

# FY2005 First QuarterD.63.9

# **Consolidated Performance**

(billions of yen, %)

1

	FY2004 1Q			FY2005 1Q			
	Results	%	YOY	Results	%	YOY	Increase (Decrease)
Net Sales	122.7	100.0	105	135.8	100.0	111	13.1
Cost of Sales	24.1	19.7	105	24.1	17.7	100	(0.0)
Gross Margin	98.6	80.3	105	111.7	82.3	113	13.1
R&D Expenses	18.2	14.8	107	19.9	14.7	110	1.8
SG&A Expenses	61.8	50.3	107	69.3	51.1	112	7.6
Operating Income	18.6	15.2	98	22.5	16.5	120	3.8
Ordinary Income	19.5	15.9	99	23.4	17.2	120	3.9
Net Income	12.4	10.1	100	14.9	11.0	120	2.5
EPS (Yen)	43.1		102	52.2		121	9.1

# **Sales of Major Products**

Product Name	Area	FY2004 1Q	FY2005 1Q	ΥΟΥ	Increase (Decrease)
Aricept	Total	34.4	41.7	121	7.3
Alzheimer's	Japan	8.9	9.9	111	1.0
Treatment	U.S. Millions of \$	18.1 165	23.5 219	130 132	5.4 54
	Europe	6.7	7.3	110	0.6
	Asia	0.7	0.9	136	0.2
Aciphex/	Total	30.3	34.1	113	3.8
Pariet	Japan	3.2	6.3	195	3.1
Proton Pump	U.S.	24.8	25.3	102	0.4
Inhibitor	Millions of \$	226	235	104	8
	Europe	1.8	1.8	99	(0.0)
	Asia	0.5	0.7	163	3

## Sales to Customers by Geographic Area

				FY20 1Q		
	65.0	53.0	69.1	50.9	106	4.1
North America	45.5	37.1	52.6	38.7	116	7.2
Europe	9.5	7.8	10.4	7.7	109	0.9
Asia and Others	2.6	2.2	3.7	2.7	138	1.0
Overseas Total	57.6	47.0	66.7	49.1	116	9.0
Total	122.7	100.0	135.8	100.0	111	13.1

# **Operating Income by Geographic Area**

(Pre-royalty deduction)

(billions of yen, %)

	FY200 1Q	04		FY2005 1Q			
	Results	%	Results	%	YOY	Increase	
Japan	11.7	54.3	11.9	47.4	101	0.2	
North America	7.9	36.4	10.6	42.2	134	2.7	
Europe	1.3	6.0	1.8	7.2	139	0.5	
Asia and Others	0.7	3.2	0.8	3.2	119	0.1	
Overseas Total	9.8	45.7	13.2	52.6	134	3.3	
Sub-Total	21.6	100.0	25.1	100.0	116	3.5	
Elimination /Corporation	(2.9)		(2.6)			0.3	
Total	18.6		22.5		120	3.8	

	165	39.5	102	219	44.5	132	54
Aciphex	226	54.1	119	235	47.8	104	8
Zonegran	23	5.4	-	33	6.7	145	10
Operating Income	14	3.4	172	28	5.7	196	14
Net Income	9	2.2	164	18	3.8	205	9
Operating Income (Pre-royalty deduction)	69	16.6	132	95	19.4	138	26

### **Consolidated Free Cash Flow**

(billions of yen)

	Cash Flow from Operating Activities		Cap Expen		Free Cash Flow		
	Results	Increase (Decrease)	Results	Increase (Decrease)	Results	Increase (Decrease)	
FY2002 1Q	12.1	-	7.0	-	5.1	-	
FY2003 1Q	16.9	4.8	4.9	(2.1)	12.1	6.9	
FY2004 1Q	9.4	(7.5)	18.3	13.4	(8.9)	(21.0)	
FY2005 1Q	12.1	2.7	10.8	(7.5)	1.3	10.2	

### Provision of corporate concept added to articles of incorporation

- 1. The Company's corporate concept is to give first thought to patients and their families, and to increase the benefits that health care provides. Under this concept, the Company endeavors to become a *human health care* (*hhc*) company.
- 2. The Company's mission is the enhancement of patient satisfaction. The Company believes that revenues and earnings will be generated as a consequence of the fulfillment of the mission. The Company places importance on this positive sequence of the mission and the ensuing results.
- 3. Positioning compliance, the observance of legal and ethical standards, as a core in all business activities, the Company strives to fulfill corporate social responsibilities.
- 4. The Company's principal stakeholders are patients, customers, shareholders and employees. The Company seeks to foster a good relationship with stakeholders and to enhance their value through making the following efforts:
  - Satisfying unmet medical needs, ensuring stable supply of high quality products, and providing useful information of safety and efficacy.
  - Timely disclosure of corporate managerial information, enhancement of corporate value, and proactive return

### The New Corporate Governance Structure

- ¥ Seven out of twelve members of the Board of Directors are outside directors.
- ¥ The Chair of the Board was appointed from outside directors.
- ¥ The Chairs of the Nominating Committee, Compensation Committee and Audit Committee were appointed from outside directors.
- ¥ All members of the Nominating Committee and Compensation Committee are outside directors.

Tadashi Kurachi: Chair of the Board (Representative Director and Chairman, Kanematsu Corporation) Ikujiro Nonaka: Chair of the Nominating Committee (Professor, Hitotsubashi University Graduate School) Stuart Meiklejohn: Chair of the Compensation Committee (Partner, Sullivan & Cromwell) Mitsuo Minami: Chair of the Audit Committee (Professor, Bunkyo Gakuin University Graduate School) Naoto Nakamura (Founder and Partner, Law firm of Nakamura, Tsunoda, Matsumoto) Tadahiro Yoshida (Chairman and President, YKK Corporation) Yoshiyuki Kishimoto (Director of Strategy of Booz Allen and Hamilton Inc.) Yuji Naito: Honorary Chairman Hiromasa Nakai: Senior Advisor Tadashi Temmyo

Shintaro Kataoka

Haruo Naito: President and CEO (Representative Executive Officer)

Notes: Blue letters shows the outside directors.

# **Reinforcing Seamless Value Chain**

- ¥ Restructuring P-1 plant in Kashima for preparing drug substance of E7389.
- ¥ Construction of the second production site in Suzhou Plant (China) corresponding to increasing sales in China.
- ¥ Expansion of Eisai Research Institute of Boston, Inc. (US)

### **Opportunities in Key Areas/Countries**<sup>12</sup>

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US Sales

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# Progress in Q1 R&D

¥ Approval, Launch

•Aricept (Alzheimer's Disease)

-Approved as orodispersible tablet in UK (May)

-Launched orally disintegrating tablet in US (June)

•Zonegran (Anti-epileptic agent):

-Launched in June as adjunctive therapy for partial seizures in adults (UK and Germany)

•Cleactor (Anti-thrombolytic agent)

-Additional indication for acute pulmonary embolism Launched in July (Japan)

¥ Phase II

•E2007: Phase IIb indicated for migraine prophylaxis

•D2E7: Psoriasis vulgaris (Japan)

¥ Withdrawn

•Cleactor: Cerebrovascular embolism (Phase II)

### **Progress of Major Clinical Trials**

#### ¥ E2007 AMPA-receptor antagonist

•Parkinson: Briefing Book for discussion about Phase III was submitted to EMEA End-of-Phase II meeting with FDA being scheduled

•Epilepsy: Phase IIb (POC)

•Migraine: Phase IIb (POC)

•Multiple Sclerosis: POC study plan is drafted

#### ¥ E7389 Microtubule growth suppressor

 Breast cancer monotherapy (3<sup>rd</sup> line): Independent reviews are underway for 35 evaluable cases, and 9 PRs were reported (4 confirmed, 5 unconfirmed) End-of-Phase II meeting with FDA scheduled in September
 Non Small Cell Lung Cancer monotherapy (2<sup>nd</sup> line): Independent reviews are underway for 52 evaluable cases, and 5 PRs were reported (2 confirmed, 3 unconfirmed)

#### ¥ E5564 (eritoran) Endotoxin antagonist

•Sepsis: Data analysis to be completed in early August

#### ¥ E7070 (indisulam) Cell-cycle G1 phase targeting agent

•Breast cancer monotherapy: Discontinued

•Colorectal & breast cancer combo therapy: Enrollment stopped.

•Small cell lung cancer: Additional Phase I in preparation in combination with irinotecan

•Stomach cancer (Japan): Phase I/II in progress

#### ¥ E5555 Thrombin receptor antagonist

•Four Phase I studies were completed, and safety and platelet coagulation inhibition were confirmed Bleeding time was not extended

•Five drug-drug interaction studies are ongoing

•POC studies will start in 4Q FY2005

Subject: Stable angina patients, Acute myocardial patients

Endpoints: Vascular intima thickness observed with intravascular echogram

Inflammation marker (CRP:C-Reactive Protein etc.)

Cardiac events

# Submissions for NDA/MAA in 2006

| Target            | E2007                                                                                                                                                                        | E7389                                                                                                                                                                                                                                                                                                                                              |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mode of Action    | AMPA Receptor Antagonist                                                                                                                                                     | Microtubule Growth Suppressor                                                                                                                                                                                                                                                                                                                      |
| Indication        | <ul> <li>Adjunctive therapy with levodopa for<br/>Parkinson's disease (PD; 2006)</li> <li>Epilepsy</li> <li>Multiple Sclerosis (MS)</li> <li>Migraine prophylaxis</li> </ul> | <ul> <li>Breast cancer: 3<sup>rd</sup> + 2<sup>nd</sup> + 1<sup>st</sup> line (2006)</li> <li>NSCLC: 2<sup>nd</sup>/3<sup>rd</sup> + 1<sup>st</sup> line</li> <li>Soft tissue sarcoma: 2<sup>nd</sup> + 1<sup>st</sup> line</li> <li>Prostate cancer: 2<sup>nd</sup> line</li> <li>Ovarian cancer: 2<sup>nd</sup> + 1<sup>st</sup> line</li> </ul> |
| Efficacy          | Similar to or better than MAO-B<br>inhibitor and COMT inhibitor in<br>shortening OFF time (PD)                                                                               | Effective for taxane refractory tumors                                                                                                                                                                                                                                                                                                             |
| Safety            | <ul> <li>–Excellent safety profile</li> <li>–No worsening of dyskinesia (PD)</li> </ul>                                                                                      | <ul> <li>–No severe peripheral neurotoxicity</li> <li>–Fewer hypersensitivity reactions (no need for premedication with steroid or anti-histamine)</li> </ul>                                                                                                                                                                                      |
| Drug Interactions | No major drug-drug interactions                                                                                                                                              | No major drug-drug interactions                                                                                                                                                                                                                                                                                                                    |
| Administration    | Once a day, oral administration                                                                                                                                              | Bolus (5-minute IV)<br>Day 1, 8, 15, every 4 weeks                                                                                                                                                                                                                                                                                                 |
| Formulation       | Small tablets                                                                                                                                                                | Vials (solution)                                                                                                                                                                                                                                                                                                                                   |

#### **New Indications and Formulations in Development for** *Aricept* **and** *Aciphex/Pariet*

Phase I (US)

# **Neurology Pipeline**

Aricept: Completed Phase II

Zonegran: Preparation for clinical studies of monotherapy (EU)

Inovelon (rufinamide): Filed Lennox-Gastaut Syndrome (EU)
Preparation for filing Lennox-Gastaut syndrome and adult partial seizures (US)
E2007: Phase II
Aricept: Dementia with Parkinson's disease, Planning to file in FY05 (EU)
Agilect (rasagiline): Filed (US, Teva)
E2007: Preparing for Phase III (US, EU), Phase I (Japan)

Multiple screlosis E2007: Planning Phase IIb

E2014 (Botulinus toxin): Phase II bridging study (Japan)

### **Cancer Agents in Clinical Development**

| Project | Phase           | Cancer<br>Type                          | Mode of Action                                    | Route | Current Status                                                                                                                                                                                                                         |
|---------|-----------------|-----------------------------------------|---------------------------------------------------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E7389   | Phase II        | Breast<br>NSCLC                         | Microtubule growth suppressor                     | I.V.  | Patient enrollment for breast cancer<br>monotherapy is nearly completed. Good<br>response was confirmed. End-of-Phase II<br>meeting with FDA scheduled in September<br>Phase I in preparation (JP)                                     |
| E7070   | Phase II        | Colorectal<br>Breast<br>Stomach<br>SCLC | Cell-cycle G1<br>phase targeting<br>agent         | I.V.  | Patient enrollment was stopped in Phase II<br>combination studies with irinotecan for<br>colorectal cancer and with capecitabine for<br>breast and colorectal cancer.<br>Phase I/II monotherapy for stomach cancer<br>in progress (JP) |
| E0167   | Phase<br>II/III | Hepato-<br>carcinoma                    | Vitamin K <sub>2</sub>                            | P.O.  | Patient enrollment is almost complete (JP)<br>Safety assessment in 1-year revealed<br>no issues                                                                                                                                        |
| E7820   | Phase I         | Solid tumor                             | Alpha-2 integrin<br>expression inhibitor          | P.O.  | Phase I in progress (US)                                                                                                                                                                                                               |
| E7080   | Phase I         | Solid tumor                             | VEGF receptor kinase inhibitor                    | P.O.  | Phase I in progress (US, EU)<br>Phase I in preparation (JP)                                                                                                                                                                            |
| E7974   | Phase I         | Solid tumor                             | Hemiasterlin type<br>tubulin binding<br>inhibitor | I.V.  | Phase I in progress (US)                                                                                                                                                                                                               |

Blue letters: Progress in 1Q FY2005

Stage

Filed for approval

Phase III

Phase II/III

|                        | E2014 (Cervical dystonia) | Botulinus toxin | Effective in patients resistant to existing Botulinus toxin                                                          |
|------------------------|---------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------|
| Preparing<br>Phase III |                           |                 | Reduction of off-time in PD as adjunct therapy with levodopa<br>Excellent safety profile; no worsening of dyskinesia |

Phase II

Phase I