



# **Second Quarter Financial Results for FY2010 (Apr. 1 to Sep. 30, 2010 )**

November 2, 2010

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# Second Quarter Financial Results for FY 2010

# Summary of Second Quarter Financial Results for FY2010

- Increases in net sales and gross profit due to U.S. subsidiary
- Decreased profit by amortization according to accounting for business combinations
- The results were almost in line with the Forecast for the second quarter FY2010.

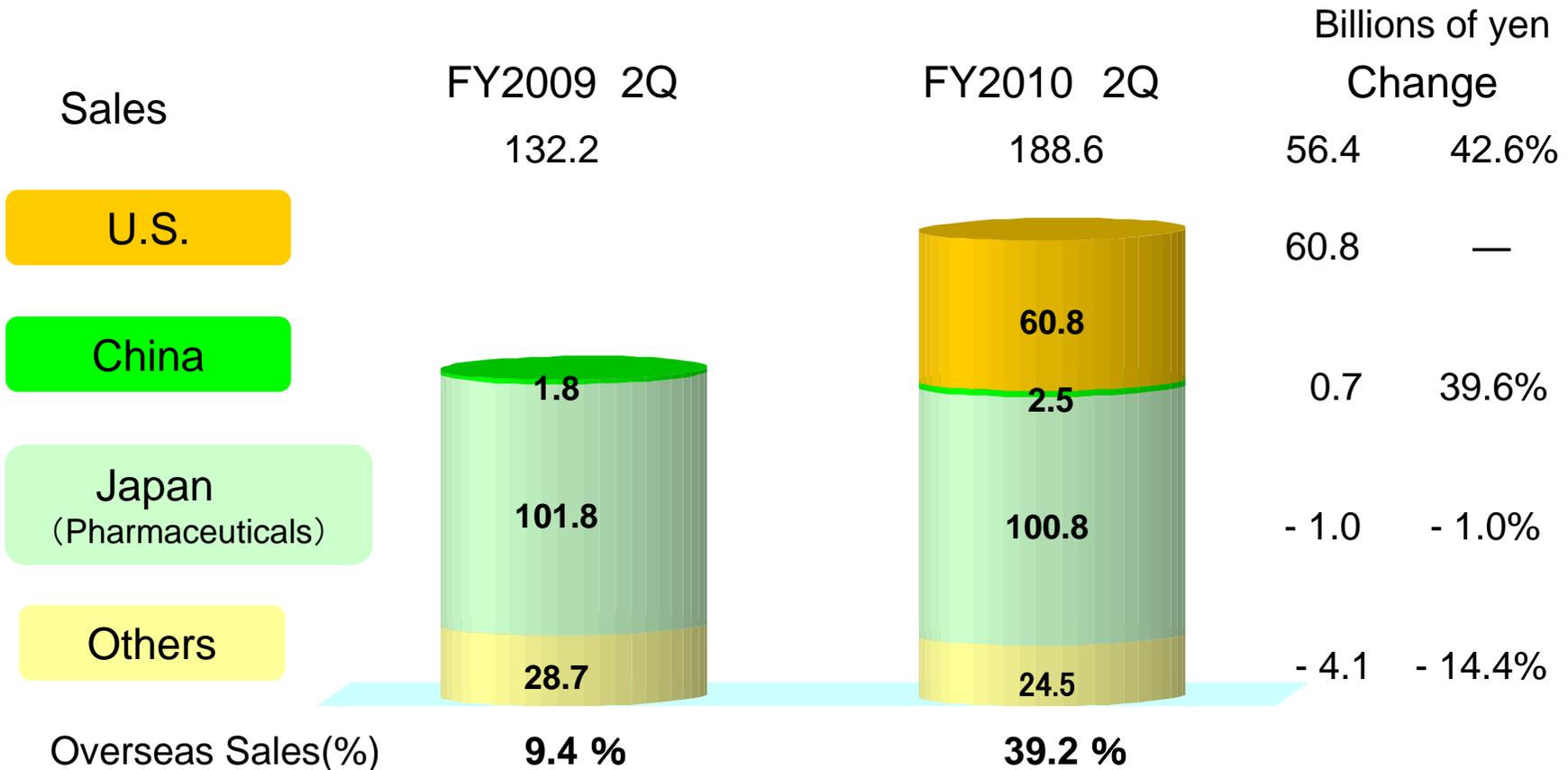
# Financial Results

Billions of yen

	FY2009 2Q	FY2010 2Q	Change		FY2010 2Q	
			Value	Percentage	Forecast (as of Jul. 30)	Difference
Net sales	132.2	188.6	56.4	42.6 %	186.0	2.6
SG&A expenses	62.0	115.8	53.8	86.9 %	115.0	0.8
R&D costs	24.2	32.8	8.6	35.3 %	31.5	1.3
Operating income	18.9	14.9	- 4.0	- 21.0 %	14.5	0.4
Ordinary income	19.1	14.4	- 4.7	- 24.5 %	13.5	0.9
Net income	12.7	8.7	- 4.0	- 31.6 %	8.1	0.6

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

# Breakdown of Sales



## 【Japan (Pharmaceuticals)】

·The influence of NHI price revision was covered by sales increase of strategic products and new products.

## 【Others】

·Only the commission equivalent part was recorded as sales on pet foods along with the spin off of Animal Health Products business into a separate company.

# Sales in Japan (Pharmaceuticals)

Billions of yen

	FY2009 2Q	FY2010 2Q	Change		FY2010 2Q	
			Value	Percentage	Forecast (as of Jul. 30)	Difference
AVAPRO®	1.0	3.7	2.7	258.7 %	3.6	0.1
LONASEN®	3.0	4.3	1.3	45.1 %	4.5	- 0.2
PRORENAL®	7.8	7.4	- 0.4	- 5.3 %	7.8	- 0.4
<b>Strategic Products Total</b>	<b>11.8</b>	<b>15.4</b>	<b>3.6</b>	<b>30.4 %</b>	<b>15.9</b>	<b>- 0.5</b>
TRERIEF®	0.4	1.6	1.2	329.2 %	1.3	0.3
MIRIPLA®	—	0.7	0.7	—	0.6	0.1
METGLUCO® (Including MELBIN®)	1.9	2.3	0.3	17.7 %	2.0	0.3
<b>New Products Total</b>	<b>2.3</b>	<b>4.6</b>	<b>2.3</b>	<b>100.8 %</b>	<b>3.9</b>	<b>0.7</b>
AMLODIN®	26.9	21.0	- 5.9	- 21.9 %	20.5	0.5
GASMOTIN®	10.4	10.2	- 0.1	- 1.3 %	10.1	0.1
MEROPEN®	7.6	6.6	- 1.1	- 13.8 %	6.0	0.6
AmBisome®	1.9	2.3	0.4	22.4 %	2.4	- 0.1
Others	30.5	30.1	- 0.4	- 1.4 %	29.3	0.8
Export	10.3	10.5	0.2	2.2 %	10.5	0.0
<b>Total</b>	<b>101.8</b>	<b>100.8</b>	<b>- 1.0</b>	<b>- 1.0 %</b>	<b>98.6</b>	<b>2.2</b>

Note: Excluding internal transactions in this sales figures

# Sales in U.S. & China

Billions of yen

	FY2009 2Q	FY2010 2Q	Change	Forecast for FY2010 2Q (as of Jul. 30)
LUNESTA®	—	28.5	28.5	28.5
XOPENEX®	—	19.0	19.0	19.0
BROVANA®	—	4.5	4.5	4.5
OMNARIS®	—	2.6	2.6	2.6
Industrial property revenues	—	3.9	3.9	3.9
Others	—	2.4	2.4	
<b>U.S. Total</b>	<b>—</b>	<b>60.8</b>	<b>60.8</b>	<b>60.8</b>
MEROPEN®	1.7	2.3	0.6	2.3
Others	0.1	0.2	0.1	
<b>China Total</b>	<b>1.8</b>	<b>2.5</b>	<b>0.7</b>	<b>2.6</b>

Note: Excluding internal transactions in this sales figures

# Segment Information

FY2010 Apr.-Sep.

Billions of yen

	Pharmaceuticals						Other business	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	102.0	63.0	—	2.9	- 3.8	164.0	24.5	188.6
Sales to customers	100.8	60.8	—	2.5	—	164.0	24.5	188.6
Intersegment	1.2	2.2	—	0.4	- 3.8	0.0	- 0.0	—
Cost of sales	29.2	6.1	2.6	1.0	- 1.1	37.8	20.0	57.8
Gross profit	72.8	56.9	- 2.6	1.9	- 2.7	126.2	4.5	130.7
SG&A expenses	56.5	40.9	16.6	1.0	- 2.6	112.4	3.4	115.8
SG&A expenses	33.3	29.4	16.6	1.0	- 0.4	80.0	3.0	83.0
R&D costs	23.2	11.5	—	—	- 2.2	32.4	0.4	32.8
Operating income	16.3	16.0	- 19.2	0.8	- 0.1	13.8	1.1	14.9

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

\*1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

\*2: Mainly amortization of patent rights and goodwill

# Financial Results of Japan ( Pharmaceuticals )

Billions of yen

	FY2009 2Q		FY2010 2Q		Change	
		% of net sales		% of net sales	Value	Percentage
Net sales	102.7	—	102.0	—	- 0.7	- 0.7 %
Sales to customers	101.8	—	100.8	—	- 1.0	- 1.0 %
Intersegment	1.0	—	1.2	—	0.3	25.4 %
Cost of sales	27.4	26.6 %	29.2	28.6 %	1.8	6.6 %
Gross profit	75.4	73.4 %	72.8	71.4 %	- 2.6	- 3.4 %
SG&A expenses	58.0	56.4 %	56.5	55.4 %	- 1.5	- 2.6 %
SG&A expenses	34.0	33.1 %	33.3	32.6 %	- 0.7	- 2.1 %
R&D costs	23.9	23.3 %	23.2	22.7 %	- 0.8	- 3.2 %
Operating income	17.4	16.9 %	16.3	16.0 %	- 1.1	- 6.1 %

Note: Cost of sales includes provision for (reversal of) reserve for sales returns



## (Cost of sales)

- Rise in cost of sales ratio due to NHI price revision

## (SG&A expense)

- Decrease in Advertising and Promotion expenses

# Ordinary income & Net income

Billions of yen

	FY2009 2Q	FY2010 2Q	Change	
			Value	Percentage
Operating Income	18.9	14.9	- 4.0	- 21.0 %
Non-operating income and expenses	0.1	- 0.6	- 0.7	
Finance income and expenses including dividend income	0.7	- 0.2	- 0.9	
Contributions	- 0.9	- 0.9	- 0.0	
Others	0.4	0.5	0.1	
Ordinary income	19.1	14.4	- 4.7	- 24.5 %
Income taxes	6.4	5.7	- 0.7	
Net income	12.7	8.7	- 4.0	- 31.6 %

# Financial Position

Billions of yen

	FY2009 (as of Mar.31)	FY2010 2Q (as of Sep.30)	Change
Assets	626.7	601.9	- 24.8
Current assets	287.6	303.5	15.9
Fixed assets	339.2	298.4	- 40.8
Liabilities	283.3	264.7	- 18.6
Current liabilities	265.0	247.3	- 17.7
Long-term liabilities	18.3	17.4	- 0.9
Net assets	343.5	337.3	- 6.2

(Shareholders' equity ratio)

54.8%

56.0%

## (Assets)

Decrease in Intangible assets ..... - 25.7 billion yen

## (Liabilities)

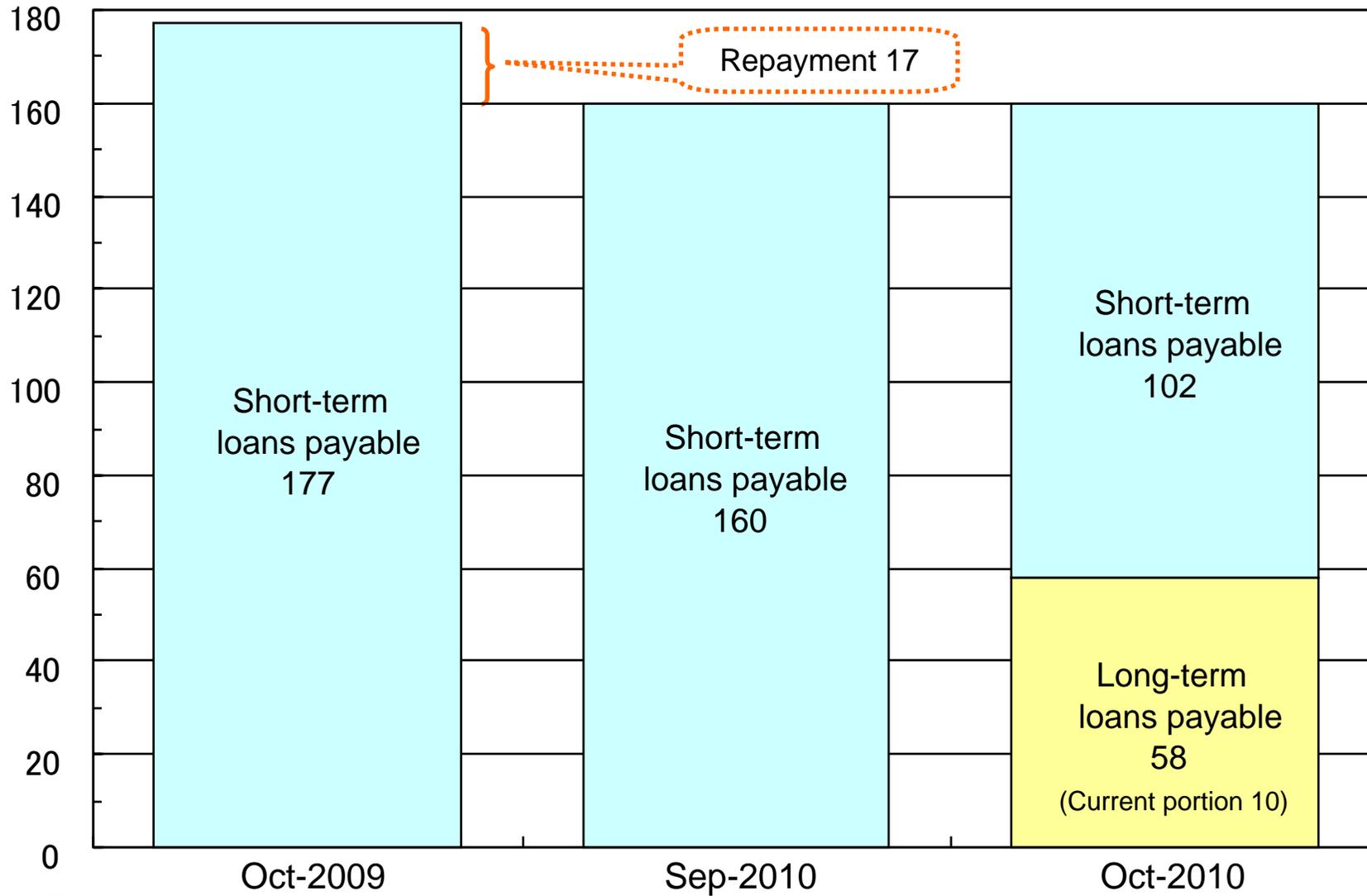
Decrease in short-term loans payable ..... - 4.9 billion yen

## (Net assets)

Decrease in valuation, translation adjustments and others ... - 11.3 billion yen

# Financing

Billions of yen



# Cash Flows

FY2010 Apr.-Sep.

Billions of yen

<b>I</b>	Net cash provided by operating activities	+ 30.0
	▪ Income before income taxes and minority interests	+ 14.4
	▪ Depreciation and amortization	+ 22.8
	▪ Decrease in inventories	+ 6.3
	▪ Income taxes paid	- 7.7
<b>II</b>	Net cash used in investing activities	+ 0.3
	▪ Proceeds from redemption of marketable securities	+ 5.2
	▪ Purchase of property, plant and equipment	- 3.4
<b>III</b>	Net cash used in financing activities	- 9.1
	▪ Net decrease in short-term loans payable	- 5.5
	▪ Dividends paid	- 3.6

Cash and cash equivalents at the end of period : 78.1 billion yen  
 (compared with the beginning of period +20.0 billion yen)

# Financial Forecast for FY2010

# Summary of Financial Forecast for FY2010

- Sales expected to surpass the estimate announced previously owing to strong sales in Japan and U.S. subsidiary despite the negative impact of the strong yen
- The financial forecast significantly boosted due to cost reduction and benefit of the strong yen
- Promote alliances and in-licensing for the purpose of enhancing our pipeline on the second half

# Financial Forecast for FY2010

Billions of yen

	Results FY 2009	Forecast for FY2010		Change (Value)	
		Forecast (as of Jul. 30)	Forecast (as of Oct. 29)	Compared to FY 2009	Compared to Forecast (as of Jul. 30)
Net sales	296.3	359.0	365.0	68.7	6.0
SG&A expenses	148.4	242.5	238.5	90.1	-4.0
R&D costs	51.4	67.5	67.0	15.6	-0.5
Operating income	35.6	8.5	18.0	-17.6	9.5
Ordinary income	33.8	6.0	15.5	-18.3	9.5
Net income	21.0	3.0	9.0	-12.0	6.0
<b>E B I T D A</b>	<b>56.4</b>	<b>57.2</b>	<b>66.8</b>	<b>10.4</b>	<b>9.6</b>

\* EBITDA : Earnings Before Interest Taxes Depreciation and Amortization

## (Reason for Revision)

- Strong sales of major products in Japan and U.S. subsidiary
- Decrease in SG&A expenses and Manufacturing costs
- Excluding potential strategic investment for alliances and in-licensing



# Segmental Forecast for FY2010

Billions of yen

		Pharmaceuticals						Other Business	Total
		Japan	U.S *1	Impact of P.P.A *2	China	Elimination	Total		
Forecast for FY2010 as of Jul. 30	Net sales	196.3	119.3	-	6.4	-7.0	315.0	44.0	359.0
	Cost of sales	56.9	12.2	3.4	2.4	-2.1	72.8	35.2	108.0
	Gross profit	139.4	107.1	-3.4	4.0	-4.9	242.2	8.8	251.0
	SG&A expenses	114.3	89.9	33.0	3.2	-4.9	235.5	7.0	242.5
	SG&A expenses	68.0	65.2	33.0	3.2	-0.6	168.8	6.2	175.0
	R&D costs	46.3	24.7	-	-	-4.3	66.7	0.8	67.5
	Operating income	25.1	17.2	-36.4	0.8	0.0	6.7	1.8	8.5
Forecast for FY2010 as of Oct. 29	Net sales	199.5	121.5	-	6.4	-7.4	320.0	45.0	365.0
	Cost of sales	56.4	12.6	3.4	2.3	-2.0	72.7	35.8	108.5
	Gross profit	143.1	108.9	-3.4	4.1	-5.4	247.3	9.2	256.5
	SG&A expenses	115.6	85.9	32.1	3.1	-5.2	231.5	7.0	238.5
	SG&A expenses	67.8	63.1	32.1	3.1	-0.7	165.4	6.1	171.5
	R&D costs	47.8	22.8	-	-	-4.5	66.1	0.9	67.0
	Operating income	27.5	23.0	-35.5	1.0	-0.2	15.8	2.2	18.0
Change	Net Sales	3.2	2.2	-	0.0	-0.4	5.0	1.0	6.0
	Operating income	2.4	5.8	0.9	0.2	-0.2	9.1	0.4	9.5

Note: Cost of sales includes provision for (reversal of) reserve for sales returns

\*1 Excluding impact of purchase price allocation by acquisition of Sunovion Pharmaceutical Inc.

\*2 Mainly amortization of patent rights and goodwill

# Financial Forecast for FY2010

## Japan Segment (Pharmaceuticals)

Billions of yen

	Forecast (as of Jul. 30)			Results and Forecast (as of Oct. 29)			Change (Value)		
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year
Net Sales	99.8	96.5	196.3	102.0	97.5	199.5	2.2	1.0	3.2
Sales to customers	98.6	95.6	194.2	100.8	96.5	197.3	2.2	0.9	3.1
Intersegment	1.2	0.9	2.1	1.2	1.0	2.2	0.0	0.1	0.1
Cost of sales	28.4%	29.6%	29.0%	28.6%	27.9%	28.3%	(0.3pt)	(- 1.7pt)	(- 0.7pt)
	28.3	28.6	56.9	29.2	27.2	56.4	0.9	-1.4	-0.5
Gross profit	71.5	67.9	139.4	72.8	70.3	143.1	1.3	2.4	3.7
SG&A expenses	55.4	58.9	114.3	56.5	59.1	115.6	1.1	0.2	1.3
SG&A expenses	33.4	34.6	68.0	33.3	34.5	67.8	-0.1	-0.1	-0.2
R&D costs	22.0	24.3	46.3	23.2	24.6	47.8	1.2	0.3	1.5
Operating income	16.1%	9.3%	12.8%	16.0%	11.5%	13.8%	(- 0.1pt)	(2.2pt)	(1.0pt)
	16.1	9.0	25.1	16.3	11.2	27.5	0.2	2.2	2.4

Note: Cost of sales includes provision for (reversal of) reserve for sales returns



### (Reason for Revision)

- Increase of sales and R&D costs

# Sales Forecast in Japan (Pharmaceuticals)

Billions of yen

	Results FY 2009	Forecast for FY 2010 (as of Jul.30)	Forecast for FY 2010 (as of Oct. 29)	Change Compared to July	
				Value	Percentage
AVAPRO®	3.7	8.0	8.0	0.0	0.0%
LONASEN®	6.3	10.5	10.5	0.0	0.0%
PRORENAL®	15.4	16.0	15.5	-0.5	-3.1%
<b>Strategic Products Total</b>	<b>25.4</b>	<b>34.5</b>	<b>34.0</b>	<b>-0.5</b>	<b>-1.4%</b>
TRERIEF®	0.8	2.8	3.4	0.6	21.4%
MIRIPLA®	0.2	1.5	1.5	0.0	0.0%
METGLUCO® (Including MELBIN®)	3.9	4.2	4.5	0.3	7.1%
<b>New Products Total</b>	<b>4.9</b>	<b>8.5</b>	<b>9.4</b>	<b>0.9</b>	<b>10.6%</b>
AMLODIN®	52.0	39.0	39.5	0.5	1.3%
GASMOTIN®	20.7	20.4	20.4	0.0	0.0%
MEROPEN®	14.7	11.0	11.6	0.6	5.5%
AmBisome®	4.0	5.1	4.9	-0.2	-3.9%
Others	62.3	58.0	59.6	1.6	2.8%
<b>Export</b>	<b>19.8</b>	<b>17.7</b>	<b>17.9</b>	<b>0.2</b>	<b>1.1%</b>
<b>Total</b>	<b>204.0</b>	<b>194.2</b>	<b>197.3</b>	<b>3.1</b>	<b>1.6%</b>



Note: Excluding internal transactions in this sales figures

# Financial Forecast for FY2010

## U.S. Segment

Millions of dollar

	Forecast (as of Jul. 30)			Results and Forecast (as of Oct. 29)			Change		
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year
Net Sales	689	625	1,314	689	686	1,375	0	61	61
Sales to customers	665	602	1,267	665	659	1,324	0	58	58
Intersegment	24	23	47	24	27	51	0	4	4
Cost of sales	9.7%	10.8%	10.2%	9.7%	11.0%	10.3%	(0.0pt)	(0.2pt)	(0.1pt)
	67	68	135	67	76	142	0	8	8
Gross profit	622	557	1,180	622	611	1,233	0	54	54
SG&A expenses	447	546	993	447	527	974	0	-19	-19
SG&A expenses	323	397	720	322	394	716	-2	-3	-5
R&D costs	124	149	273	126	133	259	2	-16	-14
Operating income	25.4%	1.8%	14.2%	25.4%	12.2%	18.8%	(0.0pt)	(10.4pt)	(4.6pt)
	175	11	187	175	84	259	0	72	72

Note: Excluding impact of purchase price allocation by acquisition

### (Reason for Revision)

- Sales increase of major products in U.S., LUNESTA® etc
- Decrease in SG&A expenses



# Sales Forecast in U.S.

Millions of dollar

	Forecast (as of Jul. 30)			Results and Forecast (as of Oct. 29)			Change (Value)			Change Percentage
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year	
LUNESTA®	312	243	555	312	285	596	0	42	42	7.5%
XOPENEX®	207	227	435	207	228	435	0	0	0	0.1%
BROVANA®	49	47	96	49	56	105	0	9	9	9.2%
OMNARIS®	28	25	53	28	28	56	0	3	3	5.3%
Industrial Property Revenues	42	30	73	42	34	76	0	4	4	5.4%
Others	26	29	55	26	29	56	0	0	0	0.5%
<b>U.S. Total</b>	<b>665</b>	<b>602</b>	<b>1,267</b>	<b>665</b>	<b>659</b>	<b>1,324</b>	<b>0</b>	<b>58</b>	<b>58</b>	<b>4.6%</b>

Note: Excluding internal transactions in this sales figures

# Financial Forecast for FY2010

## U.S. Segment

Billions of yen

	Forecast (as of Jul. 30)			Results and Forecast (as of Oct. 29)			Change			
	first half	second half	full year	first half (results)	second half	full year	first half	second half	full year	exchange
Net Sales	63.0	56.3	119.3	63.0	58.5	121.5	0.0	2.2	2.2	-3.1
Sales to customers	60.8	54.2	115.0	60.8	56.2	117.0	0.0	2.0	2.0	-3.0
Intersegment	2.2	2.1	4.3	2.2	2.3	4.5	0.0	0.2	0.2	-0.1
Cost of sales	9.7%	10.8%	10.2%	9.7%	11.1%	10.4%	(0.0pt)	(0.3pt)	(0.1pt)	
	6.1	6.1	12.2	6.1	6.5	12.6	0.0	0.4	0.4	-0.3
Gross profit	56.9	50.2	107.1	56.9	52.0	108.9	0.0	1.8	1.8	-2.7
SG&A expenses	40.8	49.1	89.9	40.9	45.0	85.9	0.1	-4.1	-4.0	-2.4
SG&A expenses	29.5	35.7	65.2	29.4	33.7	63.1	-0.1	-2.0	-2.1	-1.8
R&D costs	11.3	13.4	24.7	11.5	11.3	22.8	0.2	-2.1	-1.9	-0.7
Operating income	25.6%	2.0%	14.4%	25.3%	12.0%	18.9%	(-0.2pt)	(10.1pt)	(4.5pt)	
	16.1	1.1	17.2	16.0	7.0	23.0	-0.1	5.9	5.8	-0.4

Note: Excluding impact of purchase price allocation by acquisition

### (Reason for Revision)

- Sales increase of major products, LUNESTA® etc
- Decrease of SG&A expenses

### Exchange rate:

Forecast (Jul.)  
after 3Q ¥90 to US\$1

Forecast (Oct.)  
3Q Results ¥85.89 to US\$1  
4Q ¥85.0 to US\$1

# Sales Forecast in U.S.

Billions of yen

	Results FY 2009	Forecast for FY 2010 (as of Jul. 30)	Forecast for FY 2010 (as of Oct. 29)	Change Compared to July		
				Value	Exchange (Including)	Percentage
LUNESTA®	10.5	50.4	52.8	2.4	-1.3	4.8%
XOPENEX®	13.6	39.4	38.4	-1.0	-1.1	-2.5%
BROVANA®	1.7	8.7	9.3	0.6	-0.2	6.9%
OMNARIS®	0.6	4.8	4.9	0.1	-0.1	2.1%
Industrial Property Revenues	1.5	6.6	6.8	0.2	-0.2	3.0%
Others	0.7	5.1	4.8	-0.3	-0.1	-5.9%
<b>U.S. Total</b>	<b>28.6</b>	<b>115.0</b>	<b>117.0</b>	<b>2.0</b>	<b>-3.0</b>	<b>1.7%</b>

Note: Excluding internal transactions in this sales figures

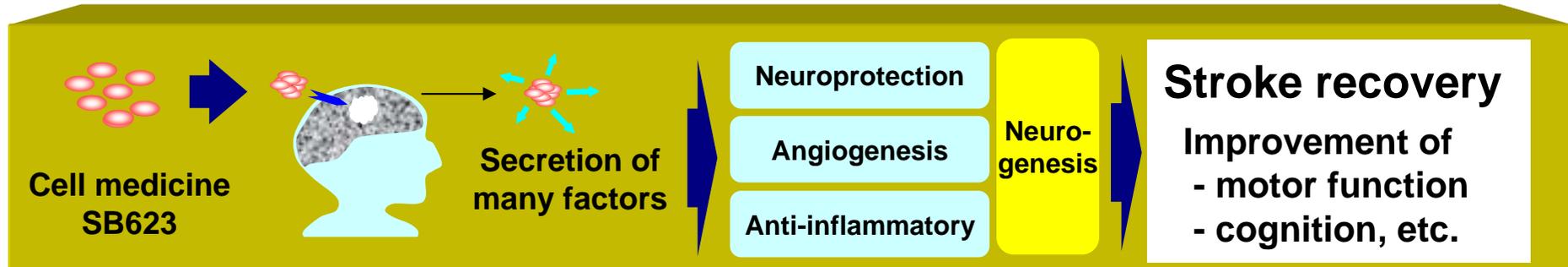
# R&D Pipeline

# Development Pipeline (as of October 29, 2010)

	Approved	NDA filed	Phase III	Phase II	Phase I
<b>Japan</b>		<p>SMP-508 (Diabetes)</p> <p>MEROPEN (Infection/ Maximum daily dose change)</p>	<p>Lurasidone (Schizophrenia)</p> <p>SMP-508 (Diabetes/ Combination Therapy with TZD/BG)</p>	<p>AS-3201 Diabetic neuropathy</p> <p>SMP-986 (Overactive bladder)</p> <p>DSP-8153 (Hypertension/ Combination product)</p>	<p>DSP-3235 (Diabetes)</p> <p>DSP-3025 (Allergic disorders)</p> <p>SMP-028 (Bronchial asthma)</p>
<b>Foreign Markets</b>	<p>Lurasidone US (Schizophrenia)</p>	<p>STEDESA™ US * (Epilepsy-Adjunct)</p>	<p>Lurasidone US·EU etc. (Bipolar disorder)</p> <p>Amurubicin hydrochloride China (Small cell lung cancer)</p> <p>OMNARIS® HFA Nasal MDI US * (Allergic Rhinitis)</p> <p>STEDESA™ US * (Epilepsy-Adult monotherapy)</p>	<p>SMP-986 US·EU (Overactive bladder)</p> <p>ALVESCO® HFA US * (Asthma-Pediatrics age range TBD)</p>	<p>SMP-028 US·EU (Bronchial asthma)</p> <p>DSP-7238 EU (Diabetes)</p> <p>DSP-8658 US (Diabetes)</p> <p>SEP-228432 US * (Neuropathic Pain, Major Depressive Disorder(MDD) )</p>
	<p> New Chemical Entities</p> <p> New Indication etc.</p> <p>* Pipeline candidates in Sunovion</p>				

# Drug for Stroke Recovery, SB623

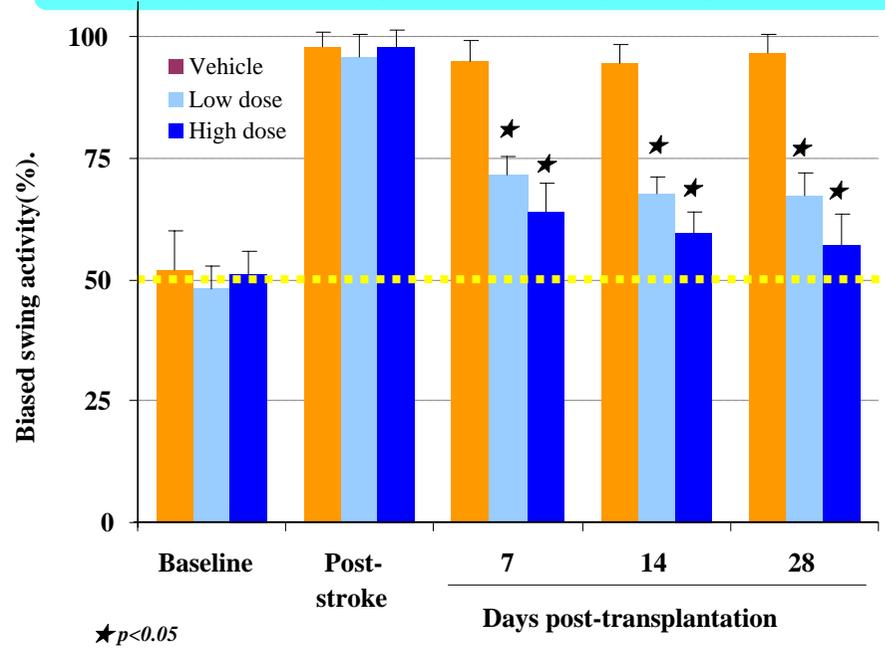
(Option Agreement to co-develop with SanBio, Inc.)



## Challenge for high unmet medical needs with innovative approach

- | Execution of an option for exclusive U.S. and Canadian marketing rights to SB623
- | Innovative drug candidate for disabilities caused by stroke for which there are currently no effective therapies.
- | Excellent efficacy in animal models of stroke disability
- | Be available to supply by vials because of allogeneic cell product
- | Phase 1/2a studies in November 2010

SB623 shows stroke recovery, motor function improvement by elevated body swing test



Lurasidone (LATUDA<sup>®</sup>) approved  
– For the launch –

 **Latuda<sup>®</sup>**  
(lurasidone HCl) tablets

# LATUDA<sup>®</sup> got the Marketing Authorization

**The date of the permission: October 28, 2010 (US)**

**Brand name: (LATUDA<sup>®</sup> )  
(Generic name: lurasidone HCl)**

- Indication: the treatment of patients with schizophrenia - Adult
- Dosage and Administration:  
The recommended starting dose is 40 mg once daily.  
The maximum recommended dose is 80 mg/day.  
LATUDA should be taken with food..

- 1st cycle approval (10 months) from the NDA (December 30, 2009)
- No Advisory Committee was requested.

# LATUDA<sup>®</sup> - A plan for commercialization -

## Schedule:

- Production and marketing/sales are in the final stage
- To get an approval from DDMAC regarding marketing materials



**Launch is in 1Q, 2011**

## An outline of the sales organization:

- The sales forces and its organization is getting ready. The training is under way.
- Hiring from external sales forces will be completed in November.
- The total number of sales forces are 300 at the launch.

# Lurasidone (LATUDA<sup>®</sup>) PEARL 3 Study

## PEARL 3 Study Design

### **Third Study in PEARL Clinical Program**

- Program to Evaluate the Antipsychotic Response to Lurasidone
- 6-week, placebo-controlled study
- 64 clinical trial sites worldwide
- 488 patients with schizophrenia
- Two fixed-doses of lurasidone – 80 and 160 mg/day
- Active comparator – quetiapine XR – 600 mg/ once a day
  - Quetiapine XR was employed for assay sensitivity in the study

## PEARL 3 Preliminary Results

### **Fifth Positive Placebo-Controlled Study**

- Both lurasidone doses were significantly more effective than placebo in PANSS total score, the primary endpoint, and CGI-S, the secondary efficacy endpoints.

### **Consistent Safety & Tolerability Profile**

- lurasidone was well tolerated with a lower discontinuation rate than placebo
- The most common adverse events reported for the lurasidone group (greater than 5% and at least twice the rate of placebo) were: akathisia, nausea, parkinsonism, dizziness and somnolence

### **Active Comparator Performed as Expected**

- Statistically significant improvement was also observed in quetiapine XR group relative to placebo

**Data will be presented at a scientific meeting in December;**

**Note: 160 mg/day dose was not included in the initial NDA for LATUDA and is under consideration of sNDA**

# Lurasidone – Clinical development status (1)

- **For Schizophrenia (on going PEARL Studies)**
  - PEARL #1: Placebo controlled (without comparator) Phase III study
    - Extension study (for two years) is on going
  - PEARL #2: Placebo controlled (with comparator [Olanzapine]) Phase III study
    - Extension study analysis is completed. Results show maintenance of clinical effects for Latuda-treated subjects for up to 8 months (6.5 months extension) and good tolerability.
  - PEARL Safety: Long term safety study
    - Under analyzing the data from one year administration
    - Extension study (for six months) is on going
  - PEARL #3: Placebo controlled (with comparator [Quetiapine XR]) Phase III study
    - The detailed data will be presented at a scientific meeting in December
    - Extension study (for two years) is on going

# Lurasidone – Clinical development status (2)

- **For Bipolar Depression (on going PREVAIL Studies)**

- PREVAIL #1: Placebo controlled, Li/VPA add-on study

- On going (Screening was initiated in April 2009)

- PREVAIL #2: Placebo controlled

- On going (Screening was initiated in April 2009)

- PREVAIL#3 Placebo controlled, Li/VPA add-on study

- US IND amendment was submitted. Screening will be initiated in November.

- An NDA for the additional indication will be made in 1-2Q, 2012.

Li: Lithium, VPA: Valproic acid

- **Pan-Asia Study**

- Phase III study with schizophrenia patients in Japan, Taiwan and Korea

- Under data analysis. Data will be available early 2011.

- An outline of the study

- Placebo controlled study (comparator: Risperidone)

- Sample size: 440

- Primary endpoint: PANSS

# Disclaimer Regarding Forward-looking Statements

The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.