

Financial Results for FY2012 (The year ended March 31, 2013)

May 10, 2013 Masayo Tada, President and CEO Dainippon Sumitomo Pharma Co., Ltd.

Financial Results for FY2012



FY2012 Financial Results

Billions of yen

			Comparison	to FY2011	FY	2012
	FY2011 Results	FY2012 Results	Change	Change(%)	Forecast (10/31)	Progress (%)
Net sales	350.4	347.7	- 2.7	- 0.8%	348.0	99.9%
Cost of sales	98.9	101.7	2.8	2.9%	100.0	101.7%
Gross profit	251.5	246.0	- 5.5	- 2.2%	248.0	99.2%
SG&A expenses	231.1	221.0	- 10.1	- 4.4%	220.0	100.5%
SG&A expenses less R&D costs	174.2	161.2	- 13.1	- 7.5%	160.8	100.2%
R&D costs	56.9	59.8	3.0	5.2%	59.2	101.1%
Operating income	20.4	25.0	4.6	22.8%	28.0	89.4%
Ordinary income	18.9	24.5	5.6	29.8%	27.0	90.8%
Extraordinary income and loss	- 2.5	- 6.3	- 3.8	—	- 3.0	_
Net income	8.6	10.0	1.4	16.4%	13.5	74.4%

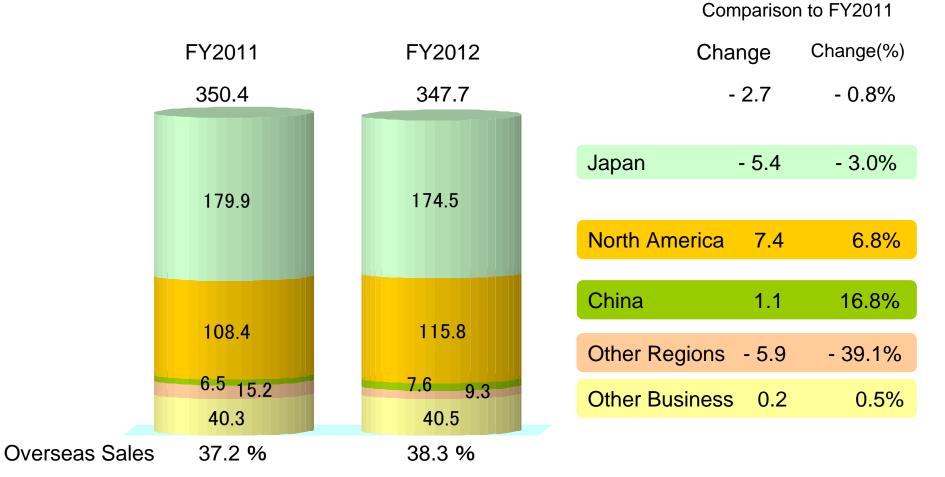
Notes: 1. All values are rounded to the nearest 100 million yen.

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

3. Exchange Rate: FY2011: 1US\$ = ¥79.8, 1RMB = ¥12.4 FY2012: 1US\$ = ¥79.8, 1RMB =¥12.7

Net Sales by Segment

Billions of yen



[Japan] While there was growth from METGLUCO[®] and AIMIX[®], impact from NHI price revisions resulted in a slight decrease.

[North America] Although there was a decrease in XOPENEX[®] sales, LATUDA[®] sales growth and license revenue resulted in an increase.

[Other Regions] Overall decrease due to decrease in MEROPEN[®] exports, etc.

Sales by Product in Japan Segment

Billions of yen

Progress

96.3 %

95.1 %

96.9 %

97.6 %

96.4 %

67.7 %

86.0 %

96.0 %

93.2 %

95.4 %

101.8 %

97.4 %

100.8 %

97.4 %

97.1 %

98.7 %

			-			
	FY2011	FY2012	Compariso	on to FY2011	FY2	2012
	Results	Results	Change	Change (%)	Forecast (10/31)	Pro
AIMIX®	—	2.0	2.0	—	-	
AVAPRO [®]	10.7	11.7	1.0	8.9 %	12.1	••
LONASEN®	9.8	10.7	0.9	9.2 %	11.3	••
PRORENAL®	15.5	14.2	- 1.3	- 8.1 %	14.7	
TRERIEF®	5.3	7.0	1.7	31.8 %	7.2	
Strategic Products Total	41.4	45.7	4.3	10.4 %	45.3	
SUREPOST®	0.1	0.7	0.6	781.9 %	1.0	
MIRIPLA®	1.3	1.1	- 0.2	- 12.1 %	1.3	
METGLUCO [®] (Including MELBIN [®])	8.5	12.0	3.5	40.7 %	12.5	
New Products Total	9.9	13.8	3.9	39.6 %	14.8	
AmBisome®	4.5	4.6	0.1	2.3 %	4.8	
AMLODIN®	36.0	29.2	- 6.8	- 18.9 %	28.7	1
GASMOTIN®	21.2	19.5	- 1.7	- 8.0 %	20.0	
MEROPEN®	12.2	10.3	- 1.9	- 15.6 %	10.2	1
REPLAGAL®	9.1	9.9	0.8	8.7 %	10.2	
Others	45.6	41.5	- 4.2	- 9.1 %	42.7	
Total	179.9	174.5	- 5.4	- 3.0 %	176.7	

Notes: 1. Sales figures before reduction of rebates.

2. Progress of Strategic Products Total excludes AIMIX[®].

Sales by Product in North America and China Segments

	FY2011 Results	FY2012 Results	Change	FY2011 Results	FY2012 Results	Change		
North America		(Million \$)			(Billion yen)			
LATUDA®	86	202	116	6.9	16.1	9.2		
LUNESTA®	528	561	34	42.1	44.8	2.7		
XOPENEX®	419	317	- 102	33.4	25.3	- 8.1		
BROVANA®	127	160	32	10.2	12.7	2.6		
ALVESCO®	35	38	3	2.8	3.1	0.3		
OMNARIS [®]	64	24	- 41	5.1	1.9	- 3.2		
ZETONNA®	—	5	5	-	0.4	0.4		
Industrial property revenues	72	98	26	5.8	7.8	2.0		
Others	27	46	19	2.1	3.7	1.5		
Total	1,359	1,451	92	108.4	115.8	7.4		
China		(Million RMB)		(Billion yen)				
MEROPEN®	447	494	47	5.5	0.7			
Others	83	110	27	1.0	1.4	0.4		
Total	529	603	74	6.5	7.6	1.1		

Exchange Rate:

FY2011: 1US\$ = ¥79.8, 1RMB = ¥12.4 FY2012: 1US\$ = ¥79.8, 1RMB = ¥12.7

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Breakdown for North America Segment

< Excluding amortization of patent rights and goodwill >

	FY2011 Results	FY2012 Results	Change	FY2011 Results	FY2012 Results	Change
		(Million \$)			(Billion yen)	
Net sales	1,359	1,451	92	108.4	115.8	7.4
Cost of sales	141	173	33	11.2	13.8	2.6
Gross profit	1,218	1,278	60	97.2	102.0	4.8
SG&A expenses	875	766	- 109	69.8	61.1	- 8.7
Income (loss) of Segment	343	513	169	27.4	40.9	13.5

< Amortization of patent rights and goodwill >

	FY2011 Results	FY2012 Results	Change	FY2011 Results	FY2012 Results	Change	
		(Million \$)		(Billion yen)			
SG&A expenses	347	324	- 23	27.7	25.9	- 1.9	
Income (loss) of Segment	- 347	- 324	23	- 27.7	- 25.9	1.9	

Exchange Rate:

FY2011: 1US\$ = ¥79.8 FY2012: 1US\$ = ¥79.8

Financial Results by Segment

Billions of yen

				Pharmaceutical	s Business			Other	
		Japan	North America ^{%1}	Amortization ^{%2}	China	Other Regions	Subtotal	Business	Total
	Net sales (Sales to customers)	174.5	115.8	—	7.6	9.3	307.2	40.5	347.7
ד [Cost of sales	50.3	13.8	—	1.8	4.5	70.5	31.2	101.7
FY201.	Gross profit	124.4	102.0	—	5.8	4.7	237.0	9.0	246.0
12	SG&A expenses less R&D costs	63.8	61.1	25.9	4.0	0.4	155.1	6.0	161.2
Re	Income (loss) of Segment	60.6	40.9	- 25.9	1.8	4.3	81.9	3.0	84.9
Results	R&D costs						59.1	0.8	59.8
	Operating income						22.8	2.3	25.0
	Net sales (Sales to customers)	179.9	108.4	—	6.5	15.2	310.1	40.3	350.4
ן די	Cost of sales	46.8	11.2	—	1.9	7.9	67.8	31.0	98.9
FY201	Gross profit	133.3	97.2	—	4.6	7.3	242.4	9.1	251.5
	SG&A expenses less R&D costs	66.8	69.8	27.7	3.6	0.3	168.3	5.9	174.2
Reg	Income (loss) of Segment	66.4	27.4	- 27.7	1.0	7.0	74.1	3.2	77.3
Results	R&D costs						56.2	0.7	56.9
Ű	Operating income						17.9	2.5	20.4
	Net sales (Sales to customers)	- 5.4	7.4	_	1.1	- 5.9	- 2.8	0.2	- 2.7
Cha	Income (loss) of Segment	- 5.8	13.5	1.9	0.9	- 2.7	7.8	- 0.2	7.6
Change	R&D costs						2.9	0.0	3.0
Ľ	Operating income						4.9	- 0.2	4.6

X 1. Excluding amortization of patent rights and goodwill

X 2. Amortization of patent rights and goodwill

Exchange Rate:

FY2011: 1US\$ = ¥79.8, 1RMB = ¥12.4 FY2012: 1US\$ = ¥79.8, 1RMB = ¥12.7

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Ordinary Income & Net Income

Billions of yen

	FY2011	FY2012	Comparise	on to FY2011
	Results	Results	Change	Change(%)
Operating Income	20.4	25.0	4.6	22.8 %
Non-operating income and expenses	- 1.5	- 0.5	1.0	
Ordinary income	18.9	24.5	5.6	29.8 %
Extraordinary income and loss	- 2.5	- 6.3	- 3.8	
Gain on sales of property, plant and equipment Business structure improvement expenses	1.2 - 1.2	 - 4.8	- 1.2 - 3.6	
Loss on litigation	—	- 1.1	- 1.1	
Impairment loss Loss on valuation of investment securities	- 2.3 - 0.2	- 0.4 —	1.9 0.2	
Income taxes	7.7	8.1	0.4	
Net income	8.6	10.0	1.4	16.4 %

(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

Financial Position

Billions of yen

		as of Mar.31, 2012	as of Mar.31,2013	Change
Asse	ets	559.4	607.2	47.8
	Current assets	334.3	333.4	- 0.8
	Fixed assets	225.2	273.8	48.6
Liab	ilities	240.2	258.0	17.8
	Current liabilities	106.0	124.8	18.9
	Long-term liabilities	134.2	133.1	- 1.1
Net assets		319.2	349.2	30.0
(Shareholders' equity ratio)		57.1%	57.5%	

+ 45.0 billion yen	
- 13.0 billion yen	
+ 21.5 billion yen	
+ 21.0 billion yen	
	- 13.0 billion yen + 21.5 billion yen

Cash Flows

FY2012	Billions of yen
I Net cash provided by operating activities	+ 49.9
 Income before income taxes and minority interests 	+ 18.2
 Depreciation and amortization 	+ 35.1
 Income taxes paid 	- 10.1
I Net cash used in investing activities	- 55.0
 Purchase of property, plant and equipment, and intangible assets 	- 10.0
 Payments for acquiring shares of newly consolidated subsidiaries 	- 24.9
III Net cash used in financing activities	- 20.2
 Net increase (decrease) in long-term loans payable 	- 13.0
 Cash dividends paid 	- 7.2

Cash and cash equivalents at the end of period : 71.4 billion yen (compared with the beginning of period - 20.7 billion yen)



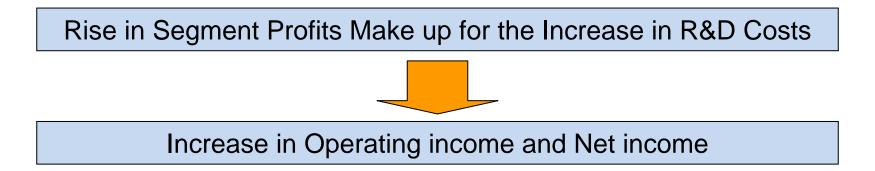
Financial Forecast for FY2013



FY2013 Financial Forecast - Brief Summary

Japan Segment: Ensure profit comparable to FY2012

- Sales: Make up for decrease due to impact of generics by focusing on Strategic products and New products
- ✓ SG&A expenses: Reduction by more efficient spending and saving
- North America Segment: Decrease both in sales and segment profits (local currency basis)
 - Sales: Increase of LATUDA[®], BROVANA[®] and ZETONNA[®]. Decrease of XOPENEX[®], LUNESTA[®] and Industrial property revenue
 - SG&A expenses: Despite an Increase of LATUDA[®] (potential additional indication), an overall reduction on a dollar basis due to improvement of business structure
- China Segment: :Increase both in sales and segment profit
- Other Regions: Increase due to industrial property revenues (lump sum payment) despite decrease in exports of MEROPEN[®]
- Other Businesses: A slight decrease in segment profit despite overall increase in sales
- R&D costs: : Increase due to development costs for BBI and effect of the weak yen



FY2013 Financial Forecast

Billions of yen

				Change				
		FY2012	FY2013	Va	alue	Percentage		
		Results	Forecast		Exchange gain/loss			
Net s	sales	347.7	369.0	21.3	28.8	6.1%		
Cost	of sales	101.7	106.0	4.3	4.1	4.2%		
Gros	s profit	246.0	263.0	17.0	24.7	6.9%		
SG8	&A expenses	221.0	237.0	16.0	27.0	7.2%		
	SG&A expenses less R&D costs	161.2	170.0	8.8	19.9	5.5%		
	R&D costs	59.8	67.0	7.2	7.1	12.0%		
Opera	ating income	25.0	26.0	1.0	- 2.3	3.8%		
Ordir	nary income	24.5	25.0	0.5		2.0%		
Extra	aordinary income or loss	- 6.3	—	6.3		_		
Net i	income	10.0	13.0	3.0		29.4%		
EBIT	DA	60.3	54.0	- 6.3		- 10.5%		

Note:

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

2. EBITDA: earning before interest, taxes, depreciation and amortization

Exchange rate

Results FY2012 : 1US\$ = ¥ 79.8, 1RMB = ¥12.7 Forecast FY2013 : 1US\$ = ¥100.0, 1RMB = ¥15.0

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FY2013 Forecast by Segment

Billions of yen

				Pharmaceutical	s Business			Other	-
		Japan	North America ^{%1}	Amortization ^{*2}	China	Other Regions	Subtotal	Business	Total
	Net sales (external)	173.7	125.8	—	10.5	15.6	325.6	43.4	369.0
FY	Cost of sales	51.1	15.0	—	2.1	3.8	72.0	34.0	106.0
FY2013	Gross profit	122.8	110.8	—	8.4	11.8	253.8	9.2	263.0
	SG&A expenses	63.1	74.7	18.8	5.8	1.1	163.5	6.5	170.0
orec	Income (loss) of Segment	59.7	36.1	- 18.8	2.6	10.7	90.3	2.7	93.0
Forecasts	R&D costs						66.0	1.0	67.0
S	Operating income						24.3	1.7	26.0
_		1							
	Net sales (external)	174.5	115.8	—	7.6	9.3	307.2	40.5	347.7
FY	Cost of sales	50.3	13.8	—	1.8	4.5	70.5	31.2	101.7
Y2012	Gross profit	124.4	102.0	—	5.8	4.7	237.0	9.0	246.0
2 R	SG&A expenses	63.8	61.1	25.9	4.0	0.4	155.1	6.0	161.2
Results	Income (loss) of Segment	60.6	40.9	- 25.9	1.8	4.3	81.9	3.0	84.9
ults	R&D costs			· · · · · · · · · · · · · · · · · · ·			59.1	0.8	59.8
	Operating income						22.8	2.3	25.0
	Net sales (external)	- 0.8	10.0	_	2.9	6.3	18.4	2.9	21.3
Cha	Income (loss) of Segment	- 0.9	- 4.8	7.1	0.8	6.4	8.4	- 0.3	8.1
Change	R&D costs						6.9	0.2	7.2
	Operating income						1.5	- 0.6	1.0

X 1. Excluding amortization of patent rights and goodwill

X 2. Amortization of patent rights and goodwill

Exchange rate

Results FY2012 : 1US\$ = ¥ 79.8, 1RMB = ¥12.7 Forecast FY2013 : 1US\$ = ¥100.0, 1RMB = ¥15.0

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Sales Forecast by Product in Japan Segment

Billions of yen

	FY2012	FY2013	Chang	ge
	Results	Forecast	Value	Percentage
AIMIX®	2.0	5.5	3.5	172.4%
AVAPRO®	11.7	12.1	0.4	3.8%
LONASEN®	10.7	13.0	2.3	20.9%
TRERIEF®	7.0	9.2	2.2	30.9%
Strategic Products Total	31.5	39.8	8.3	26.5%
METGLUCO®	12.0	15.2	3.2	26.7%
SUREPOST®	0.7	2.5	1.8	269.1%
New Products Total	12.7	17.7	5.0	39.6%
AmBisome®	4.6	5.0	0.4	9.2%
MIRIPLA®	1.1	1.3	0.2	16.2%
REPLAGAL®	9.9	10.5	0.6	5.7%
Specialty Products Total	15.6	16.8	1.2	7.5%
AMLODIN®	29.2	25.4	- 3.8	- 13.0%
GASMOTIN®	19.5	16.3	- 3.2	- 16.4%
PRORENAL®	14.2	13.3	- 0.9	- 6.6%
MEROPEN®	10.3	9.6	- 0.7	- 6.6%
Others	41.5	34.8	- 6.7	- 16.1%
Total	174.5	173.7	- 0.8	- 0.4%

Note: Sales figures before reduction of rebates.

Sales Forecast by Product in North America and China Segments

						Cha	nge
	FY2012 Results	FY2013 Forecast	Change	FY2012 Results	FY2013 Forecast		Impact of Exchange Rate
North America		(Million \$)			(Billion	yen)	
LATUDA®	202	303	101	16.1	30.3	14.2	6.1
LUNESTA®	561	465	- 96	44.8	46.5	1.8	9.4
XOPENEX®	317	74	- 243	25.3	7.4	- 17.9	1.5
BROVANA®	160	198	38	12.7	19.8	7.0	4.0
ALVESCO®	38	53	14	3.1	5.3	2.2	1.1
OMNARIS®	24	36	12	1.9	3.6	1.7	0.7
ZETONNA®	5	58	53	0.4	5.8	5.4	1.2
Industrial property revenues	98	27	- 71	7.8	2.7	- 5.1	0.5
Others	46	44	- 2	3.6	4.4	0.7	0.9
Total	1,451	1,258	- 193	115.8	125.8	10.0	25.4
China	(Million RMB	3)	(Billion yen)			
MEROPEN®	494	561	67	6.3	8.4	2.2	1.3
Others	110	140	30	1.4	2.1	0.7	0.3
Total	604	701	97	7.6	10.5	2.9	1.6

Exchange rate

Results FY2012 : 1US\$ = ¥ 79.8, 1RMB = ¥12.7

Forecast FY2013 : 1US\$ = ¥100.0, 1RMB = ¥15.0 16

Breakdown for North America Segment

< Excluding amortization of patent rights and goodwill >

Billions of yen

						Cha	nge	
	FY2012 Results	FY2013 Forecast	Change	FY2012 Results	FY2013 Forecast		Impact of Exchange Rate	
	(Million \$)			(Billion yen)				
Net sales	1,451	1,258	- 193	115.8	125.8	10.0	25.4	
Cost of sales	173	150	- 23	13.8	15.0	1.2	3.0	
Gross profit	1,278	1,108	- 170	102.0	110.8	8.8	22.4	
SG&A expenses	766	747	- 19	61.1	74.7	13.6	15.1	
Income (loss) of Segment	513	361	- 152	40.9	36.1	- 4.8	7.3	

< Amortization of patent rights and goodwill >

	FY2012 Results	FY2013 Forecast	Change	FY2012 Results	FY2013 Forecast	Cha	Inge Impact of Exchange Rate
		(Million \$)			(Billio	n yen)	
SG&A expenses	324	188	- 136	25.9	18.8	- 7.1	3.8
Income (loss) of Segment	- 324	- 188	136	- 25.9	- 18.8	7.1	- 3.8

Exchange rate

Results FY2012 : 1US\$ = ¥ 79.8, 1RMB = ¥12.7

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

Returns to Shareholders

Dividend Policy

- Allot appropriate dividends in line with performance while balancing aggressive investment and internal reserves for future growth
- Also consider stable dividends

Changes in dividends

	FY2011	FY2012 (planned)	FY2013 (planned)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	82.9	71.2	55.0

<reference>

Dividend on equity (%) 2.2 2.1 2.0
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Main Management Challenges in 2013



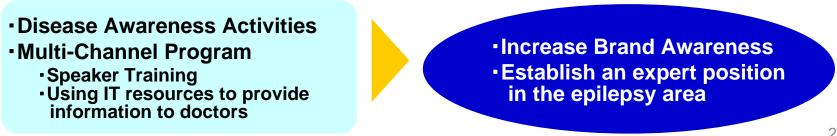
Main Management Challenges in North America

Early market penetration of products expected to be approved in FY2013

LATUDA[®]: Bipolar I Depression (Additional Indication) approval expected in 1H FY2013



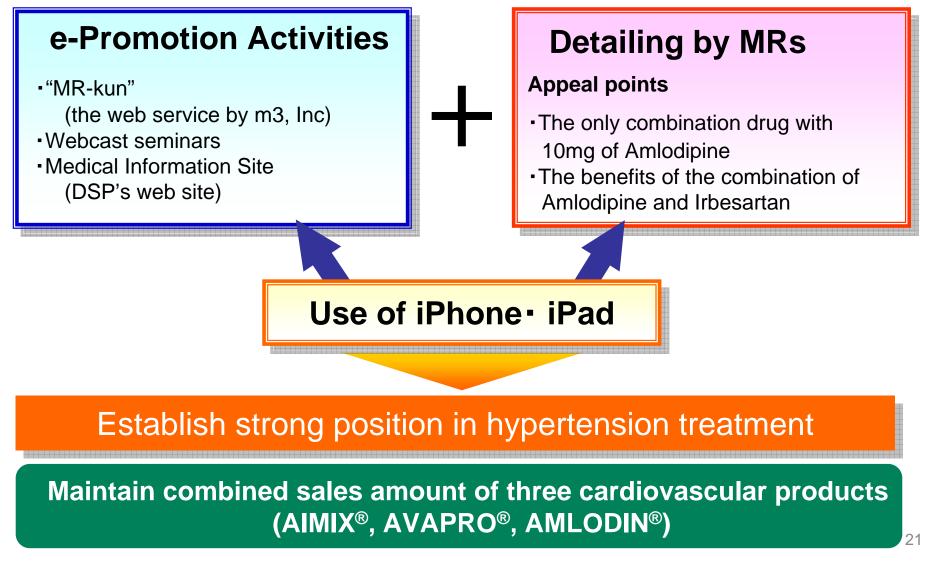
STEDESA[®] approval expected in 2H FY2013



Main Management Challenges in Japan

Maximize AIMIX[®] sales quickly

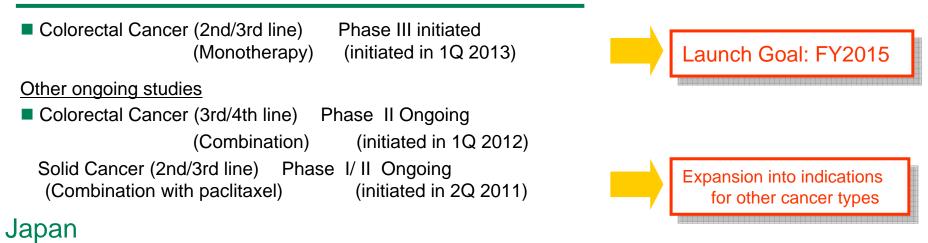
"Hybrid Marketing" establishes the base for the fastest product maximization



Main Management Challenges in Oncology

Accelerate the development of BBI608

US. Canada



Solid Cancer (Monotherapy)

Phase I initiated (initiated in March 2013)

After Phase 1, Japanese clinical sites will participate in the global Phase III study aiming for the earliest approval possible

Launch Goal: FY2016

Build oncology sales & marketing structure in the US

Establishing a commercial infrastructure beginning with hiring a head of sales and marketing

Continually create leading-edge, breakthrough products

■Accelerate the development of BBI503 and WT2725/4869

Continually create leading-edge, breakthrough products under the strong collaboration between BBI (US) and the DSP Cancer Institute (Japan)

Strengthen Business Foundation

- Towards a leaner corporate structure -

Establish a robust business management structure that can respond flexibly to changes in the business environment

In Pursuit of Management Efficiency

- Decrease SG&A costs and increase efficiency of assets
- Optimize personnel
- Promote relocation of sites
- Accelerate efficiency in decision-making processes and the execution of operations
- Streamline organization

Create Strong Corporate Culture

- Emphasize corporate culture that encourages willingness to take on a challenge
- Establish differentiated personnel evaluation system
- Further develop global talent

⇒ Setup the company-wide project

to strengthen a business foundation

Clinical Development Status



Development Pipeline ① (as of May 9, 2013)

Psychiatry & Neurology Field

Domestic Overseas

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

Revisions since the previous announcement are in red.

*Lurasidone (SM-13496) : Co-development with Takeda Pharmaceutical in Europe

Development Pipeline (2) (as of May 9, 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				
BBI608	TBD	Colorectal Cancer (2nd/3rd line) (Monotherapy)	US/Canada				
		Colorectal Cancer (3rd/4th line) (Combination therapy)	US/Canada				
		Solid Cancer(2nd/3rd line) (Combination therapy with paclitaxel)	US/Canada		*		
		Solid Cancer (Monotherapy)	Japan				
WT4869	ТВD	Myelodysplastic syndromes	Japan		*		
		Solid Cancer	Japan				
WT2725	TBD	Solid Cancer, Hematologic Cancer	US				
BBI503	TBD	Solid Cancer (Monotherapy)	US/Canada				

Respiratory Field

Xon 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				
DSP-3025	TBD	Asthma/Allergic Rhinitis	Japan				

Revisions since the previous announcement are in red.

Development Pipeline ③ (as of May 9, 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 (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				
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				



Development Pipeline State of Progress

(Main changes after January 31, 2013)

SUREPOST[®] (New indication)

 Japan: Approved for Type 2 diabetes combination therapy with biguanides and thiazolidinediones (February 2013)

STEDESA[®]

US: NDA resubmitted (February 2013)

Lurasidone hydrochloride (SM-13496)

Australia: MAA submitted (March 2013)

BBI608

Japan: Newly added in Phase I (Phase I initiated in Japan in March 2013)



LATUDA[®](Lurasidone) – Clinical development status (1)

US (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.

Planned Studies in Schizophrenia

- Low-dose Schizophrenia Study with 20mg/day: to be initiated in 2Q 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 completed in March 2013
- 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: MAA submitted by the centralized authorization procedure (September. 2012)

Bipolar disorder/ Co-development with Takeda in Europe (Phase III) DSP plans to commercialize Lurasidone independently in the UK

Australia: Schizophrenia/ MAA submitted (March 2013)

Update on New Business Area (Cell therapy and regenerative medicine)

Capital alliance with the Retina Institute Japan (RIJ) (March 2013)

- Details of the Agreement
- DSP will exclusively discuss with RIJ to collaborate in and outside Japan to use iPS cell technology to cure retinal diseases.
 - Discussions are focused on age-related macular degeneration and cover a wide area of practical use such as co-development, manufacture, sales, etc.

Purpose of the Alliance

Full-scale efforts towards the commercialization of cell therapy and regenerative medicines



- Established Cell Therapy specialized teams in Drug Research (April 2013)
- Cell therapy drug being developed for stroke by SanBio, Inc Plan to exercise option rights in FY2013

Profile of new alliance compounds: EPI-743, EPI-589

- Licensor: Edison Pharmaceuticals, Inc
- Licensed Rights: Exclusive research, development and commercial rights
- Licensed Indications: All indications (plan to start first development for Leigh syndrome)
- Licensed Territory : Japan
- Mode of Action: Synchronize energy generation in the mitochondria with the counterbalancing of redox stress
- Development stage outside Japan (By Edison):
 - EPI-743: Phase II b clinical study for Leigh syndrome ongoing
 - EPI-589: Pre-clinical studies ongoing
- Advantages:
 - Expected to be a first-in-market efficacious agent against mitochondrial diseases such as Leigh Syndrome, which currently has no treatments
 - Expected to contribute to the treatment of neuropsychiatric indications that share as a common etiology disorders of redox biochemistry



Extension of the target diseases

Neuropsychiatric diseases associated with redox stress



Leigh Syndrome

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.

