13.8	13.8	13.3	13.5
Japan prescription drugs	Billions JPY	14.8	14.9	18.1	13.1	13.1	12.7	12.8
Americas	Billions JPY	15.8	12.7	14.4	12.9	13.2	10.2	14.4
	[Millions USD]	[194]	[164]	[186]	[163]	[164]	[131]	[178]
EMEA	Billions JPY	1.4	1.3	1.4	1.1	1.2	0.8	0.5
Indo-Pacific	Billions JPY	0.4	0.5	0.3	0.4	0.4	0.4	0.4

\* The U.S. is the only country in the Americas where Eisai markets Aciphex independently.

### (4) Humira

		<u>FY2011</u>				<u>FY2012</u>		
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter
<b>Total</b>	Billions JPY	5.5	5.9	6.6	6.0	6.8	7.2	7.6
East Asia	Billions JPY	5.5	5.9	6.6	6.0	6.8	7.2	7.6
Japan prescription drugs	Billions JPY	4.6	5.0	5.7	5.1	5.8	6.1	6.3

## 8. Non-consolidated Financial Highlights

### 1) Non-consolidated Financial Highlights

#### (1) Income Statement Data

	(billions of yen)			
	Nine months ended Dec. 31			Full Year
	FY2011	FY2012	YOY %	FY2011
Net sales	322.4	264.0	81.9	408.2
Cost of sales	71.4	73.8	103.4	94.7
R&D expenses	87.1	82.1	94.3	116.3
SG&A expenses	102.0	81.0	79.4	130.3
Operating income	62.0	27.1	43.7	66.9
Ordinary income	59.0	24.3	41.2	62.9
Net income	37.6	17.6	46.9	42.4

\* "Cost of sales" includes "Provision for (reversal of) sales returns—net."

#### (2) Cash Flow Statement Data

	(billions of yen)			
	Nine months ended Dec. 31			Full Year
	FY2011	FY2012	Diff.	FY2011
Net cash provided by (used in) operating activities	38.9	28.1	(10.7)	63.5
Net cash provided by (used in) investing activities	14.3	27.3	13.1	4.7
Net cash provided by (used in) financing activities	(56.5)	(60.7)	(4.2)	(77.7)
Cash and cash equivalents at end of period	19.7	8.3	(11.4)	13.5
Free cash flow	32.1	19.2	(12.9)	52.3

\* "Free cash flow" = "Net cash provided by (used in) operating activities" - "Capital expenditures (cash basis)"

#### (3) Balance Sheet Data

	(billions of yen)			
	2012			Diff.
	March 31	Dec. 31		
Total assets	942.7	887.3	(55.4)	
Liabilities	414.1	384.2	(29.9)	
Borrowings	216.0	173.5	(42.5)	
Commercial paper	-	25.0	25.0	
Bonds and debentures	80.0	80.0	0.0	
Equity	528.6	503.1	(25.5)	
Shareholders' equity	527.6	502.0	(25.6)	
Shareholders' equity ratio (%)	56.0	56.6	0.6	

#### 2) Net Sales Highlights

	(billions of yen)			
	Nine months ended Dec. 31			Full year
	FY2011	FY2012	YOY %	FY2011
Net sales	322.4	264.0	81.9	408.2
Prescription drugs	263.8	216.3	82.0	331.0
Consumer healthcare products, etc.	16.1	16.0	99.4	21.9
Industrial property rights, etc.	15.7	3.4	21.9	18.4
Export of pharmaceuticals	26.1	27.3	104.6	35.7
Other	0.8	0.9	119.2	1.2

## 9 . Major News Releases

Date	Description
April 2012	<ul style="list-style-type: none"> <li>• Eisai and Minophagen Pharmaceutical Conclude License Agreement Concerning the Development and Commercialization of Cutaneous T-Cell Lymphoma Treatment Bexarotene in Asia, Oceania, the Middle East and Eastern Europe, etc. &lt;issued on April 2&gt;</li> <li>• Eisai Diagnostics Subsidiary EIDIA Enters into Sales Agreements with Medical Equipment Manufacturers for PROTOCO2L Carbon Dioxide Insufflation System for CT Colonography &lt;issued on April 3&gt;</li> <li>• Eisai Enters into Partnership with PharmaSwiss for Halaven (eribulin) Promotion and Distribution in Central and Eastern European (CEE) Countries &lt;issued on April 5&gt;</li> <li>• Eisai to Launch Insomnia Treatment Lunesta in Japan &lt;issued on April 17&gt;</li> <li>• Eisai Amends License Agreement with Teikoku Pharma USA for Aricept Transdermal Patch System &lt;issued on April 20&gt;</li> <li>• Abbott Japan and Eisai Have Cleared the Condition for Approval of Humira, a Fully Human Anti-TNF-<math>\alpha</math> Monoclonal Antibody, for Plaque Psoriasis and Psoriasis Arthropica in Terms of the All-Case Surveillance &lt;issued on April 23&gt;</li> <li>• German Federal Regulator Confirms Additional Benefit of Anticancer Agent Halaven for Metastatic or Locally Advanced Breast Cancer &lt;issued on April 23&gt;</li> </ul>
May	<ul style="list-style-type: none"> <li>• Eisai's US Research Subsidiary H3 Biomedicine to Collaborate with UK-Based Horizon Discovery to Identify and Validate Novel, Patient-Relevant Cancer Targets &lt;issued on May 2&gt;</li> <li>• Anti-obesity Agent Lorcaserin Receives Positive Vote from FDA Advisory Committee &lt;issued on May 11&gt;</li> <li>• Eisai Inc. Expands Marketing and Supply Agreement with Arena for Antiobesity Agent Lorcaserin &lt;issued on May 11&gt;</li> <li>• Issuance of Stock Acquisition Rights for the Purpose of Granting Stock Options to the Company's Employees &lt;issued on May 15&gt;</li> <li>• Eisai to Present New Research on Oncology Product Portfolio and Pipeline at 48th ASCO Annual Meeting &lt;issued on May 18&gt;</li> <li>• Eisai Launches New Mobile Website to Support Reflux Esophagitis Patients in Taking Their Medication &lt;issued on May 22&gt;</li> <li>• Sannova Receives Approval for Additional Indication, Additional Dosage and Administration of Kaytwo Syrup 0.2% for Prevention of Vitamin K Deficiency Hemorrhage in Neonates and Infants &lt;issued on May 25&gt;</li> <li>• Eisai Receives Positive CHMP Opinion for Zonegran (zonisamide) Monotherapy Treatment for Epilepsy &lt;issued on May 28&gt;</li> <li>• Eisai Gains Positive CHMP Opinion for AMPA Receptor Antagonist Fycompa (perampanel) &lt;issued on May 28&gt;</li> <li>• Eisai Seeks Approval to Market Pariet Triple Formulation Pack in Japan for <i>Helicobacter pylori</i> Eradication &lt;issued on May 31&gt;</li> </ul>
June	<ul style="list-style-type: none"> <li>• Notice on Allocation of Stock Options (Stock Acquisition Rights) &lt;issued on June 21&gt;</li> <li>• Lyrica Capsules Approved in Japan for Additional Indication of Pain Associated with Fibromyalgia &lt;issued on June 22&gt;</li> <li>• Eisai Receives Russian Regulatory Approval for First Product—Antiepileptic Agent Zonegran &lt;issued on June 27&gt;</li> <li>• U.S. FDA Approves Antiobesity Agent BELVIQ (lorcaserin HCl) for Adults &lt;issued on June 28&gt;</li> <li>• Eisai and Toyama Chemical Receive Approval to Market Anti-rheumatic Agent Igaratimod in Japan &lt;issued on June 29&gt;</li> </ul>
July	<ul style="list-style-type: none"> <li>• EMA Accepts Eisai's License Extension Application for Use of Antiepileptic Agent Zonegran in Pediatric Patients &lt;issued on July 3&gt;</li> <li>• Eisai Receives EMA Approval to Market Zonegran Monotherapy for Treatment of Epilepsy &lt;issued on July 3&gt;</li> <li>• Eisai Announces Launch of Chocola BB Fresh II, a Nutritional Vitamin Drink to Relieve Fatigue &lt;issued on July 4&gt;</li> <li>• Notice on Determination of Details of Stock Options (Stock Acquisition Rights) to Be Allotted &lt;issued on July 9&gt;</li> <li>• Eisai Announces Preliminary Results of Phase III Study (STUDY 301) of Anticancer Agent Halaven Versus Capecitabine in Locally Advanced or Metastatic Breast Cancer &lt;issued on July 10 &gt;</li> <li>• Eisai to Present First Clinical Data for BACE Inhibitor E2609 at Alzheimer's Association International Conference 2012 &lt;issued on July 13&gt;</li> <li>• Eisai Enters Research Collaboration with Verastem, Inc. for Small Molecule Wnt Inhibitors &lt;issued on July 17&gt;</li> <li>• Eisai Presents First Clinical Data for BACE Inhibitor E2609 at Alzheimer's Association International Conference 2012 &lt;issued on July 19 &gt;</li> <li>• Eisai Announces Full-Scale Launch of Chocola BB Sparkling White Grape Flavor &lt;issued on July 24 &gt;</li> </ul>

Date	Description
July 2012	<ul style="list-style-type: none"> <li data-bbox="268 215 1299 277">• European Commission Approves Eisai's AMPA Receptor Antagonist Fycompa (perampanel) &lt;issued on July 27&gt;</li> <li data-bbox="268 282 1299 344">• Eisai Receives Antiobesity Agent BELVIQ (lorcaserin HCl) NDA from Arena Pharmaceuticals &lt;issued on July 30&gt;</li> <li data-bbox="268 349 1299 412">• KAN Research Institute to Relocate to New Facility Inside International Strategic Innovation Zone &lt;issued on July 30&gt;</li> </ul>
August	<ul style="list-style-type: none"> <li data-bbox="268 423 1458 486">• Continuation of "Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders (Shareholder Rights Plan)" &lt;issued on August 1&gt;</li> <li data-bbox="268 490 1458 591">• Abbott Japan and Eisai Receive Approval to Market the Fully Human Anti-TNF-<math>\alpha</math> Monoclonal Antibody Humira (adalimumab) for the Inhibition of Structural Damage of Joints in Patients with Rheumatoid Arthritis &lt;issued on August 10&gt;</li> <li data-bbox="268 595 1458 624">• Morphotek Opens Pilot Antibody Manufacturing Plant &lt;issued on August 15&gt;</li> <li data-bbox="268 629 1458 692">• Eisai Announces Launch of Chocola BB Fe Charge, a Delicious, Easy-to-Drink Iron Supplement &lt;issued on August 20&gt;</li> <li data-bbox="268 696 1458 725">• Eisai Receives Orphan Drug Designation for Anticancer Agent Lenvatinib in Japan &lt;issued on August 20&gt;</li> <li data-bbox="268 730 1458 792">• Eisai Submits Application in Japan for Antiepileptic Agent Rufinamide for Lennox-Gastaut Syndrome &lt;issued on August 30&gt;</li> <li data-bbox="268 797 1458 904">• Companies Submit Joint Application Seeking Approval for Additional Indication for <i>Helicobacter pylori</i> Eradication by Concomitant Therapy with Proton Pump Inhibitors, Amoxicillin Hydrate and either Clarithromycin or Metronidazole &lt;issued on August 31&gt;</li> </ul>
September	<ul style="list-style-type: none"> <li data-bbox="268 916 1458 945">• Eisai Receives Approval for Anticancer Agent Halaven in South Korea &lt;issued on September 3&gt;</li> <li data-bbox="268 949 1458 978">• Eisai Receives Approval to Market Anticancer Agent Halaven in Australia &lt;issued on September 7&gt;</li> <li data-bbox="268 983 1458 1012">• Eisai Announces Launch of Anti-rheumatic Agent Careram &lt;issued on September 11&gt;</li> <li data-bbox="268 1016 1458 1079">• Companies Announce Reimbursement Approval and Launch of CoaguChek XS Personal, a Coagulation Analyzer for Patient Self-Testing &lt;issued on September 11&gt;</li> <li data-bbox="268 1084 1458 1146">• Eisai Announces Launch of Crystal Veil <math>\alpha</math>, a Topical Nasal Gel That Blocks Viruses from Entering the Body Through the Nose &lt;issued on September 12&gt;</li> <li data-bbox="268 1151 1458 1214">• Eisai Announces Launch of Crystal Veil Mask Bokin 24, A New 24-hour Mask Spray That Contains the Long-Acting Antimicrobial Agent Etak &lt;issued on September 12&gt;</li> <li data-bbox="268 1218 1458 1281">• Eisai Partners with the Sabin Vaccine Institute in an Effort to Develop Vaccines for Neglected Tropical Diseases &lt;issued on September 12&gt;</li> <li data-bbox="268 1285 1458 1348">• Eisai Announces Launch of AMPA Receptor Antagonist Fycompa for the Treatment of Epilepsy &lt;issued on September 13&gt;</li> <li data-bbox="268 1352 1458 1415">• Eisai Announces Launch of Chocola BB Hyper, a Nutritional Supplement Drink for the Relief of Extreme Fatigue and Exhaustion &lt;issued on September 25&gt;</li> <li data-bbox="268 1420 1458 1449">• Eisai and Santen Enter into Option Agreement for New Ophthalmic Drugs &lt;issued on September 25&gt;</li> <li data-bbox="268 1453 1458 1516">• Eisai Opens New Solid Dose Global Manufacturing Line for Antiepileptic Agent Fycompa at Its Production Plant in Hatfield, U.K. &lt;issued on September 25&gt;</li> <li data-bbox="268 1520 1458 1583">• Eisai Demand Chain Systems (EDCS) to Undergo Transformation with the Introduction of a New Global Production Structure &lt;issued on September 27&gt;</li> </ul>
October	<ul style="list-style-type: none"> <li data-bbox="268 1588 1458 1650">• Eisai Group to Transform Its Product Creation Structure to Reflect Focus on Personalized Medicine &lt;issued on October 10&gt;</li> <li data-bbox="268 1655 1458 1718">• U.S. FDA Approves Eisai's AMPA Receptor Antagonist Fycompa (perampanel) as Adjunctive Treatment for Partial-Onset Seizures in Patients with Epilepsy Age 12 and Older &lt;issued on October 23&gt;</li> <li data-bbox="268 1722 1458 1785">• Eisai Signs Global Agreement with Fundação Oswaldo Cruz to Begin Development of New Medicines and Vaccines for Malaria and Neglected Tropical Diseases &lt;issued on October 25&gt;</li> <li data-bbox="268 1789 1458 1852">• Abbott Japan and Eisai Clear All-Case Surveillance Condition for Approval of Humira, a Fully Human Anti-TNF-<math>\alpha</math> Monoclonal Antibody, in the Treatment of Crohn's Disease &lt;issued on October 29&gt;</li> </ul>
November	<ul style="list-style-type: none"> <li data-bbox="268 1868 1458 1930">• Eisai to Offer Donations to Hurricane Sandy New Jersey Relief Fund and American Red Cross &lt;issued on November 20&gt;</li> <li data-bbox="268 1935 1458 1998">• Eisai to Present New Research on Halaven at 35th Annual San Antonio Breast Cancer Symposium &lt;issued on November 29&gt;</li> <li data-bbox="268 2002 1458 2051">• Pediatric NDA for Proton-Pump Inhibitor Aciphex Granted Priority Review In The U.S. &lt;issued on November 30&gt;</li> </ul>

Date	Description
December	<ul style="list-style-type: none"> <li data-bbox="277 219 1465 286">• Phase III Study (Study 301) Results of Anticancer Agent Halaven Versus Capecitabine In Locally Advanced Or Metastatic Breast Cancer Presented At 2012 SABCS &lt;issued on December 7&gt;</li> <li data-bbox="277 293 1465 360">• Eisai Receives Six-Month Pediatric Exclusivity for Proton-Pump Inhibitor Aciphex in the U.S. &lt;issued on December 10&gt;</li> <li data-bbox="277 367 1465 434">• Scottish Medicines Consortium Approves AMPA Receptor Antagonist Fycompa As Antiepileptic Treatment Under National Health Service Scotland &lt;issued on December 11&gt;</li> <li data-bbox="277 441 1465 508">• Eisai North Carolina Plant Enters into Strategic Manufacturing Alliance Agreement with U.S.'s Biogen Idec &lt;issued on December 13&gt;</li> <li data-bbox="277 515 1465 582">• Eisai and UCL Form Major Drug Discovery Alliance to Develop New Therapeutics for Neurological Diseases &lt;issued on December 14&gt;</li> <li data-bbox="277 589 1465 656">• U.S. Subsidiary Eisai Inc. Divests U.S. Rights for Antineoplastic Gliadel Wafer to Arbor Pharmaceuticals, Inc. &lt;issued on December 18&gt;</li> <li data-bbox="277 663 1465 712">• Approval of A Once-Monthly Formulation of Risedronate Sodium Hydrate, an Antiosteoporotic Agent in Japan &lt;issued on December 25&gt;</li> </ul>
January 2013	<ul style="list-style-type: none"> <li data-bbox="277 719 1465 786">• Novartis Pharma and Eisai Terminate Co-Promotion Agreement for COPD Therapies &lt;issued on January 7&gt;</li> <li data-bbox="277 792 1465 860">• Eisai Signs Agreement with Epizyme and Roche Molecular Systems to Develop Companion Diagnostic &lt;issued on January 8&gt;</li> <li data-bbox="277 866 1465 934">• Nobel Pharma and Eisai Announce Japan Launch of Antineoplastic Agent Gliadel 7.7mg Implant &lt;issued on January 8&gt;</li> <li data-bbox="277 940 1465 992">• Eisai Announces Results of Phase III Study of Anticancer Agent Farletuzumab in Patients with Relapsed Platinum-Sensitive Ovarian Cancer &lt;issued on January 11&gt;</li> </ul>

# 10. Major R&D Pipeline

## In-house R&D Pipeline List

Product Name / Research Code	Additional Indication, etc.*	Development Stage**	Therapeutic Area
<b>New Approval</b>			
◎ Fycompa (Partial-onset seizures)		(US/EU) approved	Neurology
○ Careram (Rheumatoid arthritis)		(JP) approved	Vascular and Immunological Reaction
○ Zonegran (Monotherapy for partial-onset seizures)	AI	(EU) approved	Neurology
○ Humira (Inhibition of structural damage of joints)	AI	(JP) approved	Vascular and Immunological Reaction
<b>Submitted / Preparing for Submission</b>			
○ E2080 (Lennox-Gastaut syndrome (LGS))		(JP) submitted	Neurology
E7040 (Transcatheter arterial embolization (TAE) of hepatocellular carcinoma)		(JP) submitted	Oncology and Supportive Care
clevudine (Chronic hepatitis B)		(CN) submitted	Gastrointestinal and Hepatic Disorders
cinitapride (Functional dyspepsia)		(CN) submitted	Gastrointestinal and Hepatic Disorders
○ Zonegran (Pediatric partial-onset seizures)	AI	(EU) submitted	Neurology
Dacogen (Acute myeloid leukemia (AML))	AI	(US) submitted	Oncology and Supportive Care
◎ Aciphex (Pediatric sprinkle capsule formulation)	AI, AF	(US) submitted	Gastrointestinal and Hepatic Disorders
○ Pariet (Concomitant therapy for <i>Helicobacter pylori</i> eradication in <i>Helicobacter pylori</i> gastritis)	AI	(JP) submitted	Gastrointestinal and Hepatic Disorders
Humira (Ulcerative colitis)	AI	(JP) submitted	Vascular and Immunological Reaction
Aricept (Dry syrup)	AF	(JP) submitted	Neurology
○ Pariet (Triple formulation pack for <i>Helicobacter pylori</i> eradication)	AF	(JP) submitted	Gastrointestinal and Hepatic Disorders
<b>Clinical</b>			
Fycompa (Partial-onset seizures)		(JP/CN/AS) PIII	Neurology
E5501 (Idiopathic thrombocytopenic purpura (ITP))		(US/EU/AS) PIII	Vascular and Immunological Reaction
E5564 (Severe sepsis)		(JP/US/EU) PIII	Vascular and Immunological Reaction
○ E7040 (Transcatheter arterial embolization (TAE) of hypervascular tumors)		(JP) PIII	Oncology and supportive care
E7080 (Thyroid cancer)		(JP/US/EU/AS) PIII	Oncology and Supportive Care
◎ E7080 (Hepatocellular carcinoma)		(JP/US/EU/CN/AS) PIII	Oncology and Supportive Care
MORAb-003 (Platinum-sensitive ovarian cancer)		(JP/US/EU/AS) PIII	Oncology and Supportive Care
Fycompa (Generalized seizures)	AI	(JP/US/EU/AS) PIII	Neurology
Halaven (Second-line treatment for breast cancer)	AI	(US/EU) PIII	Oncology and Supportive Care
Halaven (Non-small cell lung cancer)	AI	(JP/US/EU/AS) PIII	Oncology and Supportive Care
Halaven (Sarcoma)	AI	(US/EU/AS) PIII	Oncology and Supportive Care
Aricept (Lewy body dementia)	AI	(JP) PIII	Neurology
Aricept (Severe Alzheimer's disease)	AI	(CN)PIII	Neurology
Inoveron/BANZEL/E2080 (Pediatric Lennox-Gastaut syndrome)	AI	(US/EU) PIII	Neurology
Aricept (Higher dose 23 mg tablet)	ADA, AF	(JP) PIII	Neurology
E0302 (Amyotrophic lateral sclerosis (ALS))		(JP) PII/III	Neurology
AS-3201 (Diabetic neuropathy)		(US/EU) PII/III	Neurology
Pariet (Prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin)	AI	(JP) PII/III	Gastrointestinal and Hepatic Disorders
◎ BAN2401 (Alzheimer's disease)		(US/EU) PII	Neurology
E5501 (Thrombocytopenia in chronic liver disease requiring surgery)		(US) PII	Vascular and Immunological Reaction
E5501 (Thrombocytopenia during interferon therapy (both initiation and maintenance) for hepatitis C)		(US) PII	Vascular and Immunological Reaction
E6005 (Atopic dermatitis)		(JP) PII	Vascular and Immunological Reaction
E6201 (Psoriasis)		(US/EU) PII	Vascular and Immunological Reaction
E7080 (Endometrial cancer)		(US/EU) PII	Oncology and Supportive Care
E7080 (Melanoma)		(US/EU) PII	Oncology and Supportive Care
E7080 (Glioma)		(US) PII	Oncology and Supportive Care
E7080 (Non-small cell lung cancer)		(JP/US/EU/AS) PII	Oncology and Supportive Care
E7820 (Colorectal cancer)		(US/EU) PII	Oncology and Supportive Care
○ E7016 (Melanoma)		(US) PII	Oncology and Supportive Care
MORAb-003 (Non-small cell lung cancer)		(US/EU) PII	Oncology and Supportive Care
MORAb-004 (Melanoma)		(US/EU) PII	Oncology and Supportive Care
MORAb-004 (Colorectal cancer)		(US/EU) PII	Oncology and Supportive Care
○ MORAb-004 (Sarcoma)		(US/EU) PII	Oncology and Supportive Care
MORAb-009 (Mesothelioma)		(US/EU) PII	Oncology and Supportive Care
Fycompa (Pediatric partial-onset seizures)	AI	(US/EU) PII	Neurology
Halaven (Sarcoma)	AI	(JP) PII	Oncology and Supportive Care
Ontak (Melanoma)	AI	(US) PII	Oncology and Supportive Care
Dacogen (Pediatric acute myeloid leukemia (AML))	AI	(US) PII	Oncology and Supportive Care
Pariet (Functional dyspepsia)	AI	(JP) PII	Gastrointestinal and Hepatic Disorders

\* AI: Additional Indication, ADA: Additional Dosage & Administration, AF: Additional Formulation

\*\* P: Clinical phase; JP: Japan, US: United States, EU: Europe, CN: China, AS: Asia (excluding Japan and China)

○ Development progress from April 2012 onwards

◎ Development progress from October 2012 onwards



## (1) Oncology and Supportive Care

Product Name: **Halaven** Research Code: **E7389** Generic Name: **eribulin** (Anticancer agent / microtubule dynamics inhibitor)

Description: A synthetic analog of halichondrin B derived from the marine sponge, *Halichondria okadai*. Believed to exert an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Currently being investigated as a potential treatment for breast cancer and various other solid tumors. Approved in 44 countries including the United States, Singapore, European Union (EU) member states, Japan, and Switzerland.

<b>Additional Indication:</b> Second-line treatment for breast cancer	US/EU: PIII	Submission Target FY2012	Inj.
<b>Additional Indication:</b> Non-small cell lung cancer	JP/US/EU/AS: PIII	Submission Target FY2013	Inj.
<b>Additional Indication:</b> Sarcoma	US/EU/AS: PIII JP: PII	Submission Target FY2014	Inj.

- Based on the results of a Phase III study conducted in the United States and Europe that evaluated the drug as a potential second-line chemotherapy in the treatment of breast cancer, MAA submission for an additional indication in Europe is currently in preparation. A development plan including NDA submission for the United States is under consideration.
- The submission timeline for non-small cell lung cancer has been reviewed and subsequently changed from FY2014 to FY2013.

Research Code: **E7820** (Anticancer agent / alpha 2 integrin suppressant)

Description: An angiogenesis inhibitor that suppresses the expression of alpha 2 integrin, a vascular endothelial cell adhesion molecule.

Colorectal cancer	US/EU: PII	Oral
-------------------	------------	------

Research Code: **E7080** Generic Name: **lenvatinib**

(Anticancer agent / VEGF receptor tyrosine kinase inhibitor / multi-kinase inhibitor)

Description: An anti-angiogenic agent that inhibits tyrosine kinase of the VEGF receptor, VEGFR2, and a number of other types of kinase involved in angiogenesis and tumor proliferation. Currently being investigated as a potential treatment for various solid tumors.

Thyroid cancer	JP/US/EU/AS: PIII	Submission Target FY2013	Oral
⊙ Hepatocellular carcinoma	JP/US/EU/CN/AS: PIII		Oral
Endometrial cancer	US/EU: PII		Oral
Melanoma	US/EU: PII		Oral
Glioma	US: PII		Oral
Non-small cell lung cancer	JP/US/EU/AS: PII		Oral

Research Code: **E7016** (Anticancer agent / poly (ADP-ribose) polymerase inhibitor)

Description: Poly (ADP-ribose) polymerase (PARP) is an enzyme that is involved in DNA repair. PARP inhibitors exhibit an antitumor effect by inhibiting DNA repair in tumor cells and are expected to enhance the effect of chemotherapy and radiotherapy, both of which damage DNA.

○ Melanoma	US: PII	Oral
------------	---------	------

Research Code: **MORAb-003** Generic Name: **farletuzumab** (Anticancer agent / humanized anti-FRA monoclonal antibody)

Description: A humanized IgG1 monoclonal antibody that targets folate receptor alpha (FRA). Expected to exhibit an antitumor effect against carcinomas that over-express FRA.

Platinum-sensitive ovarian cancer	JP/US/EU/AS: PIII	Inj.
Non-small cell lung cancer	US/EU: PII	Inj.

- Based on the topline results of a Phase III study of patients with platinum-sensitive ovarian cancer, the development strategy (previous submission timeline: FY2012) is being reviewed and a new development plan will be determined after further analysis of the clinical results and discussion with external experts and the relevant health authorities.

Research Code: **MORAb-004** (Anticancer agent / humanized anti-endosialin monoclonal antibody)

Description: A humanized IgG1 monoclonal antibody that targets Tumor Endothelial Marker 1 (TEM-1) / endothialin. Expected to exhibit an antitumor effect against carcinomas that express endothialin.		
Melanoma	US/EU: PII	Inj.
Colorectal cancer	US/EU: PII	Inj.
<input type="radio"/> Sarcoma	US/EU: PII	Inj.

Research Code: **MORAb-009** Generic Name: **amatuximab** (Anticancer agent / chimeric anti-mesothelin monoclonal antibody)

Description: A chimeric IgG1 monoclonal antibody that blocks the function of mesothelin. Expected to exhibit an antitumor effect against carcinomas that express mesothelin.		
Mesothelioma	US/EU: PII	Inj.

Product Name: **Dacogen** Research Code: **E7373** Generic Name: **decitabine** (DNA methylation inhibitor)

Description: Induces cell differentiation by inhibiting DNA methylation. Currently approved in the United States for the treatment of myelodysplastic syndromes (MDS). In March 2012, Eisai received a Complete Response Letter from the FDA concerning the supplemental New Drug Application (sNDA) for Dacogen in acute myeloid leukemia (AML). The Company is currently considering its next steps regarding the drug.		
<b>Additional Indication:</b> Acute myeloid leukemia (AML)	US: submitted (May 2011), accepted (July 2011)	Inj.
<b>Additional Indication:</b> Pediatric acute myeloid leukemia (AML)	US: PII	Inj.

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. Specifically binds to IL-2 receptors on the cell surface, causing diphtheria toxins that have entered cells to inhibit protein synthesis. Already approved in the United States as a treatment for CD25 (a component of the IL-2 receptor) positive cutaneous T-cell lymphoma.		
<b>Additional Indication:</b> Melanoma	US: PII	Inj.

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

Description: A hydrophilic microspherical particle produced from a polyvinyl alcohol polymer, this embolic bead 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) of hepatocellular carcinoma	JP: submitted (December 2010)	Embolic Agent
<input type="radio"/> Transcatheter arterial embolization (TAE) of hypervascular tumors	JP: PIII	Embolic Agent

## (2) Neurology

Product Name: **Aricept** Research Code: **E2020** Generic Name: **donepezil** (Anti-Alzheimer's agent)

Description: Increases levels of the neurotransmitter acetylcholine in the brain by inhibiting its breakdown by the enzyme acetylcholinesterase, thereby slowing the overall progression of symptoms associated with Alzheimer's disease (AD). Currently approved in more than 90 countries around the world for the treatment of mild to moderate AD. It is also approved as a treatment for patients with severe AD in numerous countries including the United States, Japan, Canada, and several others Asian and Latin American countries.		
<b>Additional Formulation:</b> Dry Syrup	JP: submitted (December 2011)	Oral
<b>Additional Indication:</b> Lewy body dementia	JP: PIII	Submission Target FY2012
<b>Additional Indication:</b> Severe Alzheimer's disease	CN: PIII	Oral
<b>Additional Dosage &amp; Administration, Formulation:</b> Higher dose 23 mg tablet	JP: PIII	Oral

Development progress from April 2012 onwards

Development progress from October 2012 onwards

Product Name: **Fycompa** Research Code: **E2007** Generic Name: **perampanel** (AMPA receptor antagonist)

Description: A selective antagonist against the AMPA receptor (a glutamate receptor subtype). Currently being investigated as a potential adjunctive therapy for partial-onset seizures as well as a treatment for generalized seizures in patients with epilepsy. Approved in 31 countries including in Europe (including Norway, Iceland and Switzerland) and the United States.

Partial-onset seizures	<input type="radio"/> EU: approved (July 2012) <input checked="" type="radio"/> US: approved (October 2012) JP/CN/AS: PIII	Oral
<b>Additional Indication:</b> Generalized seizures	JP/US/EU/ AS: PIII	Submission Target FY2013 Oral
<b>Additional Indication:</b> Pediatric partial-onset seizures	US/EU: PII	Oral

• Japanese New Drug Application (J-NDA) submission for partial-onset seizures and generalized seizures is planned for FY2014.

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.

Diabetic neuropathy	US/EU: PII/III	Oral
---------------------	----------------	------

Product Name: **Zonegran** Research Code: **E2090** Generic Name: **zonisamide** (Antiepileptic agent)

Description: Believed to exhibit a broad antiepileptic spectrum and is well-tolerated. Currently indicated as an adjunctive therapy and monotherapy for the treatment of partial-onset seizures in patients with epilepsy.

<input type="radio"/> <b>Additional Indication:</b> Monotherapy for partial-onset seizures	EU: approved (June 2012)	Oral
<input type="radio"/> <b>Additional Indication:</b> Pediatric partial-onset seizures	EU: submitted (May 2012), accepted (June 2012)	Oral

Research Code: **E0302** Generic Name: **mecobalamin** (Amyotrophic lateral sclerosis)

Description: A mecobalamin (vitamin B<sub>12</sub> coenzyme) formulation. Restores damaged peripheral nerves and is widely used for the treatment of peripheral neuropathy. Currently being investigated as a potential treatment for amyotrophic lateral sclerosis (ALS).

Amyotrophic lateral sclerosis (ALS)	JP: PII/III	Inj.
-------------------------------------	-------------	------

Product Name: **Inovelon (EU) / Banzel (US)** Research Code: **E2080** Generic Name: **rufinamide** (Antiepileptic agent)

Description: A triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). Believed to regulate the activity of sodium channels in the brain that carry excessive electrical charges. Approved in Europe (under the brand name Inovelon) and the United States (under the brand name Banzel) as an adjunctive therapy for Lennox-Gastaut syndrome (LGS).

<input type="radio"/> Adjunctive therapy for Lennox Gastaut syndrome (LGS)	JP: submitted (August 2012)	Oral
<b>Additional Indication:</b> Pediatric Lennox Gastaut syndrome	US/EU: PIII	Oral

Research Code: **BAN2401** (Anti-Alzheimer's agent / humanized anti-A $\beta$  protofibrils monoclonal antibody)

Description: A humanized IgG1 monoclonal antibody that targets amyloid beta (A $\beta$ ) protofibrils. Expected to be effective in the treatment of Alzheimer's disease by halting disease progression through the elimination of A $\beta$  protofibrils reported to exhibit neurotoxicity.

<input checked="" type="radio"/> Alzheimer's disease	US/EU: PII	Inj.
--	------------	------

### (3) Vascular and Immunological Reaction

Product Name: **Humira** Research Code: **D2E7** Generic Name: **adalimumab** (Fully human anti-TNF $\alpha$  monoclonal antibody)

Description: A fully human anti-TNF $\alpha$  monoclonal antibody, which neutralizes the tumor necrosis factor alpha (TNF $\alpha$ ), a type of cytokine that plays a central role in inflammatory reactions in patients with autoimmune diseases. Approved in Japan for the treatment of rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis, juvenile idiopathic arthritis, and inhibition of structural damage of joints.

<input type="radio"/> <b>Additional Indication:</b> Inhibition of structural damage of joints	JP: approved (August 2012)	Inj.
<b>Additional Indication:</b> Ulcerative colitis	JP: submitted (March 2012)	Inj.

Development progress from April 2012 onwards

Development progress from October 2012 onwards

Research Code: **E5564** Generic Name: **eritoran** (Treatment for severe sepsis / endotoxin antagonist)

Description: Exhibits endotoxin antagonist effects that inhibit isolation of inflammatory cytokines. Suppresses various clinical conditions caused by endotoxins.

Severe sepsis

JP/US/EU: PIII

Inj.

Research Code: **E5501/AKR-501** Generic Name: **avatrombopag**

(Treatment for thrombocytopenia / thrombopoietin receptor agonist)

Description: A novel, oral thrombopoietin receptor agonist that stimulates platelet production. Expected to exhibit effects against conditions that are associated with thrombocytopenia.

Idiopathic thrombocytopenic purpura (ITP)

US/EU/AS: PIII

Submission Target FY2013

Oral

Thrombocytopenia in chronic liver disease requiring surgery

US: PII

Oral

Thrombocytopenia during interferon therapy (both initiation and maintenance) for hepatitis C

US: PII

Oral

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

Description: A novel MEK-1/MEKK-1 kinase inhibitor. Expected to inhibit inflammatory cellular signaling as well as overgrowth of epidermal cells in patients with psoriasis.

Psoriasis

US/EU: PII

Topical

Research Code: **E6005** (Phosphodiesterase 4 inhibitor)

Description: Inhibits the activity of phosphodiesterase 4, a cyclic AMP-degrading enzyme that acts as an intracellular messenger. Expected to be effective as a treatment to suppress the various symptoms associated with atopic disease.

Atopic dermatitis

JP: PII

Topical

Product Name: **Careram** Research Code: **T-614** Generic Name: **iguratimod** (Anti-rheumatic agent)

Description: Suppresses inflammatory cytokine and immunoglobulin production and exhibits effects against rheumatoid arthritis. Approved in Japan for the treatment of rheumatoid arthritis. It is the only oral anti-rheumatic agent currently approved in Japan to demonstrate efficacy in domestic clinical trials as an add-on therapy to methotrexate (MTX), the standard of care, in patients who did not achieve satisfactory benefit with MTX alone.

Rheumatoid arthritis

JP: approved (June 2012)

Oral

#### (4) Gastrointestinal and Hepatic Disorders

Product Name: **Pariet/Aciphex** Research Code: **E3810** Generic Name: **rabeprazole** (Proton pump inhibitor)

Description: A proton pump inhibitor approved for the treatment of gastric and duodenal ulcers, reflux esophagitis and eradication of *Helicobacter pylori* infections, etc.

**Additional Indication, Formulation:** Pediatric sprinkle capsule formulation

US: submitted (September 2012), accepted (November 2012)

Oral

**Additional Indication:** Concomitant therapy for *Helicobacter pylori* eradication in *Helicobacter pylori* gastritis

JP: submitted (August 2012)

Oral

**Additional Formulation:** Triple formulation pack for *Helicobacter pylori* eradication

JP: submitted (May 2012)

Oral

**Additional Indication:** Prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin

JP: PII/III

Oral

**Additional Indication:** Functional dyspepsia

JP: PII

Oral

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

Description: An antiviral drug that exerts an anti-HBV effect by inhibiting DNA polymerase.

Chronic hepatitis B

CN: submitted (October 2010)

Oral

Generic Name: **cinitapride** (Gastroprokinetic agent)

Description: By stimulating 5-HT<sub>2</sub> and 5-HT<sub>4</sub> receptors found in the gastrointestinal tract, the agent increases acetylcholine release and improves upper gastrointestinal motility. Its antidopaminergic effects also help stimulate the release of acetylcholine by blocking dopamine receptors, thereby improving upper gastrointestinal function.

Functional dyspepsia

CN: submitted (October 2011)

Oral