

Third Quarter Financial Results for FY2012  
(Apr. 1 to Dec. 31, 2012)

January 31, 2013

Dainippon Sumitomo Pharma Co., Ltd.

# FY2012 3Q Financial Results

Billions of yen

	FY2011 3Q	FY2012 3Q	Comparison to FY2011			FY2012	
			Change	Exchange Impact	Change (%)	Forecast (10/31)	Progress (%)
Net sales	265.2	<b>269.2</b>	4.0	- 1.3	1.5	348.0	77.4
Cost of sales	74.0	<b>76.4</b>	2.4	- 0.1	3.2	100.0	76.4
Gross profit	191.2	<b>192.9</b>	1.6	- 1.1	0.9	248.0	77.8
SG&A expenses	168.9	<b>160.2</b>	- 8.7	- 1.2	- 5.2	220.0	72.8
SG&A expenses less R&D costs	128.2	<b>120.2</b>	- 8.0	- 1.0	- 6.2	160.8	74.8
R&D costs	40.7	<b>39.9</b>	- 0.8	- 0.2	- 1.9	59.2	67.5
Operating income	22.3	<b>32.7</b>	10.4	0.1	46.5	28.0	116.8
Ordinary income	22.0	<b>32.7</b>	10.8		49.0	27.0	121.2
Extraordinary income and loss	- 2.4	<b>- 4.4</b>	- 2.0		—	- 3.0	—
Net income	10.3	<b>16.9</b>	6.6		64.2	13.5	124.9

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.

3. Exchange Rate: FY2011 3Q: 1US\$ = ¥80.58, 1RMB = ¥12.42, FY2012 3Q: 1US\$ = ¥79.40, 1RMB=¥12.56

4. The forecasts announced in October 2012 have not been revised.

# Net Sales by Segment

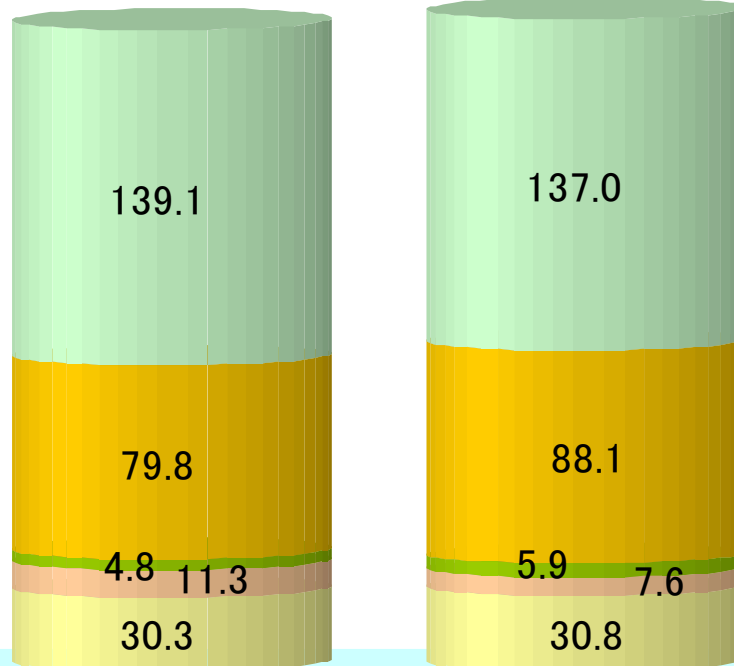
Billions of yen

Comparison to FY2011

	Change	Change(%)
	4.0	1.5%

FY2011 3Q  
265.2

FY2012 3Q  
269.2



Japan	- 2.2	- 1.6%
-------	-------	--------

North America	8.3	10.4%
---------------	-----	-------

China	1.1	23.1%
-------	-----	-------

Other Regions	- 3.7	- 32.9%
---------------	-------	---------

Other Business	0.5	1.7%
----------------	-----	------

Overseas Sales 36.3 %

37.8 %

**【Japan】** While there was growth from strategic and new products, impact from NHI price revisions resulted in a slight decrease.

**【North America】** Although there was a decrease in XOPENEX® sales, LATUDA® sales growth resulted in an increase.

**【Other Regions】** Decrease in Meropen® exports, etc.

# Sales in Japan

Billions of yen

	FY2011 3Q	FY2012 3Q	Comparison to FY2011		FY2012	
			Change	Change (%)	Forecast (10/31)	Progress
AIMIX®	—	2.6	2.6	—	2.8	91.4 %
AVAPRO®	8.6	9.0	0.5	5.3 %	12.1	74.6 %
LONASEN®	7.8	8.4	0.6	8.0 %	11.3	74.1 %
PRORENAL®	12.1	11.2	- 0.9	- 7.5 %	14.7	76.2 %
TRERIEF®	4.0	5.4	1.4	33.8 %	7.2	75.0 %
Strategic Products Total	32.5	36.6	4.1	12.6 %	48.1	76.0 %
SUREPOST®	0.1	0.5	0.4	641.3 %	1.0	47.7 %
MIRIPLA®	1.0	0.9	- 0.1	- 12.2 %	1.3	68.4 %
METGLUCO® (Including MELBIN®)	6.1	9.1	3.0	48.1 %	12.5	72.9 %
New Products Total	7.2	10.5	3.2	44.9 %	14.8	70.8 %
AmBisome®	3.5	3.6	0.1	3.0 %	4.8	74.8 %
AMLODIN®	28.2	22.8	- 5.4	- 19.0 %	28.7	79.6 %
GASMOTIN®	16.3	15.7	- 0.6	- 3.7 %	20.0	78.5 %
MEROPEN®	9.6	8.2	- 1.4	- 14.4 %	10.2	80.2 %
REPLAGAL®	7.0	7.8	0.8	11.9 %	10.2	76.4 %
Others	34.9	31.8	- 3.1	- 8.9 %	39.9	79.7 %
<b>Japan Total</b>	<b>139.1</b>	<b>137.0</b>	<b>- 2.2</b>	<b>- 1.6 %</b>	<b>176.7</b>	<b>77.5 %</b>

Note: Sales figures before reduction of rebates.

# Sales in North America & China

Billions of yen [M\$]

	FY2011 3Q		FY2012 3Q		Comparison to FY2011			FY2012		
					Change		Change (%)	Forecast (10/31)		Progress
LATUDA®	[48]	3.9	[140]	11.1	[92]	7.3	187.0 %	[201]	16.0	69.7%
LUNESTA®	[404]	32.6	[419]	33.2	[15]	0.7	2.1 %	[548]	43.6	76.2%
XOPENEX®	[302]	24.3	[263]	20.9	[- 39]	- 3.4	- 14.1 %	[296]	23.6	88.6%
BROVANA®	[92]	7.4	[117]	9.3	[25]	1.9	25.1 %	[161]	12.8	72.5%
Ciclesonide Products	[73]	5.9	[47]	3.7	[- 26]	- 2.2	- 36.6 %	[73]	5.8	64.4%
Industrial property revenues	[56]	4.5	[85]	6.8	[30]	2.3	51.4 %	[100]	7.9	85.7%
Others	[15]	1.2	[38]	3.0	[23]	1.8	154.3 %	[40]	3.2	93.8%
<b>North America Total</b>	[990]	79.8	[1,109]	88.1	[119]	8.3	10.4 %	[1,419]	112.9	78.0%
MEROPEN®		4.0		4.8		0.8	20.5 %		6.2	78.0%
Others		0.8		1.0		0.3	36.9 %		1.4	74.2%
<b>China Total</b>		4.8		5.9		1.1	23.1 %		7.6	77.3%

# FY2012 North America Segment Sales (Unaudited, U.S. Dollar Basis)

Millions of US\$

	FY2011	FY2012	Comparison to FY2011	
			Change	Change(%)
LATUDA®	86	<b>202</b>	116	134.4 %
LUNESTA®	528	<b>561</b>	34	6.4 %
XOPENEX®	419	<b>317</b>	-102	- 24.2 %
BROVANA®	127	<b>160</b>	32	25.3 %
Ciclesonide Products	99	<b>67</b>	- 32	- 32.3 %
Industrial property revenues	72	<b>98</b>	26	35.4 %
Others	27	<b>44</b>	16	60.6 %
<b>North America Total</b>	<b>1,359</b>	<b>1,449</b>	<b>90</b>	<b>6.6 %</b>

FY2012	
Forecast (10/31)	Change
201	1
548	13
296	21
161	- 1
73	- 6
100	- 2
40	4
<b>1,419</b>	<b>30</b>

While Sunovion Pharmaceuticals Inc. and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., have been consolidated for a fiscal year ending on December 31, the financial period will be changed to the year ending on March 31 from FY 2013. Their profit and loss from January to March 2013 will be posted as an increase or a decrease in retained earnings.

# Segment Breakdown for North America

< Excluding amortization of patent rights and goodwill >

Billions of yen [M\$]

	FY2011 3Q		FY2012 3Q		Change	
Net sales	[990]	79.8	[1,109]	88.1	[119]	8.3
Cost of sales	[99]	8.0	[123]	9.7	[23]	1.7
Gross profit	[890]	71.7	[986]	78.3	[96]	6.6
SG&A expenses	[632]	50.9	[555]	44.1	[ - 77]	- 6.8
Income (loss) of Segment	[258]	20.8	[431]	34.2	[173]	13.4

Breakdown	
Exchange Impact	Others
- 1.3	9.6
- 0.1	1.9
- 1.1	7.7
- 0.7	- 6.2
- 0.5	13.9

< Amortization of patent rights and goodwill >

SG&A expenses	[260]	21.0	[272]	21.6	[11]	0.6
Income (loss) of Segment	[ - 260]	- 21.0	[ - 272]	- 21.6	[ - 11]	- 0.6

- 0.3	0.9
0.3	- 0.9

# Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America <sup>*1</sup>	Amortization <sup>*2</sup>	China	Other Regions				
FY2012 3Q Results	Net sales (external)	137.0	88.1	—	5.9	7.6	238.5	30.8	269.2	
	Cost of sales	37.7	9.7	—	1.4	3.8	52.6	23.7	76.4	
	Gross profit	99.5	78.3	—	4.5	3.7	186.0	6.8	192.9	
	SG&A expenses	47.2	44.1	21.6	2.6	0.3	115.8	4.4	120.2	
	<b>Income (loss) of Segment</b>	<b>52.2</b>	<b>34.2</b>	<b>- 21.6</b>	<b>1.9</b>	<b>3.4</b>	<b>70.3</b>	<b>2.4</b>	<b>72.7</b>	
	R&D costs							39.4	0.6	39.9
	Operating income							30.9	1.8	32.7

FY2011 3Q Results	Net sales (external)	139.1	79.8	—	4.8	11.3	234.9	30.3	265.2	
	Cost of sales	35.5	8.0	—	1.5	5.7	50.7	23.3	74.0	
	Gross profit	103.8	71.7	—	3.3	5.5	184.4	6.8	191.2	
	SG&A expenses	49.3	50.9	21.0	2.4	0.2	123.9	4.3	128.2	
	<b>Income (loss) of Segment</b>	<b>54.5</b>	<b>20.8</b>	<b>- 21.0</b>	<b>0.9</b>	<b>5.3</b>	<b>60.5</b>	<b>2.5</b>	<b>63.0</b>	
	R&D costs							40.2	0.5	40.7
	Operating income							20.3	2.0	22.3

Change	Net sales (external)	- 2.2	8.3	—	1.1	- 3.7	3.5	0.5	4.0	
	<b>Income (loss) of Segment</b>	<b>- 2.2</b>	<b>13.4</b>	<b>- 0.6</b>	<b>1.0</b>	<b>- 1.9</b>	<b>9.7</b>	<b>- 0.1</b>	<b>9.6</b>	
	R&D costs							- 0.8	0.0	- 0.8
	Operating income							10.5	- 0.2	10.4

※ 1. Excluding amortization of patent rights and goodwill

※ 2. Amortization of patent rights and goodwill



# Ordinary income & Net income

Billions of yen

	FY2011 3Q	FY2012 3Q	Comparison to FY2011	
			Change	Change(%)
Operating Income	22.3	32.7	10.4	46.5 %
Non-operating income and expenses	- 0.4	0.0	0.4	
Finance income and expenses including dividend income	0.1	0.2	0.1	
Contributions	- 0.8	- 1.1	- 0.3	
Others	0.4	0.9	0.6	
Ordinary income	22.0	32.7	10.8	49.0 %
Extraordinary income and loss	- 2.4	- 4.4	- 2.0	
Gain on sales of fixed assets	1.2	—	- 1.2	
Business structure improvement expenses	- 1.2	- 3.9	- 2.7	
Impairment loss	- 2.4	- 0.4	1.9	
Income taxes	9.3	11.5	2.2	
Net income	10.3	16.9	6.6	64.2 %

【Business structure improvement expenses】 Restructuring costs in the U.S. subsidiary, transfer of assigned employees to related companies in Japan

【Impairment loss】 Impairment loss for a part of in-process R&D

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

## Central Nervous System Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA (SM-13496)	lurasidone hydrochloride	Schizophrenia	Europe, etc.*	Overseas			
		(New indication) Bipolar I Depression	U.S/Canada	Overseas			
		Schizophrenia	Japan	Domestic			
		(New indication) Bipolar Maintenance	US/Europe, etc.	Overseas			
		(New indication) MDD with mixed features	US	Overseas			
STEDESA™	eslicarbazepine acetate	Epilepsy-Adjunct	US	Overseas			
		Epilepsy-Adult monotherapy	US	Overseas			
LONASEN®	blonanserin	Schizophrenia	China	Overseas			
		(Addition of pediatric usage) Schizophrenia	Japan	Domestic			
		(New Formulation: Transdermal Tape) Schizophrenia	Japan	Domestic			
SEP-225289	TBD	Attention-deficit hyperactivity disorder (ADHD)	US	Overseas			
DSP-8658	TBD	Alzheimer's disease	US	Overseas			
DSP-1053	TBD	Depression	US	Overseas			
DSP-2230	TBD	Neuropathic Pain	UK	Overseas			
SEP-363856	TBD	Schizophrenia	US	Overseas			

\*Lurasidone (SM-13496) : Co-development with Takeda Pharmaceutical in Europe (Submitted: Schizophrenia, Phase III Study: Bipolar disorder)

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

## Cancer Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China	Overseas			
BBI608	TBD	Colorectal Cancer (2nd/3rd line) (Monotherapy)	US/Canada	Overseas		Domestic	
		Colorectal Cancer (3rd/4th line) (Combination therapy)	US/Canada	Overseas			
		Solid Cancer (2nd/3rd line) (Combination therapy with paclitaxel)	US/Canada	Overseas	※		
WT4869	TBD	Myelodysplastic syndromes	Japan	Domestic	※		
		Solid cancer	Japan	Domestic			
WT2725	TBD	Advanced cancer	US	Overseas			
BBI503	TBD	Solid cancer (monotherapy)	US/Canada	Overseas			

## Respiratory Field

※on Phase I of Phase I/II study

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	TBD	Chronic obstructive pulmonary disease (COPD)	US/UK	Overseas			
DSP-3025	TBD	Asthma/Allergic Rhinitis	Japan	Domestic			

Revisions since the previous announcement are in red.

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

## Cardiovascular/ Diabetes Field

Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (Combination therapy with thiazolidine or biguanide)	Japan				
		(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	US				

## 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				
SMP-986	afacifenacin fumarate	Overactive bladder	Japan				
			US/Europe				
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				

Revisions since the previous announcement are in red.

# Development Pipeline State of Progress (Main changes after October 31, 2012)

## ■ AIMIX® (DSP-8153)

- Launched in Japan (December 2012)

## ■ MEROPEN® (Change of dose)

- Japan: Progressed from Phase III to Submitted

## ■ BBI608

- U.S. and Canada: Progressed from Phase III under preparation to Phase III

## ■ DSP-6952

- Japan: Progressed from Phase I to Phase II

## ■ Discontinued

- PRORENAL® (New Indication) (Japan: Phase II),  
DSP-9599 (Japan: Phase I)

# Progress in Oncology

## ■ BBI608 Phase3 Study Initiated (January 2013)

- Study Design: International multi-center, double-blind, randomized Phase 3 clinical trial compared with best supportive care in patients with advanced, unresectable, refractory colorectal cancer, for whom no further standard anticancer therapy is available or appropriate.
- Estimated Enrollment: 650
- Primary Objective: Overall Survival (OS)
- Secondary Objectives: PFS; progression-free survival, DCR; disease control rate, Safety, QOL; quality of life, Others (medical economic evaluation, biomarker discovery)

## ■ Establishing a Global R&D Structure

- ✓ North America: BBI to relocate headquarters to Cambridge, MA (Relocation started on January 19, 2013)

## ■ Pipeline Expansion

- ✓ Signing of a licensing agreement for new anti-cancer candidate compounds targeting the Ras signaling pathway with Kobe University and KNC Laboratories Co., Ltd. (November 2012)

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

## US (schizophrenia)

---

### ■ Key Current LATUDA® Studies in Schizophrenia

- Schizophrenia Maintenance Study: initiated in 3Q 2011, in progress.
- Pediatric (6-17 yrs) PK Study: initiated in 2Q 2012, in progress.

### ■ Planned LATUDA® Studies in Schizophrenia

- Low-dose Schizophrenia Study with 20mg/day: to be initiated in 1Q 2013
- Pediatric (6-17 yrs) Efficacy Study: to be initiated in 3Q 2013

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

---

### ■ Bipolar I depression Phase III studies (PREVAIL Studies)

- NDA submitted for bipolar I depression in the U.S. and Canada. (Submitted in August 2012)
- PREVAIL#3: Placebo controlled, lithium or valproate adjunctive study  
Initiated in December 2010

### ■ 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

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

## Outside the U.S.

---

- Japan: Schizophrenia/ New Phase III study in progress (Initiated in April 2012)
- Canada: Schizophrenia/ Launched in Canada (September 2012)  
Bipolar I Depression/ NDA submitted in the U.S. and Canada (August 2012)
- China: Schizophrenia/ IND submitted (September 2011)
- Europe: Schizophrenia/ MAA submitted by Takeda Switzerland (March, 2012)  
Europe: (September, 2012)  
Submitted by the centralized authorization procedure  
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

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.