

# Financial Results for FY2009 (ended March 31, 2010)

May 11, 2010

Masayo Tada

President and CEO

Dainippon Sumitomo Pharma Co., Ltd.

# Financial Results for FY2009



# Summary of Financial Results for FY2009

1. Increases in net sales and gross profit due to expanding scope of consolidation
2. Increased profit by efficient use of expenses
3. Both net sales and profit exceeded the forecasts

# Financial Results

Billions of yen

	FY2008	FY2009	Change		Forecasts	Difference
			Value	Percentage		
Net sales	264.0	296.3	32.2	12.2%	295.0	1.3
Operating income	31.2	35.6	4.5	14.3%	31.0	4.6
Ordinary income	31.4	33.8	2.4	7.8%	29.0	4.8
Net income	20.0	21.0	1.0	4.9%	19.0	2.0

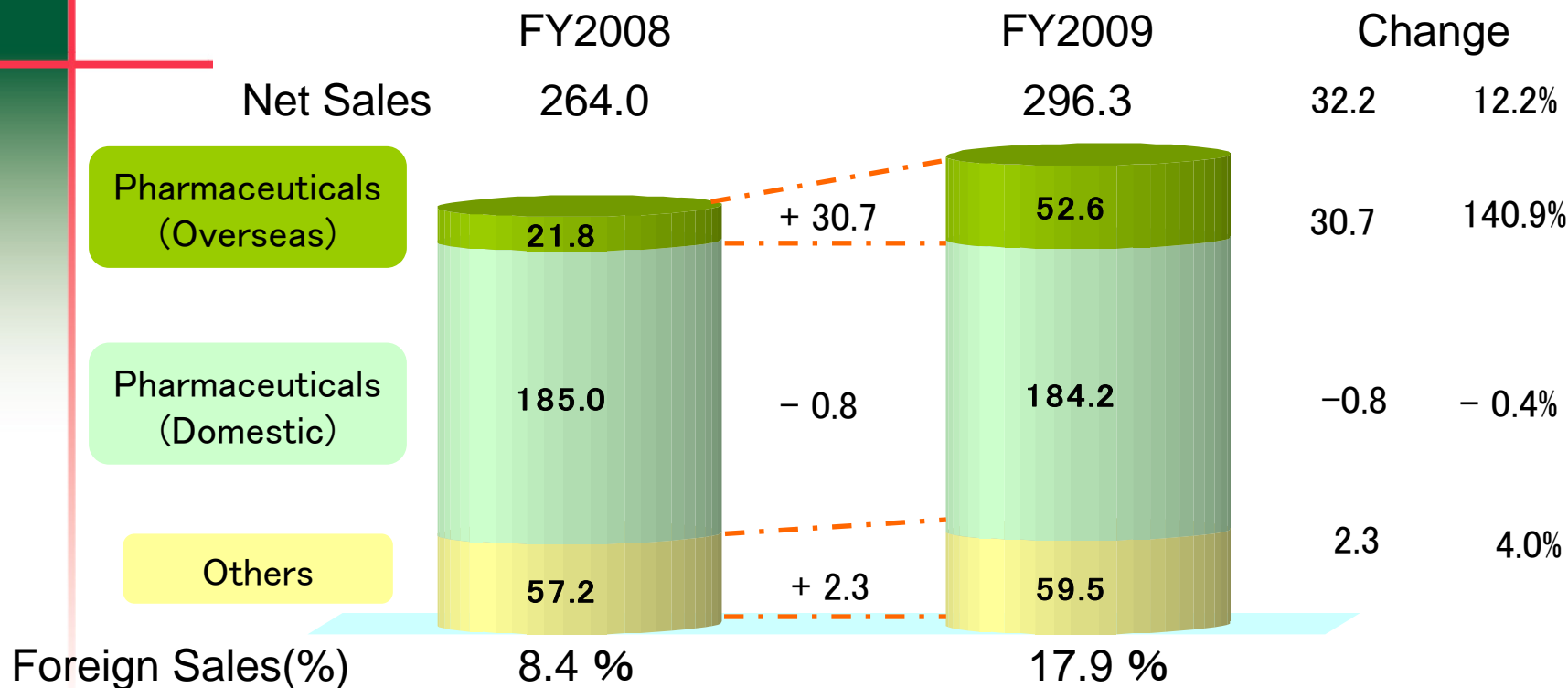
Notes: 1.All values are rounded to the nearest 100 million yen.

2.Forecasts announced on February 3,2010.

3.FY2009 includes full-year (Jan. to Dec.2009) figures of Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. and 4<sup>th</sup> quarter (Oct.15 to Dec.31,2009) figures of US subsidiaries (including Sepracor Inc.) are newly added to the scope of consolidation.

# Breakdown of Sales

Billions of yen



**(Domestic)**

- Sales decrease of AMLODIN® is covered by sales increase of the products such as AVAPRO®, LONASEN® and others

**(Overseas)**

- Contribution of Sumitomo Pharmaceuticals (Suzhou) Co., Ltd and Sepracor Inc.

**(Others)**

- Sales increase of influenza diagnostics and others

# Domestic sales of Pharmaceuticals

Billions of yen

	FY2008	FY2009	Change	
			Value	Percentage
AMLODIN®	57.9	52.0	- 5.9	- 10.1%
GASMOTIN®	20.2	20.7	0.6	2.9%
PRORENAL®	14.8	15.4	0.5	3.7%
MEROPEN®	14.8	14.7	- 0.1	- 0.6%
<b>4 Strategic Products Total</b>	<b>107.7</b>	<b>102.8</b>	<b>- 4.8</b>	<b>- 4.5%</b>
AVAPRO®	1.5	3.7	2.3	154.7%
LONASEN®	3.4	6.3	2.9	83.6%
TRERIEF®	0.1	0.8	0.7	1,100.6%
MIRIPLA®	—	0.2	0.2	—
<b>New Products Total</b>	<b>5.0</b>	<b>11.1</b>	<b>6.1</b>	<b>122.9%</b>
EBASTEL®	10.6	9.2	- 1.4	- 13.0%
SUMIFERON®	6.0	5.8	- 0.2	- 3.8%
AmBisome®	3.1	4.0	1.0	31.4%
<b>Others Total</b>	<b>72.4</b>	<b>70.3</b>	<b>- 2.1</b>	<b>- 2.9%</b>
<b>Total</b>	<b>185.0</b>	<b>184.2</b>	<b>- 0.8</b>	<b>- 0.4%</b>

# Overseas Sales of Pharmaceuticals

Billions of yen

		FY2008	FY2009	change
US Subsidiary	LUNESTA®	—	10.5	10.5
	XOPENEX®	—	13.6	13.6
	BROVANA®	—	1.7	1.7
	OMNARIS®	—	0.6	0.6
	Industrial property revenues	—	1.5	1.5
	Others	—	0.7	0.7
US Subsidiary Total		—	28.6	28.6
Sumitomo Pharmaceuticals (Suzhou)	MEPEM®	—	3.8	3.8
	Others	—	0.4	0.4
Sumitomo Pharmaceuticals (Suzhou) Total		—	4.1	4.1
Export Total (to unaffiliated customers)		21.8	19.8	- 2.0
Total		21.8	52.6	30.7

# Valuations and Accounting Procedures by Acquisition of Sepracor Inc.

Millions of dollar

	Before Purchase price allocation	After Purchase price allocation	Valuation differences	Accounting procedures (Amortization)	Impact on pretax income for FY2009	Impact on pretax income (Forecasts for FY2010)
Patent rights	—	1,197	1,197	• Amortization years by products	67	319
In-process R&D (Intangible assets)	—	59	59	• capitalize (amortize after approval)	—	—
Inventories	67	144	78	• charge to cost of sales	40	38
Deferred tax liabilities (of the above)	—	- 485	- 485	—	—	—
Other assets & liabilities (Net)	633	678	45	—	—	—
Goodwill	26	914	888	• Amortization for 20 years	10	46
Total	726	2,506	1,781	—	116	403



# Breakdown of Financial Results for FY2009

Billions of yen

	FY2009					Total
	Except US Subsidiary*1			US Subsidiary *2	Impact of Purchase price allocation *3	
	Except US & Chinese subsidiaries	Chinese Subsidiary	Total			
Net sales	264.8	2.8	267.6	28.6	—	296.3
Cost of sales	106.0	0.2	106.2	2.4	3.6	112.3
<b>Gross profit</b>	<b>158.8</b>	<b>2.6</b>	<b>161.4</b>	<b>26.2</b>	<b>- 3.6</b>	<b>184.0</b>
SG&A expenses	121.9	1.7	123.6	17.9	6.9	148.4
SG&A expenses	73.4	1.7	75.1	15.0	6.9	97.0
R&D costs	48.4	—	48.4	2.9	—	51.4
<b>Operating income</b>	<b>37.0</b>	<b>0.8</b>	<b>37.8</b>	<b>8.3</b>	<b>- 10.5</b>	<b>35.6</b>
<b>Ordinary income</b>	<b>35.6</b>	<b>0.7</b>	<b>36.4</b>	<b>7.9</b>	<b>- 10.5</b>	<b>33.8</b>
<b>Net income</b>	<b>21.9</b>	<b>0.7</b>	<b>22.6</b>	<b>5.2</b>	<b>- 6.9</b>	<b>21.0</b>

Notes \*1. Consolidation of domestic subsidiaries plus Chinese subsidiary, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

\*2. Excluding impact of purchase price allocation by acquisition

\*3. Mainly amortization of patent rights and goodwill

# Cost of sales and SG&A expenses

(Excluding US & Chinese Subsidiaries)

Billions of yen

	FY2008		FY2009		Change	
		% of net sales		% of net sales	Value	Percentage
Net Sales	264.0	—	264.8	—	0.8	0.3%
Cost of Sales	103.7	39.3%	106.0	40.0%	2.3	2.2%
Gross Profit	160.3	60.7%	158.8	60.0%	- 1.5	- 0.9%
SG&A expense	129.1	48.9%	121.9	46.0%	- 7.3	- 5.6%
SG&A expense	76.3	28.9%	73.4	27.7%	- 2.9	- 3.8%
R&D Costs	52.8	20.0%	48.4	18.3%	- 4.4	- 8.3%
Operating Income	31.2	11.8%	37.0	14.0%	5.8	18.6%

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

**(Cost of sales)**

- Rise in cost of sales ratio mainly by changes of sales structure

**(SG&A)**

- Decrease by efficient use of advertising costs and others

**(Others)**

- Decrease in clinical trial cost of lurasidone and others

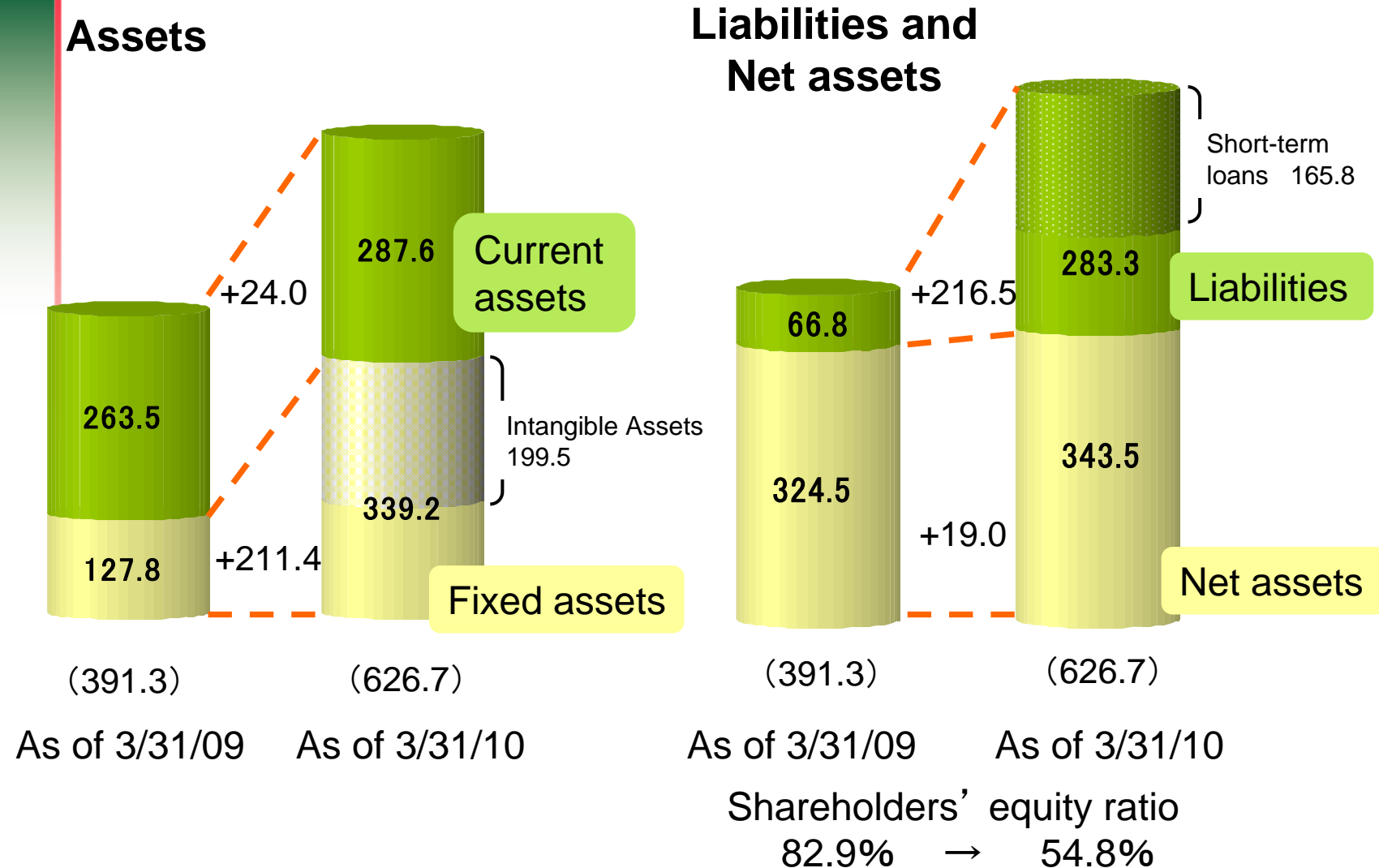
# Non-operating Income & Expenses and Extraordinary Income & Loss

Billions of yen

	FY2008	FY2009	Change	
			Value	Percentage
Operating income	31.2	35.6	4.5	14.3%
Non-operating income and expenses	0.2	- 1.8	- 2.0	
Finance income and expenses including dividend income	1.6	0.2	- 1.4	
Contributions	- 1.8	- 1.8	- 0.1	
Others	0.4	- 0.2	- 0.7	
Ordinary income	31.4	33.8	2.4	7.8%
Extraordinary income and loss	0.8	- 2.4	- 3.2	
Reversal of reserve for loss on litigation	1.1	—	- 1.1	
Compensation for revision of personnel system	—	- 1.6	- 1.6	
Loss on valuation of investment securities	- 0.3	- 0.8	- 0.6	
Income taxes and minority interests	- 12.2	- 10.5	- 1.7	
Net income	20.0	21.0	1.0	4.9%

# Changes in Financial Position

Billions of yen



# Cash Flows

Billions of yen

<b>I</b>	<b>Net cash provided by operating activities</b>	<b>+ 26.7</b>
	▪ Income before income taxes and minority interests	+ 31.4
	▪ Depreciation and amortization	+ 18.6
	▪ Income taxes paid	- 11.8
<b>II</b>	<b>Net cash used in investing activities</b>	<b>-151.8</b>
	▪ Proceeds from sales of marketable securities	+ 19.4
	▪ Decrease in short-term loans receivable	+ 25.0
	▪ Purchase of investments in subsidiaries resulting in change in scope of consolidation	- 200.6
<b>III</b>	<b>Net cash used in financing activities</b>	<b>+ 131.9</b>
	▪ Net increase in short-term loans payable	+ 164.9
	▪ Redemption of bonds	- 25.8
	▪ Dividends paid	- 7.2

Cash and cash equivalents at the end of period: 58.1 billion yen

# Financial Forecasts for FY2010



## Points of Forecasts for FY2010

1. Decrease in domestic sales of pharmaceuticals due to the influence of the NHI price revision and generic drugs
2. Increases in net sales and profit by consolidating the U.S. subsidiaries for full year
3. Full year impact of acquisition of Sepracor on financial statement
4. Significant decrease in profit on financial statement, while secured EBITDA of 50 billion yen or more.

# Financial Forecasts for FY2010

Billions of yen

	FY2009	FY2010	Changes	
	Results	Forecasts	Value	Percentage
Net sales	296.3	354.0	57.7	19.5%
Operating income	35.6	3.5	- 32.1	- 90.2%
Ordinary income	33.8	1.0	- 32.8	- 97.0%
Net income	21.0	0.0	- 21.0	- 100.0%
EBITDA	56.4	52.0	- 4.4	- 7.9%
R&D costs	51.4	67.5	16.1	31.4%



# Breakdown of Financial Forecasts for FY2010

Billions of yen

	FY2010					
	Excluding U.S. Subs * <sup>1</sup>			U.S. Subsidiary * <sup>2</sup>	Influence of P.P.A. * <sup>3</sup>	Total
	Basis	Chinese Subsidiary	Total			
Net Sales	239.2	3.8	243.0	111.0	—	354.0
Cost of sales	91.9	0.4	92.3	12.3	3.4	108.0
Gross profit	147.3	3.4	150.7	98.7	- 3.4	246.0
SG&A expenses	121.5	2.8	124.3	85.4	32.8	242.5
SG&A expenses	74.7	2.8	77.5	64.7	32.8	175.0
R&D costs	46.8	-	46.8	20.7	—	67.5
Operating income	25.8	0.6	26.4	13.3	- 36.2	3.5
Ordinary income	23.2	0.6	23.8	13.4	- 36.2	1.0
Net income	15.2	0.4	15.6	8.6	- 24.2	0.0

Notes \*1. Consolidation of domestic subsidiaries plus Chinese subsidiary, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

\*2. Excluding impact of purchase price allocation by acquisition

\*3. Mainly amortization of patent rights and goodwill

Exchange rate:  
¥90 to US\$1, ¥13 to CNY1

# Domestic Sales of Pharmaceuticals

Billions of yen

	FY2009	FY2010	Changes	
			Value	Percentage
AVAPRO®	3.7	8.0	4.3	113.9%
LONASEN®	6.3	12.0	5.7	90.1%
PRORENAL®	15.4	16.0	0.6	4.0%
<b>3 Strategic Products Total</b>	<b>25.4</b>	<b>36.0</b>	<b>10.6</b>	<b>41.5%</b>
TRERIEF®	0.8	2.8	2.0	253.6%
MIRIPLA®	0.2	1.5	1.3	524.1%
METGLUCO®	—	0.7	0.7	—
<b>New Products Total</b>	<b>1.0</b>	<b>5.0</b>	<b>4.0</b>	<b>384.4%</b>
AMLODIN®	52.0	38.5	- 13.5	- 26.0%
GASMOTIN®	20.7	20.4	- 0.3	- 1.6%
MEROPEN®	14.7	10.2	- 4.5	- 30.5%
AmBisome®	4.0	5.1	1.1	26.9%
<b>Others Total</b>	<b>157.7</b>	<b>136.0</b>	<b>- 21.7</b>	<b>- 13.8%</b>
<b>Total</b>	<b>184.2</b>	<b>177.0</b>	<b>- 7.2</b>	<b>- 3.9%</b>

# Overseas Sales of Pharmaceuticals

Billions of yen

	FY2009	FY2010	Changes		FY2009 (One Year)
			Value	Percentage	
LUNESTA®	10.5	46.5	36.0	341.2%	50.0
XOPENEX®	13.6	41.3	27.7	203.7%	49.1
BROVANA®	1.7	7.2	5.5	334.8%	7.0
OMNARIS®	0.6	4.8	4.2	700.0%	2.7
Industrial Property Revenues	1.5	6.6	5.1	337.9%	9.4
Others	0.7	4.6	3.9	517.0%	2.2
<b>US Subsidiary Total</b>	<b>28.6</b>	<b>111.0</b>	<b>82.4</b>	<b>287.5%</b>	<b>120.4</b>
MEPEM®	3.8	5.0	1.2	33.3%	
Others	0.4	0.6	0.2	53.7%	
<b>Sumitomo Pharmaceuticals (Suzhou) Total</b>	<b>4.1</b>	<b>5.6</b>	<b>1.5</b>	<b>35.2%</b>	
Export (to unaffiliated customers)	19.8	16.4	- 3.4	- 17.0%	
<b>Total</b>	<b>52.6</b>	<b>133.0</b>	<b>80.4</b>	<b>153.1%</b>	

# Financial Forecasts for FY2010

-Excluding U.S. and Chinese Subsidiaries -

Billions of yen

	FY2009		FY2010		Changes	
	Results		Forecasts		Value	Percentage
Net sales	264.8	—	239.2	—	- 25.6	- 9.7%
Cost of sales	106.0	40.0%	91.9	38.4%	- 14.1	- 13.3%
Gross profit	158.8	60.0%	147.3	61.6%	- 11.5	- 7.3%
SG&A expenses	121.9	46.0%	121.5	50.8%	- 0.4	- 0.3%
SG&A expenses	73.4	27.7%	74.7	31.2%	1.3	1.7%
R&D costs	48.4	18.3%	46.8	19.6%	- 1.6	- 3.4%
Operating income	37.0	14.0%	25.8	10.8%	- 11.2	- 30.2%

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

(Cost of sales)

- Rise due to NHI price revision
- Down due to changes of basis for recording sales on pet foods

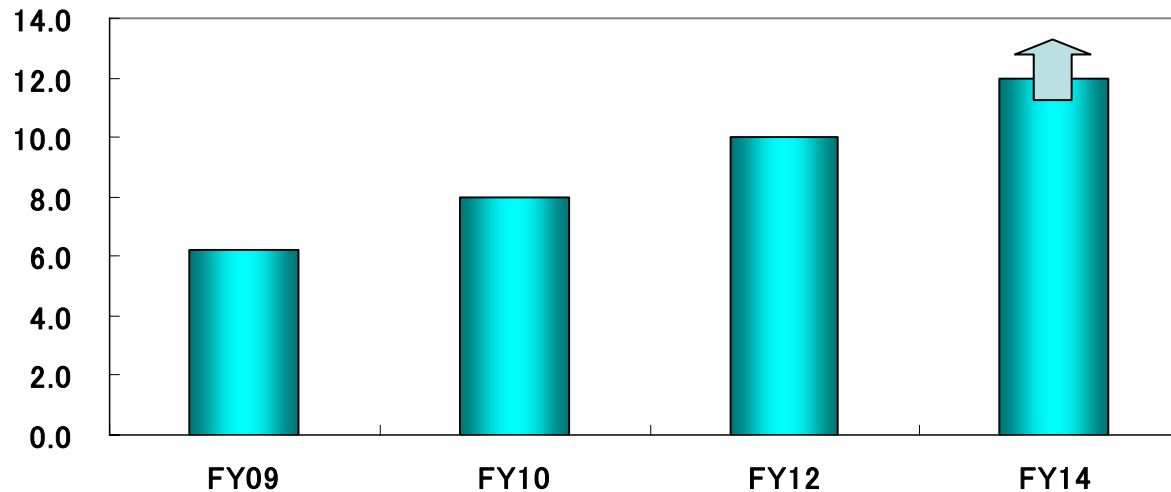
(SG&A expenses)

- Aggressive investment to increase net sales of domestic pharmaceuticals
- Reduction in overseas clinical trials of lurasidon, but increase in development of next strategic candidates
- Continuing cost reduction

# Improvement of Management Efficiency

- **Target**      Reduce costs by more than 12 billion yen by FY2014
- **Initiatives**
  - Pursuing effective use of expense
  - Split-up, outsourcing, and facility integration
  - Downsizing through organizational reformation
  - Elimination of all waste losses

**Target accumulated reduction by year toward 12 billion yen in total (base point : initial forecast for FY2009)**      Billions of yen



Great achievement in FY2009 → Try to accomplish 12 billion yen reduction earlier

# Returns to Shareholders

## ■ Dividend Policy

- Allot appropriate dividends in line with performance while balancing aggressive investment and internal reserves for future growth
- Also consider stable dividends

## ■ Changes in dividends

	FY2008	FY2909 (planned)	FY2010 (planned)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	35.8	34.1	-

<reference>

Dividends to net assets ratio (%)	2.2	2.1	2.1
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# Transform the earnings structure in Japan



# Focused Challenges in FY2010

- Change Products Structure
  - Ratio of Patent-Protected to Long-Listed Products

Medium-Term Business Plan	First Term		Second Term	
<b>Fiscal Year</b>	2007	2009	2010	Achieve ASAP
Patent Protected/ Long-Listed Products	70/30	40/60	45/55	50/50

- Focus Resources on Strategic/New Products → Maximize Products Value

Fiscal Year	2009	2010	Increases
<b>Strategic Products</b> AVAPRO® · LONASEN® · PRORENAL®	25.4	36.0	10.6
<b>New Products *1</b> TRERIEF® · MIRIPLA® · METGLUCO®	4.9	8.5	3.6
<b>Resource (Detailing)</b>	30%	55%	25%

\* 1 : Incl. MELBIN®

Billion yen



# Launch of METGLUCO®

## Biguanide Oral Hypoglycemic Agent

「METGLUCO® Tablets 250mg」(Generic Name: Metformin Hydrochloride)

- Jan. 20 : Approval      May 10 : Launch
- Clear dose-dependent hypoglycemic effect with wider dose range compared with existing metformin products
- Place the highest priority on promoting appropriate use and thoroughly provide information to make safe use in medical field
- Expect further contribution to treatment of patients with type 2 diabetes as a basal drug

# Focused Challenges in FY2010

- **Change Sales & Marketing System**
  - **Focus entirely on business operation from customer standpoint and build up trustful relationship with customers**
    - **Enhance education to strengthen abilities of MR**
    - **Strengthen capability to address diversified and sophisticated needs of customers**
    - **Accelerate customer services with enhancement of Regional Headquarters System**
  - **Change earning structure by shifting emphasis from sales to profit**
    - **Focus marketing resources on products with high profitability and growth potential**
    - **Improve efficiency of MR's behavior by instilling cost-consciousness**
    - **Promote bottom-up budgeting and gain/loss management**

# Expansion of overseas business



# Basic Policies of Sepracor Management

- Five Principles of Corporate Governance
  - To share Management Mission
  - DSP determines the global strategies through the discussion with Sepracor
  - Sepracor's important management issues are determined by its Board of Directors.
  - North America operations are determined on Sepracor's responsibilities
  - To strive to maximize business values of DSP Group and synergies
- Sepracor Managements
  - Chairman & CEO: Saburo Hamanaka  
President & COO: Mark Iwicki  
Executive Vice President & CSO: Nobuhiko Tamura
  - Board of Directors: Hamanaka, Iwicki, Tamura, Tada, Takeuchi, Nomura

# Preparing for lurasidone launch

## Timeline until launch

- December 2009, NDA submitted to FDA
- October 2010, FDA's review result to be obtained
- 1Q 2011, launch expected

## Building sales structure

- Anticipated 300 reps at the time of launch (Sepracor & recruitment)
- On FDA's approval, recruitment commenced

## Summary of results from clinical studies

- lurasidone demonstrated significantly greater improvement versus placebo on PANSS total score, in four studies
- lurasidone was well-tolerated and associated with limited weight gain or changes in metabolic parameters.
- Mild changes in movement disorder parameters and prolactin levels

## Market Opportunity

- Schizophrenia, a chronic mental illness, affects 2-3 million people in the US
- World Health Organization ranks schizophrenia as the 6<sup>th</sup> leading cause of disability worldwide
- Overall antipsychotic market in the US is \$14.5 billion (2009), 4% growth over previous year
- High rates of switching, discontinuation; need for new treatment with both efficacy and safety remains

## Further development and promotion

- Additional indication for bipolar depression
- Possibility for improvement of cognitive disorder
- Increase awareness of lurasidone and the company's name

# Expanding Business in China

## Scheme of Expanding Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.,

- Start selling GASMOTIN® from July 2010
- Expand the number of Sales Rep. from 200 (March 31, 2010) to 280 (December 31, 2010)
- Strengthen the pipeline by accelerating clinical study of CALSED, and starting the clinical study of LONASEN®

## Integration of Kyowa Hakko Pharmaceuticals (Suzhou) Co., Ltd.,



- Complete the process of integration into Sumitomo Pharmaceuticals (Suzhou) by the end of October, 2010
- Start of Packing Process 4Q CY 2011
- Start of Drug Formulation 1Q CY 2014



# R&D Pipeline



# Development Pipeline (as of May 10, 2010)

	NDA filed	Phase III	Phase II	Phase I
<b>Japan</b>	<p>SMP-508 (Diabetes)</p>	<p>Lurasidone (Schizophrenia)</p>	<p>AS-3201 Diabetic neuropathy</p> <p>DSP-8153 (Hypertension/ Combination product)</p>	<p>SMP-986 (Over-active bladder)</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 (Over-active 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-227900 US * (Cognition/Pain/AD)</p> <p>SEP-228432 US * (ADHD)</p>
	<p> New Chemical Entities</p> <p> New Indication etc.</p> <p>* Pipeline candidates in Sepracor</p>			



# Development Pipeline Highlights

- SMP-028 :  
Started Phase I Study in Japan
- Portfolio Priority Evaluation  
According to the results of the portfolio priority evaluation, the development of the following compounds were discontinued and deleted from the list.  
Phase II Stage : SEP-227018, SEP-225289, SEP-227162

# Global R & D

- **Establishment of a global committee composed of key R&D members from DSP and Sepracor**  
( Tentative name: Global PMC; Scheduled for May, 2010)
  - to discuss essential matters concerning research and development from a strategic point of view covering the entire DSP Group.
  - to decide project priorities by discussing the global R&D strategy, clinical development plan, and corresponding budget
  - to assign global projects

\* PMC (Portfolio Management Committee)

# Clinical Development of Lurasidone

## Schizophrenia:

**NDA was submitted to the U.S. FDA  
on Dec. 30<sup>th</sup> (US time) of 2009**

Program to  
Evaluate the  
Antipsychotic  
Response to  
Lurasidone

### ■ Ongoing Phase 3 studies in Schizophrenia

- Phase 3 Placebo- and Active Comparator (olanzapine)  
- Controlled Clinical Study (PEARL 2)
  - Data from the extension study under evaluation
  - Study results to be presented at APA (May 22-26, 2010, New Orleans)
- Long-term Safety Study (PEARL Safety)
  - Screening started in March, 2008, dosing underway  
Results from one-year study expected in 2010
- Phase 3 Placebo- and Active Comparator (quetiapine XR)  
- Controlled Clinical Study (PEARL 3)
  - Screening started in October, 2008, dosing underway  
Results from six-week study expected in 2010

# Clinical Development of Lurasidone

**PR**ogram to  
**EV**aluate the  
**AI**mpact of  
**L**urasidone

- Bipolar Disorder Phase 3 studies (PREVAIL study)
  - Screening started in April, 2009, dosing underway
  - Supplemental NDA is planned for the first half of year 2012
  
- Development for Japanese NDA submission (Pan-Asia study)
  - IND for Phase 3 Study (schizophrenia indication) in Japan, Taiwan and South Korea
  - Dosing underway
  - Protocol Synopsis
    - Comparator: Placebo (Reference: risperidone)
    - Number of Patients: 440
    - Primary Endpoints: 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.

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