

Financial Results for FY2013
(The year ended March 31, 2014)

May 9, 2014

Masayo Tada, President and CEO

Dainippon Sumitomo Pharma Co., Ltd.

Financial Results for FY2013

Financial Results for FY2013

Billions of yen

	FY2012 Results	FY2013 Results	Comparison to FY2012			FY2013 Forecasts (4 th April)
			Value		Percentage (%)	
				Exchange Rate Impact		
Net sales	347.7	387.7	40.0	32.2	11.5	387.0
Cost of sales	101.7	104.1	2.4	3.6	2.4	
Gross profit	246.0	283.6	37.6	28.6	15.3	
SG&A expenses	221.0	241.5	20.5	27.5	9.3	
SG&A expenses less R&D costs	161.2	171.6	10.5	20.8	6.5	
R&D Costs	59.8	69.8	10.0	6.7	16.6	
Operating income	25.0	42.1	17.1	1.1	68.3	42.0
Ordinary income	24.5	40.6	16.1		65.8	41.0
Extraordinary income (loss)	(6.3)	(5.9)	0.4			
Net income	10.0	20.1	10.0		99.7	20.0
E B I T D A	60.3	68.1	7.8		12.9	

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

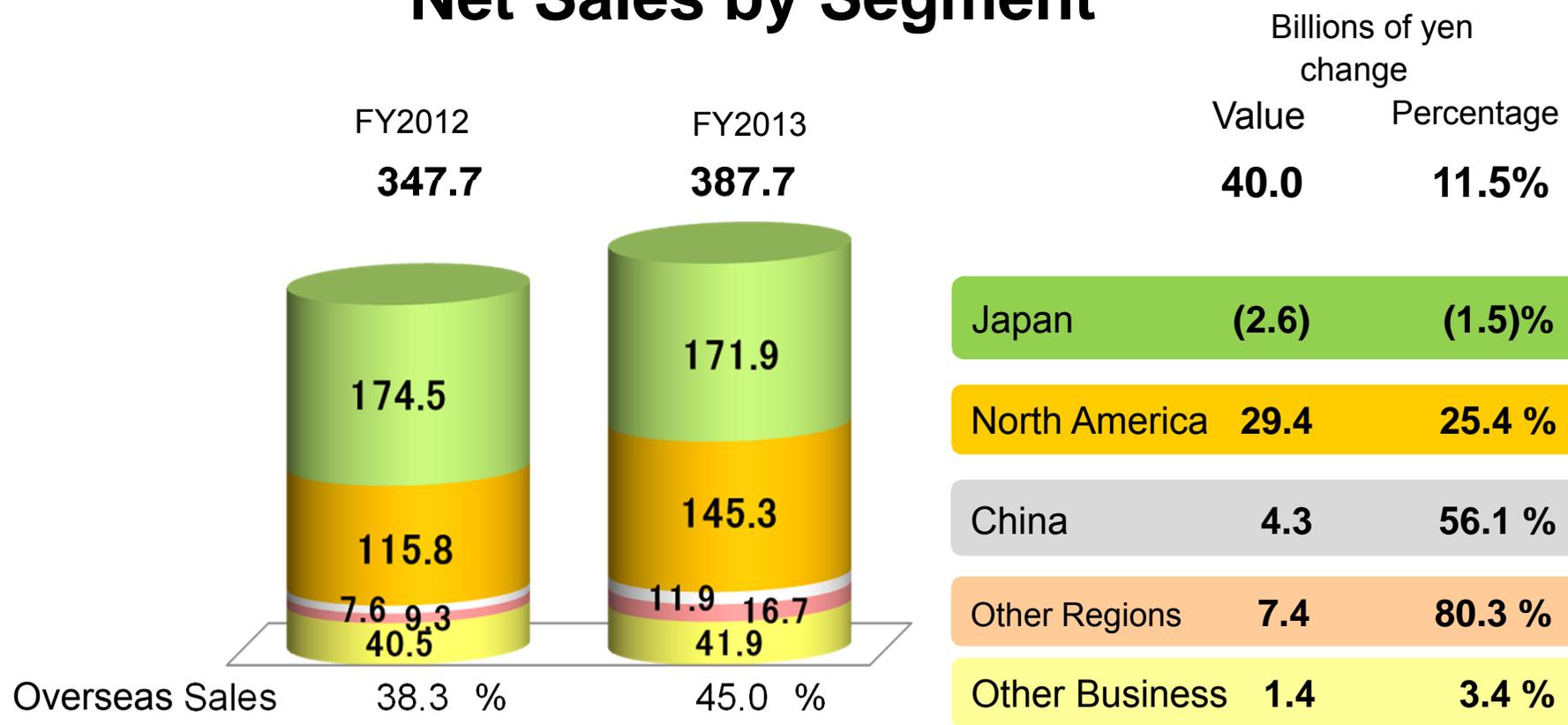
2. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization,
and Extraordinary income / loss.

Exchange Rate:

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

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

Net Sales by Segment



- 【 Japan 】 Unchanged from FY2012 in sales for the product line of sales department, decrease in industrial property revenues and contract manufacture products
- 【 North America 】 Increase from weak yen. Growth of LATUDA® covered decrease of XOPENEX®.
- 【 China 】 Increase of sales for MEROPEN®, impact of weak yen
- 【 Other Regions 】 Increase from milestone revenue related to approval of LATUDA® in Europe

Exchange Rate:
 FY2012 Results : 1US\$ = ¥ 79.8, 1RMB = ¥12.7
 FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

Sales in Japan

Billions of yen

	FY2012 Results	FY2013 Results	Comparison to FY2012	
			Value	Percentage (%)
AIMIX®	2.0	6.9	4.9	243.1
AVAPRO®	11.7	12.1	0.4	3.6
LONASEN®	10.7	12.6	1.9	17.2
TRERIEF®	7.0	9.5	2.5	35.1
Strategic products total	31.5	41.1	9.7	30.7
METGLUCO®	12.0	15.8	3.8	31.3
SUREPOST®	0.7	1.7	1.0	149.3
New products total	12.7	17.4	4.8	37.6
AmBisome®	4.6	4.8	0.2	4.3
MIRIPLA®	1.1	1.2	0.0	2.8
REPLAGAL®	9.9	9.8	(0.1)	(1.2)
Specialty products total	15.6	15.7	0.1	0.7
AMLODIN®	29.2	27.0	(2.2)	(7.5)
GASMOTIN®	19.5	15.0	(4.4)	(22.8)
PRORENAL®	14.2	13.5	(0.7)	(4.9)
MEROPEN®	10.3	9.8	(0.5)	(4.8)
Others in product line of Sales Department	35.0	30.8	(4.1)	(11.8)
Product line of Sales Department total	168.0	170.5	2.6	1.5
Others	6.5	1.4	(5.1)	(78.8)
Japan total	174.5	171.9	(2.6)	(1.5)

Note: Sales figures before reduction of rebates

Sales in North America & China

	FY2012 Results	FY2013 Results	Change	FY2012 Results	FY2013 Results	Change	
						Value	Exchange Rate Impact
North America	(Million \$)			(Billion yen)			
LATUDA®	202	421	219	16.1	42.2	26.0	8.6
LUNESTA®	561	579	18	44.8	58.0	13.2	11.8
XOPENEX®	317	121	(197)	25.3	12.1	(13.3)	2.5
BROVANA®	160	168	8	12.7	16.8	4.1	3.4
Ciclesonide	67	81	14	5.4	8.2	2.8	1.7
Industrial property revenues	98	41	(57)	7.8	4.1	(3.7)	0.8
Others	46	40	(6)	3.7	4.0	0.3	0.8
Total	1,451	1,450	(1)	115.8	145.3	29.4	29.5
China	(Million RMB)			(Billion yen)			
MEROPEN®	494	597	103	6.3	9.8	3.5	2.2
Others	110	131	21	1.4	2.1	0.8	0.5
Total	603	727	124	7.6	11.9	4.3	2.7

Note: FY2012 figures are for sales of Jan. to Dec. 2012.

Exchange Rate:
 FY2012 Results : 1US\$ = ¥ 79.8, 1RMB = ¥12.7
 FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

Segment Breakdown for North America

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

	FY2012 Results	FY2013 Results	Change	FY2012 Results	FY2013 Results	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
Net sales	1,451	1,450	(1)	115.8	145.3	29.4	29.5
Cost of sales	173	149	(24)	13.8	15.0	1.1	3.0
Gross profit	1,278	1,301	23	102.0	130.3	28.3	26.5
SG&A expenses	766	782	16	61.1	78.3	17.2	15.8
Income of segment	513	519	7	40.9	52.0	11.1	10.7

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

	FY2012 Results	FY2013 Results	Change	FY2012 Results	FY2013 Results	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
SG&A expenses	324	181	(143)	25.9	18.2	(7.7)	3.7
Income (loss) of segment	(324)	(181)	143	(25.9)	(18.2)	7.7	(3.7)

Exchange Rate:

FY2012 Results : 1US\$ = ¥ 79.8

FY2013 Results : 1US\$ = ¥ 100.2

Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total
		Japan	North America※1	Amortization ※2	China	Other Regions			
FY2013 Results	Net sales (Sales to customers)	171.9	145.3	—	11.9	16.7	345.8	41.9	387.7
	Cost of sales	49.3	15.0	—	2.6	4.4	71.3	32.8	104.1
	Gross profit	122.7	130.3	—	9.3	12.3	274.6	8.9	283.6
	SG&A expenses less R&D costs	61.9	78.3	18.2	6.1	0.9	165.4	6.2	171.6
	Income (loss) of segment	60.8	52.0	(18.2)	3.2	11.4	109.2	2.7	111.9
	R&D costs						68.9	0.9	69.8
	Operating income						40.4	1.8	42.1
FY2012 Results	Net sales (Sales to customers)	174.5	115.8	—	7.6	9.3	307.2	40.5	347.7
	Cost of sales	50.3	13.8	—	1.8	4.5	70.5	31.2	101.7
	Gross profit	124.4	102.0	—	5.8	4.7	237.0	9.0	246.0
	SG&A expenses less R&D costs	63.8	61.1	25.9	4.0	0.4	155.1	6.0	161.2
	Income (loss) of segment	60.6	40.9	(25.9)	1.8	4.3	81.9	3.0	84.9
	R&D costs						59.1	0.8	59.8
	Operating income						22.8	2.3	25.0
Change	Net sales (Sales to customers)	(2.6)	29.4	—	4.3	7.4	38.6	1.4	40.0
	SG&A expenses less R&D costs	(1.9)	17.2	(7.7)	2.1	0.5	10.3	0.2	10.5
	Income (loss) of segment	0.2	11.1	7.7	1.4	7.0	27.4	(0.3)	27.1
	R&D costs						9.8	0.2	10.0
	Operating income						17.6	(0.5)	17.1

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

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

Exchange Rate:

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

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

Ordinary income & Net income

Billions of yen

	FY2012 Results	FY2013 Results	Change	
			Value	Percentage(%)
Operating income	25.0	42.1	17.1	68.3
Non-operating income and expenses	(0.5)	(1.5)	(1.0)	
Ordinary income	24.5	40.6	16.1	65.8
Extraordinary income	—	4.1	4.1	
Gain on sales of investment securities	—	2.8	2.8	
Fair value adjustment of contingent consideration	—	1.3	1.3	
Extraordinary loss	6.3	10.0	3.6	
Impairment loss	0.4	7.6	7.2	
Business structure improvement expenses	4.8	2.3	(2.5)	
Loss on litigation	1.1	—	(1.1)	
Income taxes	8.1	14.6	6.5	
Net income	10.0	20.1	10.0	99.7

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

【 Impairment loss 】 Impairment loss for in-process R&D in the U.S. and idle real estate in Japan

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

Financial Position

Billions of yen

	as of Mar. 31, 2013	as of Mar. 31, 2014	Change
Assets	607.2	659.0	51.8
Current assets	333.4	359.6	26.2
Fixed assets	273.8	299.4	25.6
Liabilities	258.0	260.5	2.5
Current liabilities	124.8	131.2	6.4
Long-term liabilities	133.1	129.3	(3.9)
Net assets	349.2	398.5	49.3

(Shareholders' equity ratio)

57.5%

60.5%

(Assets)

Notes and accounts receivable +14.5

Intangible assets +10.5 Investment securities +10.0

(Liabilities)

Income taxes payable +8.4 Reserve for sales rebates +7.3

Interest-bearing debt (loans/bonds) (20.0)

(Net Assets)

Foreign currency translation adjustment +37.8 Retained earnings +10.3

Cash Flows

FY2013

Billions of yen

I	Net cash provided by operating activities	+49.9
	▪ Income before income taxes and minority interests	+34.7
	▪ Depreciation and amortization (Include goodwill amortization)	+26.8
	▪ Increase notes and accounts payable	(15.2)
II	Net cash used in investing activities	(26.2)
	▪ Purchase of property, plant and equipment, and intangible assets	(21.6)
	▪ Proceeds from sales of investment securities	(9.1)
III	Net cash used in financing activities	(27.2)
	▪ Net decrease in loans payable and bonds payable	(20.0)
	▪ Cash dividends paid	(7.2)

Cash and cash equivalents at the end of period : 73.9 billion yen
(compared with the beginning of period +2.5 billion yen)

Financial Forecast for FY2014

FY2014 Overview of Financial Forecast

■ Net Sales

- Result of generic entry of LUNESTA[®] (North America) and NHI price revision (Japan)
- Offset by strategic product growth but sales down by 9.2%

■ Expenses

- Decrease in amortization (LUNESTA[®] patent rights)
- Decrease in SG&A due to efficient spending
- Concentrate investment on priority programs, keeping the total R&D cost at the same level



Secure “20 billion JPY” in operating income

Financial Forecast for FY2014

Billions of yen

	FY2013 Results	FY2014 Forecast	Comparison to FY2013	
			Value	Percentage (%)
Net sales	387.7	352.0	(35.7)	(9.2)
Cost of sales	104.1	102.5	(1.6)	(1.5)
Gross profit	283.6	249.5	(34.1)	(12.0)
SG&A expenses	241.5	229.5	(12.0)	(4.9)
SG&A expenses less R&D costs	171.6	159.5	(12.1)	(7.1)
R&D Costs	69.8	70.0	0.2	0.3
Operating income	42.1	20.0	(22.1)	(52.5)
Ordinary income	40.6	19.0	(21.6)	(53.2)
Extraordinary income (loss)	(5.9)	8.0	13.9	
Net income	20.1	12.0	(8.1)	(40.2)
E B I T D A	68.1	38.0	(30.1)	(44.2)

Notes: 1. All values are rounded to the nearest 100 million yen.
 2. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization,
 and Extraordinary income / loss.

Exchange Rate:
 FY2013 Results : 1US\$ = ¥100.2, 1RMB = ¥16.4
 FY2014 Forecast.: 1US\$ = ¥100.0, 1RMB = ¥16.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America※1	Amortization ※2	China	Other Regions				
FY2014 Forecast	Net sales (Sales to customers)	169.0	119.0	—	13.2	7.8	309.0	43.0	352.0	
	Cost of sales	50.7	11.6	—	2.4	4.4	69.1	33.4	102.5	
	Gross profit	118.4	107.4	—	10.8	3.4	240.0	9.5	249.5	
	SG&A expenses less R&D costs	60.1	75.8	8.6	6.5	2.0	153.0	6.5	159.5	
	Income (loss) of segment	58.3	31.6	(8.6)	4.3	1.4	87.0	3.0	90.0	
	R&D costs							69.0	1.0	70.0
	Operating income							18.0	2.0	20.0
FY2013 Results	Net sales (Sales to customers)	171.9	145.3	—	11.9	16.7	345.8	41.9	387.7	
	Cost of sales	49.3	15.0	—	2.6	4.4	71.3	32.8	104.1	
	Gross profit	122.7	130.3	—	9.3	12.3	274.6	8.9	283.6	
	SG&A expenses less R&D costs	61.9	78.3	18.2	6.1	0.9	165.4	6.2	171.6	
	Income (loss) of segment	60.8	52.0	(18.2)	3.2	11.4	109.2	2.7	111.9	
	R&D costs							68.9	0.9	69.8
	Operating income							40.4	1.8	42.1
Change	Net sales (Sales to customers)	(2.9)	(26.3)	—	1.3	(8.9)	(36.8)	1.1	(35.7)	
	SG&A expenses less R&D costs	(1.8)	(2.5)	(9.6)	0.4	1.1	(12.4)	0.3	(12.1)	
	Income (loss) of segment	(2.5)	(20.4)	9.6	1.1	(10.0)	(22.2)	0.3	(21.9)	
	R&D costs							0.1	0.1	0.2
	Operating income							(22.4)	0.2	(22.1)

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

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

Exchange Rate:

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

FY2014 Forecast.: 1US\$ = ¥ 100.0, 1RMB = ¥16.0

Sales in Japan

Billions of yen

	FY2013 Results	FY2014 Forecast	Comparison to FY2013	
			Value	Percentage (%)
AIMIX®	6.9	12.8	5.9	84.8
AVAPRO®	12.1	11.6	(0.5)	(3.9)
LONASEN®	12.6	13.5	0.9	7.1
TRERIEF®	9.5	11.7	2.2	23.2
Strategic products total	41.1	49.6	8.5	20.7
METGLUCO®	15.8	16.1	0.3	2.2
SUREPOST®	1.7	3.2	1.5	89.6
New products total	17.4	19.3	1.9	10.7
AmBisome®	4.8	5.4	0.6	13.0
MIRIPLA®	1.2	1.0	(0.2)	(13.1)
REPLAGAL®	9.8	10.8	1.0	10.0
Specialty products total	15.7	17.2	1.5	9.2
AMLODIN®	27.0	22.4	(4.6)	(17.1)
GASMOTIN®	15.0	11.4	(3.6)	(24.2)
PRORENAL®	13.5	11.6	(1.9)	(14.3)
MEROPEN®	9.8	8.1	(1.7)	(17.3)
Others	32.2	29.4	(2.8)	(8.7)
Japan total	171.9	169.0	(2.9)	(1.7)

Note: Sales figures before reduction of rebates

Sales in North America & China

	FY2013 Results	FY2014 Forecast	Change	FY2013 Results	FY2014 Forecast	Change	
						Value	Percentage (%)
North America	(Million \$)			(Billion yen)			
LATUDA®	421	610	189	42.2	61.0	18.8	44.6
LUNESTA®	579	85	(494)	58.0	8.5	(49.5)	(85.3)
XOPENEX®	121	92	(29)	12.1	9.2	(2.9)	(23.8)
BROVANA®	168	208	40	16.8	20.8	4.0	23.6
Ciclesonide	81	93	12	8.2	9.3	1.1	14.0
APTIOM®	—	35	35	—	3.5	3.5	—
Others	80	67	(13)	8.0	6.7	1.3	(16.8)
Total	1,450	1,190	(260)	145.3	119.0	(26.3)	(18.1)
China	(Million RMB)			(Billion yen)			
MEROPEN®	597	665	68	9.8	10.6	0.8	8.3
Others	131	159	28	2.1	2.6	0.5	21.4
Total	727	824	97	11.9	13.2	1.3	10.7

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

	FY2012	FY2013 (planned)	FY2014 (planned)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	71.2	35.7	59.6

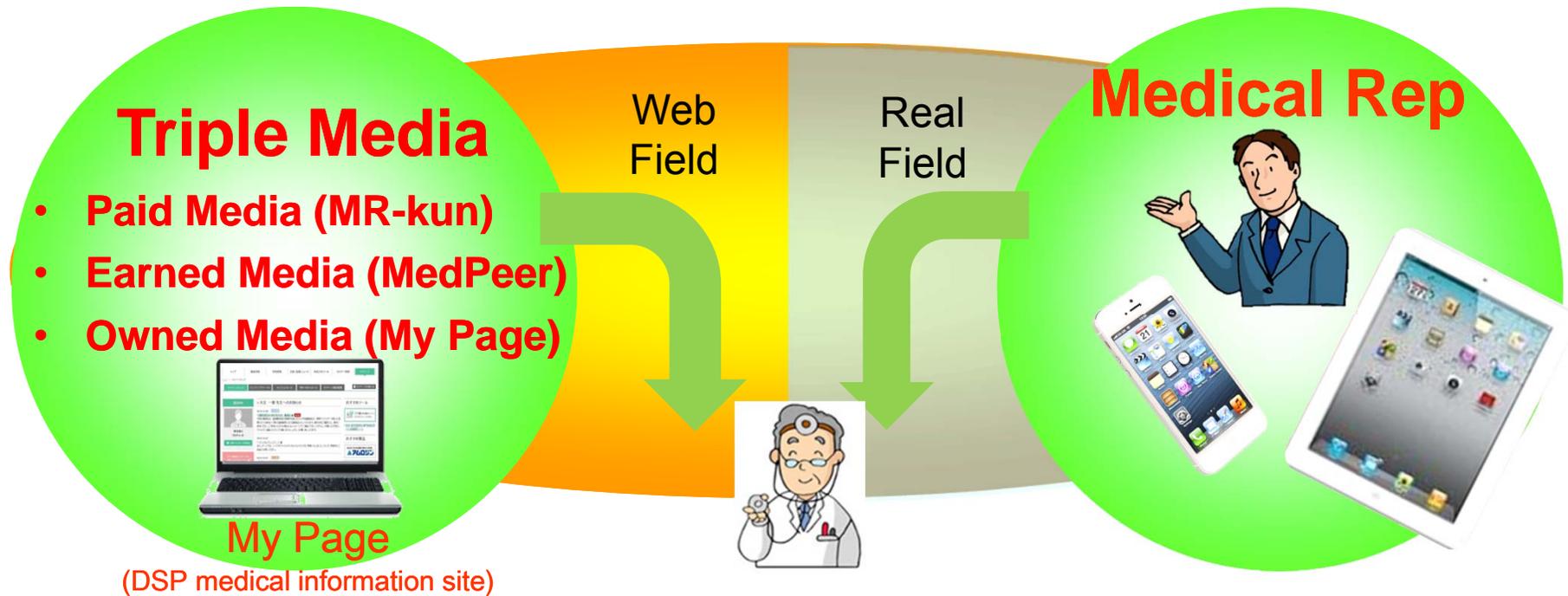
〈reference〉

Dividend on equity (%)	2.1	1.9	1.8
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FY2014 Main Management Challenges

Main Management Challenge (Japan Business)

Implement Hybrid Marketing



FY2014 Key Challenges

- Maximize total sales of three anti-hypertensive drugs: AIMIX[®], AVAPRO[®] and AMLODIN[®] in order to contribute to the hypertension treatment
- Intensify promotional activities for growth products such as LONASEN[®], TRERIEF[®] and METGLUCO[®]

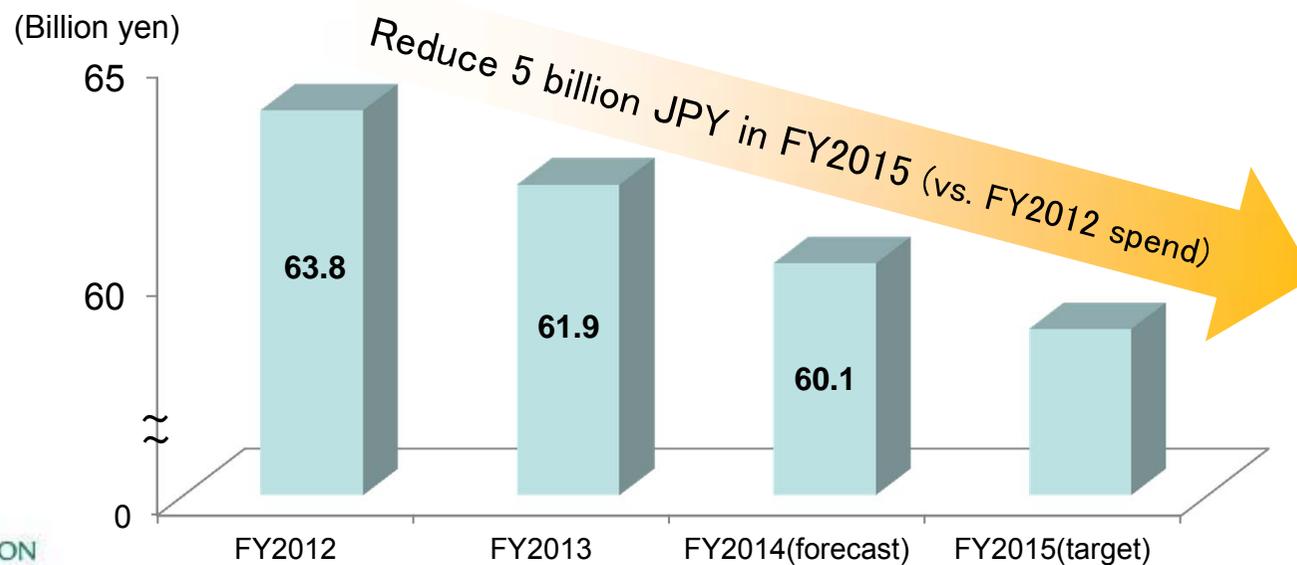
Main Management Challenge (Japan Business)

Promoting Streamlining Project to Strengthen Foundation

Pursue management efficiency

- Compress SG&A (reduce expenses, optimize resources and simplify organization, etc.)
 - ✓ Reduction target at 5 billion JPY in FY2015 (vs. FY2012 actual)
 - ✓ Projected to reduce 3.7 billion JPY in FY2014 (vs. FY2012 actual)
- Improve asset efficiency (Consolidate sites, compress inventory assets, etc.)

SG&A(Japan Business)



Main Management Challenges (North America)

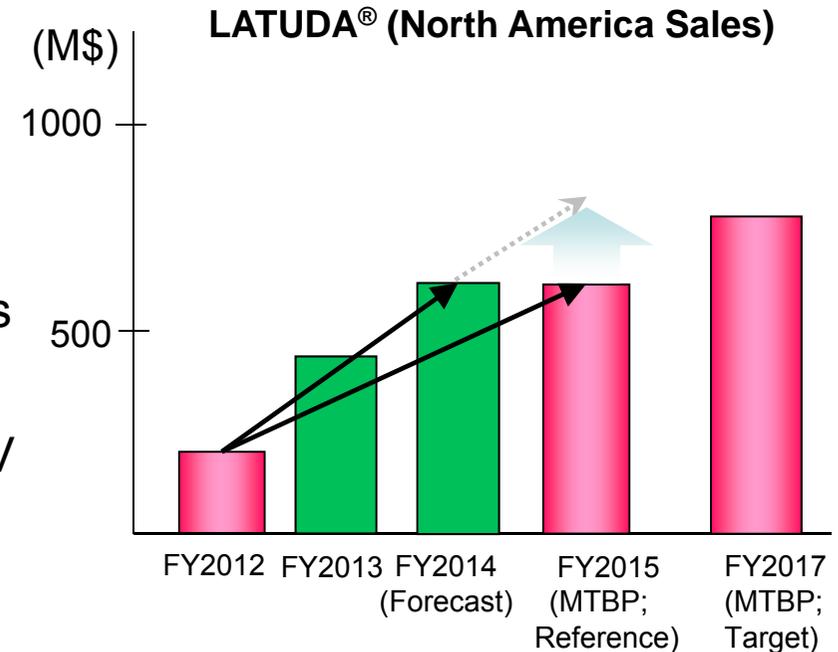
Growth of LATUDA® and APTIOM®

● LATUDA®

- ✓ Exceeding midterm business plan goal
- ✓ Further expanding prescription volume after bipolar I depression indication was approved
- ✓ Promotional activities including DTC-TV

● APTIOM®

- ✓ Significant and sustained reduction of seizure with once daily dosing
- ✓ Favorable safety profile
- ✓ Promoted by 120 dedicated reps



Clinical Development Status

Development Pipeline (1) (as of May 8, 2014)

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				
		(New indication) Bipolar I depression	Canada				
		Schizophrenia	Taiwan				
		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.				
APTIOM® (SEP-0002093)	eslicarbazepine acetate	Epilepsy- Adjunctive therapy	Canada				
		(New indication) 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 in Dementia with Lewy Bodies (DLB)	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. /U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				



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

※2 Phase II/III study

 Approved / Preparing for Launch

Revisions since the previous announcement are in red.

Development Pipeline (2) (as of May 8, 2014)

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 trial)	U.S./Canada/ Japan, etc.				
		Gastric cancer (Combination therapy) (Global clinical trial)	U.S.				
		Colorectal cancer (Combination therapy)	U.S./Canada				
		Solid cancer (Combination therapy)	U.S./Canada				
		Gastrointestinal cancer (Combination therapy)	U.S. /Canada				
		Gastric cancer (Combination therapy)	Japan				
		WT4869	TBD	Myelodysplastic syndromes	Japan		
WT2725	TBD	Solid cancer, Hematologic cancer	U.S.				
		Solid cancer	Japan				
BBI503	TBD	Solid cancer (Monotherapy)	U.S./Canada				

Revisions since the previous announcement are in red.

※1 Phase II of Phase I/II study

※2 Phase I of Phase I/II study



Development Pipeline (3) (as of May 8, 2014)

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				

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 DPP-4 inhibitors)	Japan				

Other Fields

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

Clinical Development Status

(Major Changes after January 31, 2014)

LATUDA® (lurasidone hydrochloride)

- Approved in Australia for the indication of schizophrenia (March 2014)
- Approved in Europe for the indication of schizophrenia (March 2014)
- Approved in Canada for the additional indication of bipolar I depression (March 2014)

BBI608

- Started Phase III global clinical trial for gastric cancer in the U.S. (combination therapy with paclitaxel)

Discontinued

- DSP-5990 (Japan: Phase I)
- DSP-1053 (U.S.: Phase I)

Submission target of the Main late Development Pipeline

Field	Development products	Submission target			
		FY2014	FY2015	FY2016	FY2017
Psychiatry & Neurology Field	APTIOM® <Eslicarbazepine acetate> (Epilepsy/Monotherapy) U.S.	●			
	SM-13496 <lurasidone hydrochloride> (Schizophrenia) Japan/ China		●		
	LATUDA® <lurasidone hydrochloride> (Bipolar maintenance) U.S.		●		
	★SM-13496 <lurasidone hydrochloride> (Bipolar I depression) Japan.				●
	EPI-743 (Leigh syndrome) Japan		●		
	AS-3201<ranirestat> (Diabetic neuropathy) Japan			●	
Cancer Field	BBI608 (Colorectal cancer/Monotherapy) U.S.	●			
	BBI608 (Colorectal cancer/Monotherapy) Japan		●		
	★ BBI608 (Gastric cancer/Combination therapy) U.S.			●	
	★ BBI503 (Solid cancer/Monotherapy) U.S./ Japan			●	
Respiratory Field	SUN-101<glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.			●	
Other	★ iPS cell-derived RPE cells HLS001 (Age-related macular degeneration) Japan				●

*SB623 don't have any options exercised, aren't described.

★Revisions since October 2013.

New Chemical Entities

{ New Indication etc. }

BBI608 and BBI503 - Clinical development status

BBI608

■ U.S., Canada, Japan, etc.

- Colorectal cancer (Monotherapy)
 - ✓ Phase III in progress (initiated in 1Q 2013)

■ U.S.

- Gastric cancer (Combination therapy)
 - ✓ Phase III in progress (initiated in 2Q 2014)

■ U.S., Canada

- Colorectal cancer (Combination with Cetuximab, Panitumumab, or Capecitabine) 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)
- Gastrointestinal cancer (Combination with FOLFOX*¹, FOLFIRI*³ and Bevacizumab, CAPOX*², FOLFIRI*³, FOLFIRI*³ and Bevacizumab, or Regorafenib) Phase I in progress (initiated in 4Q 2013)

■ Japan

- Gastric cancer (Combination with paclitaxel) Phase I in progress (initiated in 4Q 2013)

*1 : FOLFOX (Combination with Fluorouracil, Leucovorin, Oxaliplatin)

*2 : CAPOX (Combination with Capecitabine, Oxaliplatin)

*3 : FOLFIRI (Combination with Fluorouracil, Leucovorin, Irinotecan)

Launch Goal

North America :FY2015

Japan :FY2016

BBI503

■ U.S., Canada

- Solid cancer (Monotherapy)

Phase I in progress (initiated in 1Q 2012)

Launch Goal

FY2017

Revisions since the previous announcement are in red.

FY2014 Main Challenges <Oncology Field>

■ Clinical Development Goal

- **BBI608: Colorectal cancer (monotherapy) (U.S.) filing**
 - Planning to conduct interim analysis in 2014 and file by the end of FY2014
- **BBI503: Transition to Phase III (U.S.) in FY2014**

■ Present data at 2014 American Society of Clinical Oncology (ASCO)

- **Four presentations have been adopted and the summary to be made public on May 14 (US time)**
 - BBI608 Phase I/II study extension for solid cancer (monotherapy) (BBI608-101 study)
 - BBI608 Phase I study for solid cancer (combination with paclitaxel) (BBI608-201 study)
 - BBI608 Phase III study plan for colorectal cancer (monotherapy) (BBI608-CO23 study)
 - BBI503 Phase I study for solid cancer (monotherapy) (BBI503-101 study)

■ Article on mechanism of action

- **Submitted already, under review**

■ Establish sales organization for oncology business (U.S.)

- **Planning to start hiring sales force in FY2014 in preparation for BBI608 launch in FY2015**
- **Anticipating 100-150 sales reps at the time of BBI608 launch**

FY2014 Main Challenges <New Fields (1)>

■ SB623

- A meeting is scheduled to discuss with FDA Phase IIb/III study plan based on the Phase I/IIa study results by San Bio
- Planning to execute option rights during the first half of FY2014 (joint development and exclusive marketing rights in North America)
- Planning to start Phase IIb/III study in North America in 2014

■ Regenerative & Cellular Medicine

- Established a joint venture company “SighRegen” with Healios K.K. (February 2014)
- Promote commercialization of iPS cell-derived RPE cells products(HLS001)
- Promote research and production activities at Kobe Regenerative & Cellular Medicine Center (opened in April 2014)
- Accelerate research for the practical application of iPS cells to treat retinal diseases and spinal cord injuries

FY2014 Main Challenges <New Fields (2)>

■ DSP-1747

- Conducting Phase II study for nonalcoholic steatohepatitis (NASH)
- Consider future development plan for PBC in Japan

■ Mitochondria-related Drug Discovery & Development Project

- EPI-743
 - Promote development to file for the indication of Leigh syndrome during FY2015 (first half) in Japan
 - Consider additional indications in Japan based on clinical study results by Edison
- EPI-589
 - Planning to start Phase I study in Japan in FY2014
- Promote joint research with Edison to generate new medicine related to metabolism of intracellular energy

LATUDA®(Lurasidone) – Clinical development status

U.S. (Schizophrenia)

Key Current (or Ongoing) Studies in Schizophrenia

- 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/ Approved in March 2014
- **China:** Schizophrenia/ Phase III study in progress (Initiated in 3Q 2013)
- **Europe:** Schizophrenia/ Approved in March 2014 by Takeda
- United Kingdom : Launch target in September 2014 through a local subsidiary of DSP

Bipolar disorder/ Plan to submit by Takeda in Europe (in Phase III stage)
DSP plans to commercialize lurasidone independently in the U.K.
- **Australia:** Schizophrenia/ Approved in March 2014, Launch target is in FY2014
- **Taiwan:** Schizophrenia/ Submitted by Standard Chem. & Pharm in 3Q 2013

Revisions since the previous announcement are in red.

Disclaimer Regarding Forward-looking Statements

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Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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