



# Information Meeting

March 5, 2010

Eisai Co., Ltd.



# Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially





# Fundamentals

## Concepts

- Having a business structure with global flexibility that could respond to any cases that require global concern
- Establishing a business model to increase efficiency and productivity in value creation based on a business structure to think diligently and treats each item thoroughly



# New business models created



**JBHQ** (Japan Business Headquarters; FY2007)

Integration of prescription dr

# DLP - Strategies & Progress (1)



	Strategies (2006 announcement)	Progress
World Headquarters	<p>Concept:                      “Value creation at all places by best people with appropriate structure”                      Locate important functions for pharmaceutical company in the most appropriate countries and regions; achieve value creation by collaboration with regional headquarters</p>	<p>Established five regional headquarters U.S., JBHQ, Europe, Asia, Oceania &amp; Middle East (AOME), and China                      Eisai Product Creation Systems – structured by 13 units                      9 units have their heads stationed in the U.S. and 4 units have their heads stationed in Japan                      Established seamless value chain in each region                      Developed positions for Global Compliance Officer, Global Quality Officer, Global Safety Officer, and Global Regulatory Officer</p> <p><b>Next step: Further globalization of Eisai headquarters</b></p>
R&D Strategies	<p>Promoting franchise focus                      -Neuroscience, oncology                      Improvement of discovery research                      -Expansion of Kan Research Institute                      -Reinforcement of labs in Tsukuba, Boston, and London                      Strengthening the clinical research structure                      -Global centralization of Japan, U.S., Europe, and Asia                      -New establishment of management unit in Asia                      -Realizing simultaneous regulatory submissions in Japan, U.S. Europe, and Asia                      Realizing speedy/efficient new product planning                      -Project management by a subsidiary responsible for R&amp;D management function</p>	<p>Aiming for combination of productivity/speed of venture and knowledge of global pharma                      - Transformed to Eisai Product Creation Systems                      Investments made to labs in Boston, London, Tsukuba, and to Kan Research Institute                      - Expansion of discovery research                      Equipped with antibody technology by Morphotek acquisition and expansion of Kan Research Institute</p> <p><b>Next step: Full operation of Eisai Product Creation Systems to achieve meaningful results</b></p>
Oncology Strategies	<p>Steady progress of in-house pipeline projects                      Pursuing product acquisitions and alliances                      Establishing oncology business unit                      Structuring oncology medical rep. team in the U.S.                      Production-related investments to RTP and Kashima</p>	<p>Acquisitions of Ligand products, Morphotek, and MGI                      Successful conduct of eribulin clinical studies                      Established oncology business unit in the U.S.                      Sales from oncology franchise to reach 10% of total consolidated sales</p> <p><b>Next step: Initiating smooth commercialization by five regions</b></p>



# DLP – Status of Numerical Targets



	Progress		Challenge	
P/L Structure	<p>SG&amp;A expense ratio:</p> <p>R&amp;D expense ratio:</p>	<p>Improvement of approx. 1 point from the DLP target of 45%</p> <p>Virtually the same as the DLP target of 20%</p>	<p>Consolidated sales:</p> <p>FOREX:</p> <p>COGS:</p> <p>Operating profit:</p>	<p>Assuming deviation from the target of 1 trillion yen</p> <p>-73B yen*<sup>2</sup></p> <p>Increased by 8 pts. due to change in the product mix</p> <p>Assuming deviation of -7 pts. from the target due to above factors</p>
Sales by region	<p>Japan:</p> <p>Prescription Drugs</p> <p>AOME:</p> <p>China:</p>	<p>420B yen, largely exceeding the target of 360B yen with the integration of four businesses</p> <p>Achieved by steady growth of Aricept and Pariet</p> <p>Exceeding the target; expanded region contribution to 3%</p> <p>Little less than the target; almost achieving the challenging targets*<sup>1</sup></p>	<p>US:</p> <p>Europe:</p>	<p>Nearly achieved sales target two years in advance based on local currency; assuming deviation from the target for the final year due to Aricept LOE</p> <p>Assuming deviation from the targets due to intensified market competition for Aricpet and Pariet</p>
Sales by product	<p>Aricept:</p> <p>MGI:</p>	<p>Achieved global target of 275B yen*<sup>1</sup></p> <p>Large contribution to the sales and profit</p>	<p>Pariet/Aciphex:</p> <p>In-house new products:</p>	<p>Assuming deviation from the target due to rapid change of market landscape becoming genericized</p> <p>Assuming deviation from the targets due to delayed schedule for new product launch</p>

\*1 Estimated excluding the impact of exchange rates





## Today's Key Message

Eisai will continue to thrive after  
Aricept LOE and grow further

# Midterm Roadmap for Eisai

Managing through Aricept loss of exclusivity in the U.S. and toward further growth

Back to nearly 10% revenue growth (YOY)

(in billion yen)

Net sales

803

810

105

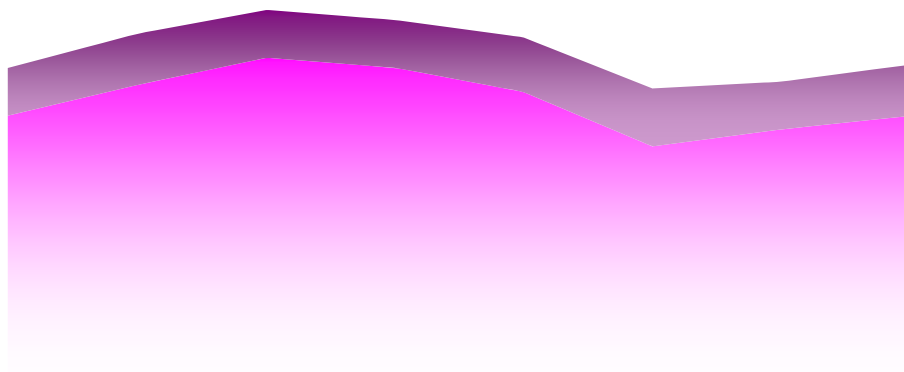
105

Operating profit

FY2009 Forecast

FY2011 Plan





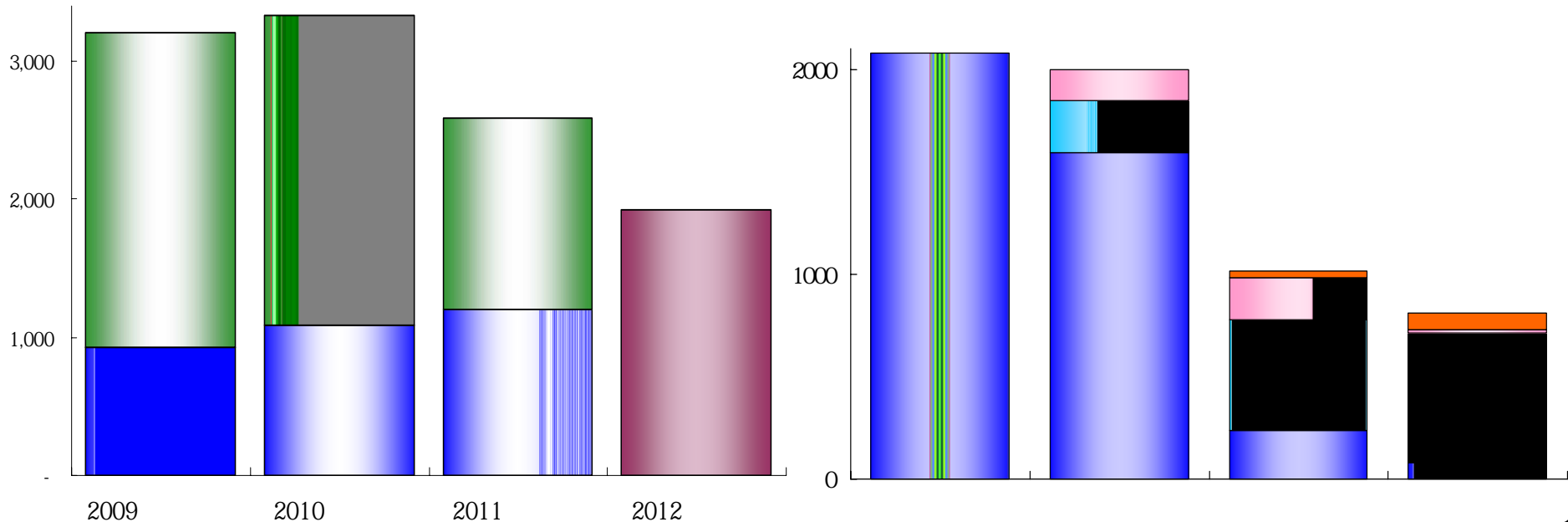


# Forecast for Aricept Sales

## Offsetting the impact by LOE during FY2010-FY2012

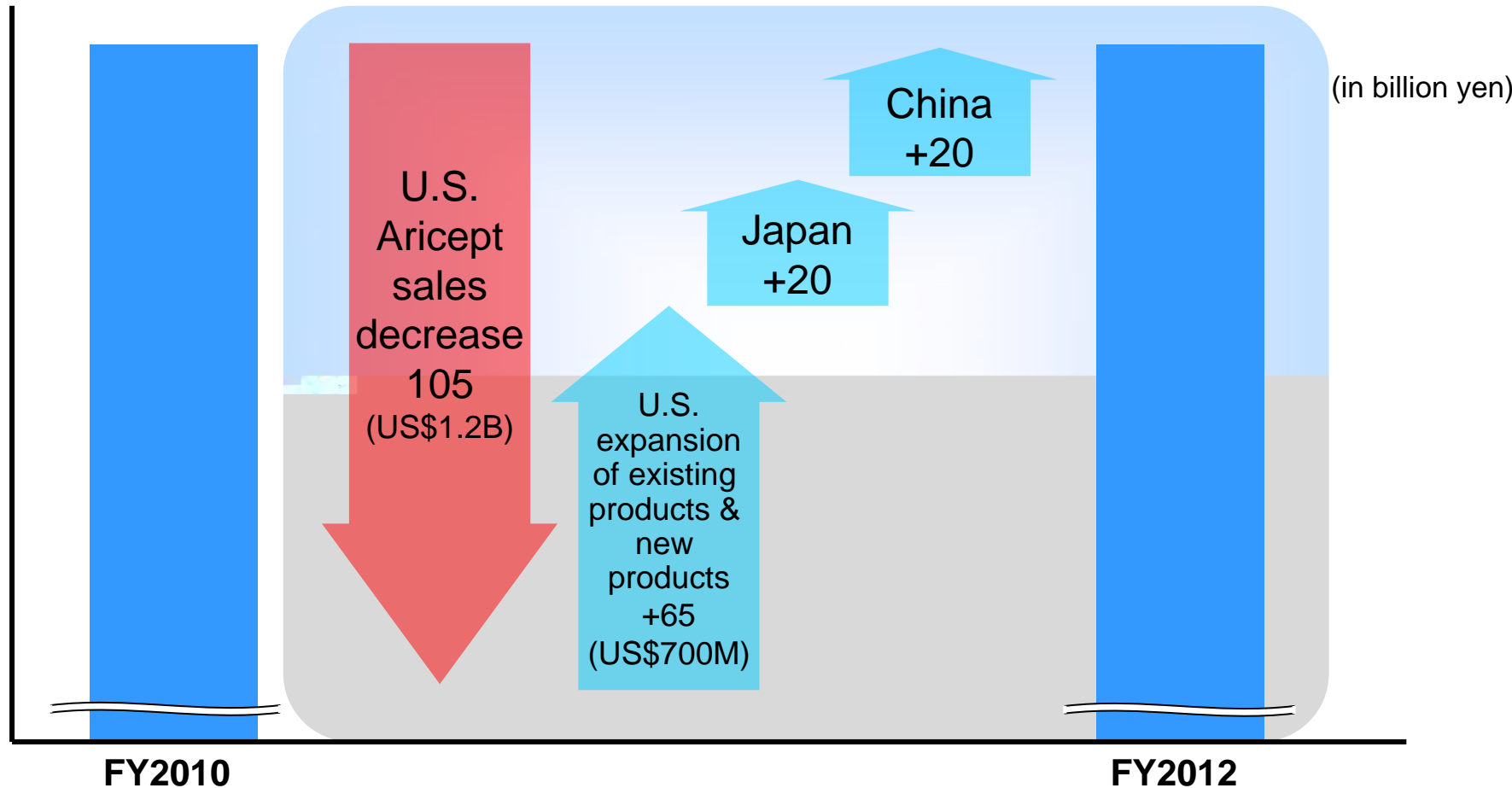
- Continuing global growth in FY2010 with contribution by Japan and China; aiming for FY2011 global sales of approx. 80% of the previous FY
- For U.S. in FY2011, aiming to maintain net sales of approx. 50% of the previous FY by seeking to reinvigorate the Aricept franchise with sustained release formulation, patch formulation, and authorized generic (AG), and current formulation

(in billion yen)





# Offsetting the impact by LOE during FY2010-2012

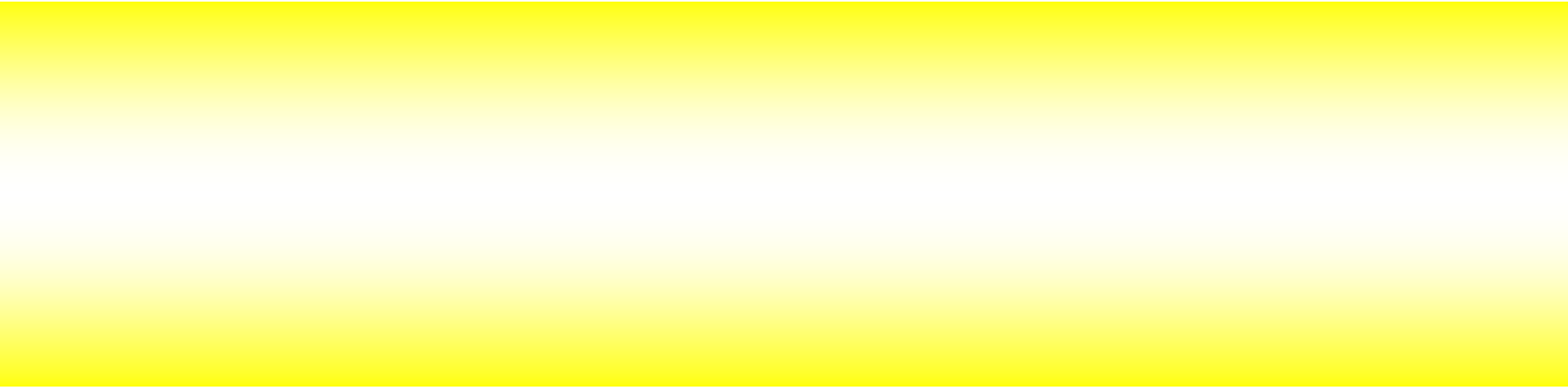




Foreseeable in  
market launch of new products,  
a source of business growth



# Objective of











**Discovery of truly innovative substance**

Higher quality of compound library and natural product library  
State-of-art screening system (utilization of panel assay, high content screening, and siRNA library)  
Utilization of SBDD (structure-based drug design) and FBDD (fragmented-based drug design)

**Superior biomarker imaging research that promotes translational research**

Diagnostic biomarker research to provide efficiency in clinical trials  
Medicinal biomarker/imaging research to shorten clinical trial time  
Toxic biomarker research to confirm human safety

**Efficient speed and size of quality clinical research**

Higher efficiency and quality for clinical operations/management  
Enhanced technology of PK/PD (pharmacokinetics/pharmacodynamics) modeling for clinical research  
New system/tracking tools for efficient and safe monitoring  
External collaboration sharing the risks

**Safety and ADME research to extrapolate clinical results**

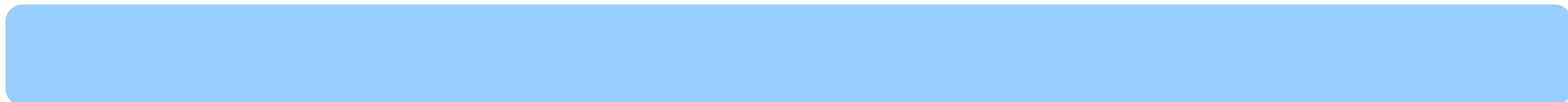
Utilization of PK/PD modeling; PK profiling applying iPS cell technology  
Cardiovascular risk assessment applying iPS cell technology

**Timely supply of high-quality investigational drug and research API**

CMC (chemistry manufacturing & control) strategies tailored to each project

**Appropriate decision making for go/no-go; operational improvement**

In principle, decision making is delegated to the unit presidents



## Aricept-SR

*Providing further benefit for moderate-to-severe Alzheimer's disease treatment*

*Trying to make a paradigm shift*

**Targeted indication:** moderate-to-severe Alzheimer's disease

New sustained-release technology with stable, favorable PK profile that maintains higher anti-cholinesterase activity to seek better benefits for patients

**NDA submission:** submitted in September 24, 2009 (U.S.)

**Anticipated FDA action date:** July 24, 2010

**Potential peak sales:** aiming for \$600M+

## Eribulin (E7389)

*Aiming for new gold standard for breast cancer*

**Targeted indications:** refractory recurrent breast cancer treated with current standard chemotherapy, non-small cell lung cancer, prostate cancer, sarcoma, and other cancers

Microtubule dynamics inhibitor with novel mechanism of action

### **Development status:**

- Successful Phase III trial for refractory recurrent breast cancer treated with current standard chemotherapy (study 305: compared to treatment of physician's choice); observed high response rate (21.3%) in study 221 in Japan; in preparation for submission
- Completed patient enrollment for phase III in refractory recurrent breast cancer patients with less prior treatment (study 301: compared to capecitabine)
- Phase II trial in sarcoma and phase Ib/II in non-small cell lung cancer (combination with carboplatin) are ongoing

### **Submission target:**

Refractory recurrent breast cancer treated with current standard chemotherapy: March 2010 (Japan, U.S., and Europe)

**Potential peak sales:** aiming for \$1B+

## **Eritoran (E5564)**

***First-in-class TLR4 antagonist for severe sepsis treatment***

***Aiming to be a truly life-saving drug***

**Indication:** severe sepsis

TLR4 antagonist with novel mechanism of action

**Development status:**

- Achieved patient-out of 1500th patient for interim analysis; continuing enrollment
- DMC (Data Monitoring Committee) scheduled on March 25th

**Submission target:** 1Q FY2010 (Japan, U.S., and Europe)

**Potential peak sales:** aiming for \$1B+

## **Aciphex-ER**

***Seeking the potentially strongest PPI maintaining the longest pH holding time***

**Indication:** Meeting then unmet medical needs of patients suffering from GERD and heartburn  
Seeking for a longer-acting drug (showed longer pH holding time versus esomeprazole)

**Development status:**

- Achieved the database lock for six phase III trials; required criteria for NDA submission have been judged to be met

**Submission target:** March 2010 (U.S.)

**Potential peak sales:** aiming for \$500M



**Targeted indication:**

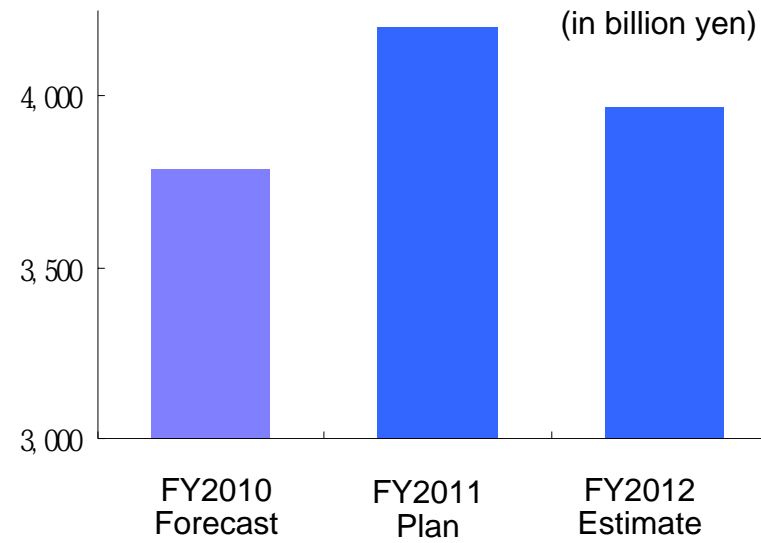


Foreseeable strong growth  
in Japan and China



## Sales growth exceeding the DLP target

- Initial sales target by Japan business of 360



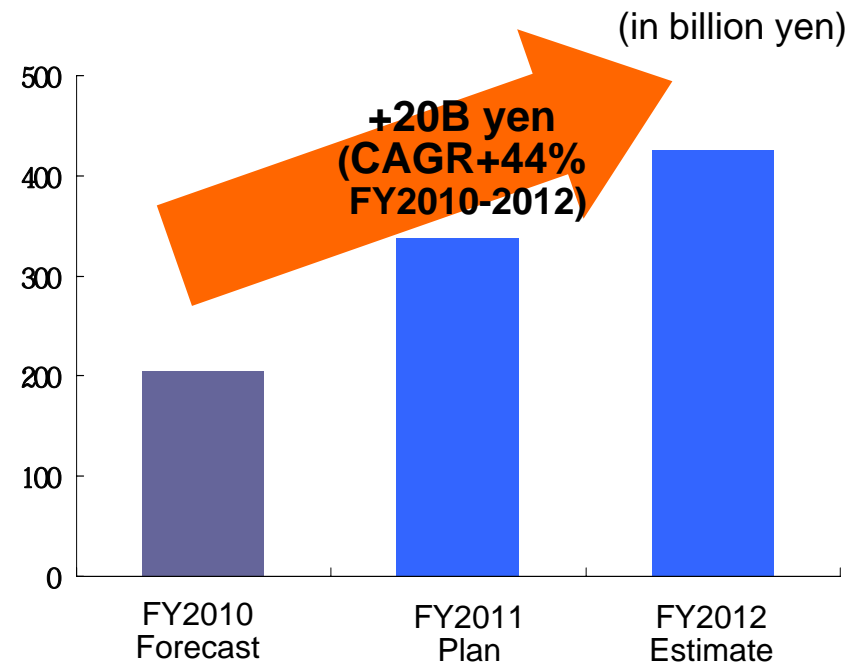




# Rapid expansion of China business with high potential

Initial sales target of 35 billion yen for FY2011  
is likely to be achieved

Strategic development for sustainable growth

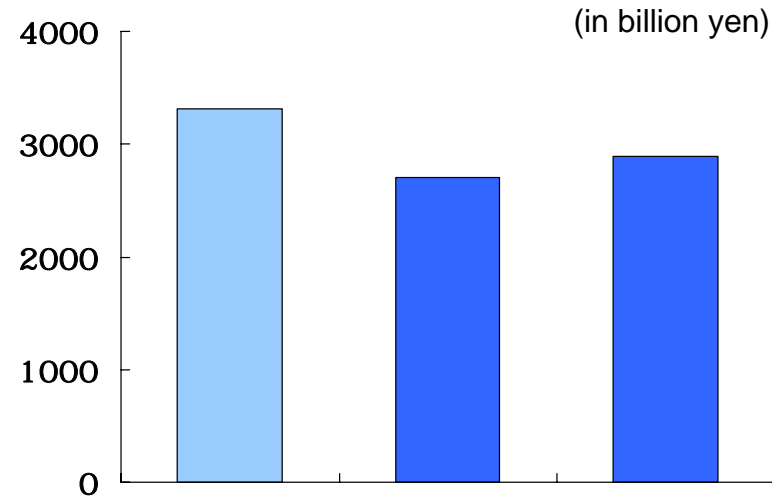




U.S. resumes growth phase in FY2012

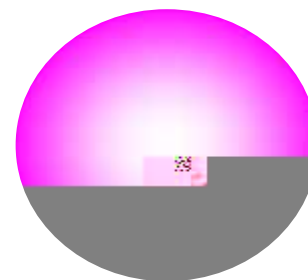


- Sales forecast for Aricept in FY2012
  - From \$2B in FY2010 to \$800M in FY2012 decrease of \$1.2B (approx. -105B yen)
  - Reinvigorating the franchise with sustained release formulation, patch formulation, authorized generic (AG), and current formulation
- Growth by existing products and new products: approx. +65B yen
  - Existing products
    - Steady growth by products which have been added to our product line within past three years
      - Aloxi, Dacogen, Fragmin, Banzel, and Lusedra
  - New products
    - Targeting market launch of eribulin, eritoran, and perampanel; acceleration for growth
    - New products to be submitted and launched in FY2012 and thereafter
      - MORAb-003, E5501 (thrombocytopenia), E7080, and others





Established  
the oncology/critical care franchise





For sustainable business development  
in the emerging markets



# Activities toward securing reach to Eisai products for patients who are unable to receive treatment

- **Reduction of manufacturing cost by Eisai Knowledge Centre, India:**

- Securing appropriate profitability even after the LOE of global products
- Providing new products at affordable pricing for emerging markets
- Innovation for API synthesis process toward global stable supply

- **Streamlining the SG&A expenses:**

- Implementing continuous



# Eisai's initiatives for neglected diseases

- Entered into a collaboration and license agreement for the clinical development of a new drug for the treatment of Chagas disease\* with Drugs for Neglected Disease initiative (DNDi), a non-profit independent foundation, in September 2009
- By innovative and cooperative collaboration for product development

PPP: public-private partnership), Eisai to provide its scientific expertise in clinical development as well as supply the drug (anti-fungal drug discovered and developed by Eisai; E1224: pro-drug of ravuconazole) for the clinical studies

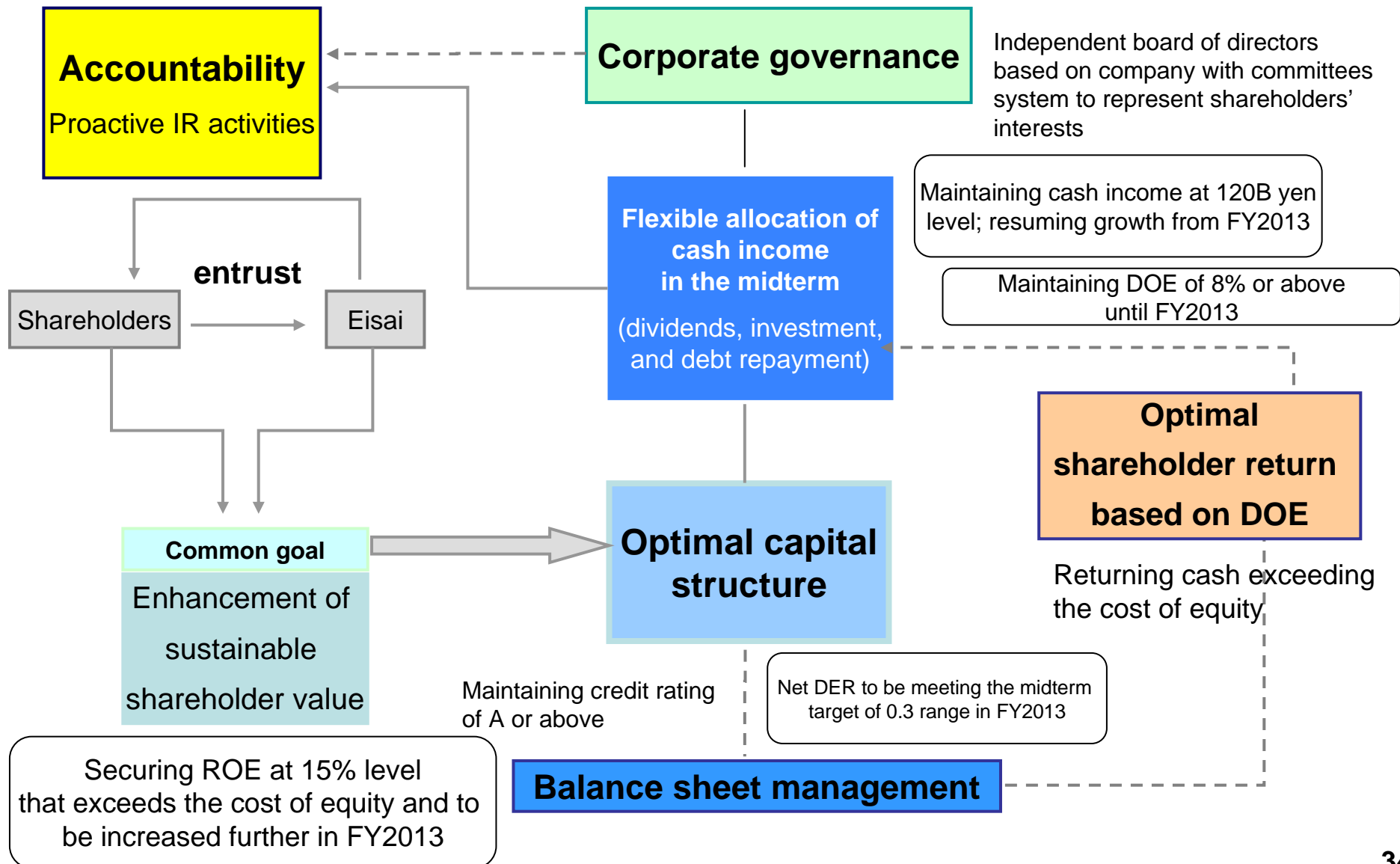




# Value creation for shareholders on a sustainable basis

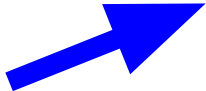
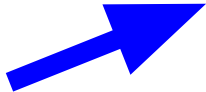
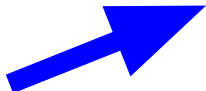


Integration of IR, corporate governance, and finance strategies





# Metrics for shareholder value creation

	<b>FY2009 Forecast</b>	<b>FY2011 Plan</b>	<b>FY2013 Estimate</b>
<b>Cash Income</b>	120.5 B yen	approx. 120 B yen	
<b>ROE</b>	9.7	approx. 15%	
<b>DOE</b>	10.3	Maintaining 8% or above as the midterm target	
<b>EPS</b>	141.4 yen	approx. 228 yen	



# Growth scenario toward FY2013



# Aiming to outperform the global pharmaceutical market growth toward FY2013

Compelling growth with 16 NMEs and 11 LCM  
projects targeted for submission during FY2009-FY2012

Realizing regionally balanced growth with maintaining  
steady growth in Japan, resuming U.S. growth trajectory,  
and rapidly expanding in the emerging markets





# Pipeline to sustain Eisai's midterm roadmap



FY2013 and thereafter

**FY2009**

**Aricept-SR  
(AD)**

**pregabalin<sup>\*1</sup>  
(Herpetic neuropathy,  
peripheral neuropathy)**

**eribulin  
(Refractory BC)**

**bendamustine<sup>\*2</sup>  
(Low-grade non-Hodgkin's  
lymphoma)**

**HUMIRA<sup>\*3</sup>  
(Ankylosing spondylitis)**

**HUMIRA<sup>\*3</sup>  
(Crohn's disease)**

**pancrelipase/SA-001<sup>\*4</sup>  
(Pancreatic exocrine  
insufficiency)**

**Aciphex-ER  
(GERD)**

**FY2011**

**Aricept-patch<sup>\*5</sup>  
(AD)**

**eszopiclone<sup>\*6</sup>  
(Insomnia)**

**LIVACT  
(Chronic type B)**