

# First Quarter Financial Results for FY2011 (Apr. 1 to Jun. 30, 2011)

July 29, 2011 Dainippon Sumitomo Pharma Co., Ltd.

### **Financial Results**

Billions of yen

		FY2010	FY2011	Ch	ange
		1Q	1Q	Value	Percentage
Net	sales	101.8	94.8	△ 7.0	△ 6.9 %
Cos	st of sales	32.6	25.8	△ 6.8	△ 20.9 %
Gross profit		69.2	69.0	△ 0.2	△ 0.2 %
SG	&A expenses	54.4	56.2	1.8	3.4 %
	SG&A expenses less R&D costs	39.9	42.6	2.7	6.8 %
	R&D Costs	14.5	13.6	△ 0.9	△ 6.0 %
Operating income		14.8	12.8	△ 2.0	△ 13.5 %
Ordinary income		14.8	13.2	△ 1.7	△ 11.3 %
Net income		9.3	8.1	Δ 1.2	△ 12.8 %

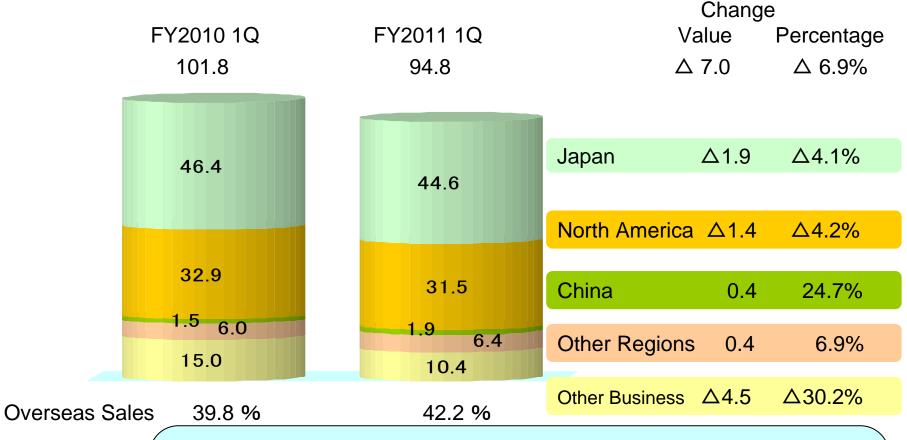


Notes: 1. All values are rounded to the nearest 100 million yen.

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

## Segment Net Sales

Billions of yen



#### [North America]

•Although there was an increase in sales in US currency, a decrease is seen because of the strength of the yen.

#### [Other business]

•There is a decrease because only the commission equivalent part was recorded as sales on pet foods (until the current fiscal quarter).



# Sales in Japan

#### Billions of yen

	FY2010 <b>FY2011</b>		Ch	Change			
	1Q	1Q	Value	Percentage			
AVAPRO®	1.8	2.3	0.6	31.5 %			
LONASEN®	2.2	2.4	0.2	8.3 %			
PRORENAL®	3.7	3.9	0.1	3.5 %			
Strategic Products Total	7.7	8.6	0.9	11.3 %			
TRERIEF®	0.8	1.2	0.4	58.6 %			
MIRIPLA®	0.4	0.3	△ 0.0	△ 7.0 %			
SUREPOST®	_	0.1	0.1				
METGLUCO®	1 1	1.6	0.5	42.7 %			
(Including MELBIN®)	1.1	1.0	0.5	42.7 70			
New Products Total	2.3	3.2	1.0	42.3 %			
AMLODIN®	10.9	9.2	△ 1.7	Δ 15.4 %			
GASMOTIN®	5.1	5.2	0.0	0.7 %			
MEROPEN®	3.3	3.0	△ 0.3	△ 9.3 %			
AmBisome®	1.1	1.0	Δ 0.1	△ 4.6 %			
REPLAGAL®	1.1	2.1	1.0	89.3 %			
Others	14.9	12.2	△ 2.7	Δ 18.2 %			
Japan Total	46.4	44.6	△ 1.9	△ 4.1 %			

FY2011 2Q						
Forecast as of May.11	Progress					
	44.0.0/					
5.5	41.9 %					
6.1	39.3 %					
8.3	46.6 %					
19.9	43.1 %					
2.2	55.0 %					
0.8	43.5 %					
0.1	54.7 %					
2.5	64.8 %					
5.6	57.7 %					
16.3	56.5 %					
10.3	50.3 %					
5.4	55.9 %					
2.4	43.3 %					
3.6	58.4 %					
24.9	49.0 %					
88.4	50.4 %					

Note: Sales figures before reduction of rebates.

# Sales in North America & China

#### Billions of yen [M\$]

						Chang	e
	FY2010	1Q	FY201	1 1Q	Valu	ie	Percentage
LATUDA®		_	(35)	2.9	[35]	2.9	_
LUNESTA®	[161]	14.6	(124)	10.2	[△ 37]	△ 4.4	Δ 30.2 %
XOPENEX®	[127]	11.5	(137)	11.3	[10]	Δ 0.3	Δ 2.2 %
BROVANA®	[25]	2.3	(33)	2.8	[8]	0.5	19.6 %
OMNARIS®	[11]	1.0	(16)	1.3	[5]	0.3	26.9 %
Industrial property revenues	[25]	2.2	(25)	2.1	[1]	Δ 0.1	Δ 6.3 %
Others	[14]	1.2	(15)	1.1	[2]	Δ 0.2	Δ 13.9 %
North America Total	[363]	32.9	[385]	31.5	[22]	Δ 1.4	Δ 4.2 %
MEROPEN®		1.2		1.6		0.4	33.4 %
Others		0.3		0.2		Δ 0.0	Δ 13.7 %
China Total 1.5		1.9			0.4	24.7 %	

FY2011 2Q					
Foreca as of Ma		Progress			
[47]	4.0	71.5 %			
[280]	23.8	42.7 %			
[194]	16.5	68.2 %			
[61]	5.2	52.9 %			
[38]	3.2	41.2 %			
[27]	2.3	90.6 %			
[32]	2.7	39.5 %			
[679]	57.7	54.6 %			
	3.0	54.6 %			
	0.6	40.4 %			
	3.6	52.2 %			



# **Segment Information**

#### Billions of yen

				Pharmaceutica	ls Business				
			North America ※1	Impact of P.P.A.※2	China	Other Regions	Subtotal	Other Business	Total
	Net sales	44.6	31.5	-	1.9	6.4	84.4	10.5	94.8
٦ ۲	Cost of sales	10.9	3.0	-	0.4	3.5	17.8	8.1	25.8
FY2011	Gross profit	33.7	28.5	1	1.4	2.9	66.6	2.4	69.0
ถื	SG&A expenses less R&D costs	15.6	17.7	7.1	0.6	0.1	41.2	1.4	42.6
Results	Income (loss) of Segment	18.1	10.8	△ 7.1	0.8	2.8	25.5	1.0	26.4
lts	R&D costs								13.6
	Operating income								12.8
	Net sales	46.4	32.9	_	1.5	6.0	86.8	15.0	101.8
l J	Cost of sales	12.0	3.1	1.6	0.2	3.0	20.0	12.6	32.6
201	Gross profit	34.4	29.7	Δ 1.6	1.3	3.0	66.8	2.4	69.2
FY2010 1Q I	SG&A expenses less R&D costs	15.6	13.9	8.2	0.5	0.1	38.3	1.5	39.9
Results	Income (loss) of Segment	18.8	15.8	△ 9.8	0.8	2.9	28.5	0.8	29.3
ਲਿ	R&D costs								14.5
	Operating income								14.8
C	Net sales	Δ 1.9	Δ 1.4	_	0.4	0.4	Δ 2.5	△ 4.5	Δ 7.0
Change	Income (loss) of Segment	△ 0.7	△ 5.0	2.7	0.0	△ 0.0	△ 3.0	0.1	△ 2.9
e	Operating income								Δ 2.0

- ※1. Excluding impact of purchase price allocation by acquisition.
  - 2. Mainly amortization of patent rights and goodwill.

### Financial Forecast for FY2011

Billions of yen

		Results FY2010	Forecast FY2011 2Q	Forecast FY2011
Net	sales	379.5	179.7	362.0
Cost	t of sales	110.0	50.1	103.8
Gros	ss profit	269.5	129.6	258.2
SG8	&A expenses	238.5	120.7	241.2
	SG&A expenses less R&D costs	170.4	90.1	179.2
	R&D costs	68.2	30.6	62.0
Operating income		31.0	8.9	17.0
Ordinary income		28.6	8.4	15.5
Net	income	16.8	4.8	8.5



Forecasts are unchanged from those announced in May, 2011.

# U.S.subsidiary (FY2011 Jan - Jun Unaudited)

M\$

	FY2011 Jan - Jun				
	Forecast	Results			
LATUDA <sup>®</sup>	47	41			
LUNESTA®	280	261			
XOPENEX®	194	216			
BROVANA®	61	62			
OMNARIS®	38	34			
ALVESCO®	22	17			
Industrial property revenues	27	42			
Others	10	14			
U.S. Total	679	688			

Forecast FY2011	Progress (FY2011 Jan- Jun)
120	34.2%
535	48.8%
388	55.7%
127	48.8%
75	45.3%
48	35.4%
46	91.3%
20	70.0%
1,359	50.6%



# **Development Pipeline (1) (Current as of July 29 2011)**

Central Nervous Sy	stem Field				Dom	estic	Overseas
Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	NDA filed
LATUDA (SM- 13496)	lurasidone hydrochloride	Schizophrenia	Canada				
		(Change of maximum dose) Schizophrenia: 160mg daily	US				
		Schizophrenia	Japan				
		(New indication) Bipolar disorder	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)

#### Cardiovascular/Diabetes Field

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

# Development Pipeline 2 (Current as of July 29 2011)

#### Respiratory Field

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

#### **Cancer Field**

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

#### ※ on Phase I of Phase I/II study

#### **Other Fields**

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

Newly added

★ under preparation

### **Development Pipeline Highlights**

(Main revisions since the announcement of May 2011)

- SUREPOST® (repaglinide) : Launched (May, 2011)
- Lurasidone hydrochloride (SM-13496):

sNDA submitted for change of maximum dose, newly added for MDD with mixed features in Phase III in the US

NDS submitted in Canada

**New Phase III study under preparation in Japan** 

- Ranirestat (AS-3201): Changed to Phase III under preparation in Japan
- PRORENAL®: Newly added in Phase II study in Japan
  - Started Phase II study for carpal-tunnel syndrome (Co-development with Ono Pharmaceutical)
- WT4869 : Newly added in Phase I study for Solid cancer in Japan (Co-development with Chugai Pharmaceutical)
- DSP-6952 : Newly added in Phase I study in Japan
  - Gastroprokinetic Agent
- DSP-1747 : Newly added in Phase I under preparation in Japan
  - FXR(Farnesoid X receptor) agonist (in-licensed from Intercept Pharmaceuticals Inc.)
- DSP-5990 : Newly added in Phase I under preparation in Japan
  - Cephem antibiotic (in-licensed from Takeda Pharmaceutical)
- DSP-3235 : Deleted because of discontinuation
- DSP-7238 : Deleted because of discontinuation

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

#### **US** (schizophrenia)

- sNDA submitted for change of maximum dose (160mg/day) (June)
- Key Current LATUDA® Studies in Schizophrenia
  - PEARL 3 Study: Placebo controlled (with comparator [Quetiapine XR]) Phase III study
     6 week double blind study completed, 12-month safety and tolerability study in progress.
  - Switch Study: initiated in 3Q 2010, in progress.
- Planned LATUDA® Studies in Schizophrenia
  - Schizophrenia Maintenance Study: to be initiated in 3Q 2011
  - Low-dose Schizophrenia Study with 20mg/d: to be initiated in 2Q 2012
  - Pediatric (10-17 yrs) PK Study: to be initiated in 3Q 2011
  - Pediatric (13-17 yrs) Efficacy Study: to be initiated in 2Q 2012

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

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

- Bipolar disorder (depression) Phase III study (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

#### sNDA planned for 2012

- MDD with mixed features
  - Phase III studies initiated in 2Q 2011
- Other studies under consideration
  - Bipolar maintenance: to be initiated in 3Q 2011
  - IM depot formulation



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

#### Outside the U.S.

Japan: Schizophrenia/ New Phase III study under preparation

Canada: Schizophrenia/ NDS submitted (June 2011)

China: Schizophrenia/ IND submission planned (2011)

Europe: Schizophrenia and Bipolar disorder/ Co-development

with Takeda Pharmaceutical in Europe (Phase III)

DSP plans to commercialize lurasidone independently in

the UK



### Disclaimer Regarding Forward-looking Statements

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