

Financial Results for FY2013 Apr.-Sep.  
(Apr. 1 to Sep. 30, 2013)

October 31, 2013

Masayo Tada, President and CEO  
Dainippon Sumitomo Pharma Co., Ltd.

# Financial Results

for the Six Month Period Ended September 30, 2013

# Financial Results for FY2013 Apr.-Sep.

Billions of yen

	FY2012 Apr.-Sep.	FY2013 Apr.-Sep.	Change			FY2013 Apr.-Sep.	
			Value	Exchange Rate Impact	Percentage (%)	Forecasts	Progress (%)
Net sales	178.7	<b>181.4</b>	2.6	13.8	1.5	178.0	101.9
Cost of sales	50.0	<b>50.4</b>	0.4	1.7	0.8	52.0	97.0
Gross profit	128.7	<b>131.0</b>	2.2	12.2	1.7	126.0	103.9
SG&A expenses	108.7	<b>113.5</b>	4.8	11.8	4.4	116.0	97.9
SG&A expenses less R&D costs	80.9	<b>82.0</b>	1.1	9.1	1.4	86.0	95.4
R&D Costs	27.8	<b>31.5</b>	3.7	2.7	13.3	30.0	105.0
Operating income	20.0	<b>17.4</b>	(2.5)	0.4	(12.7)	10.0	174.4
Ordinary income	19.9	<b>17.4</b>	(2.5)		(12.6)	10.0	174.1
Net income	11.0	<b>8.7</b>	(2.3)		(20.6)	5.0	174.0
E B I T D A	40.8	<b>31.8</b>	(9.0)		(22.1)	25.0	127.3

- 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. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

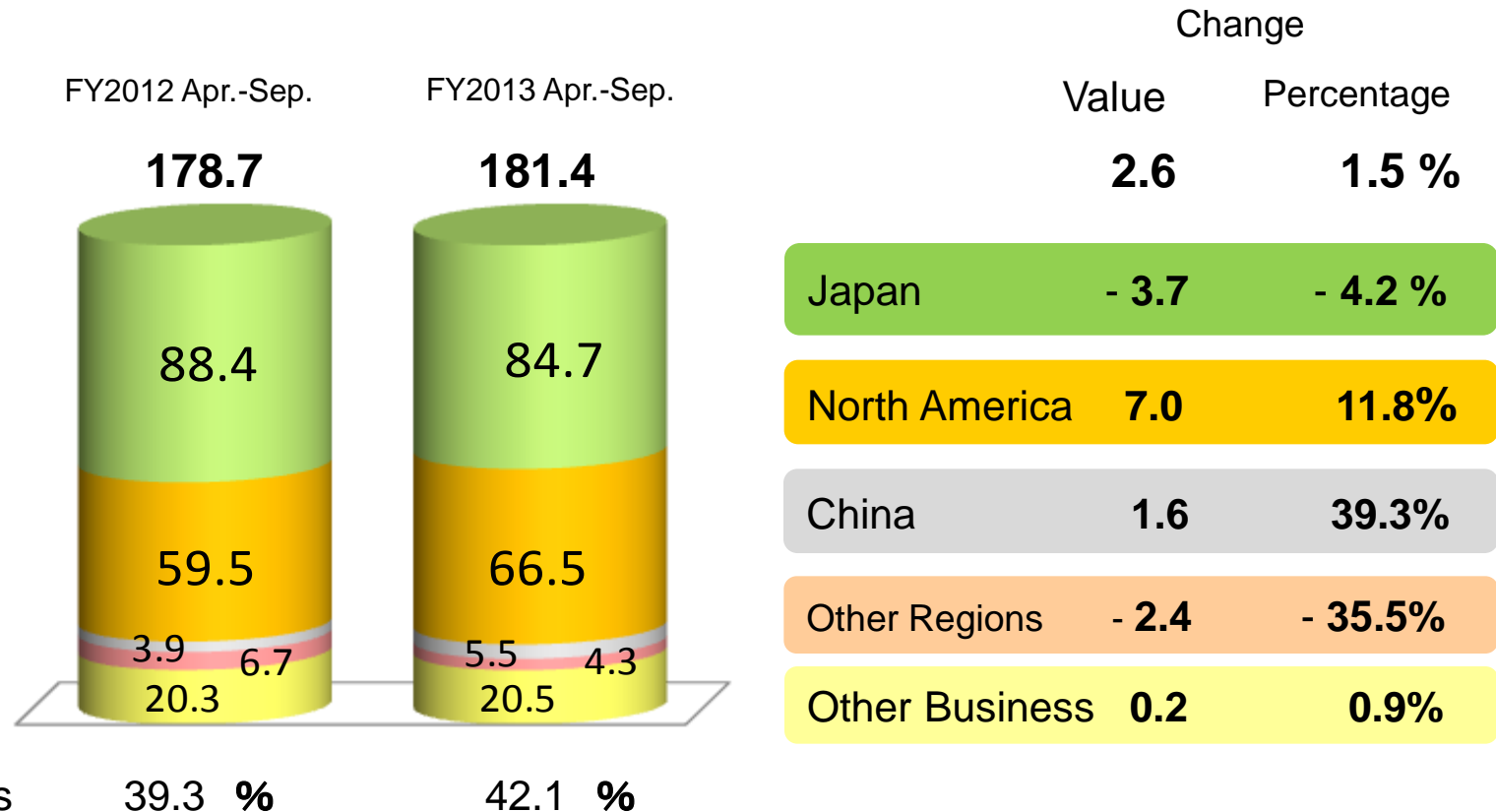
Exchange Rate:

FY2012 Apr.-Sep.: 1US\$ = ¥ 79.8, 1RMB = ¥12.7

FY2013 Apr.-Sep.: 1US\$ = ¥ 98.9, 1RMB = ¥16.1

# Net Sales by Segment

Billions of yen



【 Japan 】 Decrease in industrial property revenues and contract manufacture products

【 North America 】 Increase of sales for LATUDA<sup>®</sup>, impact of weak yen

【 China 】 Increase of sales for MEROPEN<sup>®</sup>, impact of weak yen

# Sales in Japan

Billions of yen

	FY2012 Apr.-Sep.	FY2013 Apr.-Sep.	Change		FY2013 Apr.-Sep.	
			Value	Percentage (%)	Forecasts	Progress (%)
AIMIX®	-	2.4	2.4	-	1.8	131.3
AVAPRO®	5.8	6.0	0.2	3.5	6.1	98.4
LONASEN®	5.4	6.2	0.8	14.6	6.0	103.2
TRERIEF®	3.4	4.1	0.7	20.5	4.4	93.3
Strategic products total	14.6	18.7	4.1	27.8	18.3	102.0
METGLUCO®	5.7	7.3	1.6	27.4	7.4	98.8
SUREPOST®	0.3	0.7	0.4	170.9	0.9	78.7
New products total	6.0	8.0	2.0	33.6	8.3	96.6
AmBisome®	2.2	2.4	0.1	6.7	2.5	94.9
MIRIPLA®	0.6	0.6	0.0	2.1	0.6	96.8
REPLAGAL®	5.1	5.0	(0.0)	(1.0)	5.1	98.6
Specialty products total	7.9	8.0	0.1	1.4	8.2	97.3
AMLODIN®	14.9	13.9	(1.0)	(6.6)	13.3	104.4
GASMOTIN®	10.1	7.8	(2.3)	(22.6)	8.7	89.8
PRORENAL®	7.3	7.0	(0.2)	(3.2)	6.8	103.5
MEROPEN®	5.2	5.0	(0.2)	(4.5)	5.1	97.6
Others in product line of Sales Department	17.2	15.5	(1.7)	(9.9)	16.2	95.7
Product line of Sales Department total	83.1	83.9	0.8	0.9	84.9	98.8
Others	5.3	0.8	(4.4)	(85.1)	0.8	98.4
<b>Japan total</b>	88.4	84.7	(3.7)	(4.2)	85.7	98.8

Note: Sales figures before reduction of rebates

# Sales in North America & China

	FY2012 Apr.-Sep.	FY2013 Apr.-Sep.	Change	FY2012 Apr.-Sep.	FY2013 Apr.-Sep.	Change		FY2013 Apr.-Sep.		
						Value	Exchange Rate Impact	Forecasts		Progress (%)
North America	(Million \$)			(Billion yen)				(Million \$)	(Billion yen)	
LATUDA®	80	162	82	6.4	16.0	9.6	3.1	150	15.0	107.0
LUNESTA®	278	272	(6)	22.2	26.9	4.8	5.2	236	23.6	114.1
XOPENEX®	186	68	(118)	14.9	6.7	(8.1)	1.3	40	4.0	168.3
BROVANA®	77	80	3	6.1	7.9	1.8	1.5	96	9.6	83.6
Ciclesonide	23	43	20	1.8	4.2	2.4	0.8	49	4.9	86.2
Industrial property revenues	76	21	(55)	6.0	2.1	(4.0)	0.4	13	1.3	158.9
Others	25	25	0	2.0	2.5	0.5	0.5	23	2.3	109.4
<b>Total</b>	<b>745</b>	<b>672</b>	<b>(73)</b>	<b>59.5</b>	<b>66.5</b>	<b>7.0</b>	<b>12.6</b>	<b>607</b>	<b>60.7</b>	<b>109.5</b>
China	(Million RMB)			(Billion yen)				(Million RMB)	(Billion yen)	
MEROPEN®	257	279	21	3.3	4.5	1.2	1.0	293	4.4	102.0
Others	55	63	8	0.7	1.0	0.3	0.2	73	1.1	92.3
<b>Total</b>	<b>312</b>	<b>342</b>	<b>29</b>	<b>3.9</b>	<b>5.5</b>	<b>1.6</b>	<b>1.2</b>	<b>367</b>	<b>5.5</b>	<b>100.0</b>

Note: FY2012 Apr.-Sep. figures are for sales of Jan. to Jun. 2012.

Exchange Rate:

FY2012 Apr.-Sep.: 1US\$ = ¥ 79.8, 1RMB = ¥12.7

FY2013 Apr.-Sep.: 1US\$ = ¥ 98.9, 1RMB = ¥16.1

# Segment Breakdown for North America

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

	FY2012 Apr.-Sep.	<b>FY2013 Apr.-Sep.</b>	Change	FY2012 Apr.-Sep.	<b>FY2013 Apr.-Sep.</b>	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
Net sales	745	<b>672</b>	(73)	59.5	<b>66.5</b>	7.0	12.6
Cost of sales	76	<b>77</b>	1	6.1	<b>7.6</b>	1.5	1.4
Gross profit	669	<b>595</b>	(74)	53.4	<b>58.9</b>	5.5	11.2
SG&A expenses	367	<b>353</b>	(14)	29.2	<b>34.9</b>	5.6	6.7
Income of segment	302	<b>243</b>	(60)	24.1	<b>24.0</b>	(0.1)	4.5

<Impact from amortization of patent rights and goodwill, etc.>

	FY2012 Apr.-Sep.	<b>FY2013 Apr.-Sep.</b>	Change	FY2012 Apr.-Sep.	<b>FY2013 Apr.-Sep.</b>	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
SG&A expenses	200	<b>99</b>	(101)	16.0	<b>9.8</b>	(6.1)	1.7
Income (loss) of segment	(200)	<b>(99)</b>	101	(16.0)	<b>(9.8)</b>	6.1	(1.7)

Exchange Rate:

FY2012 Apr.-Sep.: 1US\$ = ¥ 79.8, 1RMB = ¥12.7

FY2013 Apr.-Sep.: 1US\$ = ¥ 98.9, 1RMB = ¥16.1

# Segment Information

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America <sup>※1</sup>	Amortization <sup>※2</sup>	China	Other Regions	Subtotal			
FY2013 Apr.-Sep.	Net sales (Sales to customers)	84.7	66.5	—	5.5	4.3	160.9	20.5	181.4	
	Cost of sales	23.3	7.6	—	1.2	2.3	34.5	16.0	50.4	
	Gross profit	61.4	58.9	—	4.3	1.9	126.5	4.5	131.0	
	SG&A expenses less R&D costs	30.9	34.9	9.8	3.0	0.4	79.0	3.0	82.0	
	<b>Income (loss) of segment</b>	30.5	24.0	(9.8)	1.3	1.5	47.5	1.4	48.9	
	R&D costs							31.1	0.4	31.5
	Operating income							16.4	1.0	17.4
FY2012 Apr.-Sep.	Net sales (Sales to customers)	88.4	59.5	—	3.9	6.7	158.5	20.3	178.7	
	Cost of sales	23.8	6.1	—	0.9	3.6	34.4	15.7	50.0	
	Gross profit	64.7	53.4	—	3.0	3.1	124.2	4.5	128.7	
	SG&A expenses less R&D costs	31.0	29.2	16.0	1.6	0.2	78.0	2.9	80.9	
	<b>Income (loss) of segment</b>	33.7	24.1	(16.0)	1.4	2.9	46.2	1.6	47.8	
	R&D costs							27.4	0.4	27.8
	Operating income							18.8	1.2	20.0
Change	Net sales (Sales to customers)	(3.7)	7.0	—	1.6	(2.4)	2.5	0.2	2.6	
	SG&A expenses less R&D costs	(0.1)	5.6	(6.1)	1.4	0.2	1.0	0.1	1.1	
	<b>Income (loss) of segment</b>	(3.2)	(0.1)	6.1	(0.1)	(1.4)	1.3	(0.2)	1.1	
	R&D costs							3.6	0.1	3.7
	Operating income							(2.3)	(0.2)	(2.5)

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

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

(Reference) Increase of ¥6B in income of North America segment including amortization

Exchange Rate:

FY2012 Apr.-Sep.: 1US\$ = ¥ 79.8, 1RMB = ¥12.7

FY2013 Apr.-Sep.: 1US\$ = ¥ 98.9, 1RMB = ¥16.1



# Ordinary income & Net income

Billions of yen

	FY2012 Apr.-Sep.	FY2013 Apr.-Sep.	Change	
			Value	Percentage(%)
Operating income	20.0	17.4	(2.5)	(12.7)
Non-operating income and expenses	(0.1)	(0.0)	0.0	
Ordinary income	19.9	17.4	(2.5)	(12.6)
Extraordinary income	—	3.8	3.8	
Gain on sales of investment securities	—	2.8	2.8	
Fair value adjustment of contingent consideration	—	1.1	1.1	
Extraordinary loss	1.5	6.3	4.8	
Impairment loss	0.4	4.6	4.2	
Business structure improvement expenses	1.1	1.7	0.6	
Income taxes	7.5	6.3	(1.2)	
Net income	11.0	8.7	(2.3)	(20.6)

【 Gain on sales of investment securities 】 Gain on a sale of the listed stock

【 Business structure improvement expenses 】 Restructuring in the U.S. and Japan

【 Impairment loss 】 Impairment loss for production facility and in-process R&D in the U.S.

# Financial Position

Billions of yen

	as of Mar.31, 2013	as of Sep.30, 2013	Change
Assets	607.2	<b>634.6</b>	27.3
Current assets	333.4	<b>347.6</b>	14.1
Fixed assets	273.8	<b>287.0</b>	13.2
Liabilities	258.0	<b>257.1</b>	(0.8)
Current liabilities	124.8	<b>127.6</b>	2.7
Long-term liabilities	133.1	<b>129.6</b>	(3.6)
Net assets	349.2	<b>377.4</b>	28.2

(Shareholders' equity ratio)

57.5%

59.5%

## (Assets)

Increase in cash and deposits .....8.3billion yen

Increase in Property, plant and equipment .....4.6billion yen

## (Liabilities)

Decrease in interest-bearing debt .....5.0billion yen

## (Net Assets)

Increase in foreign currency translation adjustment .....25.4billion yen

# Cash Flows

Billions of yen

<b>I</b>	<b>Net cash provided by operating activities</b>	<b>+ 22.3</b>
	▪ Income before income taxes and minority interests	+ 15.0
	▪ Depreciation and amortization	+ 14.1
	▪ Increase in notes and accounts receivable	- 5.5
<b>II</b>	<b>Net cash used in investing activities</b>	<b>- 5.4</b>
	▪ Purchase of property, plant and equipment, and intangible assets	- 9.7
	▪ Proceeds from sales of investment securities	+ 2.8
<b>III</b>	<b>Net cash used in financing activities</b>	<b>- 8.6</b>
	▪ Net decrease in long-term loans payable	- 5.0
	▪ Cash dividends paid	- 3.6

**Cash and cash equivalents at the end of period :**  
**(compared with the beginning of period**

**82.4 billion yen**  
**+11.0 billion yen )**

# Financial Forecasts for FY2013

# Revised Financial Forecasts for FY2013

Billions of yen

	FY2012 (a)	FY2013 Previous Forecasts (b)	FY2013 Revised Forecasts (c)	Change (c)-(a)		Change (c)-(b)	
				Value	Exchange Rate Impact	Value	Percentage (%)
Net sales	347.7	369.0	381.0	33.3	31.1	12.0	3.3
Cost of sales	101.7	106.0	104.0	2.3	4.2	(2.0)	(1.9)
Gross profit	246.0	263.0	277.0	31.0	26.9	14.0	5.3
SG&A expenses	221.0	237.0	242.0	21.0	26.2	5.0	2.1
SG&A expenses less R&D costs	161.2	170.0	169.0	7.8	19.4	(1.0)	(0.6)
R&D costs	59.8	67.0	73.0	13.2	6.8	6.0	9.0
Operating income	25.0	26.0	35.0	10.0	0.7	9.0	34.6
Ordinary income	24.5	25.0	34.0	9.5		9.0	36.0
Extraordinary income and loss	(6.3)	—	(3.0)	3.3		(3.0)	—
Net income	10.0	13.0	17.0	7.0		4.0	30.8
EBITDA	60.3	54.0	61.0	0.7		7.0	13.0

Notes:

- All values are rounded to the nearest 100 million yen.
- EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

Exchange Rate:

FY2012 : 1US\$ = ¥79.8, 1RMB = ¥12.7  
 FY2013 Original Forecast : 1US\$ = ¥100.0, 1RMB = ¥15.0  
 FY2013 Revised Forecast : 1US\$ = ¥99.4, 1RMB = ¥15.6

# Sales by Product in Japan Segment

Billions of yen

	FY2012	FY2013 Previous Forecasts	FY2013 Revised Forecasts	Change
AIMIX®	2.0	5.5	6.1	0.6
AVAPRO®	11.7	12.1	12.1	—
LONASEN®	10.7	13.0	13.0	—
TRERIEF®	7.0	9.2	9.2	—
Strategic products total	31.5	39.8	40.4	0.6
METGLUCO®	12.0	15.2	15.2	—
SUREPOST®	0.7	2.5	1.9	(0.6)
New products total	12.7	17.7	17.1	(0.6)
AmBisome®	4.6	5.0	5.0	—
MIRIPLA®	1.1	1.3	1.3	—
REPLAGAL®	9.9	10.5	10.5	—
Specialty products total	15.6	16.8	16.8	—
AMLODIN®	29.2	25.4	26.9	1.5
GASMOTIN®	19.5	16.3	15.1	(1.2)
PRORENAL®	14.2	13.3	13.3	—
MEROPEN®	10.3	9.6	9.6	—
Others in product line of Sales Department	35.0	33.6	33.6	—
Product line of Sales Department total	168.0	172.5	172.8	0.3
Others	6.5	1.2	1.2	—
<b>Japan total</b>	<b>174.5</b>	<b>173.7</b>	<b>174.0</b>	<b>0.3</b>

Note: Sales figures before reduction of rebates

## Sales by Product in North America and China Segments

	FY2012	FY2013 Previous Forecasts	<b>FY2013 Revised Forecasts</b>	Change	FY2012	FY2013 Previous Forecasts	<b>FY2013 Revised Forecasts</b>	Change
<b>North America</b>	(Million \$)				(Billion yen)			
LATUDA®	202	350	<b>364</b>	14	16.1	35.0	<b>36.2</b>	1.2
LUNESTA®	561	465	<b>555</b>	90	44.8	46.5	<b>55.2</b>	8.7
XOPENEX®	317	74	<b>117</b>	43	25.3	7.4	<b>11.7</b>	4.3
BROVANA®	160	198	<b>177</b>	(21)	12.7	19.8	<b>17.6</b>	(2.2)
Ciclesonide	67	100	<b>88</b>	(12)	5.4	10.0	<b>8.8</b>	(1.2)
Industrial property revenues	98	27	<b>37</b>	10	7.8	2.7	<b>3.7</b>	1.0
Others	46	44	<b>41</b>	(3)	3.6	4.4	<b>4.0</b>	(0.4)
<b>Total</b>	<b>1,451</b>	<b>1,258</b>	<b>1,379</b>	<b>121</b>	<b>115.8</b>	<b>125.8</b>	<b>137.1</b>	<b>11.3</b>
<b>China</b>	(Million RMB)				(Billion yen)			
MEROPEN®	494	561	<b>566</b>	5	6.3	8.4	<b>8.8</b>	0.4
Others	110	140	<b>141</b>	1	1.4	2.1	<b>2.2</b>	0.1
<b>Total</b>	<b>604</b>	<b>701</b>	<b>706</b>	<b>5</b>	<b>7.6</b>	<b>10.5</b>	<b>11.0</b>	<b>0.5</b>

Exchange Rate:

FY2013 Original Forecast : 1US\$ = ¥100.0, 1RMB = ¥15.0

FY2013 Revised Forecast : 1US\$ = ¥ 99.4, 1RMB = ¥15.6 14

# Maximize LATUDA<sup>®</sup> (lurasidone) business

**North America Business**  
Schizophrenia  
Bipolar I Depression



- MR activities (using sales materials)
- Speakers program

**Boosting TRx volume**



**DTC campaign**  
(TVCM to begin in January 2014)

The screenshot shows the website layout with a navigation menu on the left containing 'ABOUT BIPOLAR DEPRESSION', 'ABOUT LATUDA', and 'SAVINGS & SUPPORT'. The main content area features the headline 'LATUDA Is Now Approved for Bipolar Depression' and a 'Learn More' button. A right-hand sidebar lists topics like 'ABOUT LATUDA', 'Why doctors prescribe LATUDA', and 'Side effects'. Below this is a large image of a man and a woman with the text 'Managing schizophrenia takes a team'. At the bottom, there are three yellow boxes with icons and text: 'LATUDA can help improve schizophrenia symptoms', 'What are the possible side effects?', and 'Caring for someone with schizophrenia'.

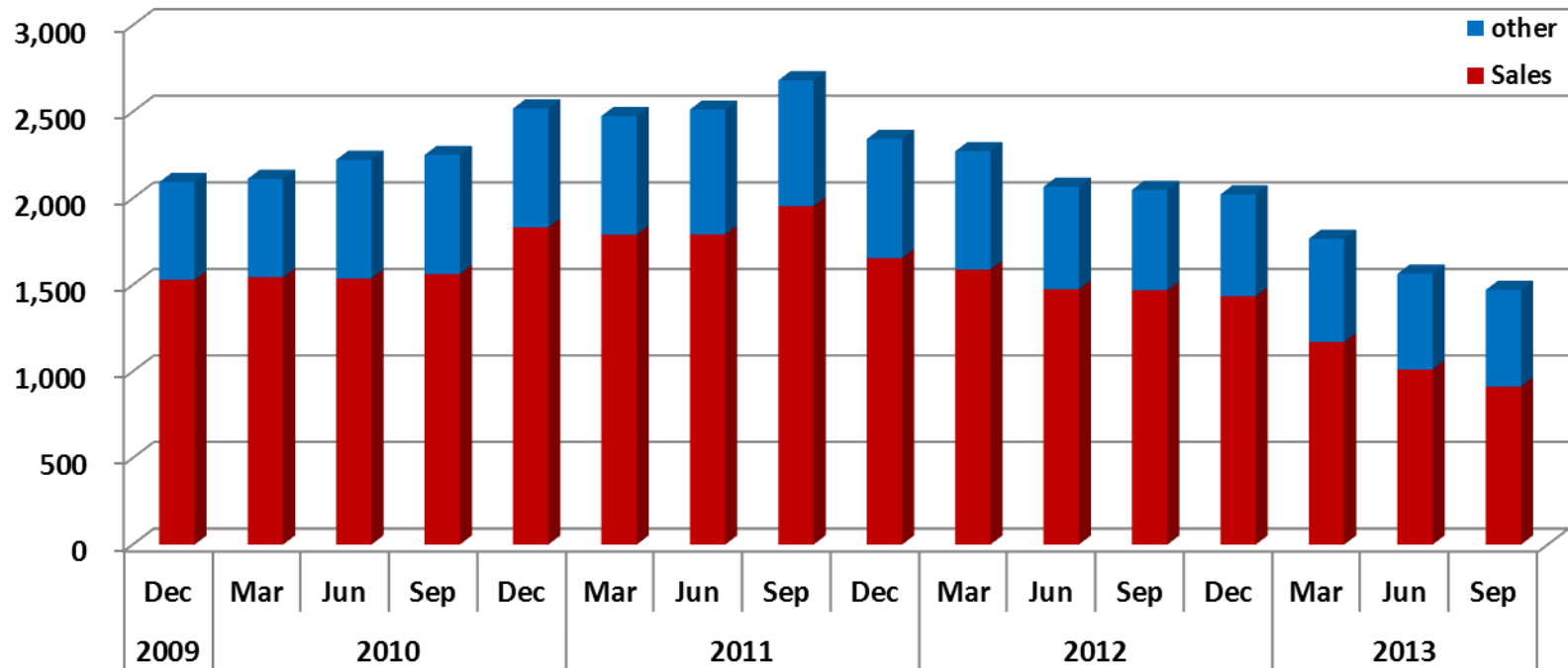


**Website (www.latuda.com)**



# SUNOVION: Strengthening and maintaining our business

## 【 Staff number of the every quarterly end 】



## 【Main actions】

- 1 Efficiency of Management and Organization (Project Benchmark)
- 2 Non-Personal Promotion
- 3 Consolidation of the sales teams
- 4 Closedown of a plant in Canada

# Revised Financial Forecasts for FY2013 (By Segment)

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America※1	Amortization※2	China	Other Regions				
FY2013 Revised Forecasts	Net sales (Sales to customers)	174.0	137.1	—	11.0	16.5	338.6	42.4	381.0	
	Cost of sales	49.7	14.7	—	2.5	4.2	71.1	32.9	104.0	
	Gross profit	124.5	122.4	—	8.5	12.3	267.7	9.3	277.0	
	SG&A expenses less R&D costs	62.9	74.4	18.0	6.0	1.1	162.4	6.6	169.0	
	<b>Income (loss) of segment</b>	61.6	48.0	(18.0)	2.5	11.2	105.3	2.7	108.0	
	R&D costs							72.0	1.0	73.0
	Operating income							33.3	1.7	35.0
FY2013 previous Forecasts	Net sales (Sales to customers)	173.7	125.8	—	10.5	15.6	325.6	43.4	369.0	
	Cost of sales	51.1	15.0	—	2.1	3.8	72.0	34.0	106.0	
	Gross profit	122.8	110.8	—	8.4	11.8	253.8	9.2	263.0	
	SG&A expenses less R&D costs	63.1	74.7	18.8	5.8	1.1	163.5	6.5	170.0	
	<b>Income (loss) of segment</b>	59.7	36.1	(18.8)	2.6	10.7	90.3	2.7	93.0	
	R&D costs							66.0	1.0	67.0
	Operating income							24.3	1.7	26.0
Change	Net sales (Sales to customers)	0.3	11.3	—	0.5	0.9	13.0	(1.0)	12.0	
	SG&A expenses less R&D costs	(0.2)	(0.3)	(0.8)	0.2	—	(1.1)	0.1	(1.0)	
	<b>Income (loss) of segment</b>	1.9	11.9	0.8	(0.1)	0.5	15.0	—	15.0	
	R&D costs							6.0	—	6.0
	Operating income							9.0	—	9.0

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

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

Exchange Rate:

FY2013 Original Forecast : 1US\$ = ¥100.0, 1RMB = ¥15.0 17

FY2013 Revised Forecast : 1US\$ = ¥ 99.4, 1RMB = ¥15.6

# Comparison of 1H Results with 2H Forecasts (By Segment)

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America <sup>※1</sup>	Amortization <sup>※2</sup>	China	Other Regions	Subtotal			
FY2013 1H Results	Net sales (Sales to customers)	84.7	66.5	—	5.5	4.3	160.9	20.5	181.4	
	Cost of sales	23.3	7.6	—	1.2	2.3	34.5	16.0	50.4	
	Gross profit	61.4	58.9	—	4.3	1.9	126.5	4.5	131.0	
	SG&A expenses less R&D costs	30.9	34.9	9.8	3.0	0.4	79.0	3.0	82.0	
	<b>Income (loss) of segment</b>	<b>30.5</b>	<b>24.0</b>	<b>(9.8)</b>	<b>1.3</b>	<b>1.5</b>	<b>47.5</b>	<b>1.4</b>	<b>48.9</b>	
	R&D costs							31.1	0.4	31.5
	Operating income							16.4	1.0	17.4
FY2013 2H Forecast s	Net sales (Sales to customers)	89.3	70.6	—	5.5	12.2	177.7	21.9	199.6	
	Cost of sales	26.4	7.1	—	1.3	1.9	36.6	16.6	53.6	
	Gross profit	63.1	63.5	—	4.2	10.4	141.2	4.8	146.0	
	SG&A expenses less R&D costs	32.0	39.5	8.2	3.0	0.7	83.4	3.6	87.0	
	<b>Income (loss) of segment</b>	<b>31.1</b>	<b>24.0</b>	<b>(8.2)</b>	<b>1.2</b>	<b>9.7</b>	<b>57.8</b>	<b>1.3</b>	<b>59.1</b>	
	R&D costs							40.9	0.6	41.5
	Operating income							16.9	0.7	17.6
Change	Net sales (Sales to customers)	4.7	4.2	—	(0.0)	7.9	16.8	1.5	18.2	
	SG&A expenses less R&D costs	1.1	4.7	(1.7)	—	0.2	4.4	0.5	4.9	
	<b>Income (loss) of segment</b>	<b>0.6</b>	<b>(0.0)</b>	<b>1.7</b>	<b>(0.2)</b>	<b>8.2</b>	<b>10.3</b>	<b>(0.1)</b>	<b>10.1</b>	
	R&D costs							9.9	0.1	10.0
	Operating income							0.4	(0.3)	0.1

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

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

Exchange Rate:

FY2013 first fiscal half : 1US\$ = ¥98.9, 1RMB = ¥16.1

FY2013 second fiscal half forecast : 1US\$ = ¥100.0, 1RMB = ¥15.0

# Clinical Development Status

# Development Pipeline (1) (as of October 30, 2013)

## Psychiatry & Neurology Field

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Europe ※1				
		Schizophrenia	Australia, Taiwan				
		(New indication) Bipolar I depression	Canada				
		Schizophrenia	Japan/China				
		Bipolar I depression, Bipolar maintenance	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. /Canada				
		Epilepsy- Monotherapy	U.S.				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	TBD	Leigh syndrome	Japan				※2
SEP-225289	TBD	Attention-deficit hyperactivity disorder (ADHD)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism of Dementia with Lewy Bodies (DLB)	Japan				
DSP-1053	TBD	Major depressive disorder	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. /U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				

Revisions since the previous announcement are in red. ※1 Lurasidone (SM-13496) : Co-development with Takeda Pharmaceutical in Europe  
 ※2 Phase II/III study

# Development Pipeline (2) (as of October 30, 2013)

## Cancer Field

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				
BBI608	TBD	Colorectal cancer (Monotherapy) (Global clinical study)	U.S./Canada/ Japan, etc.				
		Colorectal cancer (Combination therapy)	U.S./Canada				
		Solid cancer (Combination therapy with paclitaxel)	U.S./Canada			※1	
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid cancer	Japan				
WT2725	TBD	Solid cancer, Hematologic cancer	U.S. /Japan ※3				
BBI503	TBD	Solid cancer (Monotherapy)	U.S./Canada				

※1 Phase II of Phase I/II study

※2 Phase I of Phase I/II study

※3 Proposed indication for Japan is only solid cancer

## 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 October 30, 2013)

## Cardiovascular/ Diabetes Field

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (All combination therapies including DPP4 inhibitors)	Japan				

## 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				

Revisions since the previous announcement are in red.

# Development Pipeline State of Progress (Main changes after July 31, 2013)

- **lurasidone hydrochloride (SM-13496)**
  - ✓ Submitted for schizophrenia in Taiwan (October 2013)
  - ✓ Phase III study initiated for schizophrenia in China
  - ✓ Phase III study initiated for bipolar I depression and Bipolar maintenance in Japan
- **eslicarbazepine acetate (SEP-0002093)**
  - ✓ NDA submitted for epilepsy (adjunctive therapy) in Canada (June 2013)
  - ✓ Phase III studies for monotherapy in the U.S. met their primary endpoint. (already disclosed by the news release on September 2013)
- **METGLUCO® (metformin hydrochloride)**
  - ✓ Application submitted for additional indication (pediatric use) in Japan (October 2013)
- **LONASEN® (blonanserin)**
  - ✓ NDA submitted in China (September 2013)
- **BBI608**
  - ✓ Japan sites added to Phase III global clinical study for colorectal cancer (Monotherapy)
- **EPI-743**
  - ✓ Phase II / III study for leigh syndrome initiated in Japan. In-licensed from Edison.
- **TRERIEF® (zonisamide)**
  - ✓ Phase II study initiated in Japan for Parkinsonism of Dementia with Lewy Bodies (DLB)
- **DSP-2230**
  - ✓ Phase I study initiated in the U.S.
- **WT2725**
  - ✓ Phase I study initiated in Japan
- **Discontinued**
  - ✓ DSP-8658 ( U.S.: Phase I )



# Submission target of the Main late Development Pipeline

Field	Development products	Submission target			
		FY2013	FY2014	FY2015	FY2016
Psychiatry & Neurology Field	Eslicarbazepine acetate (Epilepsy/Monotherapy) U.S.	●			
	SM-13496 <lurasidone hydrochloride> (Schizophrenia) Japan/ China			●	
	LATUDA® <lurasidone hydrochloride> (Bipolar maintenance) U.S.			●	
	EPI-743 (Leigh syndrome) Japan			●	
	AS-3201 <ranirestat> (Diabetic neuropathy) Japan				●
Diabetes Field	SUREPOST® <repaglinide> (Type 2 diabetes/Combination therapies with DPP4 inhibitors.) Japan	●			
Cancer Field	BBi608 (Colorectal cancer/Monotherapy) U.S.		●		
	BBi608 (Colorectal cancer/Monotherapy) Japan			●	
Respiratory Field	SUN-101 <glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.				●



New Chemical Entities

[ New Indication etc. ]

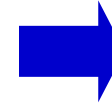
# BBI608 and BBI503 - Clinical development status

## BBI608

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### ■ U.S., Canada, Japan, etc.

- Colorectal cancer (Monotherapy)
  - ✓ Phase III in progress (initiated in 1Q 2013)
  - ✓ Japan sites added in Phase III global clinical study (initiated in 3Q 2013)



**Launch Goal**  
**North America :FY2015**  
**Japan :FY2016**

### ■ U.S., Canada

- 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)

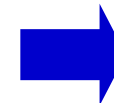
## BBI503

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### ■ U.S., Canada

- Solid cancer (Monotherapy)

Phase I in progress  
(initiated in 1Q 2012)



**Launch Goal**  
**FY2017**

## Schedule of FY2013

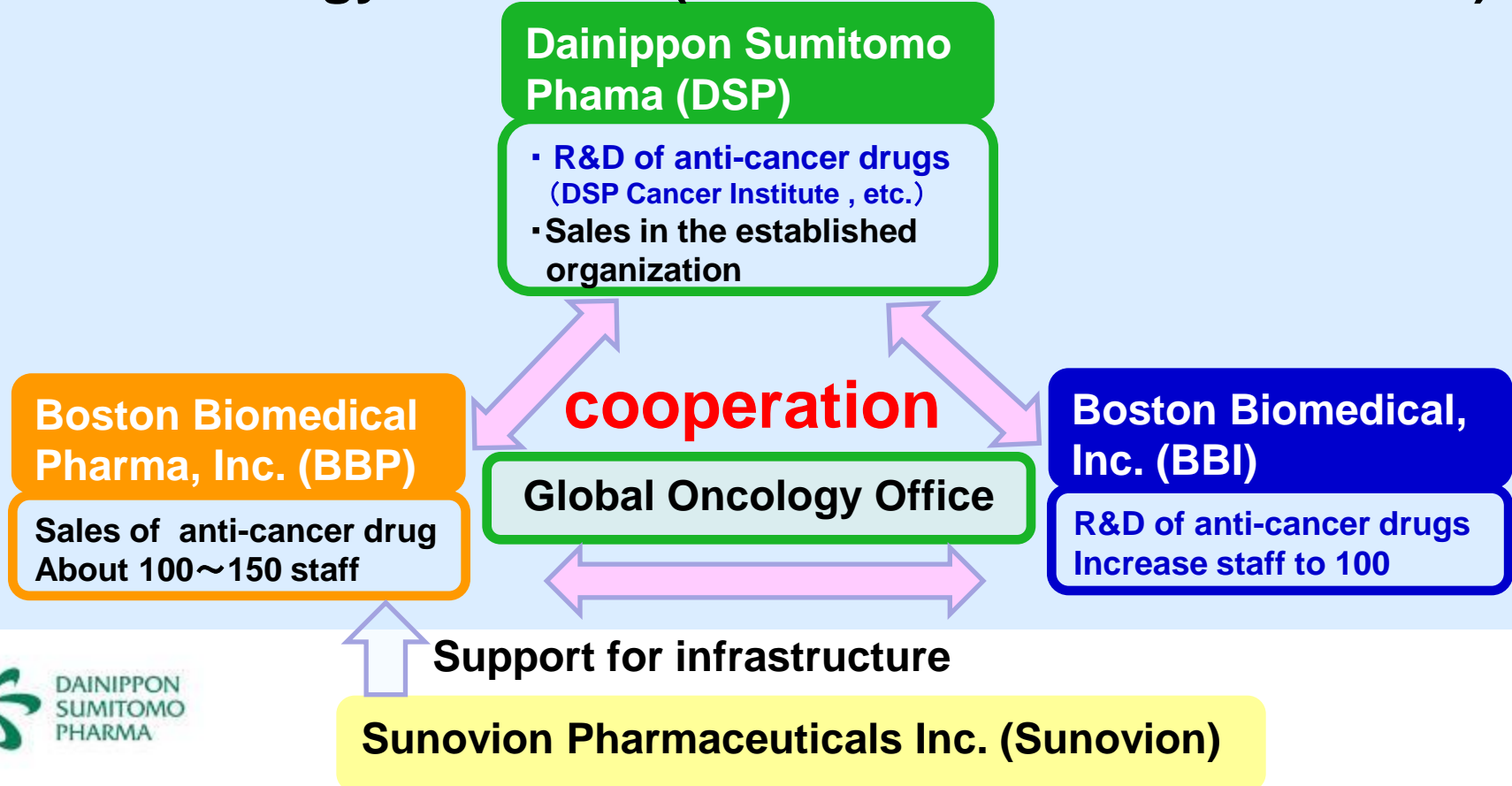
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- ✓ **BBI608** : Scientific data for the CSC suppression mechanism will be presented in top journals during FY2013.
- ✓ **BBI503** : Phase I will be initiated in Japan during FY2013.

# Establishment of an anti-cancer drugs sales company in the U.S.

- DSP established the new company specialized in the sales of anti-cancer drugs in October 2013
- Boston Biomedical Pharma, Inc. (BBP)
  - ✓ President: Mr. Hiroshi Nomura, CCO: Ms. Patricia S. Andrews
  - ✓ Paid-in capital: US\$8,100,000
  - ✓ Prepare sales organization structure towards a target launch date in FY 2015

## Global Oncology Business (At the time of BBI608 Launch)



# (Reference) Career of Ms. Patricia S. Andrews

- 1991 – 2008: Broad range of strategic planning and commercial positions at Pfizer
  - 2007 - 2008: Vice President and General Manager, US Oncology Business Unit. Led successful launch and maximization of sunitinib (renal cell carcinoma and gastrointestinal stroma tumors).
  
- 2008 - 2012: Executive Vice President and Chief Commercial Officer of Incyte
  - Led establishment of commercial organization and capability of Incyte from scratch
  - Led successful launch and rapid start of sales of ruxolitinib (myelofibrosis)

# LATUDA® (Lurasidone) – Clinical development status

## U.S. (Schizophrenia)

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

- **Schizophrenia Maintenance Study: Completed and data analysis 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 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

## Outside the U.S.

- Japan: Schizophrenia/ Phase III study in progress (Initiated in 2Q 2012)  
Bipolar I depression , Bipolar maintenance/ Phase III study in progress (Initiated in 3Q 2013)
- Canada: Bipolar I depression/ NDA submitted in August 2012
- China: Schizophrenia/ Phase III study in progress (Initiated in 3Q 2013)
- Europe: Schizophrenia/ MAA submitted by Takeda
  - Switzerland : Approved in 3Q 2013
  - Europe: MAA submitted by the centralized authorization procedure in 3Q 2012Bipolar disorder/ Plan to submit by Takeda in Europe (in Phase III stage)  
DSP plans to commercialize lurasidone independently in the U.K.
- Australia: Schizophrenia/ MAA submitted in 1Q 2013
- Taiwan: Schizophrenia/ Submitted by Standard Chem. & Pharm in 3Q 2013

# 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.