

# 3<sup>rd</sup> Quarter of Fiscal 2010 Financial Results Conference Call

January 31, 2011





### Forward-Looking Statements

- This presentation contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements.
- Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.
- 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.
- This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.





# Overview of 3<sup>rd</sup> Quarter FY2010 Financial Results

### Financial Results



(Units: billion yen)

<consolidated></consolidated>	FY2010 Forecasts	AprDec. FY2010 Results	Progress (%)	AprDec. FY2009 Results	Y on Y Change (%)	Change
Sales	283.0	217.2	76.8	206.4	5.2	10.8
<b>Operating income</b>	54.0	35.7	66.1	35.0	1.9	0.7
Ordinary income	51.5	33.7	65.5	33.3	1.0	0.4
Net income	30.0	13.5	45.1	25.5	(47.0)	(12.0)

<non-consolidated></non-consolidated>	FY2010 Forecasts	AprDec. FY2010 Results	Progress (%)	AprDec. FY2009 Results	Y on Y Change (%)	Change
Sales	244.0	187.4	76.8	169.4	10.7	18.0
<b>Operating income</b>	60.6	44.5	73.5	32.4	37.2	12.1
Ordinary income	59.6	43.9	73.7	32.4	35.3	11.5
Net income	45.3	29.4	64.9	24.8	18.3	4.6

Due to change in the accounting periods, Apr.-Dec. results of FY2010 include 12 months from Jan. to Dec. for the US subsidiaries.





### Financial Position and Cash Flows (Consolidated)

(Units: billion yen)

<financial position=""></financial>	As of Dec. 31, 2010	As of Mar. 31, 2010	Change
Total assets	505.6	540.7	(35.1)
Net assets	322.6	341.9	(19.3)
Equity ratio (%)	63.8	63.2	0.6
Net assets per share (yen)	963	1,019	(56)

<cash flows=""></cash>	AprDec. FY2010	AprDec. FY2009	Change
Net cash provided by operating activities	34.0	32.5	1.5
Net cash provided by investing activities	(16.5)	(7.6)	(8.9)
Net cash provided by financing activities	(20.4)	1.3	(21.7)
Net increase (decrease)	(5.6)	25.4	(31.0)
Cash and cash equivalents at end of period	91.9	76.9	-

## Sales by Segments (Consolidated)

S-O-N-G

(Units: billion yen)

	2 <sup>nd</sup> half FY2010 Forecasts	OctDec. FY2010 Results	Progress (%)	OctDec. FY2009 Results	Y on Y Change (%)	AprDec. FY2010 Results	AprDec. FY2009 Results	Y on Y Change (%)
<b>Prescription drugs</b>	80.3	43.9	54.6	42.4	3.3	119.0	117.1	1.6
Crestor	15.5	8.4	53.9	6.9	21.0	22.0	18.4	19.6
Irbetan	4.5	2.2	48.2	1.2	75.0	5.5	2.5	122.4
Cymbalta	1.7	0.9	51.7	-	-	1.8	-	-
Total of 3 strategic products	21.7	11.4	52.6	8.2	40.1	29.3	20.9	40.1
OxyContin	5.0	2.7	54.0	2.5	7.7	7.5	6.7	11.4
Finibax	2.2	1.0	43.5	0.8	18.1	2.8	2.6	7.6
Differin	1.5	1.0	62.0	0.6	54.4	2.4	1.6	47.6
Pirespa	1.7	0.8	46.0	0.4	79.7	2.1	1.1	95.7
Rapiacta	1.8	(0.3)	-	-	-	(0.3)	-	-
Total of 8 new products	34.0	16.6	48.7	12.5	32.1	43.7	32.8	33.0
Flomox	10.0	6.6	65.7	7.9	(16.6)	16.7	19.2	(13.0)
Rinderon	4.1	2.3	57.2	2.3	(0.5)	7.4	7.5	(1.5)
Flumarin	3.0	2.1	68.4	2.3	(9.9)	6.0	7.0	(14.7)
Claritin	5.1	2.2	43.5	2.0	9.1	5.3	5.5	(3.2)
Vancomycin	1.7	1.4	80.9	1.5	(6.9)	4.0	4.9	(19.1)
Export/Overseas subsidiaries	18.2	8.7	47.8	12.7	(31.5)	34.7	36.5	(5.1)
Shionogi Inc.	12.9	5.6	43.5	9.9	(43.5)	26.6	28.3	(6.0)
Doripenem	2.9	1.7	58.5	1.3	35.8	4.2	4.2	0.6
Contract manufacturing	1.6	1.9	119.1	1.9	0.3	3.7	5.3	(30.2)
OTC and quasi-drugs	2.7	1.3	49.3	1.4	(3.4)	4.2	4.3	(3.8)
Diagnostics	1.3	0.7	50.9	0.6	7.5	2.1	2.1	(2.2)
Royalty income	33.5	16.7	50.2	13.8	21.5	51.6	37.8	36.6
Crestor	30.7	15.2	49.4	13.2	15.1	48.0	35.7	34.2
Others	2.2	0.7	33.2	1.0	(28.7)	1.9	3.1	(38.8)
Total	139.7	73.9	52.9	73.8	0.1	217.2	206.4	5.2

# 3<sup>rd</sup> Quarter FY2010 Results Statements of Income (Consolidated)



(Units: billion yen)

	2 <sup>nd</sup> half FY2010 Forecasts	OctDec. FY2010 Results	Progress (%)	OctDec. FY2009 Results	Y on Y Change (%)	AprDec. FY2010 Results	AprDec. FY2009 Results	Y on Y Change (%)
Sales	139.6	73.9	52.9	73.8	0.1	217.2	206.4	5.2
[Royalty income]	[33.4]	[16.7]	[50.2]	[13.8]	[21.5]	[51.6]	[37.8]	[36.6]
Cost of sales	26.7 (35.1)	29.6 (38.3)		27.5 (33.8)		28.1 (36.8)	27.7 (33.9)	
	37.2	21.9	58.8	20.2	8.0	60.9	57.1	6.7
Gross profit	102.3	52.0	50.8	53.5	(2.9)	156.3	149.3	4.7
	48.4	48.1		49.3		55.5	55.4	
SG&A expenses	67.6	35.5	52.5	36.3	(2.3)	120.6	114.2	5.5
Selling & general expenses	42.2	24.5	58.1	23.8	3.1	81.5	73.8	10.4
R&D expenses	25.4	10.9	43.2	12.5	(12.5)	39.1	40.4	(3.4)
	24.9	22.3		23.3		16.4	17.0	
<b>Operating income</b>	34.7	16.4	47.4	17.1	(4.1)	35.7	35.0	1.9

Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.





### Financial Results of US Operations

(Units: upper/million dollar, lower/billion yen)

	2 <sup>nd</sup> Half FY2010 Forecasts	OctDec. FY2010 Results	Progress (%)	JanMar. FY2010 Results	AprJun. FY2010 Results	JulSep. FY2010 Results
Sales	160 12.9	68 5.6	42.5	110 10.1	<b>56</b> 5.1	<b>69</b> 5.8
Cost of sales	27 2.1	12 1.0	44.4	18 1.6	23 2.1	15 1.3
SG&A expenses	113 9.0	<b>55</b> 4.5	48.6	<b>76</b> 7.0	83 7.6	54 4.6
Operating income	20 1.8	1 0.1	5.0	16 1.5	(51) (4.6)	(1) (0)
Extraordinary loss	L 68 L 5.6	L 62 L 5.4	-	-	L 25 L 2.3	L 47 L 4.2

#### <Current Situation>

- Returns or delayed delivery by quality issues of some products and recall expenses
- Incurred extraordinary loss in the 3rd Quarter of Fiscal 2010
  - ➤ Impairment loss on intangible assets of discontinued products : 4.2 billion yen
  - ➤ Improvement expenses of business structure : 0.8 billion yen
  - ➤ Recall expenses : 0.3 billion yen





# FY2010 Financial Forecasts

#### **FY2010 Financial Forecasts**

# FY2010 Financial Forecasts

(Units: billion yen)

<consolidated></consolidated>	FY2010 Forecasts	FY2009 Results	Y on Y Change (%)	Change
Sales	283.0	278.5	1.6	4.5
<b>Operating income</b>	54.0	52.4	3.0	1.6
Ordinary income	51.5	50.5	1.9	1.0
Net income	30.0	38.6	(22.3)	(8.6)

Due to change in the accounting periods, FY2010 forecasts include 15 months from Jan., 2010 to Mar., 2011 for the US subsidiaries.



#### **FY2010 Financial Forecasts**

# Revised Forecasts and Next Actions of US Operations

(Units: upper/million dollar, lower/billion ven)

	Original	Revised	Change from
	Forecasts	Forecasts	Original
Sales	395	382	(13)
	33.9	32.9	(1.0)
Cost of sales	83	82	(1)
	7.2	7.1	(0.1)
SG&A expenses	327	324	(3)
	28.1	27.9	(0.2)
Operating income	(15)	(24)	(9)
	(1.3)	(2.1)	(0.8)
Extraordinary loss	L 140	L 144	L 4
	L 12.0	L 12.4	L 0.4

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1 <sup>st</sup> Half FY2010	2 <sup>nd</sup> Half FY2010				
Results*	Revised Forecasts				
235	147				
21.0	11.9				
<b>56</b> 5.0	26 2.1				
214	110				
19.1	8.8				
(35)	11				
(3.2)	1.1				
L 72	L 72				
L 6.5	L 5.9				

L 72	L 72
L 6.5	L 5.9

<Actions>

\*: 9 months from Jan. to Sep.

- Ongoing activities for more effective and stable US operations
  - Further consolidation of US operations to New Jersey headquarters for the new administrative structure from next April (Facilities in Georgia will be closed next June except for the Distribution Center)
  - > Improvement of collaboration between Japan and the United States to address frequent quality issues in manufacturing
  - > Consolidating the management of the developing pipelines between Japan and the United States
  - > Aggressive license activities continued to strengthen product portfolio
- Anticipation of extraordinary loss in the second half of FY2010
  - ➤ Impairment loss on intangible assets of pre-determinate discontinued products : 4.2 billion yen
  - ► Improvement expenses of business structure : 1.4 billion yen
  - Recall expenses : 0.3 billion yen



# **Pipeline**

#### **Pipeline (since November 2010)**



### Progress of Developmental Compounds

- **♦** New Launch
  - KAPVAY<sup>TM</sup> (Clonidine HCL, Alpha 2 specific adrenergic agonist, Oral): ADHD, Pediatric
    - USA: Launched January 2011
    - ➤ The first and only FDA-approved ADHD treatment indicated for use as add-on therapy to stimulant medication, in addition to use as mono-therapy
- Change of Phases in Clinical Studies
  - S-888711 (Small molecule TPO mimetic, Oral): Thrombocytopenia
    - > Japan: Phase IIa
  - S-488410 (Peptide caner vaccine, Injection): Esophageal cancer
    - ➤ Japan: Phase I/II



### **Pipeline**

# S-O-N-G for youl

### License Agreements

- **♦** Peptide vaccines for the treatment of ophthalmic disease
  - Licensed from OncoTherapy Science, Inc.
    - **▶** Global exclusive right to develop, manufacture and commercialize
  - Ophthalmologic disease of the retina resulted by abnormal blood vessel growth (pathological angiogenesis) including age-related macular degeneration
  - The peptide vaccine is expected to prevent and reverse vision loss by activating the immune system which leads to specifically inhibit vessel endothelial cells for pathological angiogenesis.
- **♦** NF- *K* B Decoy Oligodeoxynucleotide
  - Licensed from AnGes MG, Inc.
    - ➤ Collaborative research and development and exclusive rights to globally commercialize
  - Atopic dermatitis and other skin disorders
  - NF-  $\kappa$  B decoy oligodeoxynucleotide binds to NF-  $\kappa$  B by pretending the genome region to which original NF-  $\kappa$  B should bind. As a result, the transcription process causing dermatitis could be inhibited. NF-  $\kappa$  B decoy oligodeoxynucleotide is expected to be a new treatment option of different mechanism of action for atopic dermatitis.



### Pipeline (as of January 2011)

Cymbalta® (DNP)

Phase I Phase II Phase III **Filing Approved** S-474474 (Hypertension) Japan: Phase III **USA: Phase II S-2367 (Obesity)** Japan: Phase II Metabolic S-707106 (Type2 diabetes) USA: Phase IIa **Syndrome** ADX415 (Hypertension) USA: Phase II in preparation S-234462 (Obesity) USA: Phase I Rapiacta® (Influenza infection, Pediatric) Japan: Approval October 2010 Finibax<sup>®</sup> (Addition of new dosage regimen) Japan: Filed March 2010 Infectious **Diseases** Finibax<sup>®</sup> (Infection, Pediatric) Japan: Phase III S-349572/S-265744/S-247303 (HIV infection) Global: Phase III S-265744 LAP (HIV infection) **USA: Phase I** 

Pain

S-811717 (Cancer pain) Japan: Filed September 2010

S-297995 (Alleviation of opioid-induced adverse effect) USA: Phase IIa Japan: Phase I

Japan: Filed September 2009

### Pipeline (as of January 2011)



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Phase I	Phase II	Phase II			
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Women's Health PSD502 (Premature ejaculation) USA/EU: Phase III

Ospemifene (Post-menopausal vaginal atrophy) USA: Phase III



CUVPOSA<sup>TM</sup> (Chronic drooling) USA: Approved July 2010

KAPVAY<sup>TM</sup> (ADHD) USA: Approved September 2010, Launched January 2011

S-555739 (Allergic disease)

**EU: Proof of Mechanism** 

Japan: Phase IIa

S-888711 (Thrombocytopenia)

USA/EU: Phase II

Japan: Phase IIa

**Others** 

S-288310 (Peptide cancer vaccine, Bladder cancer) Japan: Phase I/II

S-488410 (Peptide cancer vaccine, Esophageal cancer) Japan: Phase I/II

S-222611 (Malignant tumor) EU: Phase Ib

S-524101 (Allergic rhinitis caused by house-dust mite allergen) Japan: Phase I in preparation

#### <Out-licensed>

Doripenem (Respiratory tract infection) USA: Filed

S-3013 (Acute coronary syndrome) USA/EU: Phase III

S-0373 (Spinocerebellar ataxia) Japan: Phase II



# End of File