

# CONSOLIDATED FINANCIAL REPORT [IFRS] for the First Six-Month Period ended September 30, 2015

October 30, 2015  
Eisai Co., Ltd.

Stock exchange listing: Tokyo Stock Exchange  
TSE Code: 4523  
URL: <http://www.eisai.com>

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Expected date of dividend payment commencement: November 18, 2015  
Preparation of quarterly supplementary explanatory material: Yes  
Quarterly results briefing held: Yes

(Figures are rounded to the nearest million yen.)

## 1. Consolidated Financial Results for the First Six-Month Period ended September 30, 2015

### (1) Consolidated Operating Results

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

	Revenue		Operating profit		Profit before income taxes		Profit for the period	Profit for the period attributable to owners of the parent	Comprehensive income for the period
First six-month period ended September 30, 2015	275,503	2.4	18,076	0.3	17,334	(¥)21983		(¥)	

First six-month period ended September 30, 2015	38.61	38.50
First six-month period ended September 30, 2014	36.50	36.46

### (2) Consolidated Financial Position

	Total assets	Total equity	Total equity attributable to owners of the parent	Ratio of equity attributable to owners of the parent	Equity per share attributable to owners of the parent
	(¥ million)	(¥ million)	(¥ million)	(%)	(¥)
As of September 30, 2015	987,104	590,004	586,660	59.4	2,052.90
As of March 31, 2015	1,053,818	602,061	598,749	56.8	2,096.39

## 2. Dividends

	Annual dividends				
	End of Q1	End of Q2	End of Q3	End of year	Total
FY ended March 31, 2015	— (¥)	70.00 (¥)	— (¥)	80.00 (¥)	150.00 (¥)



## 1. Qualitative Information Concerning Financial Results

### 1) Explanations Concerning Consolidated Operating Results

[Revenue and Profit]

Eisai Co., Ltd. (“the Company”) and its affiliates (collectively referred to as “the Group”) recorded the following consolidated financial results for the first six-month period ended September 30, 2015.

Revenue:	¥275,503	million	(2.4% increase year on year)
Operating profit:	¥18,076	million	(0.3% increase year on year)
Profit before income taxes:	¥17,334	million	(6.2% increase year on year)
Profit for the period:	¥11,134	million	(6.0% increase year on year)

Revenue for the Group increased due to the growth of anticancer agents Halaven and Lenvima and antiepileptic agent Fycompa, as well as the high growth recorded by the Group’s pharmaceutical businesses in China, Asia and EMEA (Europe, Middle East, Africa and Oceania).

By therapeutic area, total revenue from oncology-related products increased to ¥57,316 million (up 22.5% year on year), reflecting the growth of Halaven and smooth launches of Lenvima in the U.S., Europe and Japan. Meanwhile, overall revenue from epilepsy franchise products reached ¥18,050 million (up 23.7% year on year), reflecting Fycompa’s expansion in the U.S. and Europe.

By product, combined revenue from all four global brands totaled ¥29,784 million (up 43.4%); this included ¥19,916 million (up 20.8% year on year) from Halaven and ¥4,057 million from Lenvima in addition to the revenue from Fycompa and the antiobesity agent BELVIQ. Aricept, a treatment for Alzheimer’s disease and dementia with Lewy bodies, and Pariet (U.S. brand name: AcipHex), a proton pump inhibitor, recorded respective revenues of ¥33,988 million (up 6.6% year on year) and ¥23,732 million (down 18.9% year on year).

By segment, growth was achieved in all overseas segments, highlighted by sustained growth in the China pharmaceutical business (up 37.2% year on year) as well as business expansion in South Korea and other key markets in Asia.

\* Revenue for Pariet includes revenue for triple-formulation combination packs for *Helicobacter pylori* eradication, Rabecure 400/800 and Rabefine.

Regarding profit, despite temporary expenses incurred from structural reforms being undertaken in the U.S., the Group achieved improved cost efficiency as well as increased gross profit due to increased revenue, gain on sale of non-current assets related to a business transfer, and upfront payment received under a joint development and promotion agreement. As a result, operating profit totaled ¥18,076 million (up 0.3% year on year). Furthermore, profit for the period stood at ¥11,134 million (up 6.0% year on year), partly the result of a decrease in financial costs due to reduced interest costs.

Basic earnings per share for the period attributable to owners0 -1.3ye pylo re pyl<081699 TD.00090

71.3% year on year).

#### [Performance by Segment]

(Revenue for each segment indicates revenue from external customers.)

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan (Prescription medicines, Generics and Diagnostics), Americas (North, Central and South America), China, Asia (primarily South Korea, Taiwan, Hong Kong, India and ASEAN), EMEA (Europe, the Middle East, Africa and Oceania) and Consumer healthcare business Japan. In addition, all year-on-year figures related to segment information in this report are based on the aforementioned reporting segments.

#### Japan pharmaceutical business

Revenue totaled ¥134,236 million (down 3.8% year on year) and segment profit was ¥56,751 million (down 9.5% year on year). Of this amount, the revenue totals for Prescription Medicines, Generics and Diagnostics were, respectively, ¥118,187 million (down 4.9% year on year), ¥13,160 million (up 5.6% year on year) and ¥2,888 million (up 1.9% year on year).

By product, revenue from Humira, a fully human anti-TNF-alpha monoclonal antibody, amounted to ¥15,699 million (up 5.7% year on year), co-promotion revenue from Lyrica, a pain treatment being co-promoted with Pfizer Japan Inc., was ¥11,844 million (up 20.7%

#### China pharmaceutical business

Revenue amounted to ¥26,071 million (up 37.2% year on year). Segment profit also continued to grow, recording ¥8,014 million (up 42.7% year on year).

By product, revenue for the peripheral neuropathy treatment Methycobal amounted to ¥10,300 million (up 26.1% year on year), for the hepatic/allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets, ¥4,803 million (up 58.5% year on year), for Aricept, ¥2,740 million (up 23.4% year on year), and for Pariet, ¥1,764 million (up 33.9% year on year), reflecting solid growth for the region's key products.

#### Asia pharmaceutical business

Revenue totaled ¥17,291 million (up 16.9% year on year) and segment profit was ¥4,638 million (up 26.8% year on year), with high growth sustained in key markets such as South Korea, Taiwan and Thailand.

By product, revenue for Aricept came to ¥5,119 million (up 16.1% year on year), Humira ¥4,604 million (up 15.9% year on year) and Methycobal ¥1,735 million (up 34.3% year on year), each indicating sustained growth. Pariet recorded ¥1,755 million (down 0.6% year on year).

#### EMEA pharmaceutical business

Revenue totaled ¥20,182 million (up 11.4% year on year) and segment profit was ¥4,417 million (up 42.6% year on year), with year-on-year increases recorded across all epilepsy and oncology-related products.

By product, for oncology-related products, not only did Halaven sustain growth with revenue totaling ¥6,597 million (up 23.4% year on year), but also Lenvima, which was launched in June 2015, recorded revenue of ¥201 million. Epilepsy products Zonegran, Zebinix, and Fycompa all sustained steady revenue growth at ¥4,071 million (up 4.6% year on year), ¥1,851 million (up 22.6% year on year), and ¥1,555 million (up 46.9% year on year), respectively.

Lenvima was launched in the U.K., Austria and Nordic countries including Sweden in June 2015, and launched in Germany and Spain in July and September 2015, respectively.

#### Consumer healthcare business Japan

Revenue totaled ¥9,011 million (up 6.0% year on year) and segment profit was ¥1,448 million.

Revenue from the Chocola BB group of products totaled ¥5,630 million (up 0.9% year on year).

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

### Status of Ongoing Research & Development Pipelines

The anticancer agent Halaven (eribulin) has obtained indication approval as a (generally either second- or third-line) chemotherapy for breast cancer in approximately 60 countries worldwide including Japan, the U.S. and in Europe and Asia. A Phase III study in China to investigate the agent as a third-line chemotherapy for breast cancer is underway. Applications for indication expansion of the agent for use in the treatment of soft tissue sarcoma were submitted in Japan, the U.S. and Europe in July 2015, and the application for the U.S. was granted Priority Review status by the U.S. FDA. Furthermore, a Phase I/II study was initiated to investigate the agent in combination with the anti-PD-1 therapy pembrolizumab from Merck & Co., Inc. (Kenilworth, New Jersey, U.S.) in metastatic triple-negative breast cancer.

The anticancer agent Lenvima (lenvatinib) has obtained indication approval as a treatment for thyroid cancer over 35 countries. Following initial approval in the U.S. in February 2015, the agent received approval in Japan and Europe in March and May respectively this year. In October 2015, the agent was also approved in South Korea as the first country in Asia outside Japan to receive approval. In addition, a Phase III study of the agent in hepatocellular carcinoma is underway in the U.S., Europe and Asia, including Japan and China. Furthermore, a Phase II study of the agent in renal cell carcinoma conducted in the U.S. and Europe met its primary endpoint. Discussions with the regulatory authorities are ongoing to determine further development plans for this indication. Moreover, the agent received a Breakthrough Therapy Designation from the U.S. FDA for this indication. In Japan, a Phase II study of the agent in biliary tract cancer has been initiated. Additionally, several other Phase II studies of the agent are underway, including in third-line non-small cell lung cancer (NSCLC) single-agent treatment, NSCLC with RET translocations and endometrial cancer. A Phase I/II study to investigate the agent in combination with the anti-PD-1 therapy pembrolizumab from Merck & Co., Inc. (Kenilworth, New Jersey, U.S.) in select solid tumors is underway.

The antiepileptic agent Fycompa (perampanel) has been approved in over 45 countries, including the U.S. and in Europe and Asia, as an adjunctive therapy for the treatment of partial-onset seizures in adult and adolescent patients from 12 years of age with epilepsy. In June 2015, the agent was approved for an indication expansion to include the a3o ca





In August 2015, the Company and Purdue Pharma L.P. (U.S.) entered into a worldwide collaboration agreement for the development and commercialization of the Company's clinical candidate lemborexant (development

**3) Explanations Concerning Consolidated Financial Position**  
Assets, Liabilities And Equity

#### 4) Basic Policy Concerning Profit Allocation and Interim Dividend for the End of the Second Quarter of Fiscal 2015

At Eisai Co., Ltd., the dividend payments are to be determined by a resolution of the Board of Directors as specified in the Company's Articles of Incorporation. Regarding profit appropriation policy, the Board of Directors has determined "Eisai's Policy on Shareholder Returns" as follows.

##### <Eisai's Policy on Shareholder Returns>

The Company is devoted to providing sustainable and stable dividends based on a healthy balance sheet while giving consideration to various factors such as consolidated financial performance, the dividend on equity ratio (DOE)<sup>\*1</sup> and free cash flow. Acquisition of treasury stock may be carried out appropriately after factors such as the market environment and capital efficiency are taken into account.

DOE is an index contributing to shareholder value that encompasses both the dividend payout ratio, which measures the extent to which profits are distributed to shareholders in the form of dividends, and return on equity (ROE)<sup>\*2</sup>, which measures capital efficiency. Also, DOE shows the ratio of dividend to shareholders' equity and thus serves as an index for balance sheet management.

The Company intends to set the interim dividend for the period (at the end of the second quarter) at ¥70 per share (same amount as the previous year) as previously forecast.

<sup>\*1</sup> DOE (Dividend on equity attributable to owners of the parent ratio) = Total dividend payout / Equity attributable to owners of the parent

<sup>\*2</sup> ROE (Profit ratio to equity attributable to owners of the parent) = Profit attributable to owners of the parent / Equity attributable to owners of the parent

**5) Explanations Concerning Consolidated Financial Forecasts for the Fiscal Year  
(April 1, 2015 to March 31, 2016)**

Consolidated Forecasts

Consolidated forecasts for the full fiscal year remain unchanged.

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

## **6) Corporate Governance**

### **(1) Basic Approach to Corporate Governance**

The Company believes that the focus of corporate governance is to respect the rights of all our shareholders, ensure fair and transparent management, and enhance corporate vitality. Always aiming for the best corporate governance, the Company strives to achieve corporate governance in accordance with the following basic points of view.

#### **a. Shareholder Relations**

The Company shall:

Respect the rights of all shareholders;

Ensure the equality of all shareholders;

Develop positive and smooth relations with the Company's stakeholders including all shareholders; and

Ensure transparency by properly disclosing Company information.

incorporates the following provisions.

- a. The Policy precludes arbitrary action on the part of management.
- b. The continuation, amendment or abolishment of the Policy shall be deliberated each year.
- c. Shareholders' opinions concerning the Policy may be reflected through the election of Directors at the Ordinary General Meeting of Shareholders.

### (3) Corporate Governance Initiatives

The Company has published its Corporate Governance Guidelines, which are determined by the Board of Directors as policies to achieve good corporate governance. In order to increase the effectiveness of corporate governance, the Board of Directors conducts a self-review every year to determine whether the duties of the Board of Directors are being executed in accordance with the Guidelines, and also updates the Guidelines as necessary.

Regarding the Tokyo Stock Exchange's Corporate Governance Code, which applies to all publicly listed companies from June 2015, the Company complies with all the principles prescribed within, and has published a Corporate Governance Report, which outlines the status of efforts regarding the 11 items requiring disclosure by this Code.

The Company's Corporate Governance Guidelines, Rules of the Board of Directors and Rules of each individual Committee, as well as the Corporate Governance Report, can be found on Eisai's corporate website:

<http://www.eisai.com/company/cgregulations.html>

## 2. Explanatory Notes for Financial Results Summary

### 1 Changes in Number of Significant Subsidiaries during the Period

Not applicable

### 2 Changes in Accounting Policies and Accounting Estimates

With the exception of the following, all significant accounting policies that apply to these condensed interim consolidated financial statements are the same as those that were applied to the consolidated financial statements for the previous fiscal year. None of the below accounting standards and interpretations applied by the Group has any material impact on the condensed interim consolidated financial statements for the period.

Accounting standards and interpretations	Mandatory application (Date of commencement)	To be applied by the Group	Description of new standards / amendments
IAS 19 Employee Benefits	July 1, 2014	Fiscal year ending March 2016	Amendment of accounting for contributions from employees or third parties to defined benefit plans

All significant accounting estimates and judgments used in these condensed interim consolidated financial statements are the same as the estimates and judgments applied to the consolidated financial statements for the previous fiscal year, with the following exception:

From the consolidated fiscal year ended March 31, 2016, the useful life of sales rights was revised by changing the estimation method regarding exclusive sales periods for pharmaceutical products. As a result, amortization expenses (Cost of sales) for the first six-month period ended September 30, 2015, have been reduced by ¥1,175 million.

Additionally, the reporting segment mainly affected by this change is the Americas pharmaceutical business.

### 3. Condensed Interim Consolidated Financial Statements

#### 1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Note	First six-month period ended September 30, 2015	First six-month period ended September 30, 2014
Revenue		275,503	269,056
Cost of sales	(1)	(99,490)	(93,810)
Gross profit		176,013	175,246
Selling, general and administrative expenses	(1)	(96,406)	(94,689)
Research and development expenses	(1)	(62,844)	(62,099)
Other income	(2)	1,959	571
Other expenses		(645)	(1,008)
Operating profit		18,076	18,020
Financial income		989	917
Financial costs		(1,732)	(2,610)
Profit before income taxes		17,334	16,327
Income taxes		(6,199)	(5,818)
Profit for the period		11,134	10,509
Attributable to			
Owners of the parent		11,030	10,413
Non-controlling interests		104	96
Earnings per share			
Basic (yen)		38.61	36.50
Diluted (yen)		38.50	36.46



## 2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	First six-month period ended September 30, 2015	First six-month period ended September 30, 2014
Profit for the period	11,134	10,509
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	2,139	(858)
Subtotal	2,139	(858)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(2,979)	25,717
Cash flow hedges	(53)	345
Subtotal	(3,032)	26,062
Total other comprehensive income (loss), net of tax	(893)	25,204
Comprehensive income for the period	10,241	35,713
Attributable to		
Owners of the parent	10,151	35,605
Non-controlling interests	90	109



(Millions of yen)

	As of September 30, 2015	As of March 31, 2015
Equity		
Equity attributable to owners of the parent		
Share capital	44,986	44,986
Capital surplus	58,094	58,040
Treasury shares	(36,772)	(37,308)
Retained earnings	378,306	387,967
Other components of equity	142,046	145,064
Total equity attributable to owners of the parent	586,660	598,749
Non-controlling interests	3,344	3,313
Total equity	590,004	602,061
Liabilities		
Non-current liabilities		
Bonds and borrowings	205,807	205,846
Other financial liabilities	2,536	2,352
Retirement benefit liabilities	6,614	7,238
Provisions	1,306	1,198
Other liabilities	23,478	25,543

#### 4) Condensed Interim Consolidated Statement of Changes in Equity

For the first six-month period ended September 30, 2015

(Millions of yen)

	Equity attributable to owners of the parent					Other components of equity Financial assets measured at fair value through other comprehensive income
	Share capital	Capital surplus	Treasury shares	Retained earnings		
As of April 1, 2015	44,986	58,040	(37,308)	387,967	—	
Profit for the period	—	—	—	11,030	—	
Other comprehensive income (loss)	—	—	—	—	2,139	
Comprehensive income (loss) for the period	—	—	—	11,030	2,139	
Dividends	—	—	—	(22,856)	—	
Share-based payments	—	(107)	—	—	—	
Acquisition of treasury shares	—	—	(60)	—	—	
Disposal of treasury shares	—	161	597	—	—	
Reclassification	—	—	—	2,139	(2,139)	
Other changes	—	—	—	25	—	
Total transactions with owners	—	55	536	(20,692)	(2,139)	
As of September 30, 2015	44,986	58,094	(36,772)	378,306	—	

Equity attributable to owners of the parent

Non-controlling  
interests      Total equity

For the first six-month period ended September 30, 2014

(Millions of yen)

	Equity attributable to owners of the parent				Other components of equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Financial assets measured at fair value through other comprehensive income
As of April 1, 2014	44,986	57,949	(38,481)	379,210	—
Profit for the period	—	—	—	10,413	—
Other comprehensive income (loss)	—	—	—	—	(858)
Comprehensive income for the period	—	—	—	10,413	(858)
Dividends	—	—	—	(22,829)	—
Share-based payments	—	(28)	—	—	—
Acquisition of treasury shares	—	—	(14)	—	—
Disposal of treasury shares	—	40	342	—	—
Reclassification	—	—	—	(858)	858
Other changes	—	—	—	19	—
Total transactions with owners	—	11	328	(23,668)	858
As of September 30, 2014	44,986	57,960	(38,153)	365,955	—

	Equity attributable to owners of the parent				Non-controlling interests	Total equity
	Other components of equity			Equity attributable to owners of the parent		
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity			
As of April 1, 2014	83,587	(931)	82,656	526,320	3,084	529,405
Profit for the period	—	—	—	10,413	96	10,509
Other comprehensive income (loss)	25,705	345	25,192	25,192	13	25,204
Comprehensive income for the period	25,705	345	25,192	35,605	109	35,713
Dividends	—	—	—	(22,829)	(48)	(22,877)
Share-based payments	—	—	—	(28)	—	(28)
Acquisition of treasury shares	—	—	—	(14)	—	(14)
Disposal of treasury shares	—	—	—	382	—	382
Reclassification	—	—	858	—	—	—
Other changes	—	—	—	19	(0)	19
Total transactions with owners	—	—	858	(22,471)	(48)	(22,518)
As of September 30, 2014	109,292	(585)	108,707	539,454	3,145	542,599

## 5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

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First six-month period  
ended September 30, 2015

First six-month period  
ended September 30, 2014

## **6) Condensed Interim Notes to Consolidated Financial Statements**

(Going Concern)

Not applicable

(Segment Information)

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report:  
Japan (Prescription medicines, Generics and Diagnos

(Consolidated Statement of Income)

(1) Cost of sales, selling, general and administrative expenses, and research and development expenses

For the first six-month period ended September 30, 2015, termination benefits of ¥2,404 million were recorded as a result of structural reform and the transfer of the North Carolina Plant in the U.S.

The termination benefits by account item were ¥222 million in cost of sales, ¥2,059 million in selling, general and administrative expenses and ¥123 million in research and development expenses.

(2) Other income

For the first six-month period ended September 30, 2015, gain on sales of non-current assets totaling ¥1,367 million was recorded as a result of the transfer of the North Carolina Plant in the U.S.

(Consolidated Statement of Financial Position)

(1) Property, plant and equipment

For the three month period ended June 30, 2015, the Group's U.S. subsidiary Eisai Inc. entered into an agreement to transfer the North Carolina Plant to Biogen Inc. (U.S.). This transfer was based on the Group's global logistics strategy, which aims to optimize its supply chain. In the first six-month period ended September 30, 2015, Eisai Inc. subsequently transferred the plant to Biogen Inc. Following the transfer of the plant, the carrying amounts for buildings and structures; machinery, equipment and vehicles; land; and other property, plant and equipment decreased by ¥6,673 million, ¥3,357 million, ¥545 million and ¥163 million yen, respectively.

(Significant Subsequent Events)

On October 15, 2015, the Company and Ajinomoto Co., Inc. (Tokyo) signed an integration



As consideration for the absorption-type company split, AJINOMOTO PHARMACEUTICALS CO., LTD. will allocate 6,000 ordinary shares of AJINOMOTO PHARMACEUTICALS CO., LTD. to the Company. As a result, the Company will hold 60% of the total shares issued in the new integrated company, and the new integrated company will become a consolidated subsidiary of the Company.

(4) Primary reasons for the business combination

The field of gastrointestinal disease is one with significant unmet medical needs. By integrating the Company's gastrointestinal disease business and AJINOMOTO PHARMACEUTICALS CO., LTD., this new integrated company will become one of Japan's largest gastrointestinal specialty pharma with a product lineup that will comprehensively cover the upper and lower digestive tract as well as the liver and pancreas, enabling the provision of an even wider range of solutions in the field of gastrointestinal disease as well as specialized information for healthcare professionals. In addition, consolidating both companies' in-development products will serve to enhance the pipeline toward the consistent launch of new treatments, and the companies aim to discover innovative new medicines by exchanging expertise and know-how. The new integrated company will seek greater profitability through marketing synergies from integration and the pursuit of efficiency through the review of overlapping functions, as well as to secure necessary resources for new drug development and sustained growth.