

# Semiannual Financial Results Fiscal Year 2005

Eisai Co., Ltd.

#### Safe Harbor Statement

- Materials and information provided during this presentation may contain socalled "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 from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors, challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; obtaining regulatory approvals; domestic and foreign healthcare reforms; trends toward managed care and healthcare cost containment, and governmental laws and regulations affecting domestic and foreign operations.
- Also, for products that are approved, there are manufacturing and marketing
  risks and uncertainties, which include, but are not limited to, inability to build
  production capacity to meet demand, unavailability of raw materials, and failure
  to gain market acceptance.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

### **Consolidated Performance**

#### 1H FY2005

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Gross Margin	210.6	80.7	233.9	82.8	111	23.3
R&D Expenses	37.5	14.4	44.4	15.7	119	6.9
SG&A Expenses	131.5	50.4	144.3	51.0	110	12.7
Operating Income	41.6	15.9	45.3	16.0	109	3.7
Ordinary Income	43.2	16.6	47.1	16.7	109	3.9
Net Income	27.6	10.6	30.2	10.7	109	2.6
EPS (Yen)	95.8		105.5		110	9.7

		Results	Results	YOY
Aricept Alzheimer's Disease	U.S.	44.2	52.6	119
Treatment119				
	Total	64.8	71.6	110
	Japan	8.4	13.2	157
Aciphex/Pariet	U.S.	51.9	53.4	103
Proton Pump Inhibitor	Millions of Dollars	472	488	103
	Europe	3.6	3.5	96
	Asia	1.0	1.5	152
	Total	6.1	7.6	124
Zonegran	U.S.	6.1	7.5	122
Anti-epileptic Drug	Millions of Dollars	56	68	123
	Europe, Asia	-	0.1	-

# Sales to Customers by Geographic Area

(billions of yen, %)

	1H FY2004		1H FY2005			
	Results	%	Results	%	YOY	Increase
Japan	133.3	51.1	139.6	49.4	105	6.2
North America	102.7	39.3	114.0	40.3	111	11.3
Europe	19.2	7.4	21.2	7.5	110	2.0
Asia and Others	5.8	2.2	7.9	2.8	137	2.1
Overseas Total	127.7	48.9	143.1	50.6	112	15.4
Total	261.0	100.0	282.6	100.0	108	21.6

	1H FY2	1H FY2004		1H FY2005		
	Re <u>\$</u> u <b>ß</b> s	%	Results	%	YOY	Increase (Decrease)
Japan	21.3	47.5	19.8	39.9	93	(1.4)
North America	19.6	43.7	24.4	49.1	125	4.9
Europe	2.7	6.0	3.9	7.9	146	1.2
Asia and Others	1.3	2.8	1.5	3.1	120	0.2
Overseas Total	23.5	52.5	29.9	60.1	127	6.3
Sub-total	44.8	100.0	49.7	100.0	111	5.0
Eliminations	(3.2)		(4.4)		139	(1.2)
Total	41.6		45.3		109	3.7

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Aciphex 472 50.3 488 46.6 103 16

#### **Consolidated Free Cash Flow**

(billions of yen)

	Cash Flow from Operating Activities		Capital Expenditure		Free Cash Flow	
	Results	Increase (Decrease)	Results	Increase (Decrease)	Results	Increase (Decrease)
1H FY2002	19.6	(13.6)	14.2	3.9	5.3	(17.5)
1H FY2003	45.8	26.3	9.8	(4.4)	36.0	30.7
1H FY2004	40.8	(5.1)	24.2	14.3	16.6	(19.4)
1H FY2005	39.9	(0.9)	19.2	(5.0)	20.7	4.1

# R&D Progress (1)

Europe

# R&D Progress (2)

Research Code	Initiation of Phase III		
E2007	Phase III study for Parkinson's disease will be initiated in 4Q FY2005 (US, Europe)		
E7290	Phase II study in refractory breast cancer to support Subpart H NDA filing initiated in 3Q FY2005 (US)		
E7389	Phase III study for breast cancer (monotherapy) will be initiated in 4Q FY2005 (US, Europe)		
E5564	Phase III study for severe sepsis will be initiated in 4Q FY2005 (US, Europe)		

Research Code	Indication	Progress	Area
E2007	Migraine Prophylaxis	In Phase IIb	US
D2E7 Psoriasis		Initiated Phase II/III	Japan

Research Code	Indication	Progress	Area
E1224	Fungal Infection	Initiated Phase I	US
E7080	Cancer	Initiated Phase I	US, Europe

<sup>\*</sup> Studies for Cleactor (cerebral embolism), E3620, E2051, and E3024 we

### R&D Progress (4)

- E5555: Acute Coronary Syndrome (ACS), Stable Angina (PAR-1 antagonist)
  - Phase I studies ongoing
  - Phase II study will be initiated in FY2005
- E7820: Anti-cancer (Integrin Alpha-2 Expression Inhibitor)
  - Phase I study ongoing
- E7080: Anti-cancer (VEGF Receptor Tyrosine Kinase Inhibitor)
  - Phase I studies ongoing
- E7974: Anti-cancer (Tubulin Polymerization Inhibitor)
  - Phase I study ongoing
- E2012: Alzheimer's Disease (γ Secretase Modulator)
  - IND will be submitted in FY2005

## Consecutive Filings in Japan

#### FY2005

Product Name/ Research Code	Indication	Stage	Expected Application
Aricept Severe Dementia due to Alzheimer's Disease		Phase II	December 2005 (Bridging Study)
D2E7 Rheumatoid Arthritis		Phase II/III	December 2005 (Bridging Study)

#### FY2006

Research Code	Indication	Stage	Expected Application
E2014	Cervical Dystonia	Phase II/III	FY2006

#### FY2007

Research Code	Indication	Stage	Expected Application
D2E7	Psoriasis	Phase II/III	FY2007
KES524 Obesity Management		Phase III	FY2007

# New Molecular Entities Pipeline 11 Projects within Preparing Phase III and Filed for Approval

Stage	Project	Mode of Action	Target Profile
	<i>Inovelon</i> - rufinamide (Epilepsy)	Na+ channel modulation	Adjunctive therapy for Lennox-Gastaut Syndrome, a severe disease with high unmet medical needs, and adult partial seizures
Filed for approval	Agilect- rasagiline (Parkinson's Disease, Teva)	MAO-B inhibition	Neuroprotective effect (Phase II for Alzheimer's Disease ongoing) Better safety profile than existing MAO-B inhibitors
	Careram <sup>®</sup> - igratimod (Rheumatoid arthritis)	Cytokine/Immunoglobulin suppression	Similar efficacy to salazosulfapyridine, a standard drug for RA. Better safety profile with fewer severe side effects
	KES524 (Obesity management)	Serotonin/Noradrenarin reuptake inhibition	Natural body weight loss based on dual actions of appetite suppression and energy consumption increase
Phase III	Clevudine (Hepatitis B)	HBV polymerase inhibition	Higher rate of lever enzyme normalization due to strong anti-virus effect, less occurrences of resistant viruses
	AS-3201 (Diabetic Neuropathy)	Aldose reductase inhibition	Indicating strong inhibition of aldose reductase and suppress the accumulation of sorbitol within cells
Subpart H NDA	E7389 (Breast cancer)	Microtubule growth suppression	Better anti-cancer efficacy than taxanes Good tolerability, less neurotoxicity
Phase II / III	D2E7 (Rheumatoid arthritis)	Anti-TNF alpha monoclonal antibody	Strong and long-lasting efficacy for RA symptoms
	E2014 (Cervical dystonia)	Botulinum toxin	Effective in patients resistant to existing Botulinum toxin
Preparing Phase III	E2007 (Parkinson's Disease)	AMPA receptor antagonism	Reduction of off-time in PD as adjunct therapy with levodopa. Excellent safety profile; no worsening of dyskinesia
I mase iii	E5564 (Severe Sepsis)	Endotoxin antagonism	Reduce mortality and morbidity; good safety profile
Phase II	E7070 (Cancer)	G1 Phase targeting	Different anti-cancer spectrum from existing cytotoxics
	E5555 (Acute Coronary Syndrome)	PAR-1antagonism	Dual action of anti-platelet and smooth muscle cell proliferation inhibition
	E7820 (Cancer)	Alpha-2 integrin suppression	Survival benefit due to chronic tumor growth suppression
Phase I	E7080 (Cancer)	VEGF receptor tyrosine kinase inhibition	Survival benefit due to chronic tumor growth suppression
Filase I	E7974 (Cancer)	Hemiasterlin type tubulin polymerization inhibition	Effective in multi-drug-resistant tumors
	E1224 (Fungal Infection)	Elgosterol synthesis inhibition	Originally synthesized triazole type agent having wide spectrum effect
	E3030 (Diabetes)	PPAR alpha/gamma dual agonism	Dual effect of glycemic control and dyslipidemia for type II diabetes

### **Business Development Results**

- Launched products: Contribution to 2<sup>nd</sup> half financial results
  - Fragmin (Injectable Anti-Clotting Agent) US Promotional Rights
  - Actonel (Osteoporosis Treatment)
     Marketing Rights in Japan
- Developing products: Challenge to fulfill unmet medical needs
  - AS-3201 (Diabetic Neuropathy)
     Phase III in US
- Strengthening discovery research: Alzheimer's disease area
  - TorreyPines Therapeutics, Inc. (US)
    - Alliance contract regarding discovery of genes causing Alzheimer's disease
  - BioArctic Neuroscience Inc. (Sweden)
    - Strategic alliance to develop an immunotherapy for Alzheimer's disease

Cognitive function

**Disease modifier** 

Disease-associated genes

Major hypotheses

Choline hypothesis
Cholinergic neuron
dysfunction à
cognitive dysfunction

Amyloid cascade hypothesis

Beta Amyloid deposit à neuronal death

Therapeutic approaches

**AChE inhibitors** 

**Muscarinic agonists** 

**Beta secretase inhibitors** 

Gamma secretase inhibitors

Gamma secretase modulators

**Amyloid vaccines** 

**Anti-amyloid antibodies** 

Eisai's approaches

Aricept (AChE inhibitor)

E2012

(Gamma secretase modulator)

# New Business Operations in European Countries and India

- Established pharmaceutical marketing subsidiaries in Switzerland (June) and Sweden (July)
- Started medical representatives' activities for Pariet in Italy (September)
- Launched donepezil (Aricep®) and rabeprazole (Parit®) in India (September)



Aricep Parit

# **Enhancing Return to Shareholders**

Maintaining both investment for growth and steady distribution of dividends

Interim Dividends 40 Yen (1H FY2004: 21 Yen)

**Annual Dividends 80 Yen (Forecast)** 

DOE 4.8% (Forecast End of FY2005)

Payout Ratio 38.1% (Forecast End of FY2005)



Aiming for payout ratio of over 50% and continuously stable distribution of dividends

**Target DOE: 7.5%** 

#### **Financial Forecast for FY2005**

(billions of yen, %)

	FY2004		FY2005		
	Results	%	Forecast	%	YOY
Net Sales	533.0	100.0	585.0	100.0	110
Cost of Sales	98.5	18.5	103.0	17.6	105
Gross Margin	434.5	81.5	482.0	82.4	111
R&D Expenses	78.3	14.7	92.0	15.7	117
SG&A Expenses	269.4	50.5	295.0	50.4	110
Operating Income	86.8	16.3	95.0	16.2	109
Ordinary Income	89.1	16.7	96.0	16.4	108
Net Income	55.5	10.4	60.0	10.3	108
EPS (Yen)	193.4		209.9		109