# CONSOLIDATED FINANCIAL REPORT [IFRS] for the Three-Month Period ended June 30, 2014

August 1, 2014

Eisai Co., Ltd. Stock exchange listing: Tokyo Stock

Exchange

TSE Code: 4523 URL: http://www.eisai.com

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Vice President, Corporate Affairs

Expected date of quarterly report submission: August 13, 2014

Expected date of dividend payment commencement: —

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 Three-Month Period ended June 30, 2014

#### 2. Dividends

	Annual dividends					
	End of Q1	End of Q1 End of Q2 End of Q3 End of year Total				
	(¥)	(¥)	(¥)	(¥)	(¥)	
FY ended March 31, 2013	_	70.00	_	80.00	150.00	
FY ended March 31, 2014	_					

FY ending March 31, 2015 (Forecast)

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- 1. Qualitative Information Concerning Financial Results
  - 1) Explanations Concerning Consolidated Operating Results

#### [Performance by Segment]

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

The Group's segments include pharmaceutical business and other business. The pharmaceutical business is organized into the following reporting segments in this report: Japan (Prescription medicines, Generics and Diagnostics), Americas (North America, Central and South America); Asia (primarily China, South Korea, Taiwan, India and ASEAN), EMEA (Europe, the Middle East, Africa and Oceania) and Consumer healthcare business (CHB) Japan (mainly over-the-counter [OTC] products).

#### Japan pharmaceutical business

Revenue totaled ¥73,694 million (down 9.1% year-on-year), with segment profit at ¥33,680 million (down 21.5% year-on-year). Of this amount, revenue totals for Prescription medicines, Generics and Diagnostics were, respectively, ¥65,951 million (down 10.7% year-on-year), ¥6,360 million (up 9.9% year-on-year), and ¥1,383 million (down 1.8% year-on-year).

Revenue from Humira, a fully human anti-TNF-alpha monoclonal antibody, came to ¥7,764 million (up 12.1% year-on-year). Co-promotion revenue for Lyrica, a pain treatment being co-promoted with Pfizer Japan Inc., came to ¥4,280 million (up 3.7% year-on-year), while revenue for Lunesta, an insomnia treatment, increased to ¥1,007 million (up 76.3% year-on-year). Meanwhile, due to factors including the influence of drug price revisions and intensifying market competition, revenue from Aricept and Pariet decreased to ¥13,440 million (down 26.7% year-on-year) and ¥10,756 million (down 15.8% year-on-year), respectively. Halaven recorded revenue of ¥1,564 million (down 4.3% year-on-year).

#### Americas pharmaceutical business

Revenue totaled ¥25,405 million (down 38.5% year-on-year). Further, segment profit decreased to ¥86 million (down 99.0% year-on-year) due to proactive investment in nurturing global brands.

Aloxi, Halaven and BELVIQ recorded revenue of ¥12,564 million (up 21.6% year-on-year), ¥3,803 million (up 16.9% year-on-year) and ¥1,011 million (up 149.5% year-on-year), respectively. Revenue for antiepileptic agent Banzel came to ¥2,244 million (up 45.5% year-on-year) and Fycompa ¥155 million (¥145 million increase over same period of previous fiscal year), both contributing to the growth of the Group's epilepsy franchise. Meanwhile, Aciphex was impacted by LOE from November 2013, recording revenue of ¥3,864 million (down 75.1% year-on-year).

#### Asia pharmaceutical business

Revenue totaled ¥16,289 million (up 21.8% year-on-year) and segment profit ¥4,308 million (up 41.8% year-on-year). Of this amount, revenue in China continued to increase significantly as it had in the previous period, recording ¥9,161 million (up 30.2% year-on-year).

Revenue for Methycobal, a peripheral neuropathy treatment, achieved significant growth in China, amounting to ¥4,618 million (up 29.1% year-on-year). Revenue from Aricept came to ¥3,225 million (up 9.6% year-on-year), Humira ¥1,973 million (up 22.3% year-on-year), Pariet ¥1,546 million (up 8.2% year-on-year) and Halaven ¥219 million (up 247.5% year-on-year).

Urief, a treatment for dysuria associated with benign prostatic hyperplasia (BPH), was launched in Thailand in April 2014.

#### EMEA pharmaceutical business

Revenue totaled ¥8,840 million (up 15.3% year-on-year), with segment profit of ¥1,077 million (up 44.4% year-on-year).

Revenue from Halaven totaled ¥2,582 million (up 29.5% year-on-year). Revenue for epilepsy franchise products of Zonegran and Zebinix increased to ¥1,948 million (up 26.9% year-on-year) and ¥688 million (up 27.5% year-on-year), respectively, while Fycompa recorded revenue of ¥541 million (down 4.4% year-on-year), partially due to the impact of temporary suspension of commercial distribution of the agent in Germany.

#### Consumer healthcare business Japan

Revenue totaled ¥3,772 million (down 9.9% year-on-year), while a loss of ¥164 million was recorded for segment profit (loss) in part due to proactive investment in new products.

Revenue from the Chocola BB group of products totaled ¥2,501 million (down 12.5% year-on-year) partially due to sluggish demand following the consumption tax increase.

Joma, an energy drink, was launched in April 2014.

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

Status of Ongoing Research & Development Pipelines

Halaven (eribulin), an anticancer agent, obtained approval as a treatment for breast cancer sequentially around the world and as of July 2014 is approved in 54 countries and territories worldwide. Furthermore, in June 2014, an indication expansion of Halaven was approved in Europe by the European Commission (EC) to contribute to earlier treatment of patients with locally advanced or metastatic breast cancer. In the United States, a Phase III study to investigate the agent as a potential first- or second-line chemotherapy for HER2-negative breast cancer has been initiated and is underway. Similarly, in China, a Phase III study to investigate the agent as a potential third-line chemotherapy for breast cancer has been initiated and is underway. In addition, a Phase III study in non–small cell lung cancer is being conducted in the United States, Europe and Asia, including Japan. Also, 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.

Fycompa (perampanel, an AMPA receptor antagonist), which is an antiepileptic drug, was approved by the EC in July 2012 as an adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy aged 12 years and older. The agent obtained approval for

the same indication by the Food and Drug Administration (FDA) in the United States in October 2012. As of July 2014, Fycompa is approved in 39 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 conducted in the United States, Europe and Asia, including Japan, met its primary endpoint and the Company is planning to submit applications for an indication expansion of the agent in the United States and Europe in the second quarter of fiscal 2014. In addition, a Phase II study of the agent as a potential therapy for partial-onset epilepsy in pediatric patients is being conducted in the United States and Europe.

A Phase III study of E7080 (lenvatinib), a potential anticancer agent, in patients with radioiodine-refractory differentiated thyroid cancer conducted in the United States, Europe and Asia, including Japan, was completed and an application for indication approval of the agent as a treatment for thyroid cancer was filed in Japan in June 2014. The Company is planning to submit applications for approval in the United States and Europe in the second quarter of fiscal 2014. Currently, lenvatinib has been granted Orphan Drug Designation for

[Status of Major Alliances and Agreements and Other Company Developments]

In April 2014, the Company entered into a joint industry–academia collaboration to develop a new inflammatory bowel disease treatment utilizing the Company's integrin activation inhibitor E6007 and biomarkers developed by the University of Tsukuba's Life Science Center of Tsukuba Advanced Research Alliance. This project has been adopted by the Japan Science and Technology Agency (JST) for its Newly extended Technology transfer Program (NexTEP).

In May 2014, the Company resubmitted Fycompa, an antiepileptic drug, to the German Federal Joint Committee (G-BA) for additional benefit assessment. The reason for the resubmission was that the value of Fycompa as an innovative new treatment had been not appropriately assessed in the previous additional benefit assessment conducted after marketing authorization was granted.

In May 2014, the Company exercised its option to also include Japan in joint development and commercialization of next-generation Alzheimer's disease treatment candidates E2609, a BACE inhibitor, and BAN2401, an anti-amyloid beta (A ) protofibril antibody, as set out in an agreement with Biogen Idec Inc. (United States).

In May 2014, the Company's research and development subsidiary KAN Research Institute, Inc. (Hyogo prefecture, Japan) held a dedication ceremony for its new research facility located within the Kobe Biomedical Innovation Cluster and has now officially commenced full-scale operation of its research and development activities at this facility.

#### 3) Explanations Concerning Consolidated Financial Position

Assets, Liabilities and Equity

Total assets as of the end of the period amounted to ¥938,583 million (down ¥35,240 million from the end of the previous fiscal year). This decrease in total assets was primarily attributable to the decrease in cash and cash equivalents used for the payment of long-term borrowings and year-end dividends.

Total liabilities as of the end of the period amounted to ¥431,187 million (down ¥13,231 million from the end of the previous fiscal year).

Total equity as of the end of the period amounted to ¥507,396 million (down ¥22,009 million from the end of the previous fiscal year), while ratio of equity attributable to owners of the parent was 53.7% (down 0.3 percentage points from the end of the previous fiscal year). The net debt equity ratio (Net DER) as of the end of this period was 0.18 (up 0.04 points from the end of the previous fiscal year).

(Note) Net DER: (Interest-bearing debts (bonds and borrowings - cash and cash equivalents – time deposits exceeding three months) / equity attributable to owners of the parent

#### Cash Flows (For the three-month period ended June 30, 2014)

Net cash provided by operating activities amounted to ¥7,941 million (down ¥6,619 million from the same period of the previous fiscal year). Specifically, profit before income taxes was ¥7,729 million; depreciation and amortization were ¥9,317 million. Income taxes paid amounted to ¥3,438 million.

Net cash used in investing activities amounted to ¥4,102 million (compared to ¥26,791 million provided in the same period of the previous fiscal year). Capital expenditure totaled ¥3,205 million.

Net cash used in financing activities amounted to ¥28,737 million (down ¥53,471 million from the same period of the previous fiscal year). Repayment of long-term borrowings was ¥10,216 million, and the amount of dividends paid was ¥22,829 million.

As a result, cash and cash equivalents as of the end of this period stood at ¥127,147 million (down ¥26,774 million from the end of the previous fiscal year).

Free cash flows (net cash provided by operating activities less capital expenditure) amounted to ¥4,735 million (up ¥1,962 million from the same period of the previous fiscal year).

4) Explanations Concerning Consolidated Financial Forecasts for the Fiscal Year Ending March 31, 2015 (April 1, 2014 to March 31, 2015) and Other Future Forecast Information

**Consolidated Forecasts** 

Consolidated forecasts for the first half and full fiscal year remain unchanged.

(Fiscal year percentage shows year-on-year change, six-month percentage shows increase from the corresponding period of the previous fiscal year.)

Revenue

Operating profit

Profit before income taxes

#### 5) Notes regarding Corporate Governance

#### (1) Appointment of Directors

Eleven Directors, including seven Outside Directors, were appointed and assumed their respective offices effective from June 20, 2014, the date of the 102nd Ordinary General Meeting of Shareholders.

The seven Outside Directors must meet the requirements for Outside Directors set forth in Article 2-3-7 of the Ordinance for Enforcement of the Companies Act of Japan, as well as satisfy the following Requirements for the Independence and Neutrality of Outside Directors established by the Company's Nomination Committee.

The Company has notified the Tokyo Stock Exchange (TSE) of the names and details of all seven Outside Directors as Independent Directors.

#### Requirements for the Independence and Neutrality of Outside Directors

(Revised on December 20, 2013)

- 1. An Outside Director must neither currently be nor in the past have been an Officer (see Note 1 below) or an employee of Eisai or any of its affiliated companies ("Eisai Group").
- 2. An Outside Director's economic independence and neutrality from Eisai Group and specified enterprises, etc., is ensured by satisfying the following requirements:
  - 1) None of the following shall be applicable to the Outside Director within the past five years:
    - Having been an Officer or employee of an enterprise, etc., of a Major Business Partner (see Note 2 below) of Eisai Group, or otherwise an Officer or employee of an enterprise, etc., conducted by a Major Business Partner of Eisai Group;
    - b. Regardless of the value of the transaction, having been an Officer or employee of an enterprise, etc., with whom Eisai conducts necessary transactions, Eisai's audit corporation, or any other enterprise, etc., that has a relationship of substantive interest with Eisai Group;
    - c. Having been an Officer or employee of a person or an enterprise, etc., who is a Major Shareholder (see Note 3 below) of Eisai or of an enterprise, etc., in which Eisai Group is a Major Shareholder;
    - d. Excluding Officer compensation from Eisai Group, having directly received a Large Amount (see Note 4 below) of money or other property as a provider of professional services, etc. (i.e., a consultant, a lawyer, an accountant, etc.);
    - e. Having received a Large Amount of money or other property from Eisai Group as a contribution or having been an Officer or employee of an entity, organization, etc., that has received such a contribution or
    - f. Having been an Officer or employee of an enterprise, etc., which enterprise, etc., had an Officer, etc., who was at the same time an Officer, etc., of Eisai Group;
  - Even if more than five years has passed, the Nomination Committee must evaluate (see Note 5 below) the relationship with the enterprise, etc., in each item of the preceding clause 2(1) and determine that independence and neutrality is ensured; and
  - 3) In addition, from the perspectives of independence and neutrality, there must not be any other reason that would impede the performance of the duties as an Outside Director.
- 3. An Outside Director must not be a close relative of, or have a similar relationship to (see Note 6 below), or otherwise derive such person's sole livelihood through a relationship with, any of the following persons:
  - 1) An Officer or Important Employee (see Note 7 below) of Eisai Group; or
  - Based on the requirements of paragraph 2 of this Article above, those as determined by the Nomination Committee whosw2Comm

1) Shareholding or stock options ownership in the relevant enterprise, etc.;

2) Post-retirement remuneration, company pension, etc., from the relevant enterprise, etc.; and

3) Human interaction between the Eisai Group and the relevant enterprise, etc.

Note 6: "A close relative of, or have a similar relationship to" means a relative within two degrees of

kinship or having a human relationship that can be reasonably recognized as that which would impede the execution of the individual's duties as an Outside Director, such as a personally

interested individual.

Note 7: "An Important Employee" means an employee with a title of at least the head of a section.

#### (2) Structure of the Board of Directors

At the Board of Directors meeting held following the closing of the 102nd Ordinary General Meeting of Shareholders, the Chair of the Board of Directors, as well as Chairs and members of the Nomination, Audit and Compensation Committees, were appointed and assumed their respective offices. (\*denotes outside directors)

The Independent Committee of Outside Directors is comprised of all the outside directors. At the Independent Committee of Outside Directors meeting held on June 20, 2014, Mr. Osamu Suzuki was appointed as Committee Chair and subsequently took up the position.

Haruo Naito Representative Corporate Officer and CEO

Tokuji Izumi\* Chair of the Board of Directors

Member of the Independent Committee of Outside Directors

Kiyochika Ota\* Chair of the Nomination Committee

Compensation Committee Member

Member of the Independent Committee of Outside Directors

Hideaki Matsui Audit Committee Member

Nobuo Deguchi

Graham Fry\* Chair of the Compensation Committee

**Nomination Committee Member** 

Member of the Independent Committee of Outside Directors

Osamu Suzuki\* Audit Committee Member,

Chair of the Independent Committee of Outside Directors

Patricia Robinson\* Audit Committee Member,

Member of the Independent Committee of Outside Directors

Toru Yamashita\* Nomination Committee Member

Compensation Committee Member

Member of the Independent Committee of Outside Directors

Ikuo Nishikawa\* Chair of the Audit Committee

Member of the Independent Committee of Outside Directors

Noboru Naoe Audit Committee Member

(3) Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders At a meeting on June 20, 2014, the Independent Committee of Outside Directors (Chair: Osamu Suzuki) resolved to propose that the "Policy for Protection of the Company's Corporate Value and Common Interests of Shareholders" (the "Policy") be continued in its present form as it incorporates the following provisions.

- a. The Policy precludes arbitrary action on the part of management.
- b. The continuation, amendment or abandonment 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.

At the Board of Directors meeting held on August 1, 2014, the above proposal by the Independent Committee of Outside Directors regarding the continuation of the Policy was deliberated and approved.

The Policy was initially adopted after being proposed by the Independent Committee of Outside Directors at the Board of Directors meeting held in February 2006. At its meeting held in August 2011, the Board of Directors deliberated and approved a proposal put forward by the Independent Committee of Outside Directors, which recommended that the Policy, since it incorporates the above-mentioned three provisions, remain in effect until June 30, 2016, to cover the entire period of the new Mid-term Strategic Plan "HAYABUSA" (April 2011 through March 2016), and that necessary revisions be made, including the addition of new clauses or amendment of wording, to reflect revisions made to relevant laws and regulations and rules of the Tokyo Stock Exchange since enactment of this Policy as well as recent discussions regarding anti-takeover measures.

### 3. Consolidated Financial Statements

# 1) Consolidated Statement of Income

(Millions of yen)

		(millionio di yon)
	Three-month period ended June 30, 2014	Three-month period ended June 30, 2013
Revenue	132,829	152,848
Cost of sales	(48,132)	(46,234)
Gross profit	84,697	106,613
Selling, general and administrative expenses	(47,165)	(50,611)
Research and development expenses	(29,100)	(37,268)
Other income	155	267
Other expenses	(122)	(433)
Operating profit	8,466	18,568
Financial income	588	715
Financial costs	(1,325)	(1,628)
Profit before income taxes	7,729	17,655
Income taxes	(2,000)	(5,315)
Profit for the period	5,730	12,341
Attributable to		
Owners of the parent	5,678	12,252
Non-controlling interests	51	89
Earnings per share		
Basic (yen)	19.90	42.97
Diluted (yen)	19.89	42.92

# 2) Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three-month period ended June 30, 2014	Three-month period ended June 30, 2013
Profit for the period	5,730	12,341

Other comprehensive income Items that will not be reclassified to profit o

# 3) Consolidated Statement of Financial Position

(Millions of yen)

	As of June 30, 2014	As of March 31, 2014
Assets		
Non-current assets		
Property, plant and equipment	131,780	134,083
Goodwill	154,993	157,378
Intangible assets	103,558	108,351
Other financial assets	40,735	40,814
Other assets	3,009	4,213
Deferred tax assets	70,124	69,210
Total non-current assets	504,198	514,049
Current assets		
Inventories	85,849	87,746
Trade and other receivables	187,378	186,549
Other financial assets	21,917	20,182
Other assets	12,094	11,377
Cash and cash equivalents	127,147	153,921
Total current assets	434,385	459,774
Total assets	938,583	973,823

	As of June 30, 2014	As of March 31, 2014
Equity		
Equity attributable to owners of the parent		
Share capital	44,986	44,986
Capital surplus	57,942	57,949
Treasury shares	(38,350)	(38,481)
Retained earnings	362,141	379,210
Other components of equity	77,557	82,656
Total equity attributable to owners of the	F04 07F	F0C 200
parent	504,275	526,320
Non-controlling interests	3,121	3,084
Total equity	507,396	529,405
Liabilities		
Non-current liabilities		
Bonds and borrowings	155,165	195,740
Other financial liabilities	3,107	2,635
Retirement benefit liabilities	15,337	15,497
Provisions	1,197	1,145
Other liabilities	25,556	27,727
Deferred tax liabilities	333	340
Total non-current liabilities	200,694	243,085
Current liabilities		
Bonds and borrowings	85,814	51,493
Trade and other payables	56,793	62,234
Other financial liabilities	4,594	5,131
Income tax payables	3,240	3,915
Provisions	11,681	13,031
Other liabilities	68,370	65,529
Total current liabilities	230,493	201,334
Total liabilities	431,187	444,419
Total equity and liabilities	938,583	973,823

# 6) Notes to Consolidated Financial Statements

(Going Concern) Not applicable

(Segment Information)

# (2) Difference between reporting segment totals and consolidated financial statements

(Millions of yen)

Profit	Three-month period ended June 30, 2014	Three-month period ended June 30, 2013
Reporting segment total	38,988	55,886
Profit included in "Other"	1,324	2,648