

# First Quarter Financial Results for FY2013 (Apr. 1 to Jun. 30, 2013)

# July 31, 2013 Dainippon Sumitomo Pharma Co., Ltd.

### FY2013 1Q Financial Results

Billions of yen

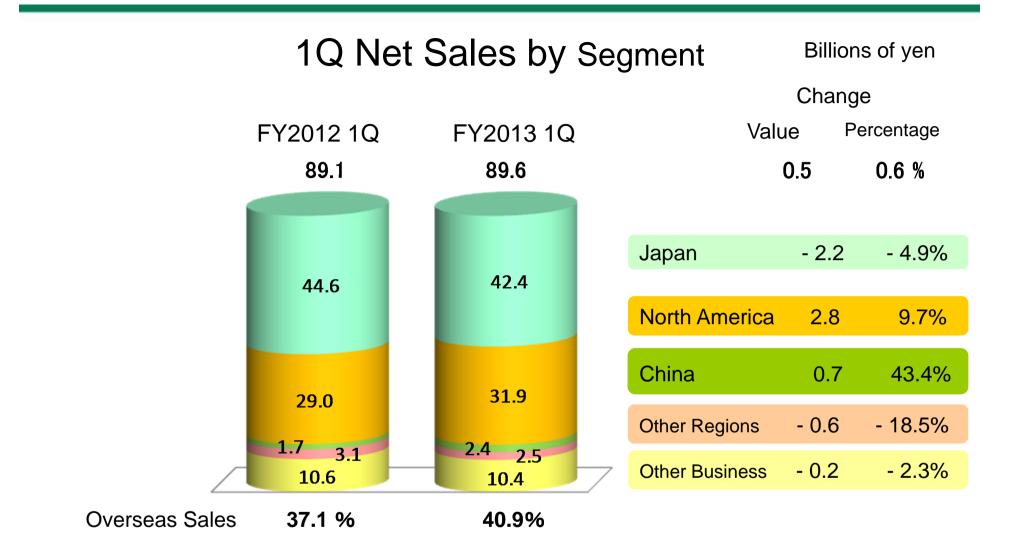
					Change		FY20	13 2Q	FY2	FY2013	
		FY2012 1Q	FY2013 1Q	Val	U <b>C</b> Exchange Impact	Percentage (%)	Forecast	Progress (%)	Forecast	Progress (%)	
Net	sales	89.1	89.6	0.5	6.2	0.6	178.0	50.3	369.0	24.3	
Cos	st of sales	25.2	25.3	0.0	0.8	0.2	52.0	48.6	106.0	23.8	
Gro	ss profit	63.9	64.4	0.5	5.4	0.8	126.0	51.1	263.0	24.5	
SG8	A expenses	53.0	55.3	2.4	5.6	4.4	116.0	47.7	237.0	23.3	
	SG&A expenses less R&D costs	38.9	40.6	1.7	4.3	4.4	86.0	47.3	170.0	23.9	
	R&D Costs	14.1	14.7	0.6	1.3	4.5	30.0	49.0	67.0	21.9	
Ope inco	rating me	10.9	9.0	- 1.9	- 0.2	- 17.1	10.0	90.3	26.0	34.7	
Ordi	nary income	11.5	9.5	- 2.0		- 17.4	10.0	94.9	25.0	38.0	
Net	income	5.7	4.8	- 0.9		- 15.6	5.0	96.2	13.0	37.0	
E	BITDA	21.9	16.8				25.0		54.0		

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.

FY2012 1Q	: 1US\$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 1Q	: 1US\$ = ¥ 98.8, 1RMB = ¥16.1
FY2013 Forecast	: 1US\$ = ¥100.0, 1RMB = ¥15.0

Exchange Rate:



【 Japan 】 Decrease in long-term listed products and contract manufacture products 【 North America 】 Increase of sales for LATUDA<sup>®</sup>, impact of weak yen



#### Exchange Rate: FY2012 1Q : 1US = ¥ 79.4, 1RMB = ¥12.6 FY2013 1Q : 1US = ¥ 98.8, 1RMB = ¥16.1 FY2013 Forecast : 1US = ¥100.0, 1RMB = ¥15.0

	1Q Sales in Japan								
	FY2012	FY2013	Cha	ange	FY2013 2Q				
	1Q	1Q	Value	Percentage (%)	Forecast	Progress (%)			
AIMIX®	_	0.8	0.8	_	1.8	45.8			
AVAPRO <sup>®</sup>	2.9	3.0	0.1	4.5	6.1	49.5			
LONASEN®	2.7	3.0	0.2	8.5	6.0	49.7			
TRERIEF®	1.7	2.1	0.3	18.4	4.4	46.8			
Strategic products total	7.4	8.9	1.5	20.5	18.3	48.5			
METGLUCO®	2.9	3.5	0.7	23.7	7.4	47.8			
SUREPOST®	0.1	0.3	0.2	209.2	0.9	36.6			
New products total	3.0	3.9	0.9	30.3	8.3	46.6			
AmBisome®	1.1	1.1	0.1	8.2	2.5	45.7			
MIRIPLA®	0.3	0.3	0.0	2.3	0.6	49.9			
REPLAGAL®	2.6	2.6	- 0.1	- 2.3	5.1	50.2			
Specialty products total	4.0	4.0	0.0	0.9	8.2	48.8			
AMLODIN®	7.8	7.2	- 0.6	- 7.5	13.3	53.9			
GASMOTIN®	5.2	4.0	- 1.1	- 22.1	8.7	46.3			
PRORENAL®	3.7	3.5	- 0.1	- 3.9	6.8	51.8			
MEROPEN <sup>®</sup>	2.6	2.5	- 0.2	- 6.7	5.1	48.3			
Others	11.1	8.5	- 2.6	- 23.4	17.0	50.0			
Japan total	44.6	42.4	- 2.2	- 4.9	85.7	49.5			

Note: Sales figures are before reduction of rebates

### 1Q Sales in North America & China

	FY2012	FY2013		FY2012	FY2013	Cha	ange	F		
	1Q	1Q	Change	1Q	1Q	Value	Exchange Rate Impact	Forecast as of May 9 <sup>%</sup>		Progress (%)
North America		(Million \$)			(Billion	yen)		(Million \$)	(Million \$) (Billion yen)	
LATUDA®	39	68	29	3.1	6.8	3.6	1.3	134	13.4	50.4
LUNESTA®	142	136	- 6	11.3	13.4	2.2	2.6	236	23.6	57.0
XOPENEX®	101	36	- 65	8.0	3.5	- 4.5	0.7	40	4.0	88.3
BROVANA®	39	41	2	3.1	4.0	0.9	0.8	96	9.6	41.9
Ciclesonide	9	23	14	0.7	2.2	1.5	0.3	65	6.5	34.6
Industrial property revenues	28	10	- 18	2.2	0.9	- 1.3	0.2	13	1.3	72.8
Others	7	9	2	0.6	0.9	0.3	0.2	23	2.3	39.8
Total	366	323	- 43	29.0	31.9	2.8	6.2	607	60.7	52.5
China		(Million RMB)			(Billion yen)			(Million RMB) (Billion yen)		
MEROPEN®	103	114	12	1.3	1.8	0.5	0.4	293	4.4	41.7
Others	30	35	5	0.4	0.6	0.2	0.1	73	1.1	50.7
Total	132	149	17	1.7	2.4	0.7	0.5	367	5.5	43.5

Note: FY2012 1Q figures are for sales of Jan to Mar 2012

X New sales forecast as of July 31 for LATUDA® and Ciclesonide is;

LATUDA®:(FY2013 2Q) \$150M , (FY2013) \$350M , Ciclesonide: (FY2013 2Q) \$49M , (FY2013) \$100M FY2013 Forecast

Exchange Rate: FY2012 1Q FY2013 1Q

:1US\$ = ¥ 79.4, 1RMB = ¥12.6 :1US\$ = ¥ 98.8, 1RMB = ¥16.1 : 1US\$ = ¥100.0, 1RMB = ¥15.0

### 1Q Segment Breakdown for North America

< Excluding amortization of patent rights and goodwill, etc. >

	FY2012 1Q	FY2013 1Q	Change	FY2012 1Q	FY2013 1Q	Exchange Rate Impact		
		(Million \$)		(Billion yen)				
Net sales	366	323	- 43	29.0	31.9	6.2		
Cost of sales	36	39	3	2.9	3.9	0.8		
Gross profit	329	283	- 46	26.1	28.0	5.4		
SG&A expenses	173	174	1	13.7	17.2	3.4		
Income (loss) of segment	156	110	- 47	12.4	10.8	2.0		

< Amortization of patent rights and goodwill, etc. >

	FY2012 1Q	FY2013 1Q	Change	FY2012 1Q	FY2013 1Q	Exchange Rate Impact	
		(Million \$)		(Billion yen)			
SG&A expenses	101	53	- 48	8.0	5.2	0.9	
Income (loss) of segment	- 101	- 53	48	- 8.0	- 5.2	- 0.9	



Exchange Rate:

FY2012 1Q	: 1US\$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 1Q	: 1US\$ = ¥ 98.8, 1RMB = ¥16.1
FY2013 Forecast	: 1US\$ = ¥100.0, 1RMB = ¥15.0

### **1Q Segment Information**

Billions of yen

				Pharmaceutical	s Business			Other	_
		Japan	North America <sup>%1</sup>	Amortization <sup>%2</sup>	China	Other Regions	Subtotal	Business	Total
	Net sales (Sales to customers)	42.4	31.9	—	2.4	2.5	79.2	10.4	89.6
FY2013	Cost of sales	11.4	3.9	_	0.6	1.3	17.2	8.0	25.3
013	Gross profit	31.0	28.0	—	1.8	1.2	62.0	2.3	64.4
1Q	SG&A expenses less R&D costs	15.2	17.2	5.2	1.4	0.2	39.2	1.5	40.6
	Income (loss) of segment	15.9	10.8	- 5.2	0.4	1.0	22.9	0.9	23.7
Results	R&D costs						14.5	0.2	14.7
0	Operating income						8.4	0.6	9.0
п	Net sales (Sales to customers)	44.6	29.0	—	1.7	3.1	78.5	10.6	89.1
FY2012	Cost of sales	12.1	2.9	—	0.4	1.6	17.0	8.2	25.2
	Gross profit	32.5	26.1	—	1.3	1.5	61.5	2.4	63.9
1Q	SG&A expenses less R&D costs	15.0	13.7	8.0	0.7	0.1	37.5	1.5	38.9
Res	Income (loss) of segment	17.6	12.4	- 8.0	0.6	1.4	24.0	1.0	24.9
Results	R&D costs						13.9	0.2	14.1
•	Operating income						10.1	0.8	10.9
	Net sales (Sales to customers)	- 2.2	2.8		0.7	- 0.6	0.8	- 0.2	0.5
Q	Income (loss) of segment	- 1.7	- 1.6	2.8	- 0.2	- 0.4	- 1.1	- 0.1	- 1.2
Change	R&D costs		1.0	2.0	0.2	0.4	0.6	0.0	0.6
Φ	Operating income						- 1.7	- 0.1	- 1.9

% 1. Excluding amortization of patent rights and goodwill, etc.

※ 2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2012 1Q	: 1US\$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 1Q	: 1US\$ = ¥ 98.8, 1RMB = ¥16.1
FY2013 Forecast	: 1US\$ = ¥100.0, 1RMB = ¥15.0

### 1Q Ordinary income & Net income

Billions of yen

	EV2012 10	EV2012.10	Change			
	FY2012 1Q	FY2013 1Q	Value	Percentage		
Operating income	10.9	9.0	- 1.9	- 17.1%		
Non-operating income and expenses	0.6	0.5	- 0.1			
Ordinary income	11.5	9.5	- 2.0	- 17.4%		
Extraordinary loss	1.5	1.0	- 0.5			
Business structure improvement expenses Impairment loss	1.1 0.4	0.6 0.4				
Income taxes	4.3	3.7	- 0.6			
Net income	5.7	4.8	- 0.9	- 15.6%		

【Business structure improvement expenses】 Restructuring costs in the U.S. subsidiary 【Impairment loss 】 Impairment loss for production facility in the U.S.



# **Clinical Development Status**



# Development Pipeline ① (as of July 31, 2013)

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA®	lurasidone	(New indication) Bipolar I depression	U.S.				
(SM-13496)	hydrochloride	Schizophrenia	Europe*			••••	
		Schizophrenia	Australia				
		(New indication) Bipolar I depression	Canada				
		Schizophrenia	Japan		• • • • • • • • • • • •		
		(New indication) Bipolar maintenance	U.S./Europe, etc.				
		(New indication) MDD with mixed features	U.S./Europe, etc.				
SEP-0002093	eslicarbazepine acetate	Epilepsy- Adjunctive therapy	U.S.				
		Epilepsy- Monotherapy	U.S.				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
SEP-225289	TBD	Attention-deficit hyperactivity disorder (ADHD)	U.S.				
DSP-8658	TBD	Alzheimer's disease	U.S.				
DSP-1053	TBD	Major depressive disorder	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K.				
SEP-363856	TBD	Schizophrenia	U.S.				

\*Lurasidone (SM-13496) : Co-development with Takeda Pharmaceutical in Europe Revisions since the previous announcement are in red.

9

# Development Pipeline 2 (as of July 31, 2013)

Cancer Field					Do	omestic	Overseas
Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED <sup>®</sup> (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
BBI608	TBD	Colorectal cancer (Monotherapy)	U.S./Canada				
		Colorectal cancer (Combination therapy)	U.S./Canada				
		Solid cancer (Combination therapy with paclitaxel)	U.S./Canada	-		<b>※</b> 1	
		Solid cancer (Monotherapy)	Japan				
WT4869	TBD	Myelodysplastic syndromes	Japan		<b>※</b> 2		
		Solid cancer	Japan				
WT2725	TBD	Solid cancer, Hematologic cancer	U.S.				
BBI503	TBD	Solid cancer (Monotherapy)	U.S./Canada				

%1 on Phase II of Phase I/II study

%2 on Phase I of Phase I/II study

#### **Respiratory Field**

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				
DSP-3025	TBD	Bronchial asthma/Allergic rhinitis	Japan				

Revisions since the previous announcement are in red.

# Development Pipeline ③ (as of July 31, 2013)

#### **Cardiovascular/ Diabetes Field**

Domestic Overseas

	Donn	00110	01013	
				_

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (All combination therapies including DPP4 inhibitors)	Japan				
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
DSP-8658	TBD	Type 2 diabetes	U.S.				

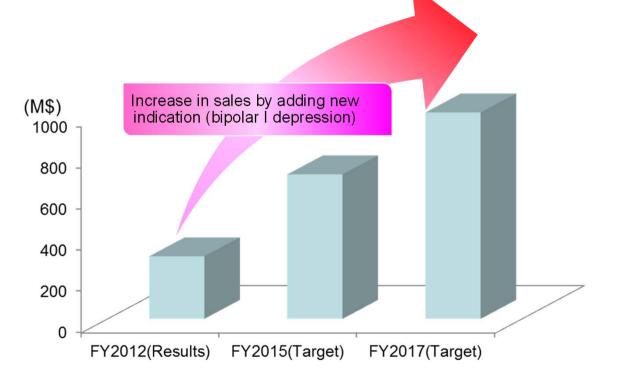
#### **Other Fields**

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
MEROPEN®	meropenem hydrate	(Change of dose) Purulent meningitis: 6g daily	Japan				
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				
DSP-5990	ceftaroline fosamil	MRSA infection	Japan				



# LATUDA<sup>®</sup>(Lurasidone)-Bipolar I depression

- LATUDA<sup>®</sup> is the first atypical antipsychotic to be approved for two indications as 1) monotherapy and 2) adjunctive therapy with lithium or valproate for the treatment of bipolar I depression by the U.S. FDA (Approved in June 2013).
  - Dose range: 20 mg/day to 120 mg/day for bipolar I depression (40 mg/day to 160 mg/day for schizophrenia)
- Promotion started in late July 2013.
  - ✓ Promotion planned to start using branded sales materials in late September 2013.
  - ✓ DTC campaign planned to start in Q1 2014.
- Sales reps are about 410.





## LATUDA<sup>®</sup>(Lurasidone) – Clinical development status

### U.S. (Schizophrenia)

#### Key Current (or Ongoing) Studies in Schizophrenia

- Schizophrenia Maintenance Study: initiated in 3Q 2011, in progress
- Pediatric (6-17 yrs) PK Study: initiated in 2Q 2012, in progress
- Low-dose Schizophrenia Study with 20mg/day: initiated in 2Q 2013, in progress
- Pediatric (6-17 yrs) Efficacy Study: initiated in 3Q 2013, in progress

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

- Bipolar I depression
  - NDA submitted for bipolar I depression in Canada in August 2012
- Bipolar maintenance
  - Phase III study initiated in 2Q 2011
- MDD with mixed features
  - Phase III study initiated in 2Q 2011
- IM depot formulation
  - Pre-clinical stage

#### **Planned Studies in Schizophrenia**

Japan:	Schizophrenia/ Phase III study in progress (Initiated in 2Q 2012)
Canada:	Bipolar I depression/ NDA submitted in August 2012
China:	Schizophrenia/ IND submitted in 3Q 2011
Europe:	Schizophrenia/ MAA submitted by Takeda - Switzerland : MAA submitted in 1Q 2012 - Europe: MAA submitted by the centralized authorization procedure in 3Q 2012
	Bipolar disorder/ Co-development with Takeda in Europe (in Phase III stage) DSP plans to commercialize Lurasidone independently in the U.K.
Australia:	Schizophrenia/ MAA submitted in 1Q 2013



### BBI608 and BBI503 - Clinical development status BBI608

# U.S., Canada

Launch Goal Phase III in progress Colorectal cancer (Monotherapy) **FY2015** (initiated in 1Q 2013) Dose-escalation study results from Phase I/II were presented at the American  $\checkmark$ Society of Clinical Oncology (ASCO) Annual Meeting in June 2013 (already disclosed by the news release on June 4, 2013) Colorectal cancer (Combination) Phase II in progress (initiated in 1Q 2012) Solid cancer (Combination with paclitaxel) Phase II of Phase I / II in progress (initiated in 2Q 2013) Japan Solid cancer (Monotherapy) Phase I in progress Launch Goal (initiated in 1Q 2013) **FY2016** 

### **BBI503**

- U.S., Canada
  - Solid cancer (Monotherapy)





# **Disclaimer Regarding Forward-looking Statements**

The statements made in this presentation material are forwardlooking 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.

