

**CONSOLIDATED FINANCIAL REPORT**  
**For the Second Quarter of Fiscal 2013**  
**(Fiscal Year Ending March 31, 2014, Japan GAAP)**

November 1, 2013

Eisai Co., Ltd.		Stock exchange listing: Tokyo
TSE Code:	4523	URL: <a href="http://www.eisai.com">http://www.eisai.com</a>
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	Vice President, Corporate Affairs	
Expected date of quarterly report submission:		November 13, 2013
Expected date of dividend payment commencement:		November 15, 2013
Preparation of quarterly supplementary explanatory material:		Yes
Quarterly results briefing held:		Yes

(Figures are rounded down to t22(g)36(u)23(r)26(e)36(s)33( )-201(a)23(r)40(e36(e0(e36(e0(e

Q Fiscal 2012	288,460	-12.9	37,339	-26.0	34,554	-27.0	24,
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## 2. Dividends

	Annual dividend per share				
	1Q end	2Q end	3Q end	Year-end	Total
Fiscal 2012	-	70.00	-	80.00	150.00
Fiscal 2013					

**\* 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

1. Qualitative Information Concerning Consolidated Financial Results (April 1, 2013 to September 30, 2013)	
1) Explanations Concerning Consolidated Operating Results .....	2
2) Research & Development Pipeline, Alliances, and Other Events .....	5
3) Explanations Concerning Consolidated Financial Position.....	9
4) Basic Policy Concerning Profit Allocation and Interim Dividend for the End of the Second Quarter of Fiscal 2013 .....	10
5) Explanations Concerning Consolidated Financial Forecasts for Fiscal 2013 (April 1, 2013 to March 31, 2014) and Other Future Forecast Information .....	11
6) Corporate Governance .....	12
2. Explanatory Notes in Financial Results Summary	
1) Changes in Number of Significant Subsidiaries during the Period .....	14
2) Application of g	

# 1. Qualitative Information Concerning Consolidated Financial Results (April 1, 2013 to September 30, 2013)

## 1) Explanations Concerning Consolidated Operating Results

[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 second quarter of this fiscal year:

Net sales:	¥307,481 million	(up 6.6
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< Asia Pharmaceutical Business

- Net sales totaled ¥28,089 million (up 43.4% year on year), with segment profit of ¥6,

## 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 October 2013, the agent is approved in 52 countries worldwide. Also, a Phase III study in non-small cell lung cancer is being conducted in the United States, Europe and Asia, including Japan. Furthermore, 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. 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 submitted an application to the European Medicines Agency (EMA) in April 2013 seeking approval for an additional, earlier-line indication and the EMA has accepted the application for review. A submission and development plan for the indication in the United States is under consideration. A Phase III study to investigate the agent as a potential third-line chemotherapy for breast cancer has been initiated in China.
- The AMPA receptor antagonist Fycompa (perampanel) was approved by the European Commission (EC) as an adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy aged 12 years and older in July 2012. The agent obtained approval for the same indication by the Food and Drug Administration (FDA) in the United States in October 2012. As of October 2013, the agent is approved in 34 countries worldwide. A Phase III study for the same indication is ongoing in Asia, including Japan and China. A Phase III study of the agent as an adjunctive therapy for the treatment of generalized seizures in patients with epilepsy is underway 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 April 2013, the DC Bead, a vascular embolization device (specially controlled medical device), received manufacturing and marketing authorization in Japan as a device for transcatheter arterial embolization (TAE) therapy in patients with hepatocellular carcinoma.
- In May 2013,



- In October 2013, the Company submitted an application for an additional indication in Japan regarding the use of anti-Alzheimer's disease agent Aricept (donepezil hydrochloride) in the treatment of dementia with Lewy bodies.
- The Company received a non-approval letter from the Chinese regulatory authority for clevudine (generic name) regarding its use in the treatment of patients with chronic hepatitis B. Plans for future development of the compound are currently under review.
- Proof of Concept (POC, validation of the concept of drug discovery) of the anticancer agent E7080 (lenvatinib mesylate, multi-kinase inhibitor) on melanoma has been achieved in a joint development program being conducted as part of the Company's strategic collaboration with Quintiles (U.S.). Based on this event, the Company will proceed with the preparations for a Phase III study after consultation with regulatory authorities in relevant countries.
- A Phase II study being conducted in the United States and Europe to investigate the anti-Alzheimer's disease agent BAN2401 (humanized anti-A $\beta$  protofibrils monoclonal antibody) has achieved initiation of dosing for the first patient and is underway.
- A Phase I study being conducted in the United States to investigate the anti-Alzheimer's disease agent E2609, a BACE inhibitor, was completed and preparation for a Phase II study to be initiated this fiscal year is underway.
- A Phase II study to investigate the anti-Alzheimer's disease agent Aricept (donepezil hydrochloride) as a potential treatment for regression symptoms in people with Down syndrome has been initiated and is underway in Japan.
- A Phase III study to investigate the proton pump inhibitor (PPI) Pariet (rabeprazole sodium) as a potential maintenance therapy for PPI-resistant reflux esophagitis has been initiated and is underway in Japan.
- The Company decided to discontinue the

- In April 2013, the Company decided to establish a parenteral facility at the Suzhou Industrial Park in Jiangsu, China. Construction is planned for commencement in the third quarter of fiscal 2013 and completion in the first half of fiscal 2014.
- In June 2013, the Company decided to expand the packaging facility at its Hatfield plant in the United Kingdom ahead of plans to launch multiple new products. The new facility will include a packaging area for handling highly potent compounds so as to handle packaging operations for the investigational anticancer agent lenvatinib. Construction began in September 2013 and launch of operations is planned for September 2014.
- In June 2013, the Company decided to temporarily suspend commercial distribution of the antiepileptic drug Fycompa in Germany based on its belief that the German Federal Joint Committee (G-BA) failed to appropriately assess the value of Fycompa as an innovative new treatment in an additional benefit assessment conducted by the G-BA after German marketing approval was granted for the drug last year. The Company will be providing a Patient Access Program for patients who require Fycompa treatment so that the drug can still be used.
- In June 2013, the world's first Phase I/II study on the novel mechanism of E7438 (EZH2 inhibitor), an anticancer agent being jointly devel

- In October 2013, the Company's subsidiary in the United States, Eisai Inc., decided to increase the number of sales representatives in charge of providing information about the antiobesity agent Belviq (lorcaserin hydrochloride) by more than 200 contract employees by December 2013, making the total number of sales representatives about 400 personnel.

**3) Explanations Concerning Consolidated Financial Position**

Assets, Liabilities and Equity



**4) Basic Policy Concerning Profit Allocation and Interim**

**5) Explanations Concerning Consolidated Financial Forecasts**

## **6) Corporate Governance**

### **(1) Basic Framework**

The Eisai Group pursues good corporate governance at all times in order to enhance corporate value as well as the common interests of shareholders on a long-term basis through the realization of the “Corporate Philosophy” stipulated in its Articles of Incorporation, and thereby enables shareholders’ long-term possession of the Company’s shares along with a sense of security. To this end, the Company continues to make efforts toward the enhancement of its corporate governance in accordance with the following basic framework:

#### **1) Shareholder Relations**

The Company shall:

- Respect the rights of all shareholders,
- Ensure the equality of all shareholders,
- Structure favorable and smooth relations with the Company’s stakeholders, including all shareholders, and
- Properly disclose and ensure the transparency of corporate information.

#### **2) Corporate Governance System**

- The Company is a company with a committees system.
- The Board of Directors shall broadly delegate to the Corporate Officers decision-

(2) Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders

The Company has established the Independent Committee of Outside Directors, composed of all



## **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

### **4) Additional Information**

(Performance-related stock compensation system distributing treasury stock to Corporate Officers through a trust)

The Compensation Committee meeting held on May 13, 2013, resolved the introduction of a Performance-Related Stock-Based Compensation System (the "System") that distributes the Company's stock every year based on performance, in order to contribute to motivating Corporate Officers to enhance medium- to long-term corporate value.

In accordance with the resolution regarding the introduction of the System made at the Board of Directors' meeting held on the same day, the Company completed procedures for the disposal of treasury stock by means of third-party allotment with Mitsubishi UFJ Trust and Banking Corporation (Trust Account for Officers' Compensation Board Incentive Plan) on May 30, 2013, and recognized "Gain on disposal of treasury stock."

Gross method is used as an accounting treatment for the Trust. The Company's stock held through the Trust is, therefore, included in "Treasury stock" in shareholders' equity with the book value carried in the Trust. Disposal of treasury stock will be recognized at the point of distributing the share from the Trust to Corporate Officers.

The book value of the Company's stock held through the Trust was ¥477 million (105,400 shares) as of

### 3. Consolidated Financial Statements

#### 1) Consolidated Balance Sheet

	(millions of yen)	
	Fiscal 2012 (As of March 31, 2013)	2Q Fiscal 2013 (As of September 30, 2013)
<b>Assets</b>		
Current assets		
Cash and deposits	88,669	65,974
Notes and accounts receivable-trade	185,486	190,406
Short-term investments	98,788	75,024
Merchandise and finished goods	54,860	57,034
Work-in-process	17,816	17,765
Raw materials and supplies	14,944	15,519
Deferred tax assets	47,094	48,620
Other	23,185	22,953
Allowance for doubtful accounts	(117)	(145)
Total current assets	530,727	493,153
Noncurrent assets		
Property, plant and equipment		
Buildings and structures net	85,907	85,059
Other net	56,341	54,945
Total property, plant and equipment	142,248	140,004
Intangible assets		
Goodwill	127,342	127,761
Sales rights	51,432	51,268
Core technology	43,724	43,745
Other	13,546	12,607
Total intangible assets	236,046	235,383
Investments and other assets		
Investment securities	34,293	32,439
Deferred tax assets	40,727	44,469
Other	6,339	6,917
Allowance for doubtful accounts	(133)	(133)
Total investments and other assets	81,226	83,693
Total noncurrent assets	459,521	459,080
Total assets	990,249	952,234



## 2) Consolidated Statement of Income and Consolidated Statement of Comprehensive Income (Consolidated Statement of Income)

(millions of yen)

	2Q Fiscal 2012 (April 1, 2012- September 30, 2012)	2Q Fiscal 2013 (April 1, 2013- September 30, 2013)
Net sales	288,460	307,481
Cost of sales	84,944	93,252
Gross profit	203,516	214,229
Provision for sales returns	19	21
Gross profit net	203,496	214,207
Selling, general and administrative expenses	166,157	178,823
Operating income	37,339	35,384
Nonoperating income		
Interest income	509	472
Dividend income	397	309
Other	164	164
Total nonoperating income	1,071	946
Nonoperating expenses		
Interest expense	3,399	2,873
Foreign exchange loss	200	604
Other	255	125
Total nonoperating expenses	3,856	3,602
Ordinary income	34,554	32,727
Special gains		
Gain on sales of noncurrent assets	568	3,049
Gain on negative goodwill	1,960	249
Gain on sales of investment securities	132	2,486
Other	204	535
Total special gains	2,866	6,321
Special losses		
Loss on disposal of noncurrent assets	53	88
Loss on impairment	778	-
Loss on devaluation of investment securities	295	-
Other	0	0
Total special losses	1,127	88
Income before income taxes and minority interests	36,292	38,959
Income taxes current	13,899	18,598
Income taxes deferred	(2,265)	(7,425)
Total income taxes	11,633	11,173
Income before minority interests	24,659	27,786
Minority interests in income	180	135
Net income	24,479	27,651

## (Consolidated Statement of Comprehensive Income)

(millions of yen)

Income before minority interests	24,659	27,786
Other comprehensive income (loss)		
Valuation difference on available-for-sale securities	(322)	271
Deferred gain (loss) on derivatives under hedge accounting	(43)	165
Foreign currency translation adjustments		

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#### **4) Notes Concerning Consolidated Financial Results**

##### **(Going Concern)**

Not applicable

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

Not applicable

##### **(Segment Information)**

Effective from the first quarter of fiscal 2013

For the three months ended in September 30, 2012, the Americas Pharmaceutical Business recognized a loss on impairment of noncurrent assets in relation to exclusivity rights (sales rights) of some of its prescription drugs. As a result, loss on impairment of noncurrent assets for the second quarter of fiscal 2012 amounted to ¥778 million.

(Significant gain on negative goodwill)

For the three months ended in September 30, 2012, the Asia Pharmaceutical Business recognized negative goodwill after the Company'



America), EMEA (Europe, the Middle East, and Africa), and Indo-Pacific (South Asia, ASEAN and Oceania). Effective from the first quarter of fiscal 2013, the Group has redesignated the