

# Second Quarter Financial Results for FY2011 (Apr. 1 to Sep. 30, 2011)

November 1, 2011

Dainippon Sumitomo Pharma Co., Ltd.

Note: This presentation material includes an additional four reference slides added to the end of the presentation dated October 31, 2011.

# Second Quarter Financial Results for FY 2011

# Financial Results

(Compared with the corresponding period of the previous year)

Billions of yen

	FY2010 2Q	FY2011 2Q	Change	
			Value	Percentage
Net sales	188.6	<b>178.0</b>	- 10.5	- 5.6 %
Cost of sales	57.8	<b>49.8</b>	- 8.1	- 13.9 %
Gross profit	130.7	<b>128.3</b>	- 2.5	- 1.9 %
SG&A expenses	115.8	<b>113.5</b>	- 2.3	- 2.0 %
SG&A expenses less R&D costs	83.0	<b>86.2</b>	3.2	3.9 %
R&D costs	32.8	<b>27.3</b>	- 5.5	- 16.8 %
Operating income	14.9	<b>14.7</b>	- 0.2	- 1.4 %
Ordinary income	14.4	<b>14.5</b>	0.1	0.7 %
Extraordinary income	—	<b>1.2</b>	1.2	—
Net income	8.7	<b>9.6</b>	0.9	10.6 %



Notes: 1. All values are rounded to the nearest 100 million yen.

2. Cost of sales includes provision for (reversal of) reserve for sales returns.

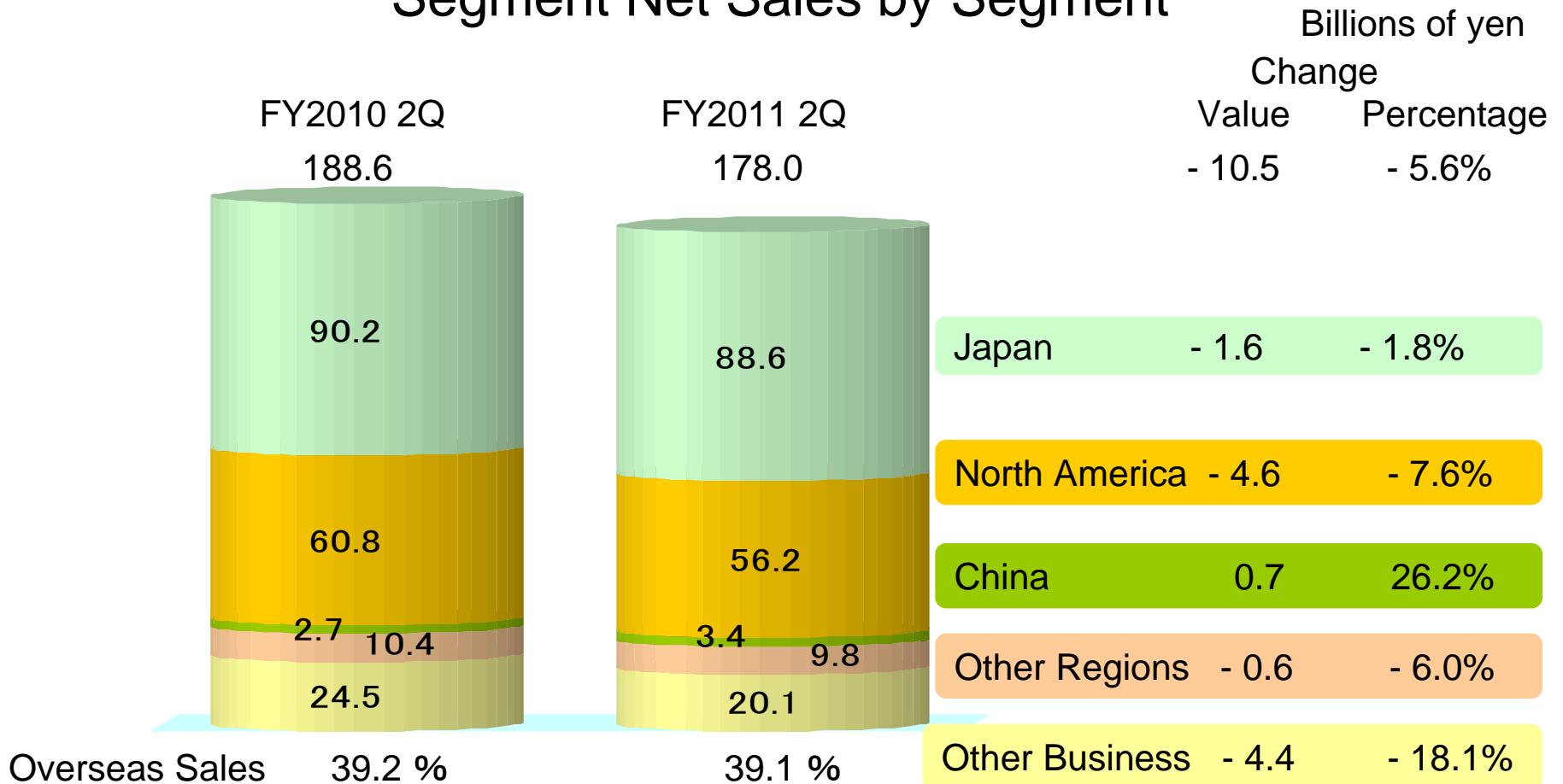
# Financial Results

(Compared with the previous forecast dated May 11, 2011)

Billions of yen

	Forecast FY2011 2Q (as of May 11)	Results FY2011 2Q	Change	
			Value	Percentage
Net sales	179.7	<b>178.0</b>	- 1.7	- 0.9 %
Cost of sales	50.1	<b>49.8</b>	- 0.3	- 0.7 %
Gross profit	129.6	<b>128.3</b>	- 1.3	- 1.0 %
SG&A expenses	120.7	<b>113.5</b>	- 7.2	- 5.9 %
SG&A expenses less R&D costs	90.1	<b>86.2</b>	- 3.9	- 4.3 %
R&D costs	30.6	<b>27.3</b>	- 3.3	- 10.8 %
Operating income	8.9	<b>14.7</b>	5.8	65.5 %
Ordinary income	8.4	<b>14.5</b>	6.1	72.4 %
Extraordinary income	—	<b>1.2</b>	1.2	—
Net income	4.8	<b>9.6</b>	4.8	99.4 %

# Segment Net Sales by Segment



## 【North America】

- Although there was an increase in sales in the local currency, a decrease is seen because of the yen appreciation.

## 【Other business】

- There is a decrease because only the commission equivalent part was recorded as sales on pet foods since July last year.

# Sales in Japan Segment

Billions of yen

	FY2010 2Q	FY2011 2Q	Change	
			Value	Percentage
AVAPRO®	3.7	4.9	1.2	33.0 %
LONASEN®	4.3	5.0	0.7	15.5 %
PRORENAL®	7.4	7.8	0.4	4.8 %
Strategic Products Total	15.4	17.7	2.2	14.5 %
TRERIEF®	1.6	2.5	0.9	56.9 %
MIRIPLA®	0.7	0.7	- 0.1	- 9.5 %
SUREPOST®	—	0.1	0.1	—
METGLUCO® (Including MELBIN®)	2.3	3.6	1.4	61.3 %
New Products Total	4.6	6.9	2.3	49.5 %
AMLODIN®	21.0	18.2	- 2.8	- 13.3 %
GASMOTIN®	10.2	10.4	0.1	1.2 %
MEROPEN®	6.6	6.2	- 0.4	- 6.5 %
AmBisome®	2.3	2.2	- 0.1	- 4.5 %
REPLAGAL®	2.5	4.3	1.8	73.8 %
Others	27.6	22.8	- 4.8	- 17.2 %
<b>Japan total</b>	<b>90.2</b>	<b>88.6</b>	<b>- 1.6</b>	<b>- 1.8 %</b>

FY2011 2Q	
Forecast as of May 11	Change
5.5	- 0.6
6.1	- 1.1
8.3	- 0.5
19.9	- 2.2
2.2	0.3
0.8	- 0.1
0.1	- 0.0
2.5	1.1
5.6	1.3
16.3	1.9
10.3	0.1
5.4	0.8
2.4	- 0.2
3.6	0.7
24.9	- 2.1
<b>88.4</b>	<b>0.2</b>

Note: Sales figures of each product are before reduction of rebates.

# Sales in North America & China Segments

Billions of yen [M\$]

	FY2010 2Q		FY2011 2Q		Change		FY2011 2Q		
					Value	Percentage	Forecast as of May 11	Change	
LATUDA®	—		[ 41 ]	3.4	[ 41 ]	3.4	[ 47 ]	4.0	- 0.6
LUNESTA®	[ 312 ]	28.5	[ 261 ]	21.4	[ - 50 ]	- 7.0	[ 280 ]	23.8	- 2.4
XOPENEX®	[ 207 ]	19.0	[ 216 ]	17.7	[ 9 ]	- 1.2	[ 194 ]	16.5	1.2
BROVANA®	[ 49 ]	4.5	[ 62 ]	5.1	[ 13 ]	0.6	[ 61 ]	5.2	- 0.1
OMNARIS®	[ 28 ]	2.6	[ 34 ]	2.8	[ 6 ]	0.2	[ 38 ]	3.2	- 0.4
Industrial property revenues	[ 42 ]	3.9	[ 42 ]	3.4	[ - 1 ]	- 0.5	[ 27 ]	2.3	1.1
Others	[ 26 ]	2.4	[ 28 ]	2.3	[ 2 ]	- 0.1	[ 32 ]	2.7	- 0.2
<b>North America Total</b>	[ 665 ]	60.8	[ 685 ]	56.2	[ 20 ]	- 4.6	[ 679 ]	57.7	- 1.5
MEROPEN®		2.3		2.9		0.6		3.0	- 0.1
Others		0.4		0.5		0.1		0.6	- 0.1
<b>China Total</b>		2.7		3.4		0.7		3.6	- 0.2

# Financial Results in North America Segment

Billions of yen [M\$]

<Excluding impact of purchase price allocation>

	FY2010 2Q		FY2011 2Q		Change		Breakdown	
							Exchange	Others
Net sales	[ 665 ]	60.8	[ 685 ]	56.2	[ 20 ]	- 4.6	- 6.0	1.4
Cost of sales	[ 67 ]	6.1	[ 72 ]	5.9	[ 5 ]	- 0.2	- 0.7	0.5
Gross profit	[ 598 ]	54.7	[ 613 ]	50.2	[ 14 ]	- 4.4	- 5.3	0.9
SG&A expenses	[ 323 ]	29.5	[ 425 ]	34.9	[ 102 ]	5.4	- 4.0	9.4
Income (loss) of Segment	[ 276 ]	25.2	[ 188 ]	15.4	[ - 88 ]	- 9.8	- 1.3	- 8.5

< Impact of purchase price allocation >

	FY2010 2Q		FY2011 2Q		Change		Breakdown	
							Exchange	Others
Net sales	—	—	—	—	—	—	—	—
Cost of sales	[ 29 ]	2.6	—	—	[ - 29 ]	- 2.6	—	- 2.6
Gross profit	[ - 29 ]	- 2.6	—	—	[ 29 ]	2.6	—	2.6
SG&A expenses	[ 182 ]	16.6	[ 174 ]	14.3	[ - 7 ]	- 2.3	- 1.6	- 0.7
Income (loss) of Segment	[ - 210 ]	- 19.2	[ - 174 ]	- 14.3	[ 36 ]	4.9	1.6	3.3



# Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America※1	Impact of P.P.A.※2	China	Other Regions				
FY2011 2Q Results	Net sales	88.6	56.2	—	3.4	9.8	157.9	20.1	178.0	
	Cost of sales	22.3	5.9	—	0.9	5.1	34.3	15.5	49.8	
	Gross profit	66.4	50.2	—	2.4	4.6	123.7	4.5	128.3	
	SG&A expenses less R&D costs	32.5	34.9	14.3	1.5	0.2	83.4	2.9	86.2	
	Income (loss) of Segment	33.9	15.4	- 14.3	0.9	4.5	40.4	1.6	42.0	
	R&D costs							26.9	0.3	27.3
	Operating income							13.4	1.3	14.7

FY2010 2Q Results	Net sales	90.2	60.8	—	2.7	10.4	164.0	24.5	188.6	
	Cost of sales	23.7	6.1	2.6	0.6	4.8	37.8	20.0	57.8	
	Gross profit	66.6	54.7	- 2.6	2.1	5.6	126.2	4.5	130.7	
	SG&A expenses less R&D costs	32.7	29.5	16.6	1.1	0.2	80.0	3.0	83.0	
	Income (loss) of Segment	33.9	25.2	- 19.2	1.0	5.4	46.3	1.5	47.7	
	R&D costs							32.4	0.4	32.8
	Operating income							13.8	1.1	14.9

Change	Net sales	- 1.6	- 4.6	—	0.7	- 0.6	- 6.1	- 4.4	- 10.5	
	Income (loss) of Segment	- 0.0	- 9.8	4.9	- 0.1	- 0.9	- 5.9	0.1	- 5.7	
	R&D costs							- 5.5	- 0.0	- 5.5
	Operating income							- 0.4	0.2	- 0.2

※ 1. Excluding impact of purchase price allocation by acquisition

※ 2. Mainly amortization of patent rights and goodwill

# Ordinary income & Net income

Billions of yen

	FY2010 2Q	FY2011 2Q	Change	
			Value	Percentage
Operating Income	14.9	14.7	- 0.2	- 1.4 %
Non-operating income and expenses	- 0.6	- 0.2	0.3	
Finance income and expenses including dividend income	- 0.2	- 0.0	0.2	
Contributions	- 0.9	- 0.7	0.2	
Others	0.5	0.5	- 0.0	
Ordinary income	14.4	14.5	0.1	0.7 %
Extraordinary income	—	1.2	1.2	
Gain on sales of property, plant and equipment	—	1.2	1.2	
Income taxes	5.7	6.1	0.4	
Net income	8.7	9.6	0.9	10.6 %

# Financial Position

Billions of yen

	as of Mar.31,2011	as of Sep.30,2011	Change
Assets	589.9	566.3	- 23.6
Current assets	333.0	323.3	- 9.7
Fixed assets	256.9	243.0	- 13.8
Liabilities	265.9	237.8	- 28.1
Current liabilities	157.2	98.7	- 58.5
Long-term liabilities	108.7	139.1	30.4
Net assets	324.0	328.5	4.5

(Shareholders' equity ratio)

54.9%

58.0%

## (Assets)

Decrease in intangible assets ..... 15.1 billion yen

## (Liabilities)

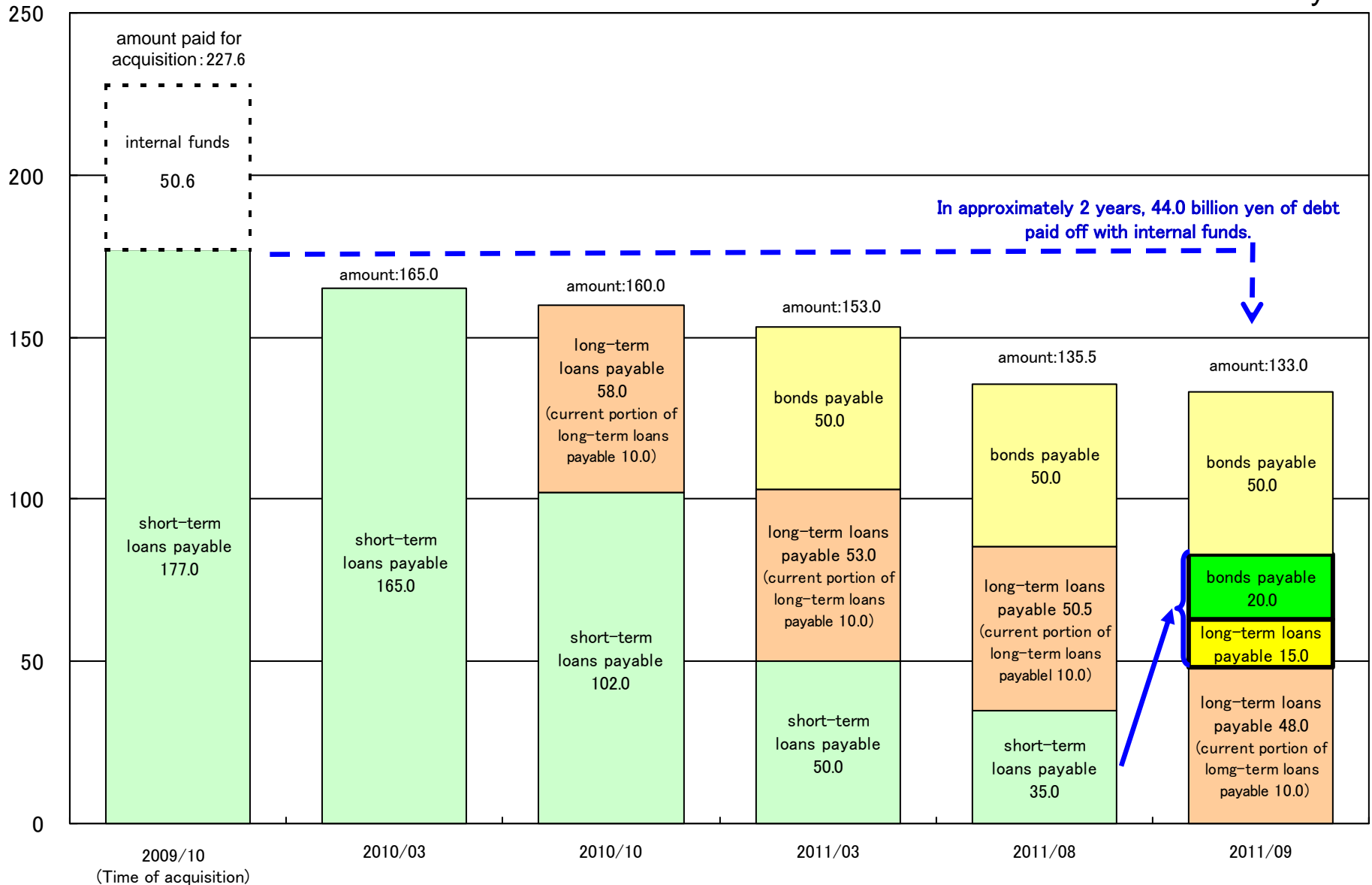
Decrease in total interest-bearing debt ..... 20.6 billion yen

## (Net Assets)

Increase in retained earnings ..... 6.0 billion yen

# Transition of interest-bearing debt accompanying the acquisition of Sunovion Pharmaceuticals

Billions of yen



# Cash Flows

FY2011 2Q

Billions of yen

<b>I</b>	Net cash provided by operating activities	+ 34.1
	▪ Income before income taxes and minority interests	+ 15.7
	▪ Depreciation and amortization	+ 20.4
<b>II</b>	Net cash used in investing activities	- 6.3
	▪ Purchase of marketable securities	- 22.1
	▪ Proceeds from sales and redemption of marketable securities	+ 20.6
	▪ Purchase of property, plant and equipment	- 4.0
<b>III</b>	Net cash used in financing activities	- 24.3
	▪ Net decrease in short-term loans payable	- 50.0
	▪ Net increase in long-term loans payable	+ 9.4
	▪ Proceeds from issuance of bonds	+ 19.9
	▪ Cash dividends paid	- 3.6

Cash and cash equivalents at the end of period : 86.2 billion yen  
(compared with the end of the previous fiscal year : + 3.3 billion yen)

# Financial Forecast for FY2011

# Summary of Financial Forecast for FY2011

## ■ Sales

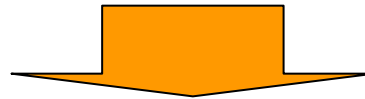
- ✓ Sales in the Japan segment are expected to show steady performance compared to the previous forecast.
- ✓ Sales of the North America segment are expected to remain unchanged in dollar compared to the previous forecast, however, to decrease in yen due to the yen appreciation.

## ■ SG&A expenses

- ✓ SG&A expenses (excluding R&D costs) are expected to remain at the same level as the previous forecast. But, a decrease is expected due to the yen appreciation.
- ✓ R&D costs are expected to fall below the previous forecast, and to decrease even further under impact from the yen appreciation.

## ■ Operating income

- ✓ Expected to exceed the previous forecast because the decrease in SG&A expenses is expected to be larger than the amount of gross profit decrease.



## Revisions of Financial Forecast for FY2011

- Excluding potential strategic investment for alliances and in-licensing

# Financial Forecast for FY2011

Billions of yen

	Results FY2010	Forecast FY2011 (as of May 11)	Forecast (as of Oct. 31)	Change (Value)	
				Compared to FY 2010	Compared to Forecast (as of May 11)
Net sales	379.5	362.0	<b>352.0</b>	-27.5	-10.0
Cost of sales	110.0	103.8	<b>100.0</b>	- 10.0	- 3.8
Gross profit	269.5	258.2	<b>252.0</b>	- 17.5	- 6.2
SG&A expenses	238.5	241.2	<b>232.0</b>	-6.5	-9.2
SG&A expenses less R&D costs	170.4	179.2	<b>173.5</b>	3.1	- 5.7
R&D Costs	68.2	62.0	<b>58.5</b>	-9.7	-3.5
Operating income	31.0	17.0	<b>20.0</b>	-11.0	3.0
Ordinary income	28.6	15.5	<b>19.0</b>	-9.6	3.5
Net income	16.8	8.5	<b>12.0</b>	-4.8	3.5
EBITDA	78.0	59.5	<b>61.0</b>	-17.0	1.5



Notes: 1. All values are rounded to the nearest 100 million yen.

2. EBITDA : Earnings Before Interest Taxes Depreciation and Amortization



# Financial Forecast in Japan Segment

Billions of yen

	Forecast (as of May 11)			Forecast (as of Oct.31)			Change(Value)		
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year
Net Sales	88.4	91.5	179.9	88.6	91.6	180.2	0.2	0.1	0.3
	24.8%	26.4%	25.7%	25.1%	27.7%	26.4%			
Cost of sales	22.0	24.2	46.2	22.3	25.4	47.7	0.3	1.2	1.5
Gross profit	66.6	67.3	133.9	66.4	66.4	132.8	-0.2	-0.9	-1.1
SG&A expenses less R&D costs	32.9	33.5	66.4	32.5	34.0	66.5	-0.4	0.5	0.1
	38.0%	36.9%	37.5%	38.2%	35.3%	36.7%			
Income(loss) of Segment	33.7	33.8	67.5	33.9	32.4	66.3	0.2	-1.4	-1.2

Note: Sales figures exclude internal transactions.

# Sales Forecast in Japan Segment

Billions of yen

	Results FY2010	Forecast for FY2011		Change (Value)	
		Forecast (as of May 11)	Forecast (as of Oct. 31)	Compared to FY 2010	Compared to Forecast (as of May 11)
AVAPRO <sup>®</sup>	8.3	12.0	11.5	3.2	-0.5
LONASEN <sup>®</sup>	9.0	13.0	11.0	2.0	-2.0
PRORENAL <sup>®</sup>	14.9	17.0	15.5	0.6	-1.5
<b>Strategic Products Total</b>	<b>32.2</b>	<b>42.0</b>	<b>38.0</b>	<b>5.8</b>	<b>-4.0</b>
TRERIEF <sup>®</sup>	3.7	4.6	5.4	1.7	0.8
MIRIPLA <sup>®</sup>	1.5	1.7	1.4	-0.1	-0.3
METGLUCO <sup>®</sup> (Including MELBIN <sup>®</sup> )	4.7	6.0	8.2	3.5	2.2
SUREPOST <sup>®</sup>	—	0.2	0.2	0.2	—
<b>New Products Total</b>	<b>9.9</b>	<b>12.5</b>	<b>15.2</b>	<b>5.3</b>	<b>2.7</b>
AMLODIN <sup>®</sup>	41.4	31.0	35.5	-5.9	4.5
GASMOTIN <sup>®</sup>	21.0	21.0	21.0	—	—
MEROPEN <sup>®</sup>	12.6	10.0	11.0	-1.6	1.0
AmBisome <sup>®</sup>	4.6	5.0	4.5	-0.1	-0.5
REPLAGAL <sup>®</sup>	6.2	7.5	8.9	2.7	1.4
Others	55.0	50.9	46.1	-8.9	-4.8
<b>Japan Total</b>	<b>182.9</b>	<b>179.9</b>	<b>180.2</b>	<b>-2.7</b>	<b>0.3</b>

Note: Sales figures of each product are before reduction of rebates.

Sales figures exclude internal transactions.

# Domestic CNS Business Reinforcement

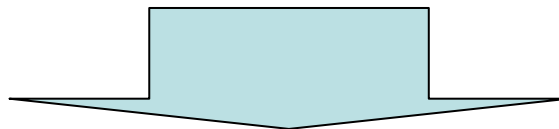
- Reinforcement of CNS Sales & Marketing

April 2011            Inauguration of CNS Sales & Marketing (200 MRs)

October 2011        CNS MRs increased to 230

Established the “CNS Medical Science Group” within CNS Sales & Marketing (13 members)

⇒ Reinforcement and strengthening of the academic support system for CNS products



## Early Maximization of LONASEN<sup>®</sup>

- Launch of Donepezil hydrochloride (Planned for November 2011)

- Dealing in generic drugs with the purpose of enhancing the product lineup in the CNS Field and based on trends in the development pipeline.
- Setting up the Established Products & Chain Pharmacies Group (26 members)

# Financial Forecast in North America Segment

Millions of dollars

	Forecast (as of May 11)			Forecast (as of Oct.31)			Change(Value)		
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year
<b>Net Sales</b>	<b>679</b>	<b>680</b>	<b>1,359</b>	<b>685</b>	<b>663</b>	<b>1,348</b>	<b>6</b>	<b>-17</b>	<b>-11</b>
LATUDA <sup>®</sup>	47	73	120	41	49	90	-6	-24	-30
LUNESTA <sup>®</sup>	280	255	535	261	272	533	-19	17	-2
XOPENEX <sup>®</sup>	194	194	388	216	194	410	22	0	22
BROVANA <sup>®</sup>	61	66	127	62	61	123	1	-5	-4
Others	97	92	189	104	88	192	7	-4	3
	10.8%	12.2%	11.5%	10.6%	9.3%	9.9%			
Cost of sales	73	83	156	72	62	134	-1	-21	-22
Gross profit	606	596	1,202	613	601	1,214	7	5	12
SG&A expenses less R&D costs	445	408	853	425	434	859	-20	26	6
	23.7%	27.6%	25.7%	27.4%	25.3%	26.3%			
Income(loss) of Segment	161	188	349	188	167	355	27	-21	6



Notes: Excluding impact of purchase price allocation by acquisition

# Financial Forecast in North America Segment

Billions of yen

	Forecast for FY 2011 (as of May 11)	Forecast for FY 2011 (as of Oct.31)	Change		
			Difference	Impact of foreign currency fluctuations	Actual
Net sales	115.5	108.4	-7.1	-6.1	-1.0
	11.5%	9.9%			
Cost of sales	13.3	10.8	-2.5	-0.5	-2.0
Gross profit	102.2	97.6	-4.6	-5.6	1.0
SG&A expenses less R&D costs	72.5	69.1	-3.4	-3.9	0.5
	25.7%	26.3%			
Income(loss) of Segment	29.7	28.5	-1.2	-1.7	0.5

Notes: Excluding impact of purchase price allocation by acquisition

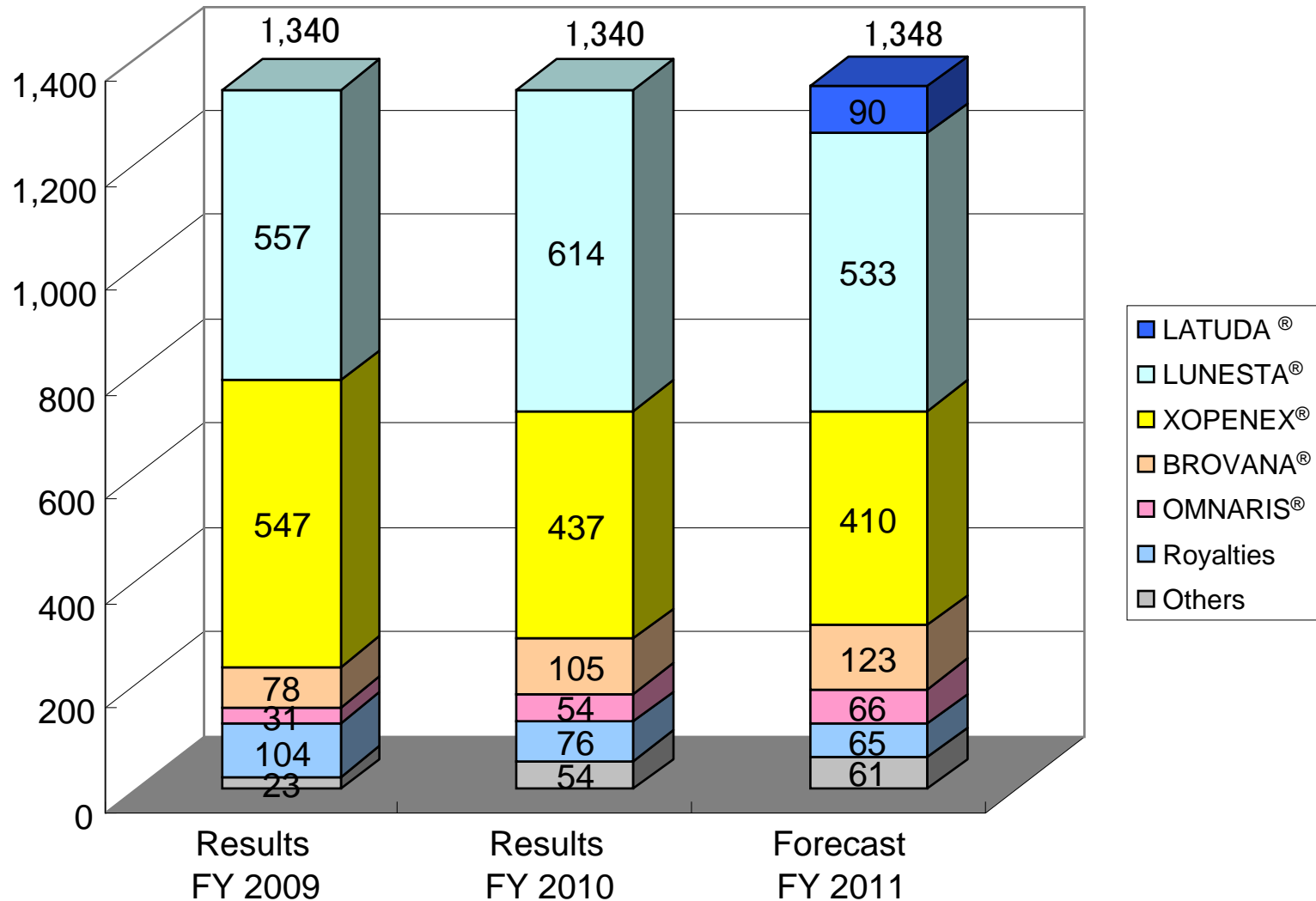
## Exchange rate

Forecast (as of May 11) ¥85 to US\$1

Forecast (as of Oct. 31) ¥80 to US\$1

# Sales Forecast in North America Segment

Millions of dollars



# Reinforcement of LATUDA Business in the U.S

- Increase of specialist MRs
- Enhancing the Speakers Program



Further improvement of Share of Voice

- Focusing on Market access support (Medicaid in particular)

# Forecast for FY2011 (by Segment)

(Compared with the previous forecast dated May 11, 2011)

Billions of yen

		Pharmaceuticals Business						Other Business	Total
		Japan	North America*1	Impact of P.P.A*2	China	Other Regions	Subtotal		
(as of Oct.31)	Net sales	180.5	108.4	—	6.6	16.2	311.7	40.3	352.0
	Cost of sales	47.7	10.8	—	2.0	8.3	68.8	31.2	100.0
	Gross profit	132.8	97.6	—	4.6	7.9	242.9	9.1	252.0
	SG&A expenses less R&D costs	66.5	69.1	28.0	3.6	0.3	167.5	6.0	173.5
	Income(loss) of Segment	66.3	28.5	-28.0	1.0	7.6	75.4	3.1	78.5
	R&D costs						57.7	0.8	58.5
	Operating income						17.7	2.3	20.0
(as of May 11)	Net sales	180.1	115.5	—	7.0	18.1	320.7	41.3	362.0
	Cost of sales	46.2	13.3	—	1.6	10.8	71.9	31.9	103.8
	Gross profit	133.9	102.2	—	5.4	7.3	248.8	9.4	258.2
	SG&A expenses less R&D costs	66.4	72.5	29.7	4.2	0.3	173.1	6.1	179.2
	Income(loss) of Segment	67.5	29.7	-29.7	1.2	7.0	75.7	3.3	79.0
	R&D costs						61.1	0.9	62.0
	Operating income						14.6	2.4	17.0
Change	Net sales	0.4	-7.1	—	-0.4	-1.9	-9.0	-1.0	-10.0
	Income(loss) of Segment	-1.2	-1.2	1.7	-0.2	0.6	-0.3	-0.2	-0.5
	R&D costs						-3.4	-0.1	-3.5
	Operating income						3.1	-0.1	3.0



\*1 Excluding impact of purchase price allocation by acquisition

\*2 Mainly amortization of patent rights and goodwill



# Clinical Development Status

# Development Pipeline (1) (as of October 31, 2011)

## Central Nervous System Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA submitted
LATUDA (SM-13496)	lurasidone hydrochloride	Schizophrenia	Canada				
		(Change of maximum dose) Schizophrenia: 160mg daily	US				
		Schizophrenia	Japan				
		(New indication) Bipolar disorder (depression)	US/Europe, etc.				
		(New indication) Bipolar disorder (maintenance)	US/Europe, etc.				
		(New indication) MDD with mixed features	US				
STEDESA™	eslicarbazepine acetate	Epilepsy-Adjunct	US				
		Epilepsy-Adult monotherapy	US				
DSP-8658	TBD	Alzheimer's disease	US				
SEP-228432	TBD	Neuropathic Pain, Depression	US				
DSP-1053	TBD	Depression	US				

LATUDA(SM-13496) : Co-development with Takeda Pharmaceutical in Europe (Phase III Study : Schizophrenia , Bipolar disorder )

## Cancer Field

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA submitted
CALSED® (Product name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
WT4869	TBD	Myelodysplastic syndromes	Japan		※		
		Solid cancer	Japan				

Revisions since the previous announcement are in red.

※ on Phase I of Phase I/II study

# Development Pipeline (2) (as of October 31, 2011)

## Respiratory Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA submitted
Ciclesonide HFA Nasal Aerosol	ciclesonide	(New dose form) Allergic rhinitis	US				
DSP-3025	TBD	Asthma/Allergic Rhinitis	Japan				

## Cardiovascular/ Diabetes Field

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA submitted
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (Combination therapy with thiazolidine or biguanide)	Japan				
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				※
DSP-8153	amlodipine besilate/irbesartan	Hypertension/Combination agent	Japan				
DSP-8658	TBD	Type 2 diabetes	US				

## Other Fields

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA submitted
SMP-986	afacifenacin fumarate	Overactive bladder	Japan				
			US and Europe				
PRORENAL®	limaprost alfadex	Carpal-tunnel syndrome	Japan				
DSP-1747	obeticholic acid	Primary biliary cirrhosis (PBC), Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				
DSP-5990	ceftaroline fosamil	MRSA Infection	Japan		※		

Revisions since the previous announcement are in red.

※ under preparation

# LATUDA® (Lurasidone) – Clinical development status (1)

## US (schizophrenia)

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- **sNDA submitted for change of maximum dose (160mg/day) (June 2011)**
  
- **Key Current LATUDA® Studies in Schizophrenia**
  - PEARL 3 Extension Study: Phase III extension study (12-month effectiveness and safety / tolerability study) with comparator [Quetiapine XR] completed. Results of the study announced (October, 2011).
  - Switch Study: initiated in 3Q 2010. Completed, data analysis in progress.
  - Schizophrenia Maintenance Study: initiated in 3Q 2011, in progress.
  
- **Planned LATUDA® Studies in Schizophrenia**
  - Low-dose Schizophrenia Study with 20mg/day: to be initiated in 2Q 2012
  - Pediatric (10-17 yrs) PK Study: to be initiated in 4Q 2011
  - Pediatric (13-17 yrs) Efficacy Study: to be initiated in 2Q 2012

# LATUDA® (Lurasidone) – Clinical development status (2)

## U.S. (Bipolar disorder, others)

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- **Bipolar disorder (depression) Phase III studies (PREVAIL Studies)**
  - PREVAIL#1 : Placebo controlled, lithium or divalproex add-on study initiated in April 2009
  - PREVAIL#2 : Placebo controlled, monotherapy initiated in April 2009
  - PREVAIL#3 : Placebo controlled, lithium or divalproex add-on study initiated in December 2010

**Bipolar disorder (depression)  
sNDA planned for 2012**

- **Bipolar maintenance**
  - Phase III study initiated in 2Q 2011
- **MDD with mixed features**
  - Phase III study initiated in 2Q 2011
- **Other studies under consideration**
  - IM depot formulation

# LATUDA® (Lurasidone) – Clinical development status (3)

## Outside the U.S.

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- Japan: Schizophrenia/ New Phase III study under preparation
- Canada: Schizophrenia/ NDS submitted (June 2011)
- China: Schizophrenia/ IND submitted (September 2011)
- Europe: Schizophrenia and Bipolar disorder/ Co-development with Takeda Pharmaceutical in Europe (Phase III)

DSP plans to commercialize lurasidone independently in the UK

# LATUDA® (Lurasidone) PEARL 3 Extension Study (1)

- Double-blind study comparing LATUDA to Quetiapine XR
  - Study patients: adult patients with schizophrenia
  - Treatment period: 12-months extension study that followed the six-week, placebo-controlled PEARL 3 study
  - Primary efficacy endpoint : time to relapse of psychotic symptoms
  - Dosing Regimen :
    - LATUDA: Patients on LATUDA 80 mg/day or 160 mg/day, and placebo\* in the six-week PEARL3 Study.
      - ⇒ For week 1, 120mg/day (fixed dose)
      - ⇒ Then for up to 52 weeks, 40mg/day - 160mg/day (flexibly dosed)
    - Quetiapine XR: Patients on Quetiapine XR 600mg/day in the six-week PEARL3 Study.
      - ⇒ For week 1, 600mg/day
      - ⇒ Then for up to 52 weeks, 200mg/day – 800mg/day (flexibly dosed)
- \* : Results of the primary analysis do not include PEARL 3 study placebo patients who entered the extension study.

# LATUDA® (Lurasidone) PEARL 3 Extension Study (2)

**LATUDA was shown to be non-inferior to Quetiapine XR in risk for relapse, with a 27% reduction in relapse risk for LATUDA patients. LATUDA was also associated with low rates of weight gain and metabolic changes.**

*\*Hazard ratio 0.728*

## Other Key Findings

- Probability of Relapse (Kaplan-Meier):\*<sup>1</sup>                      23.7% for LATUDA                      33.6% for Quetiapine XR
- Discontinuation (due to treatment failure)\*<sup>1</sup>: 16% for LATUDA                      26% for Quetiapine XR (P=0.006)
- PANSS Total Scores\*<sup>2</sup>:    -34.6 for LATUDA                      -25.7 for Quetiapine XR
- Weight\*<sup>2</sup> :    +0.7 kg (1.5 lbs) for LATUDA                      +1.2 kg (2.6 lbs) for Quetiapine XR
- Cholesterol\*<sup>3</sup>:    0.0 mg/dL for LATUDA                      +4.0 mg/dL for Quetiapine XR
- Triglycerides\*<sup>3</sup>:    -18.0 mg/dL for LATUDA                      -7.0 mg/dL for Quetiapine XR
- Glucose\*<sup>3</sup>:    +1.0 mg/dL for both LATUDA and Quetiapine XR

*\*<sup>1</sup> Results during the extension study*

*\*<sup>2</sup> The mean change from the start of the PEARL3 study*

*\*<sup>3</sup> The median change from the start of the PEARL 3 study*

## Adverse Events (greater than or equal to 5%)

- LATUDA: akathisia, headache, insomnia, anxiety, increased weight and Parkinsonism
- Quetiapine XR: schizophrenia, headache, insomnia, psychotic disorder, increased weight and agitation.

**The full study findings will be presented at a future psychiatric medical congress**

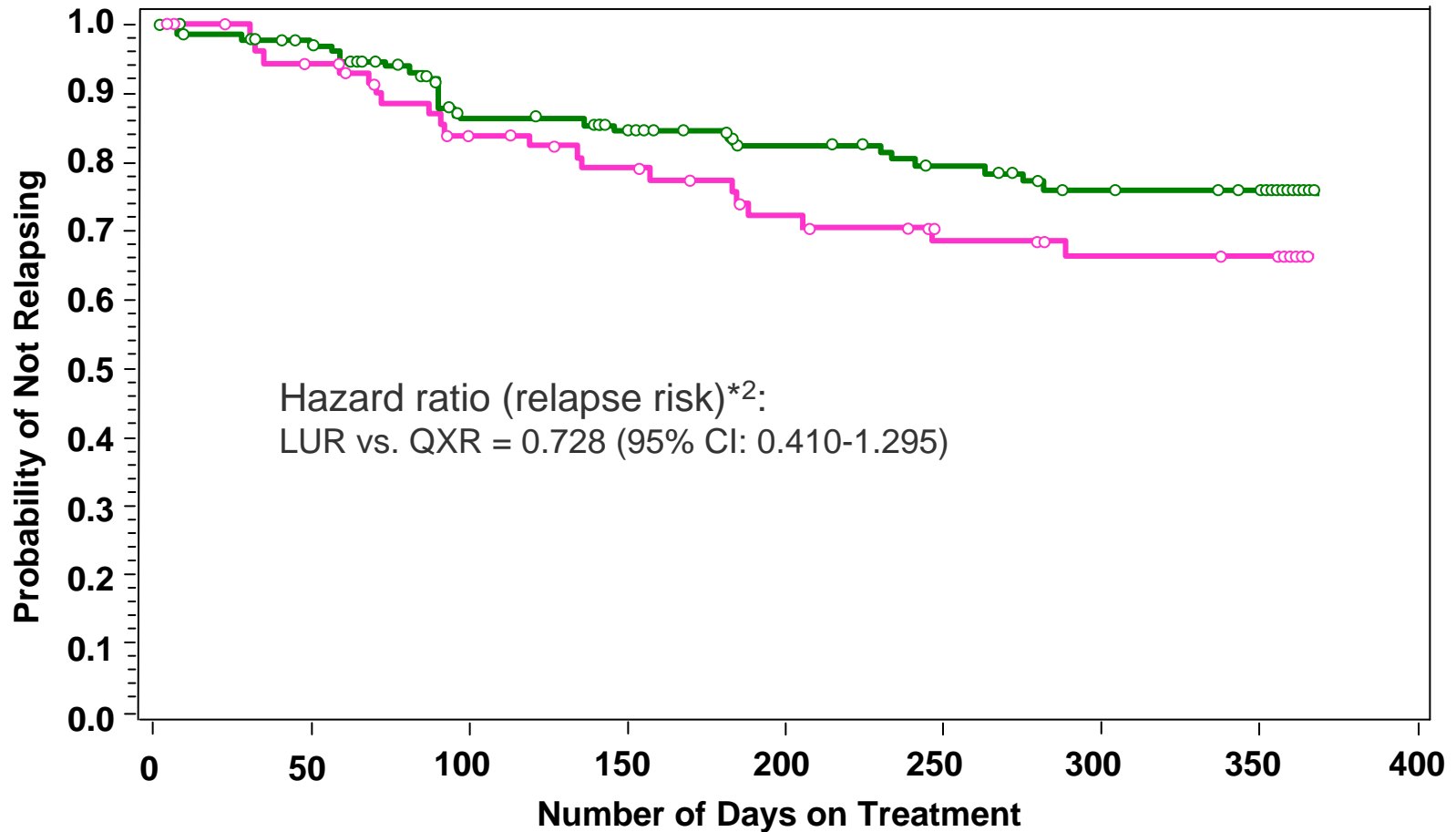
Note: Doses of 120 mg/day and 160 mg/day are under review at the FDA but have not been approved for use<sub>3,1</sub>



# LATUDA® (Lurasidone) PEARL 3 Extension Study (3)

A 27% reduction in relapse risk for LATUDA patients compared to Quetiapine XR patients

## Kaplan-Meier Survival Analysis\*1



Hazard ratio (relapse risk)\*2:  
LUR vs. QXR = 0.728 (95% CI: 0.410-1.295)

Treatment Group    **—**    LUR - LUR (n=139)    **—**    QXR - QXR (n=79)

\*1 Kaplan-Meier Survival Curve up to 365 Days

\*2 Derived from the Cox Proportional Hazards Model

# Commitment to Oncology (Cancer Field) (1)

## Reasons for focus on oncology

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- The challenge of researching and developing cancer treatments is a mission for R&D oriented pharmaceutical enterprises.
- There is a very high unmet medical need.
- The market is growing rapidly in the world.
- With the rapid progress of science, new breakthroughs can be expected.
- The therapeutic area can be covered by few MRs because specialists are the main prescriber.
- We have a business base in domestic marketing and R&D in the oncology area.

# Commitment to Oncology (Cancer Field) (2)

## Achievements to date

### Marketing

#### [ Japan ]

- SUMIFERON<sup>®</sup> (Launched 1987, on sale)
- CALSED<sup>®</sup> (Launched 2002, Sales transfer to Nippon Kayaku)
- MIRIPLA<sup>®</sup> (Launched 2010, on sale)

### Development

#### [Japan]

- WT4869 (MDS : Ph1/2, Solid Cancer: Ph1)

#### [ China ]

- CALSED<sup>®</sup> (Ph3)
- MIRIPLA<sup>®</sup> (Plan to submit IND this year)

### Global Oncology Business Development Office

### Research

- Focusing on specialty areas including the challenge area of oncology.
- For anti-cancer agents, we have ongoing biopharmaceutical approaches involving proteins, peptides, antibodies and nucleic acids in addition to small molecules.

### Alliances/ In-licensing

- Promoting collaborative research with Kyoto University (DSK Project)
- Exclusive option agreement with Boston Biomedical, Inc. for development and commercialization in Japan of the compound "BBI608" that targets cancer stem cells. (Japan: Option right. North America: Exclusive negotiation rights).

# Earthquake Disaster Reconstruction Support – Main Efforts to Date

- **Establishment of the Earthquake Disaster Reconstruction Support Office**
  - Established on May 1, 2011 (For 1 year)  
Full-time organization for the investigation, planning, and implementation of earthquake disaster reconstruction support activities.
- **Volunteer Pharmacists**
  - From about 200 applicants, volunteer pharmacists in groups of 3 volunteered in Miyagi Prefecture (72 people in 24 groups). ※ Activities completed on August 2.
  - Provided maximum support in earthquake disaster reconstruction activities of the Miyagi Prefecture Pharmaceutical Association.  
(Sorting of OTC medicine, transporting goods, administrative support of private volunteer pharmacists, assistance in general operations, etc.)
- **General Volunteers**
  - About 150 applicants went via volunteer bus to work in Rikuzentakata City, Iwate Prefecture. (99 people in 6 groups until now)
  - Clearing mud from roadside drains, removal of rubble, cleaning facilities, etc.
- **Other Activities**
  - Support of Fukushima Prefecture School Athletics Festival
  - Dispatch to Fukushima Disaster Volunteer Center
  - “Dream Care Team” with Tohoku University, etc.

# Disaster Reconstruction – Plans For Future Efforts

- **General Volunteers**
  - Iwate Prefecture Volunteer Bus
  - Miyagi Prefecture Volunteer Bus, etc.
- **Decontamination Volunteers**
  - Activity Period: November 2011 – March 2012
  - Activity Location: Fukushima City
  - Activity Description: Removing topsoil from private home gardens, etc. (For employees who have experience dealing with radiation)
- **Healthy Project**
  - Activity Period: November 2011 – March 2012
  - Activity Location: Ohshima, Kesenuma City, Miyagi Prefecture
  - Protection activities to prevent loneliness for temporary housing residents. Teaching children the correct usage of medicine. Children then tell the elderly temporary housing residents.
- **Marché (Market)**
  - Providing support through selling products from the disaster area.

**Future plans to expand reconstruction support  
meeting the needs of the disaster area**

Reference slide  
(for P2)

# Financial Results

(Compared with the corresponding period of the previous year)

Billions of yen

	FY2010 2Q	FY2011 2Q	Change		
			Value	Impact of exchange fluctuations	Percentage
Net sales	188.6	<b>178.0</b>	- 10.5	- 6.0	- 5.6 %
Cost of sales	57.8	<b>49.8</b>	- 8.1	- 0.7	- 13.9 %
Gross profit	130.7	<b>128.3</b>	- 2.5	- 5.3	- 1.9 %
SG&A expenses	115.8	<b>113.5</b>	- 2.3	- 7.1	- 2.0 %
SG&A expenses less R&D costs	83.0	<b>86.2</b>	3.2	- 5.6	3.9 %
R&D costs	32.8	<b>27.3</b>	- 5.5	- 1.5	- 16.8 %
Operating income	14.9	<b>14.7</b>	- 0.2	1.8	- 1.4 %
Ordinary income	14.4	<b>14.5</b>	0.1		0.7 %
Extraordinary income	—	<b>1.2</b>	1.2		—
Net income	8.7	<b>9.6</b>	0.9		10.6 %

Notes: 1. All values are rounded to the nearest 100 million yen.

2. Cost of sales includes provision for (reversal of) reserve for sales returns.

Reference slide  
(for P3)

# Financial Results

(Compared with the previous forecast dated May 11, 2011)

Billions of yen

	Forecast FY2011 2Q (as of May 11)	Results FY2011 2Q	Change		
			Value	Impact of exchange fluctuations	Percentage
Net sales	179.7	<b>178.0</b>	- 1.7	- 2.1	- 0.9 %
Cost of sales	50.1	<b>49.8</b>	- 0.3	- 0.3	- 0.7 %
Gross profit	129.6	<b>128.3</b>	- 1.3	- 1.8	- 1.0 %
SG&A expenses	120.7	<b>113.5</b>	- 7.2	- 2.5	- 5.9 %
SG&A expenses less R&D costs	90.1	<b>86.2</b>	- 3.9	- 1.9	- 4.3 %
R&D costs	30.6	<b>27.3</b>	- 3.3	- 0.6	- 10.8 %
Operating income	8.9	<b>14.7</b>	5.8	0.6	65.5 %
Ordinary income	8.4	<b>14.5</b>	6.1		72.4 %
Extraordinary income	—	<b>1.2</b>	1.2		—
Net income	4.8	<b>9.6</b>	4.8		99.4 %

# Financial Forecast for FY2011

(Compared with the FY2010 Results)

Billions of yen

	Results FY2010	Forecast FY2011 (as of Oct. 31)	Change		
			Value	Impact of exchange fluctuations	Percentage
Net sales	379.5	<b>352.0</b>	- 27.5	- 9.9	- 7.2 %
Cost of sales	110.0	<b>100.0</b>	- 10.0	- 0.9	- 9.1 %
Gross profit	269.5	<b>252.0</b>	- 17.5	- 9.0	- 6.5 %
SG&A expenses	238.5	<b>232.0</b>	- 6.5	- 11.4	- 2.7 %
SG&A expenses less R&D costs	170.4	<b>173.5</b>	3.1	- 8.9	1.8 %
R&D Costs	68.2	<b>58.5</b>	- 9.7	- 2.5	- 14.2 %
Operating income	31.0	<b>20.0</b>	-11.0	2.4	- 35.4 %
Ordinary income	28.6	<b>19.0</b>	- 9.6	/	- 33.6 %
Extraordinary income	- 3.6	<b>1.2</b>	4.8		—
Net income	16.8	<b>12.0</b>	- 4.8		- 28.6 %
EBITDA	78.0	<b>61.0</b>	- 17.0		21.8 %

Notes: 1. All values are rounded to the nearest 100 million yen.

2. EBITDA : Earnings Before Interest, Taxes, Depreciation and Amortization



Reference slide  
(for P15)

# Financial Forecast for FY2011

(Compared with the previous forecast dated May 11, 2011)

Billions of yen

	Forecast FY2011 (as of May 11)	Forecast FY2011 (as of Oct. 31)	Change		
			Value	Impact of exchange fluctuations	Percentage
Net sales	362.0	<b>352.0</b>	- 10.0	- 6.1	- 2.8 %
Cost of sales	103.8	<b>100.0</b>	- 3.8	- 0.5	- 3.7 %
Gross profit	258.2	<b>252.0</b>	- 6.2	- 5.6	- 2.4 %
SG&A expenses	241.2	<b>232.0</b>	- 9.2	- 7.1	- 3.8 %
SG&A expenses less R&D costs	179.2	<b>173.5</b>	- 5.7	- 5.6	- 3.2 %
R&D Costs	62.0	<b>58.5</b>	- 3.5	- 1.5	- 5.6 %
Operating income	17.0	<b>20.0</b>	3.0	1.5	17.6 %
Ordinary income	15.5	<b>19.0</b>	3.5	/	22.6 %
Extraordinary income	—	<b>1.2</b>	1.2		—
Net income	8.5	<b>12.0</b>	3.5		41.2 %
EBITDA	59.5	<b>61.0</b>	1.5		2.5 %

# Disclaimer Regarding Forward-looking Statements

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