

## First Quarter Financial Results for FY2008 (April 1 to June 30, 2008)

July 31, 2008

Dainippon Sumitomo Pharma Co., Ltd.



### **Financial Results**

Billions of Yen

Progress against forecast for 1st Half FY08

	1Q	1Q	С	hange	
	FY2007	FY2008	Value	Percentage	
Net sales	65.3	70.1	4.8	7.4 %	
Operating income	12.1	10.2	- 1.9	- 15.7 %	
Ordinary income	12.8	10.8	- 2.0	- 15.8 %	
Net income	7.8	6.4	- 1.4	- 17.6 %	

1 <sup>st</sup> Half FY08 Forecast	Progress
132.6	52.9 %
14.6	69.9 %
14.6	74.0 %
8.8	73.3 %

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



## Increase and Decrease Factors of Net Sales

#### Billions of Yen

	1Q	1Q	Change	
	FY2007	FY2008	Value	Percentage
Net sales	65.3	70.1	4.8	7.4 %

#### (Positives)

- Increased sales of strategic products
- Sales of new products (LONASEN® 

  ✓ AVAPRO®)
- Start of new contract manufacturing

#### (Negatives)

NHI price revision



## Domestic Sales of 4 Strategic Products and New Products

Billions of Yen

	1Q	1Q	Change	
	FY2007	FY2008	Value	Percentage
AMLODIN®	15.2	16.4	1.2	8.2 %
GASMOTIN®	4.7	5.0	0.3	6.6 %
PRORENAL®	3.5	3.7	0.2	5.1 %
MEROPEN®	3.5	3.6	0.1	2.9 %
4 Strategic Products Total	26.9	28.7	1.8	6.8 %

AVAPRO®	_	1.1	1.1	_
LONASEN®		0.5	0.5	
New Products Total		1.6	1.6	



# Cost of Sales and Selling, General & Administrative Expenses

Billions of yen

		1Q FY2007		1Q FY2008		Change
			% of net sales		% of net sales	Change
Net	sales	65.3	_	70.1	_	4.8
Co	st of sales	25.4	38.9 %	27.8	39.6 %	2.4
Gros	ss profit	39.9	61.1 %	42.3	60.4 %	2.4
SG	&A expenses	27.8	42.6 %	32.1	45.8 %	4.3
	SG&A expenses	18.5	28.3 %	19.5	27.8 %	1.0
	R&D costs	9.3	14.2 %	12.7	18.0 %	3.4
Ope	rating income	12.1	18.5 %	10.2	14.6 %	- 1.9

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 and the application of "Accounting Standard for Measurement of Inventories" (SG&A expenses)
- •Increase of advertising expenses and sales promotion cost due to launch of new products
- Increase of R&D costs due to overseas clinical trials of lurasidon in progress



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

#### Billions of yen

	1Q	1Q	Change
	FY2007	FY2008	J
Operating income	12.1	10.2	- 1.9
Non-operating income and expenses	0.7	0.6	- 0.1
Finance income and expenses including dividend income	0.6	0.6	0.0
Contribution	- 0.2	- 0.3	- 0.1
Others	0.3	0.3	- 0.0
Ordinary income	12.8	10.8	- 2.0
Extraordinary income and expenses		1	_
Income taxes and minority interests	- 5.0	- 4.4	0.6
Net income	7.8	6.4	- 1.4



### Financial Forecasts for FY2008

#### Billions of yen

	FY07	FY08 forecasts	
	results	1st half	Full year
Net sales	264.0	132.6	266.0
Operating income	39.8	14.6	30.5
Ordinary income	37.7	14.6	30.5
Net income	25.6	8.8	18.5

R&D costs	47.3	28.1	56.5
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Forecasts are unchanged from those announced in May, 2008.



## Development Pipeline

Pre-registration	Phase III	Phase I	II	Phase I
Hepatocellular carcinoma  SM-11355 (miriplatin)  Diabetes	Diabetes  SMP-508 (repaglinide)	Diabetic neuro		Over-active bladder syndrome  SMP-986
Parkinson's disease  AD-810N (zonisamide)	Schizophrenia  SM-13496 (lurasidone)	Rheumatoid a		Diabetes  DSP-3235  Allergic disorders (Under preparation for Phase I)
Compensated cirrhosis associated with chronic hepatitis C	Febrile neutropenia  MEROPEN	Dementia  AC-3933		DSP-3025  Bronchial asthma (US)  SMP-028
Improvement in bowel cleansing by orally gastrointestinal lavage solution prior to barium enema X-ray examination	Schizophrenia (US/EU etc.)  SM-13496 (lurasidone)	Rheumatoid arthritis (EU) SMP-114	Dementia (US/EU)  AC-3933	Diabetes (EU)
Addition of fungal species  AmBisome		Schizophrenia (US/EU)  AD-5423 (blonanserin)	Over-active bladder syndrome (US/EU)  SMP-986	Diabetes (US: Under preparation for Phase I)  DSP-8658
Development in Japan (New Chemical Entity)  Development in Japan for new indications etc.  Overseas development  White font indicates updated projects				



### Development Pipeline Highlight

- SMP-862 (metformin hydrochloride):
   Changed from "Phase II" to "NDA filed"
  - To obtain approval for metformin hydrochloride with appropriate indication and dosage regimen which maximizes the therapeutic potential of this drug (Currently, the indication and dosage in Japan are different from those outside Japan.)
- AmBisome (amphotericin B):
   Newly added in "NDA filed for new indication"
  - To obtain approval for additional indications of AmBisome, leishmaniasis and additional mycoses



## Establishment of Strategic Planning & Business Development Division as of June 27, 2008

**■**Further strengthening of the strategic planning function of DSP's pharmaceutical business



Clear vision of DSP's pharmaceutical business

Optimization of resource allocation by "selection and focus"



### Clinical Development of Lurasidone

#### Global studies (ongoing)

- Schizophrenia
  - Phase 3 Placebo-Controlled Clinical Trial (PEARL #1)
    - ➤ Target Number of Enrolled Patients: 480 (4 groups)
    - ➤ Country: US, France, Russia etc.
    - > Screening started on October 25, 2007. Progressing smoothly
  - Phase 3 Placebo- and Active Comparator Controlled Clinical Trial (PEARL #2)
    - ➤ Target Number of Enrolled Patients: 480 (4 groups), Comparator: Olanzapine
    - Country: US, India etc.
    - Screening started on January 31, 2008. Progressing smoothly
  - Long-term Safety Study (PEARL Safety)
    - ➤ Target Number of Enrolled Patients: 600, Comparator: Risperidone
    - ➤ Country: US, South Africa, Thailand, etc.
    - > Screening started on March 17, 2008. Progressing smoothly



### Clinical Development of Lurasidone

#### Global studies (planning)

- Schizophrenia
  - Phase 3 Placebo-Controlled Clinical Trial (PEARL #3): Planned to start within FY2008
- Bipolar Disorder
  - Phase 3 studies planned to start within FY2008
- Cognitive dysfunction in Schizophrenia
  - Planned to obtain clinical data to differentiate from competitors

#### Development for Japanese NDA submission Japan (Pan-Asia study)

- IND for Phase 3 Study in Japan (April), Taiwan (June) and South Korea (July)
- Screening started in June, 2008 (Japan)
- Protocol Synopsis
  - Target Patient: Schizophrenia
  - Comparator: Placebo (Reference : Risperidone)
  - Target Number of Enrolled Patients: 440
  - Country: Japan, South Korea and Taiwan



## 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.

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