

# CONSOLIDATED FINANCIAL REPORT [IFRS] for the Six-Month Period Ended September 30, 2016

October 31, 2016  
Eisai Co., Ltd.

Stock exchange listing: Tokyo Stock Exchange (TSE)

TSE Code: 4523

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Expected date of dividend payment commencement: November 18, 2016

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 Six-Month Period Ended September 30, 2016

### (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	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
Six-month period ended September 30, 2016	269,894	-2.0	38,590	113.5	38,107	119.8	29,577	165.6	27,909	153.0	(20,970)	—
Six-month period ended September 30, 2015	275,503	2.4	18,076	0.3	17,334		6.0		11,030	5.9	10,241	-71.3

	Earnings per share attributable to owners of the parent (basic)	Earnings per share attributable to owners of the parent (diluted)
	(¥)	(¥)
Six-month period ended September 30, 2016	97.60	97.45
Six-month period ended September 30, 2015	38.61	38.50

### (2) Consolidated Financial Positions

	Total assets	Total equity	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, 2016	965,198	564,933	547,692	56.7	1,915.14
As of March 31, 2016	973,987	576,828	573,661	58.9	2,006.22

## 2. Dividends

	Annual dividend per share				
	End of Q1 (¥)	End of Q2 (¥)	End of Q3	End of FY	Total



# 1 Analysis Concerning Operating Results and Financial Position

## 1) Analysis Concerning Operating Results

### (1) Outline of 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 six-month period ended September 30, 2016.

Revenue:	¥269,894 million	(2.0% decrease year on year)
Operating profit:	¥38,590 million	(113.5% increase year on year)
Profit before income taxes:	¥38,107 million	(119.8% increase year on year)
Profit for the period:	¥29,577 million	(165.6% increase year on year)
	¥27,909 million	(153.0% increase year on year)

While an increase was recorded following growth of Lenvima (anticancer agent) and Fycompa (antiepileptic agent) as well as the contribution from newly added consolidated subsidiary EA Pharma Co., Ltd., Group revenue finished overall at ¥269,894 million (down 2.0% year on year) due in part to the impact of national drug price revisions in Japan and foreign currency fluctuations.

By segment, revenue from the Group’s Japan pharmaceutical business increased 4.5% year on year. Similarly, on a local currency basis, all pharmaceutical businesses outside Japan achieved steady growth.

By product, combined revenue from all four global brands soared by 16.1% year on year to ¥34,584 million, despite the impact of foreign currency fluctuations. This included ¥18,634 million from Halaven (anticancer agent), ¥9,580 million from Lenvima, ¥4,727 million from Fycompa, and ¥1,642 million from BELVIQ (anti-obesity agent).

Operating profit totaled ¥38,590 million (up 113.5% 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 five reporting segments in this report: Japan (Prescription Medicines, Generics, and OTC), Americas (North, Central and South

107.8% on a local currency basis) due to reduced marketing costs as a result of efficient marketing activities and to

The availability of Lenvima has expanded into various countries including France, Italy, the Netherlands and Russia during this fiscal year.

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

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

The anticancer agent Halaven (eribulin) has been approved for use in the treatment of breast cancer in over 60 countries including Japan, the U.S. and in Europe and Asia. In July 2016, a New Drug Application for Halaven for use in the treatment of patients with locally advanced or metastatic breast cancer was submitted in China. Additionally, the agent was approved for use in treatment of liposarcoma in the U.S., Japan (for treatment of soft tissue sarcoma), and in Europe, in January, February, and May respectively this year. Furthermore, a Phase I/II study to investigate the agent in combination with the anti-PD-1 antibody pembrolizumab from Merck & Co., Inc. (Kenilworth, New Jersey, U.S.) in metastatic triple-negative breast cancer is underway. A Phase I/II study in patients with HER2-negative breast cancer in combination with PEGPH20, a PEGylated recombinant human hyaluronidase being developed by Halozyme Therapeutics, Inc., was initiated and is underway.

The anticancer agent Lenvima (lenvatinib, product name for renal cell carcinoma indication in Europe: Kisplyx) has been approved for use in the treatment for thyroid cancer over 45 countries. The agent was also approved in combination with everolimus for the treatment of renal cell carcinoma (second-line) in the U.S. and Europe in May and August 2016, respectively. 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. Meanwhile, a Phase III study of the agent in separate combinations with everolimus and pembrolizumab in renal cell carcinoma (first-line) has been initiated. Additionally, several other Phase II studies of the agent are underway, including in biliary tract cancer in Japan, third-line non-small cell lung cancer (NSCLC) (monotherapy), NSCLC with RET translocations and endometrial cancer. A Phase I/II study to investigate the agent in combination with pembrolizumab in select solid tumors is also underway.

The antiepileptic agent Fycompa (perampanel) has been approved in over 50 countries as an adjunctive therapy for use in the treatment of partial-onset seizures in adult and

In June 2016, the fully human anti-TNF-alpha monoclonal antibody Humira (adalimumab) was additionally approved in Japan for a new dosing regimen of the agent in patients with moderate or severe Crohn's disease who become less responsive to treatment with 40 mg every two weeks to double the dose to 80 mg every two weeks.

In July 2016, lorcaserin (U.S. brand name: BELVIQ) was approved for chronic weight management in Mexico. The product will be launched in Mexico under the brand name VENESPRI.

In July 2016, BELVIQ XR, a New Drug Application for a once-daily formulation of lorcaserin, was approved in the U.S.

In September 2016, Humira was additionally approved in Japan for the treatment of non-infectious intermediate, posterior and panuveitis.

In October 2016, an application for the protein pump inhibitor (PPI) Pariet for a new dosing regimen for maintenance therapy for reflux esophagitis was submitted in Japan. The new regimen, if approved, will enable the prescription of 10 mg of Pariet twice daily for reflux esophagitis patients who are resistant to PPIs.

In October 2016, a new drug application for the local steroid AJG511 (budesonide) as a treatment for ulcerative colitis was submitted in Japan.

A Phase III study of the orexin receptor antagonist E2006 (lemborexant) in insomnia disorder was initiated and is underway in Japan, the U.S., and Europe. Additionally, a Phase II study of the agent in patients with irregular sleep-wake rhythm disorder (ISWRD) and Alzheimer's disease was initiated in Japan and the U.S.

Enrollment has commenced in a global Phase III study of the beta secretase cleaving enzyme (BACE) inhibitor E2609 in early Alzheimer's disease in the U.S.

A Phase II study of the anti-fractalkine antibody E6011 in rheumatoid arthritis was initiated in Japan.

A Phase II study of the integrin activation inhibitor E6007 in ulcerative colitis was initiated in Japan.

Regarding the Phase I study of a transdermal formulation for donepezil jointly conducted with Teikoku Pharmaceuticals Co., Ltd., the study sponsor has been transferred to Teikoku Pharmaceuticals.

#### [Major Alliances, Agreements and Other Events]

In April 2016, the gastrointestinal specialty pharma EA Pharma Co., Ltd. (EA Pharma) was established through the splitting off of a portion of Eisai's gastrointestinal disease treatment business and its subsequent succession by AJINOMOTO PHARMACEUTICALS CO., LTD. (Tokyo), a wholly-owned subsidiary of Ajinomoto Co. Inc. (Tokyo), via absorption-type split. EA Pharma is a consolidated subsidiary of



In June 2016, EA Pharma and AbbVie GK commenced the co-promotion of fully human anti-TNF- monoclonal antibody Humira for indications in the field of gastrointestinal disease (ulcerative colitis, Crohn's disease, intestinal Behçet's disease). In addition, Eisai Co., Ltd. and AbbVie will continue co-promotion for Humira of indications outside of the gastrointestinal disease field.

In June 2016, Eisai's U.S. subsidiary Eisai Inc. entered into a collaboration agreement with Novartis Pharmaceuticals Corporation, a U.S. affiliate of Novartis AG (Basel, Switzerland), to co-promote the Eisai's novel anticancer agent Lenvima and the anticancer agent everolimus as a treatment for advanced

### **(3) Explanations C**

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 rate 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, uncertainties in new drug development, risks in alliances with other companies, impact of medical cost containment measures, risks related to generic products, risks related to intellectual property, risks related to occurrences of side effects, risks regarding laws and regulations, risks relating to lawsuits, plant closure or 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 market conditions and currency movement, risks concerning internal control systems, and risk concerning disasters.

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

## **2) Analysis Concerning Consolidated Financial Position**

[Assets, Liabilities and Equity]

Total assets as of the end of the period amounted to ¥965,198 million (down ¥8,790 million from the end of the previous fiscal year). While total assets increased following the acquisition of a Japanese subsidiary EA Pharma Co., Ltd., this was countered by a decrease in assets held by foreign subsidiaries due to continued appreciation of the yen since the previous fiscal year as well as a decrease in assets held for sale following the transfer of Sannova Co., Ltd.

Total liabilities as of the end of the period amounted to ¥400,265 million (up ¥3,106 million



## 4) 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.

#### b. Corporate Governance System

The Company is a “Company with a Nomination Committee, etc. System” as defined in Japan's Companies Act.

The Board of Directors (“the Board”) shall delegate to the Corporate Officers broad powers of decision-making over business execution, to the extent permitted by the laws and regulations, and it shall exercise the function of management oversight.

The majority of the Board shall be independent and neutral Outside Directors.

The Representative Corporate Officer and CEO shall be the only Director who is concurrently a Corporate Officer.

To clarify the management oversight function, the positions of Chair of the Board and of Representative Corporate Officer and CEO shall be separated and performed by different people.

The Nomination Committee and the Compensation Committee shall be entirely composed of Outside Directors, and the majority of the Audit Committee shall consist of Outside Directors.

Each of the Chairs of the Nomination Committee, the Audit Committee and the

When conducting self-reviews, the Board of Directors also reviews the Corporate Governance Guidelines as necessary.

b) Amendments to the Corporate Governance Guidelines

In June 2015, the Company released a Corporate Governance Report indicating that it was in

## 2. Explanatory Notes for Financial Results Summary

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

In April 2016, the Company established EA Pharma Co., Ltd. after splitting off a portion of its Japanese gastrointestinal disease related business to be succeeded by AJINOMOTO PHARMACEUTICALS CO., LTD. (Tokyo), a wholly owned subsidiary of Ajinomoto Co., Inc. (Tokyo). As the Company acquired 60% of common stock of EA Pharma, the Company regards EA Pharma as its consolidated subsidiary.

### 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 major impact on the condensed interim consolidated financial statements for the period.

Accounting standards and interpretations	Mandatory application (Date commenced)	Date applied by the Group	Description
IAS 16 Property, Plant and Equipment IAS 38 Intangible Assets	January 1, 2016	Fiscal 2016	Clarification of acceptable methods of depreciation and amortization
IFRS 11 Joint Arrangements	January 1, 2016	Fiscal 2016	Accounting for acquisitions of interests in joint operations
IAS 1 Presentation of Financial Statements	January 1, 2016	Fiscal 2016	Clarifying disclosure requirement regarding materiality considerations
IFRS 10 Consolidated Financial Statements IFRS 12 Disclosure of Interests in Other Entities IAS 28 Investments in Associates	January 1, 2016	Fiscal 2016	Clarifying exceptions for applying consolidation and the equity method for investment entities

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.



**3. Condensed Interim Consolidated Financial Statements**  
**1) Condensed Interim Consolidated Statement of Income**

(Millions of yen)

## 2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	First six-month period ended September 30, 2016	First six-month period ended September 30, 2015
Profit for the period	29,577	11,134
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(1,271)	2,139
Subtotal	(1,271)	2,139
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(49,195)	(2,979)
Cash flow hedges	(80)	(53)
Subtotal		

**3) Condensed Interim Consolidated Statement of Financial Position**

(Millions of yen)

(Millions of yen)

	Note	As of September 30, 2016	As of March 31, 2016
<b>Equity</b>			
Equity attributable to owners of the parent			
Share capital		44,986	44,986
Capital surplus		77,615	58,232
Treasury shares		(36,234)	(36,231)
Retained earnings		398,862	394,974
Other components of equity		62,463	111,701
Total equity attributable to owners of the parent		547,692	573,661
Non-controlling interests		17,241	3,168
Total equity		564,933	576,828
<b>Liabilities</b>			
Non-current liabilities			
Borrowings		210,129	203,593
Other financial liabilities		3,220	3,214
Retirement benefit liabilities		13,745	13,203
Provisions		1,211	1,189
Other liabilities		21,180	20,962
Deferred tax liabilities		297	287
Total non-current liabilities		249,781	242,448
Current liabilities			
Trade and other payables		57,882	56,399
Other financial liabilities		3,875	4,221
Income tax payables		5,547	5,437
Provisions		11,949	11,143
Other liabilities		71,230	74,728
Subtotal		150,484	151,927
Liabilities directly associated with assets held for sale	(1)		2,784
Total current liabilities		150,484	154,711
Total liabilities		400,265	397,159
Total equity and liabilities		965,198	973,987

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

For the first six-month period ended September 30, 2016

(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, 2016



## 5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	First six-month period ended September 30, 2016	First six-month period ended September 30, 2015
Operating activities		
Profit before income taxes	38,107	17,334
Depreciation and amortization	13,845	20,476
Impairment losses	160	200
(Increase) decrease in working capital	(11,129)	13,677
Interest and dividends received	883	913
Interest paid	(1,293)	(2,261)
Income taxes paid	(7,789)	(4,819)
Income taxes refund	1,759	1,512
Other	(7,741)	(3,243)
Net cash from operating activities	26,799	43,789
Investing activities		
Purchases of property, plant and equipment	(2,462)	(2,855)
Proceeds from sale of property, plant and equipment	245	13,179
Purchases of intangible assets		

## 6) Notes to Condensed Interim 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 five reporting segments in this report: Japan (Prescription Medicines, Generics, and OTC), Americas (North, Central and South America), China, Asia (primarily South Korea, Taiwan, Hong Kong, India, and ASEAN), and EMEA (Europe, the Middle East, Africa, and Oceania).

Following reorganization aimed at achieving sustained growth of the Japan business, the Consumer Healthcare Business—Japan reporting segment of the previous fiscal year has been integrated into the Japan pharmaceutical business reporting segment.

From the fiscal year ending March 31, 2017, the method for calculating the segment profit of pharmaceutical business and other business has changed. Following the change, other income and expenses that had been allocated to pharmaceutical business and o



(Note 3) "Group headquarters' management costs and other expenses" are the costs and expenses covering Group-wide operations.

**(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, 2016, gain from a bargain purchase of

non-controlling interests and the ¥20,000 million decrease in fair value interests of transferred business was accounted for as capital surplus.

The increase in the Company's interests in AJINOMOTO PHARMACEUTICALS CO., LTD. was accounted for using the acquisition method with the abovementioned company as acquiree, a summary of which follows:

(1) Name of the acquiree

AJINOMOTO PHARMACEUTICALS CO., LTD. (New name: EA Pharma Co., Ltd.)

(2) Acquisition date

April 1, 2016

(3) Method for acquiring shares and percentage of voting rights for the acquisition

The Company acquired 6,000 shares of common stock of AJINOMOTO PHARMACEUTICALS CO., LTD. (60% in the voting rights ratio) as consideration for the absorption-style split.

(4) Primary reasons for the business combination

- (5) Fair value of consideration transferred, assets acquired and liabilities assumed, and gain from a bargain purchase

(Millions of yen)

	As of acquisition date (April 1, 2016)
Consideration transferred (Note 1)	20,000
Non-controlling interests in the acquiree (Note 2)	13,320
Assets acquired and liabilities assumed	
Property, plant and equipment	4,141
Intangible assets	11,161
Other non-current assets	3,198
Cash and cash equivalents	19,346
Other current assets	23,859
Non-current liabilities	(3,932)
Current liabilities	(15,169)
Total	42,603
Gain from a bargain purchase (Note 3)	9,283

(Note 1) Consideration transferred is measured as 40% of non-controlling interests in the Company's transferred business, which has a business value of ¥50,000 million. Acquisition-related costs resulting from the business combination totaled ¥270 million and is recognized as selling, general and administrative expenses (SG&A). Acquisition-related costs recognized as expenses in the previous fiscal year was ¥250 million and acquisition-related costs recognized as expenses for the first six month period ended September 30, 2016, was ¥20 million.

(Note 2) Following the business combination, the Company chose to measure non-controlling interests at 40% of the shares of the acquiree with fair value of ¥33,320 million.

(Note 3) The Company, based on all information available at the time of the acquisition date, evaluated the fair value of assets acquired and liabilities assumed. As a result, assets acquired and liabilities assumed that were measured at fair value totaled ¥42,603 million. However, as this exceeded the ¥33,320 million combined total of ¥20,000 million in consideration transferred and ¥13,320 million in non-controlling interests in the acquiree, the difference of ¥9,283 million is recognized as gain from a bargain purchase in other income.

- (6) Net cash inflow on acquisition of subsidiaries

Consideration transferred following the business combination was 40% in interests for transferred business of the Company; no cash payment was made. For this reason, net cash inflow on acquisition of subsidiaries following the business combination was ¥19,346 million in cash and cash equivalents held by the acquiree.

- (7) Revenue and profit for the s5( )-41 Tm[(, )esh p

consolidated statement of income, respectively. Revenue of ¥16,305 million and profit for the period of the Company's transferred business are included in the revenue and profit for the period of the acquiree, respectively.

**(Sales of Subsidiaries)**

On April 1, 2016, the Group transferred all shares of Sannova Co., Ltd., a consolidated subsidiary of the Company, to Alfresa Holdings Corporation.

(1) Consideration received, assets and liabilities over which control was lost

(Millions of yen)

	First six-month period ended September 30, 2016
Consideration received	8,955
Assets and liabilities over which control was lost	
Property, plant and equipment	5,430
Other non-current assets	144
Cash and cash equivalents	2,495
Other current assets	3,661
Non-current liabilities	(1,093)
Current liabilities	(1,754)
Gain on sale of investments in subsidiaries	70

(2) Net cash inflow on sales of subsidiaries

(Millions of yen)

	First six-month period ended September 30, 2016
Consideration received in cash	8,955
Cash and cash equivalents in the subsidiaries sold	(2,495)
Net cash inflow on sale of subsidiaries	6,459

**(Significant Subsequent Events)**

Not applicable