



# FY2013

(Fiscal Year Ended March 31, 2014)

# Financial Results Presentation

**Eisai Co., Ltd.**

May 13, 2014





\*1: One time charge occurred in relation to structural reform through transformation of R&D function in the U.S. and Europe, transfer of business operation at the Misato plant, a voluntary retirement program and tax rate changes implemented following the abolishment of the special reconstruction corporation tax one year ahead of its original schedule

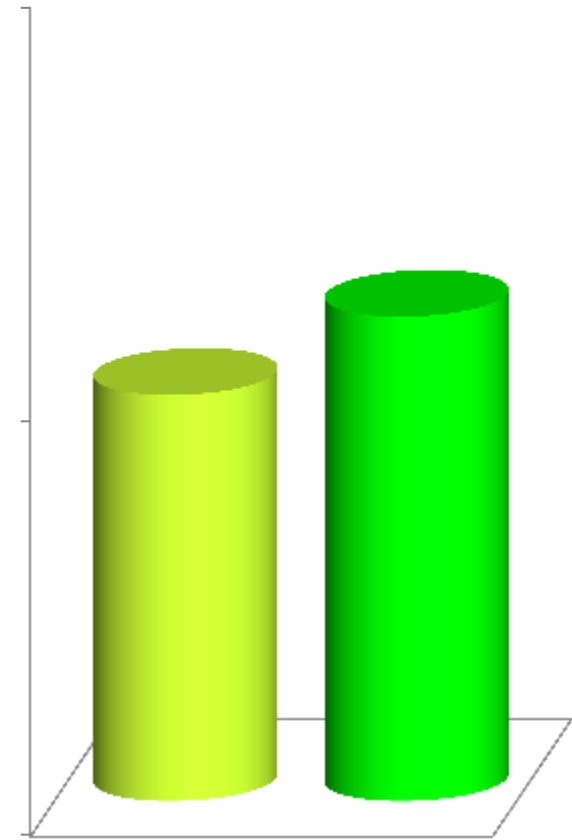
\*2: Pharma EBIT: Operating Income+ R&D Expenses

\*3: Cash income is the total amount of cash available for investments for growth, shareholders return, and repayment of borrowings, etc.

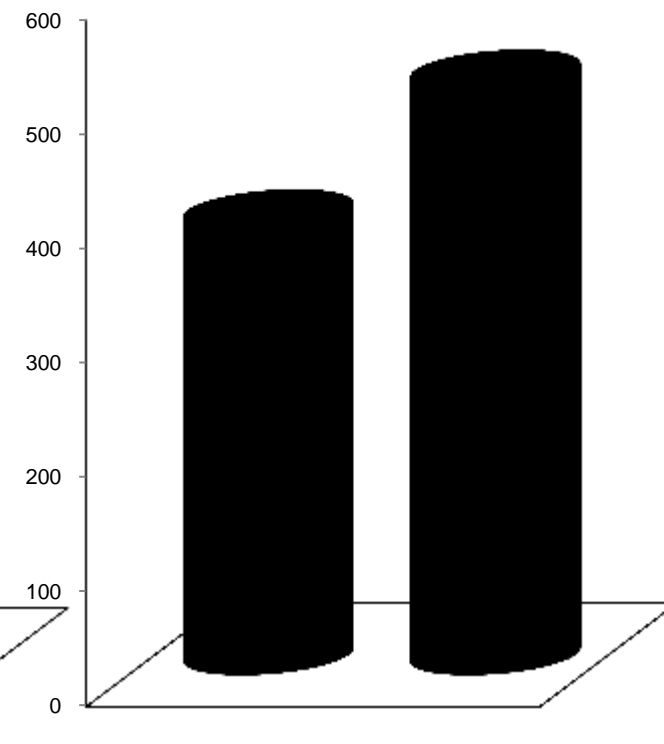
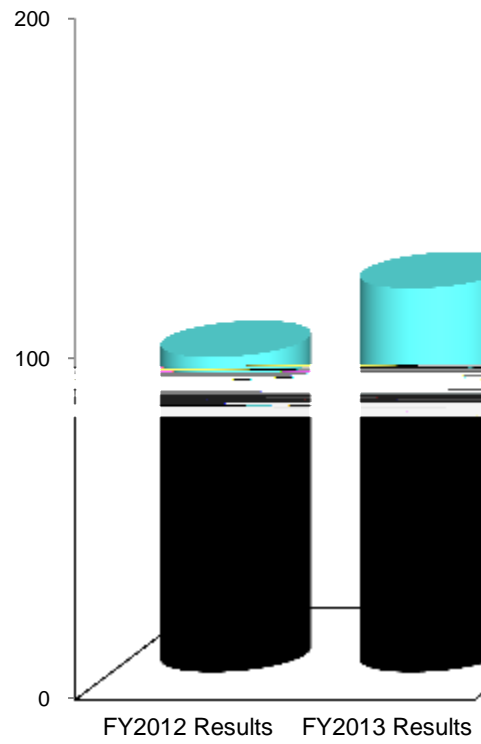
Cash income = Net income + Depreciation of PP&E and Amortization of intangible assets + In-process R&D + Amortization of goodwill + Loss on impairment

# Recap of FY2013 Performance





FY2012  
Results



# Eisai and Biogen Idec Enter Collaboration to Develop and Commercialize Next Generation AD Treatments; Investigational E2609 and BAN2401

Eisai serves as the operational lead in the co-development of E2609 and BAN2401

Eisai serves as the regulatory lead, and both companies share overall costs including research and development expenses

Eisai will book all sales following marketing approval and launch, and profits will be split between the companies

Biogen Idec provides Eisai with an upfront payment and a fixed amount

**Enhance R&D capabilities and  
accelerate development of new therapies**

# FY2013 Breakdown of Net Sales Migration Contribution by next







# Background for the Shift to New Business Model: Eisai Global Business Matrix

- ◆ Simultaneous global development becomes common practice
- ◆ Convergence of global markets in pricing/ reimbursement
- ◆ Standardization of medical practice
- ◆ Initiation of international collaboration between agencies and reimbursement agencies
- ◆ Global expansion of Universal Health Coverage



Vulnerability derived from different strategies in respective regions

Necessity to operate under integrated  
global brand strategy based on  
each  $i^* \{ \} \circ \acute{A}$  circumstance



Global Business Committee  
 Realization of new business unit and region  
 with interactive communication

Americas Region\*1      Japan Region      EMEA

Eisai Global Oncology  
 Business Unit

Halaven, Lenvatinib\*3

Americas  
 Neurology  
 (Metabolic,  
 Epilepsy)

Japan  
*hnc*

Asia  
 Neurology  
 &  
 General

EMEA  
 Neurology

Eisai Global Neurology  
 Business Unit

Fycompa, BELVIQ®,  
 Banzel/Inovelon,  
 Zonegran

Focus on multi-brand expansion through integrated global strategy

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\*1: U.S., Canada, Mexico and Brazil \*2: Europe, Middle East, Africa, Russia, and Oceania



# Proactive Investment in FY2014 for Return to Growth Trajectory from FY2015



**FY2014**  
**110B yen level investment**

Acceleration of Product Creation



35B yen level  
investment

# Global Brand Launch and Expansion of Halaven

Goal backbone chemotherapy with potential new indications



Treatment line of MBC\*1

Aim to expand market share in each the treatment line of MBC\*1 appropriate to each region

(Japan: All lines, E.U.: earlier line\*2, The U.S.: 3<sup>rd</sup> line+)

Rapid expansion in newly launched countries

Plan to launch in FY2014 (15 countries) : Mexico, Brazil, Jordan

# Global Brand Launch and Expansion of Investigational Lenvatinib

Met the primary endpoint in Phase III study (SELECT)



Phase III study in radioactive iodine-refractory differentiated thyroid cancer

Met the primary endpoint with highly statistically significant improvement in PFS<sup>\*1</sup>

Oral presentation to be held at ASCO<sup>\*2</sup>



# Global Brand Launch and Expansion of Investigational Lenvatinib

Seek to establish position as gold standard treatment  
for refractory thyroid cancer



**Plan global submission in FY2014**

**Global approval anticipated in FY2014 - FY2015**

Japan: plan to submit in 1Q FY2014

U.S. and EU: plan to submit in 2Q FY2014

Canada, Australia and Russia: plan to submit in 2H FY2014

Global approval and launch anticipated in Japan/US/EU in FY2014-FY2015

**Launch preparation with integrated global brand strategy**

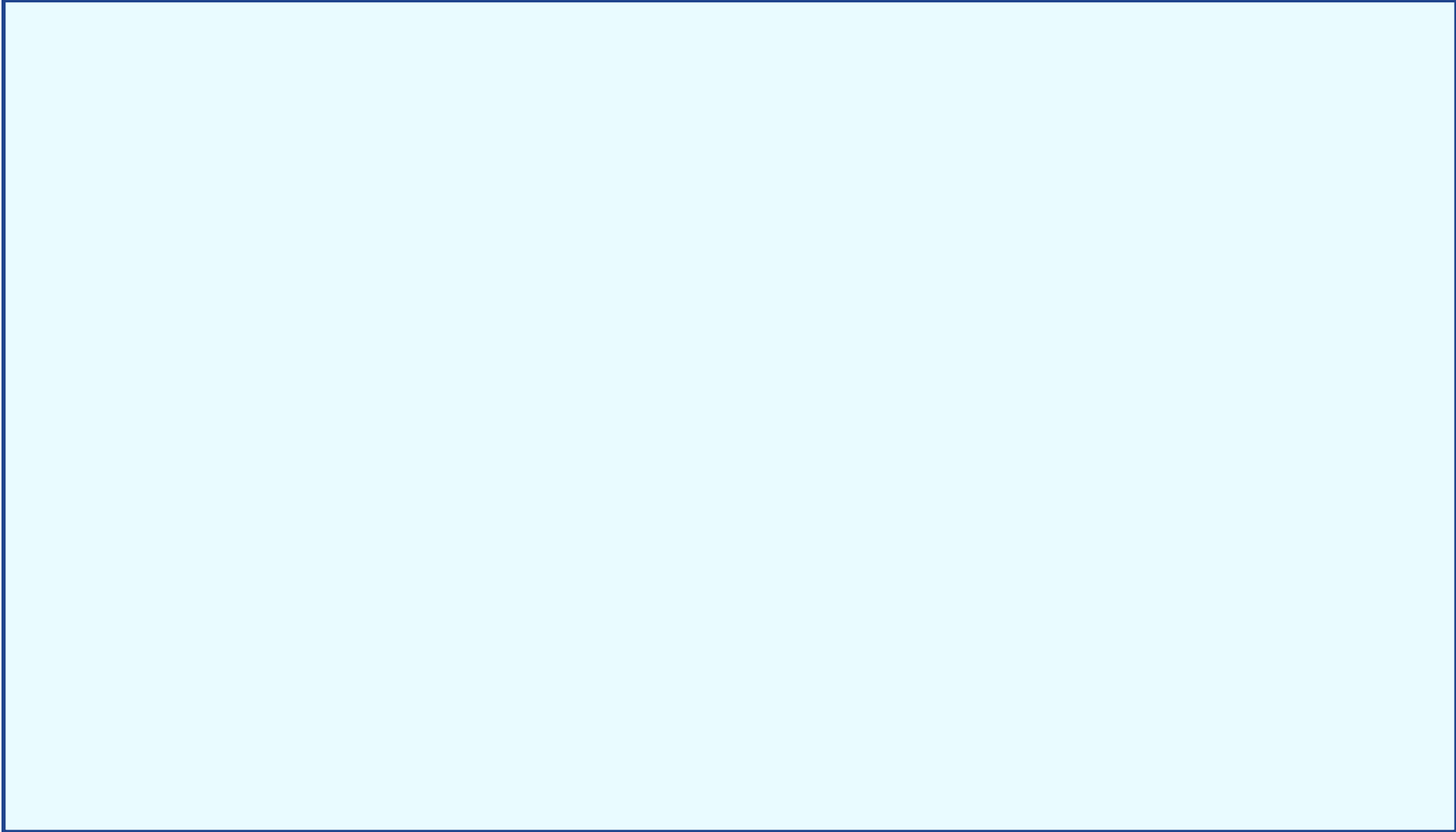
Utilize phase III study

The result of clinical trial in 3<sup>rd</sup> line monotherapy to be presented at the poster presentation at ASCO\*<sup>2</sup>  
Session on May 31<sup>st</sup>: Lung Cancer - Non-small Cell Metastatic

\*1: Non-small cell lung cancer

\*2: The American Society of Clinical Oncology The 50th annual meeting will be held in Chicago, USA, on May 30 . June 3, 2014.





# Global Brand Launch and Expansion of Fycompa

Aim to further establish Eisai as providing a gold standard franchise in treatment of epilepsy



## Seek to expand promotion and access in the U.S.

Increased sales representatives from 55 in January at launch to approx. 90 in April

Launch Patient Assistance Program aim at further contribution to patients with partial-onset seizure



Launch meeting of Fycompa in the U.S.

## Seek 4 times increase in patients who start treatment with Fycompa in EU

Resubmission in Germany for additional benefit assessment in May 2014 to support reintroduction

Robust launch and outperform competitors since launch in Spain in January 2014

## Global expansion of launch countries

Americas: Mexico and Brazil

Asia: Hong Kong, Taiwan, Singapore, Thailand, Philippines

EMEA: France, Italy, The Netherlands, Belgium, Portugal, Russia, Luxemburg, Greece, Jordan, Lebanon, Kuwait, Qatar, Yemen, Libya, Australia



“ Breast cancer (2<sup>nd</sup> line)<sup>\*1</sup> : CHMP opinion anticipated in 1Q FY2014

## Fycompa

- “ PGTC<sup>\*1\*2</sup> : Plan to submit in U.S./EU in 2Q FY2014 depending upon outcome  
**Approval anticipated in FY2015**
- “ Epilepsy (Japan) : Topline result for phase III study anticipated in FY2014  
**Plan to submit in FY2015 after consultation with PMDA**
- “ Suspension program in pediatric and adult patients  
: **Plan to submit in the U.S./EU in FY2015**
- “ Lennox-Gastaut syndrome<sup>\*2</sup>: Plan to initiate phase III study in 4Q FY2014

“ Cardiovascular Outcomes Trial is ongoing

- “ Obesity (Japan) : Submit CTN<sup>\*3</sup> to PMDA<sup>\*4</sup> in 1Q FY2014
- “ Obesity (China) : Submit CTA

# Toward Realization of Creation Neurology area

Investigational  
BAN2401

Anti amyloid-beta protofibrils antibody

” 0Æ: @ã ^!qÁã^æ^

Phase II study (POC study and Study 201):

Clinical trials with adaptive design

Topline results anticipated in FY2015

Investigational  
E2609

Beta-secretase (BACE) inhibitor

” 0Æ: @ã ^!qÁ disease

Phase II study (POC study and Study 202)

: Plan to initiate in 3Q FY2014

Investigational  
E2006

Orexin receptor antagonist

” Insomnia

Phase II study (POC study and Study 201) with adaptive design:

Achieved LPI<sup>\*1</sup> by early completion advice from DMC<sup>\*2</sup>

Topline results anticipated in 1Q FY2014

Phase III study: Plan to initiate in 4Q FY2014 subject to consultation  
with FDA/EMEA etc.



Investigational  
Avatrombopag

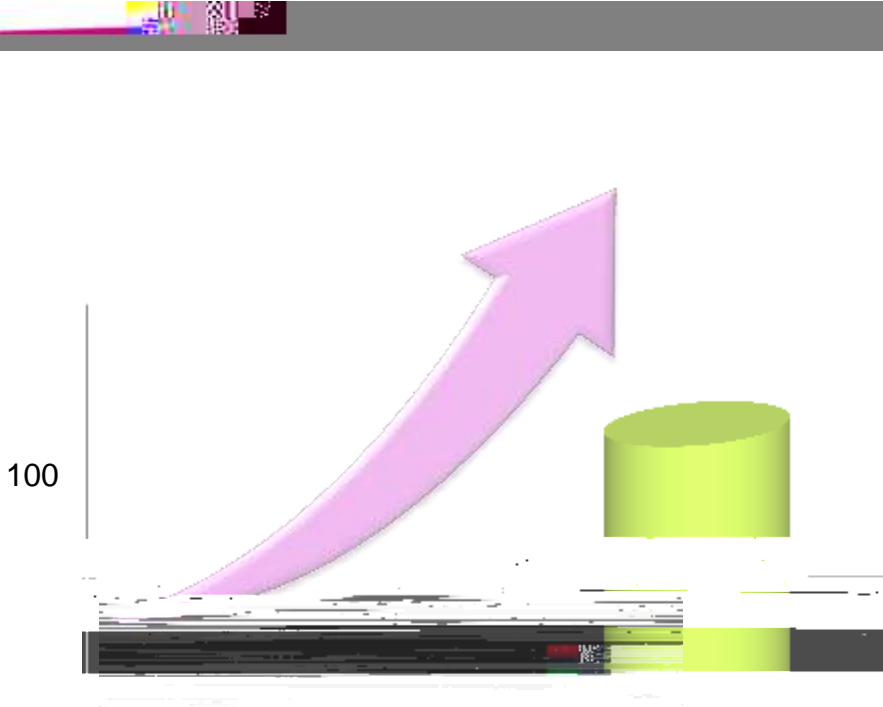
## Thrombopoietin receptor agonist

“Thrombocytopenia with chronic liver disease patients who will undergo elective surgical or diagnostic procedures:


Phase III studies ongoing  
(Study 310 and 311)

Aim to submit globally in FY2015





**Russia**  
 Enhancement of sales activity for Halaven and

 **Mexico**  
 Submitted 7 products\*<sup>3</sup> including Halaven, BELVIQ® and Fycompa

 **Brazil**  
 Obtained approval for Halaven and submitted 4 products\*<sup>4</sup> including BELVIQ® and Fycompa

 **Australia**  
 Plan to launch Halaven in FY2014  
 Submitted Fycompa

**Middle East**  
 Enhancement of sales activity for Halaven (launched in 3 countries\*<sup>5</sup>) and Fycompa in Israel





# Financial Strategy Map for Resilience of Eisai

## Proactive investment to resume growth trajectory

- " Expansion of global brand
- " Growth of Asian countries  
and strategic markets
- " Accelerate product creation
- " M&A and partnerships

## Stable dividend policy

- " Sustainability of 150 yen/ share
- " 8% level DOE which surpasses  
cost of equity

VCIC  
(Value Creative











# Performance of Japan Pharmaceuticals Business



(Billion yen, %)

	FY2012		FY2013		
	Results	%	Results	%	YoY
<b>Sales</b>					







	FY2012		FY2013			
	Results	%	Results	%	YoY	
<b>Sales</b>	41.3	100.0	58.0	100.0	141	[116]
<b>Methycobal</b>	10.4	25.1	16.1	27.7	156	[127]
<b>Aricept</b>	8.1	19.6	12.0	20.6	148	[122]
<b>HUMIRA</b>	4.9	11.9	6.8	11.7	139	[114]



