

# First Quarter Financial Results for FY2009 (April 1 to June 30, 2009)

July 31, 2009
Dainippon Sumitomo Pharma Co., Ltd.



#### **Financial Results**

Billions of yen

Progress against forecasts for 1st Half FY2009

	1Q	1Q	С	hange	1 <sup>st</sup> Ha
	FY2008	FY2009	Value	Percentage	FY200 Forecas
Net sales	70.1	66.0	- 4.1	- 5.8 %	130
Operating income	10.2	11.2	1.0	10.1 %	12
Ordinary income	10.8	11.8	1.0	9.6 %	12
Net income	6.4	7.8	1.4	21.3 %	-

101 1 116					
1 <sup>st</sup> Half FY2009 Forecasts	Progress				
130.6	50.6 %				
12.8	87.8 %				
12.4	95.4 %				
7.8	100.2 %				

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

2. Sumitomo Pharmaceuticals (Suzhou) Co.,Ltd. is newly added as a consolidated subsidiary from 1Q FY2009.



## Increase and Decrease Factors of Net Sales

#### Billions of yen

			1Q	1Q	Change		
			FY2008	FY2009	Value	Percentage	
Ne	t sale	es	70.1	66.0	- 4.1	- 5.8 %	
	Pharmaceuticals		55.6	52.0	- 3.6	- 6.5 %	
		Domestic	48.9	45.9	- 3.0	- 6.1 %	
		Overseas	6.8	6.1	- 0.7	- 10.0 %	
Other products		14.5	14.0	- 0.4	- 3.1 %		

#### (Positives)

- Increased sales of strategic products other than AMLODIN<sup>®</sup>
- Increased sales of new products (LONASEN® / TRERIEF®)

#### (Negatives)

Decreased sales of AMLODIN® due to the influence of generics



## Domestic Sales of Pharmaceutical Products

Billions of yen

	1Q	1Q	Cha	ınge
	FY2008	FY2009	Value	Percentage
AMLODIN®	16.4	13.6	- 2.8	- 16.9 %
GASMOTIN®	5.0	5.2	0.2	3.7 %
PRORENAL®	3.7	3.9	0.2	6.8 %
MEROPEN®	3.6	3.7	0.1	3.3 %
4 Strategic Products Total	28.7	26.5	- 2.2	- 7.8 %
LONASEN®	0.5	1.4	0.9	155.3 %
AVAPRO®	1.1	0.2	- 0.8	- 77.8 %
TRERIEF®	_	0.2	0.2	_
New Products Total	1.6	1.8	0.2	12.8 %
EBASTEL®	2.2	2.0	- 0.2	- 9.9 %
SUMIFERON®	1.6	1.5	- 0.0	- 2.5 %
AmBisome®	0.6	0.8	0.2	30.9 %
Other Products	14.1	13.2	- 0.9	- 6.2 %
Domestic Sales Total	48.9	45.9	- 3.0	- 6.1 %



# Cost of Sales and Selling, General & Administrative Expenses

Billions of yen

		1Q FY2008		1Q FY2009		Change	
			% of net sales		% of net sales	Value	Percentage
Net sales		70.1		66.0	1	- 4.1	- 5.8%
Cost of sa	les	27.8	39.6%	25.4	38.5%	- 2.4	- 8.6%
Gross profit		42.3	60.4%	40.7	61.5%	- 1.7	- 4.0%
SG&A exp	enses	32.1	45.8%	29.4	44.5%	- 2.7	- 8.4%
SG&A e	expenses	19.5	27.8%	17.5	26.5%	- 1.9	- 9.9%
R&D cos	sts	12.7	18.0%	11.9	18.0%	- 0.8	- 6.2%
Operating in	ncome	10.2	14.6%	11.2	17.0%	1.0	10.1%

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

#### (Cost of sales)

• Decrease in the influence of the application of "Accounting Standard for Measurement of Inventories"

#### (SG&A expenses)

- Decrease in advertising costs and sales promotion costs related to new products
- Decrease in overseas development cost of lurasidone



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

Billions of yen

	1Q	1Q	Change	
	FY2008	FY2009	Value	Percentage
Operating income	10.2	11.2	1.0	10.1%
Non-operating income and expenses	0.6	0.6	0.0	
Finance income and expenses including dividend income	0.6	0.5	- 0.1	
Contribution Others	- 0.3 0.3	- 0.3 0.3	0.0 0.0	
Ordinary income	10.8	11.8	1.0	9.6%
Extraordinary income and loss	_	_	_	
Income taxes and minority interests	- 4.4	- 4.0	0.3	
Net income	6.4	7.8	1.4	21.3%



### Financial Forecasts for FY2009

Billions of yen

	FY08	FY09		
	Results	1 <sup>st</sup> Half Forecasts	Full Year Forecasts	
Net sales	264.0	130.6	264.0	
Operating income	31.2	12.8	25.0	
Ordinary income	31.4	12.4	24.0	
Net income	20.0	7.8	15.0	

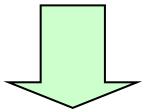
R&D costs	52.8	26.7	54.5
-----------	------	------	------

Forecasts are unchanged from those announced in May, 2009.



## Strengthening our domestic business foundation

- Establishment of regional headquarters within the Sales and Marketing Division as of June 26, 2009
  - Advancement and enhancement of communitybased business framework
  - Efficient operation of regional headquarters based on a management perspective
  - Profit responsibility clarified by adopting P&L management to regional headquarters

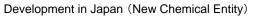


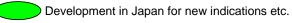
Improvement of profitability



## Development Pipeline (as of July 31,2009)

Pre-registration	Phase III	Phase II	Phase I
Hepatocellular carcinoma  SM-11355 (miriplatin)	Diabetes  SMP-508 (repaglinide)	Diabetic neuropathy  AS-3201 (ranirestat)	Over-active bladder syndrome  SMP-986  Diabetes
Diabetes  SMP-862 (metformin)	Schizophrenia SM-13496 (lurasidone)	Hypertension (Combination Product)  DSP-8153	Allergic disorders  DSP-3025
Febrile neutropenia  MEROPEN	Schizophrenia Bipolar disorder (US/EU etc.)  SM-13496 (lurasidone)  Small cell lung cancer (China)  Amrubicin	Over-active bladder syndrome (US/EU)  SMP-986	Bronchial asthma (US)  SMP-028  Diabetes (EU)  DSP-7238  Diabetes (US)  DSP-8658





Overseas development



### Development Pipeline Highlight

(Revisions since the announcement in May 2009)

■ AmBisome: Deleted because of approval in June 2009

Additional indication;

- Fungal infections caused by *Mucor* species, *Absidia* specicies, *Rhizopus* species, *Rhizomucor* species, *Cladosporium* species, *Cladophialophora* species, *Fonsecaea* species, *Phialophora* species, *Exophialia* species, *Coccidioides* species, *Histoplasma* species, and *Blastomyces* species
- Visceral Leishmaniasis (caused by Leishmania protozoa)



### Clinical Development of Lurasidone

Global studies (ongoing)

- Schizophrenia
  - Phase 3 Placebo-Controlled Clinical Study (PEARL 1)
    - Study completed as scheduled
    - ➤ Poster presentation at APA on May 20, 2009.
    - ➤ Issued press release on May 21, 2009.
    - ➤ Analyst meeting on June 12, 2009.
  - Phase 3 Placebo- and Active Comparator- Controlled Clinical Study (PEARL 2)
    - Screening started on January 31, 2008, dosing underway
  - Long-term Safety Study (PEARL Safety)
    - > Screening started on March 17, 2008, dosing underway
  - Phase 3 Placebo- and Active Comparator- Controlled Clinical Study (PEARL 3)
    - Screening started on October 27, 2008, dosing underway

Program to
Evaluate the
Antipsychotic
Response to
Lurasidone



### Clinical Development of Lurasidone

Global studies (ongoing)

- Bipolar Disorder (Phase 3 studies)
  - IND submitted to FDA on December 17, 2008.
  - Screening started in April, 2009, dosing underway
- Development for Japanese NDA submission (Pan-Asia study)
  - IND for Phase 3 Study (against schizophrenia) in Japan, Taiwan and South Korea
  - Dosing underway in Japan, Taiwan and South Korea
  - Protocol Synopsis
    - Comparator: Placebo (Reference: risperidone)
    - Target Number of Enrolled Patients: 440
    - Primary Endpoints: PANSS

PRogram to
EValuate the
Antidepressant
Impact of
Lurasidone



## Preparing an international operation structure

#### ■ Lurasidone Schedule

- PEARL 2 Trial Results: to be received in autumn, 2009
- NDA to the U.S. FDA: to be submitted no later than the first half year, 2010

#### Preparation for US sales organization

- A wholly-owned holding company established in the U.S. on July 13, 2009
   Dainippon Sumitomo Pharma America, Inc. to be a 100%-owned subsidiary of this holding company
- US sales organization under consideration
- A new sales subsidiary planned to be formed under the holding company in the future.



## 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.