Sumitomo Dainippon Pharma

Financial Results for FY2014 Apr.-Sep.
(Apr. 1 to Sep. 30, 2014)

October 31, 2014

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

Financial Results

for the Six Month Period Ended September 30, 2014

Sumitomo Dainippon Pharma

Financial Results for FY2014 Apr.-Sep.

Billions of yen

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change			FY2014 2Q		FY2014	
			Value	Exchange Impact	Percentage (%)	Forecasts	Progress (%)	Previous forecasts *	Progress (%)
Net sales	181.4	**178.3**	(3.1)	2.9	(1.7)	178.0	100.2	352.0	50.7
Cost of sales	50.4	**48.5**	(2.0)	0.3	(3.9)	51.0	95.0	100.0	48.5
Gross profit	131.0	**129.8**	(1.1)	2.7	(0.9)	127.0	102.2	252.0	51.5
SG&A expenses	113.5	**117.9**	4.4	2.7	3.8	115.0	102.5	232.0	50.8
SG&A expenses less R&D costs	82.0	**84.7**	2.7	2.0	3.3	82.5	102.7	162.0	52.3
R&D Costs	31.5	**33.2**	1.7	0.7	5.3	32.5	102.1	70.0	47.4
Operating income	17.4	**11.9**	(5.5)	(0.0)	(31.5)	12.0	99.5	20.0	59.7
Ordinary income	17.4	**12.7**	(4.7)		(27.0)	11.5	110.5	19.0	66.9
Net income	8.7	**11.8**	3.1		35.2	11.0	106.9	12.0	98.0
E B I T D A	31.8	**22.7**				21.0		38.0	

* The forecasts for FY2014 have been revised.

Exchange Rate:
FY2013 2Q : 1US$ = ¥ 98.9, 1RMB = ¥16.1
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6

Sumitomo Dainippon Pharma

(Reference) Profit impact from Pharma Fee

■ Pharma Fee

Pharma Fee is legislated as a part of health care reform signed by President Obama. This legislation imposed an annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs.

■ Pharma Fee Calculation

Pharma Fee is computed by sales of the products in US government programs, which is calculated by determining the ratio of the entity's sales to the aggregate sales for all entities, and applying this ratio to the applicable amount determined by the law (CY2014:$3.0B).

$$\frac{\text{Sales in Sunovion}}{\text{Aggregated sales of all entities}} \times \text{Applicable amount (CY2014:\$3.0B)}$$

■ Change of expense recognition

	Year of expense recognition
Before	Year when the fee is paid (Following year of the year when sales are recorded)
After	Year when sales are recorded

In addition to expense recognized by previous method, one-time catch up is required by new method in Q2.

■ Profit impact for DSP group

Expense by previous method → **Fee for sales of Apr.-Sep. 2013 ($6.5M)**

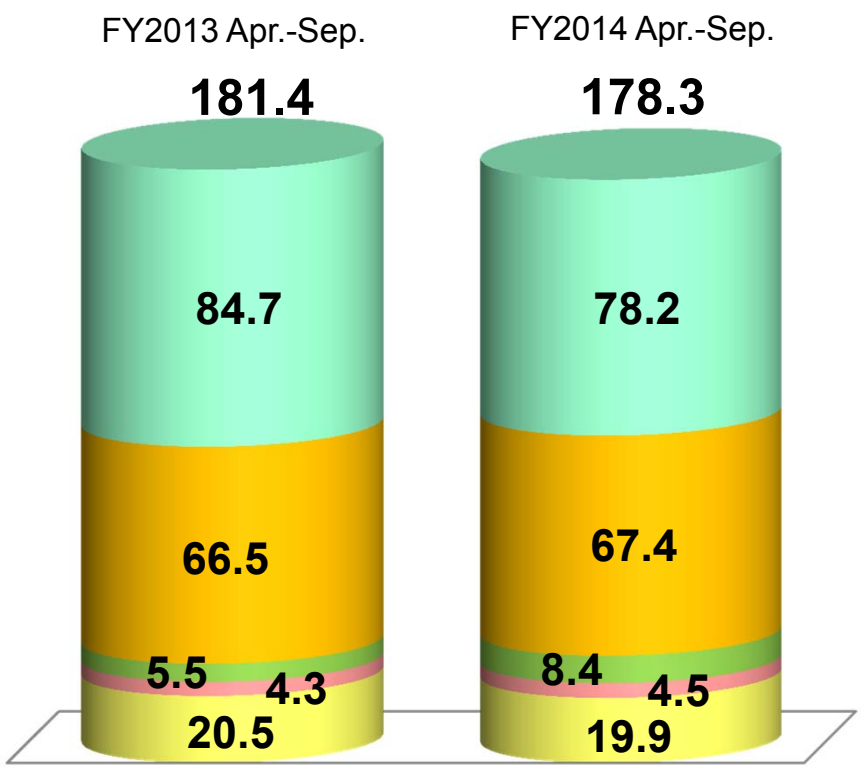
Additional by the change → **Fee for sales of Oct.-Dec. 2013 ($3.4M)**

Fee for sales of Jan.-Sep. 2014 ($15.4M)

We have recorded expense $18.8M as one-time catch up adjustment (This amount was unrecognized as to Sep. 2014).

Net Sales by Segment

Billions of yen



	FY2013 Apr.-Sep.	FY2014 Apr.-Sep.	Change Value	Change Percentage
	181.4	178.3	(3.1)	(1.7)%
Japan	84.7	78.2	(6.5)	(7.7)%
North America	66.5	67.4	1.0	1.4%
China	5.5	8.4	2.9	51.9%
Other Regions	4.3	4.5	0.2	4.2%
Other Business	20.5	19.9	(0.6)	(2.8)%
Overseas Sales	42.1 %	45.2 %		

【 **Japan** 】 Effect from NHI price revision and decrease in long-term listed products
【 **North America** 】Growth of LATUDA® offset drop in LUNESTA®
【**China**】 Strong sales of MEROPEN®

Exchange Rate:
FY2013 2Q : 1US$ = ¥ 98.9, 1RMB = ¥16.1
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6

Sumitomo Dainippon Pharma

Sales in Japan

Billions of yen

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change		FY2014 Apr.-Sep.	
			Value	Percentage (%)	Previous forecasts	Progress (%)
AIMIX®	2.4	**5.4**	3.0	126.5	5.5	97.3
AVAPRO®	6.0	**5.6**	(0.4)	(7.2)	5.5	101.3
LONASEN®	6.2	**5.4**	(0.8)	(12.9)	6.3	85.6
TRERIEF®	4.1	**5.3**	1.2	28.2	5.5	95.7
Strategic Products Total	18.7	**21.6**	2.9	15.6	22.8	94.6
METGLUCO®	7.3	**7.9**	0.6	8.4	7.9	100.3
SUREPOST®	0.7	**1.0**	0.3	44.6	1.5	68.2
AmBisome®	2.4	**2.1**	(0.3)	(11.0)	2.3	91.7
MIRIPLA®	0.6	**0.4**	(0.1)	(24.3)	0.5	87.9
REPLAGAL®	5.0	**4.8**	(0.2)	(4.2)	5.4	89.2
New / Specialty Products Total	16.0	**16.3**	0.3	2.0	17.6	92.7
AMLODIN®	13.9	**9.9**	(4.0)	(29.0)	10.0	98.6
GASMOTIN®	7.8	**5.3**	(2.5)	(32.0)	5.5	96.6
PRORENAL®	7.0	**5.3**	(1.7)	(24.2)	5.5	97.0
MEROPEN®	5.0	**4.1**	(0.9)	(18.2)	4.2	97.0
Others	16.3	**15.7**	(0.6)	(3.7)	14.9	105.2
Japan Total	84.7	**78.2**	(6.5)	(7.7)	80.5	97.1

Note: Sales figures are before reduction of rebates

Sales in North America & China

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	
						Value	Exchange Rate Impact
North America	(Million $)			(Billion yen)			
LATUDA®	162	**354**	192	16.0	**36.5**	20.4	1.5
BROVANA®	80	**93**	13	7.9	**9.6**	1.6	0.4
LUNESTA®	272	**69**	(203)	26.9	**7.1**	(19.8)	0.3
XOPENEX®	68	**50**	(18)	6.7	**5.1**	(1.6)	0.2
Ciclesonide	43	**33**	(10)	4.2	**3.4**	(0.9)	0.1
APTIOM®	—	**9**	9	—	**0.9**	0.9	—
Industrial property revenues	21	**25**	4	2.1	**2.6**	0.5	0.1
Others	25	**22**	(3)	2.5	**2.3**	(0.2)	0.1
Total	672	**654**	(18)	66.5	**67.4**	1.0	2.7
China	(Million RMB)			(Billion yen)			
MEROPEN®	279	**417**	138	4.5	**6.9**	2.4	0.2
Others	63	**86**	24	1.0	**1.4**	0.4	0.0
Total	342	**503**	162	5.5	**8.4**	2.9	0.3

FY2014 Apr.-Sep.		
Previous forecasts		Yen-based Progress
(Million $)	(Billion yen)	(%)
346	35.0	104.2
96	9.7	98.5
60	6.1	116.5
41	4.1	125.4
31	3.1	108.4
12	1.2	76.1
22	2.2	118.5
26	2.6	86.7
634	64.0	105.3
(Million RMB)	(Billion yen)	(%)
420	6.8	101.8
74	1.2	119.6
494	8.0	104.5

Exchange Rate:
FY2013 2Q : 1US$ = ¥ 98.9, 1RMB = ¥16.1
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6

Sumitomo Dainippon Pharma

Segment Breakdown for North America

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

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	Exchange Rate Impact
	(Million $)			(Billion yen)			
Net sales	672	**654**	(18)	66.5	**67.4**	1.0	2.7
Cost of sales	77	**55**	(22)	7.6	**5.7**	(1.9)	0.2
Gross profit	595	**599**	4	58.9	**61.7**	2.9	2.5
SG&A expenses	353	**419**	66	34.9	**43.2**	8.3	1.7
Income (loss) of Segment	243	**180**	(62)	24.0	**18.6**	(5.4)	0.8

< Amortization of patent rights and goodwill, etc. >

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	Exchange Rate Impact
	(Million $)			(Billion yen)			
SG&A expenses	99	**48**	(52)	9.8	**4.9**	(4.9)	0.2
Income (loss) of Segment	(99)	**(48)**	52	(9.8)	**(4.9)**	4.9	(0.2)

Exchange Rate:
FY2013 2Q : 1US$ = ¥ 98.9
FY2014 2Q : 1US$ = ¥103.0

Sumitomo Dainippon Pharma

Segment Information

Billions of yen

		Pharmaceuticals Business						Other Business	Total
		Japan	North America※1	Amortization※2	China	Other Regions	Subtotal		
FY2014 2Q Results	Net sales（Sales to customers）	78.2	67.4	—	8.4	4.5	158.4	19.9	178.3
	Cost of sales	22.8	5.7	—	1.4	2.8	32.7	15.8	48.5
	Gross profit	55.3	61.7	—	7.0	1.7	125.7	4.1	129.8
	SG&A expenses less R&D costs	29.1	43.2	4.9	3.3	1.1	81.6	3.1	84.7
	Income (loss) of Segment	26.2	18.6	(4.9)	3.7	0.6	44.1	1.0	45.1
	R&D costs						32.7	0.4	33.2
	Operating income						11.4	0.6	11.9
FY2013 2Q 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
	Income (loss) of Segment	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
Change	Net sales（Sales to customers）	(6.5)	1.0	—	2.9	0.2	(2.5)	(0.6)	(3.1)
	SG&A expenses less R&D costs	(1.8)	8.3	(4.9)	0.3	0.7	2.6	0.1	2.7
	Income (loss) of Segment	(4.3)	(5.4)	4.9	2.3	(0.9)	(3.4)	(0.4)	(3.8)
	R&D costs						1.7	(0.0)	1.7
	Operating income						(5.1)	(0.4)	(5.5)

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

Exchange Rate:
FY2013 2Q : 1US$ = ¥ 98.9, 1RMB = ¥16.1
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6

Ordinary income & Net income

Billions of yen

	FY2013 Apr.-Sep.	**FY2014 Apr.-Sep.**	Change	
			Value	Percentage(%)
Operating Income	17.4	**11.9**	(5.5)	(31.5)
Non-operating income and expenses	(0.0)	**0.8**	0.8	
Ordinary income	17.4	**12.7**	(4.7)	(27.0)
Extraordinary income	3.8	**10.0**	6.2	
Gain on sales of property, plant and equipment	—	**8.3**		
Compensation income for damage	—	**1.7**		
Gain on sales of investment securities	2.8	**—**		
Fair value adjustment of contingent consideration	1.1	**—**		
Extraordinary loss	6.3	**0.6**	(5.6)	
Business structure improvement expenses	1.7	**0.6**		
Impairment loss	4.6	**—**		
Income taxes	6.3	**10.3**	4.0	
Net income	8.7	**11.8**	3.1	35.2

Financial Position

Billions of yen

	as of Mar.31, 2014	**as of Sep.30, 2014**	Change
Assets	659.0	**670.8**	11.7
Current assets	359.6	**371.8**	12.2
Fixed assets	299.4	**299.0**	(0.4)
Liabilities	260.5	**250.8**	(9.7)
Current liabilities	131.2	**124.9**	(6.3)
Long-term liabilities	129.3	**125.9**	(3.4)
Net assets	398.5	**420.0**	21.5
(Shareholders' equity ratio)	60.5%	62.6%	

（**Assets**）
Marketable securities +21.2　Cash and deposits　+6.8
Notes and accounts receivable　(17.6)
（**Liabilities**）
Decrease in interest-bearing debt　(4.7)　Accounts payable-other (4.5)
（**Net Assets**）
Foreign currency translation adjustment　+13.3　Retained earnings　+7.9

Cash Flows

Billions of yen

Ⅰ Net cash provided by operating activities	**+21.6**
・Income before income taxes and minority interests	+22.1
・Gain on sales of property, plant and equipment	(8.3)
・Decrease in notes and accounts receivable	+19.1
・Income taxes paid	(12.2)
Ⅱ Net cash provided by investing activities	**+15.2**
・Proceeds from sales of property, plant and equipment	+10.6
・Decrease in marketable securities	+5.7
Ⅲ Net cash used in financing activities	**(8.3)**
・Repayment of loans payable	(5.0)
・Cash dividends paid	(3.6)

Cash and cash equivalents at the end of period : 106.3 billion yen
（compared with the beginning of period +32.4 billion yen）

Sumitomo Dainippon Pharma

Financial Forecasts for FY2014

Sumitomo Dainippon Pharma

Forecasts Summary for FY2014
（Change from the previous forecasts）

Positive factor

✓ Favorable sales growth of LATUDA® in North America • Previous forecast：$716M → Latest forecast：$749M	$ +33M
✓ Divestiture of Xopenex IS (Consideration: $45M)	$ +45M
✓ Progress in strengthening business foundation • Promote relocation of sites • Optimize personnel	+ α

Negative factor

✓ Sales decrease in Japan (¥3B)	$－30M
✓ Aggressive expenditure for sales and marketing as up-front investment to maximize sales of LATUDA® • Previous forecast: $376M → Latest forecast : $414M	$－38M
✓ One-time increase in Pharma Fee ($22M up)	$－22M

※Forex sensitivity by 1 yen weak/ 1$　Sales: + ¥1.5B, Operating income: even

Revised Financial Forecasts for FY2014

Billions of yen

	FY2013 (a)	FY2014 Previous Forecasts (b)	**FY2014 Revised Forecasts (c)**	Change (c)-(b)		
				Value	Exchange Rate Impact	Percentage (%)
Net sales	387.7	352.0	**366.0**	14.0	6.8	4.0
Cost of sales	104.1	100.0	**100.5**	0.5	0.7	0.5
Gross profit	283.6	252.0	**265.5**	13.5	6.1	5.4
SG&A expenses	241.5	232.0	**245.5**	13.5	6.1	5.8
SG&A expenses less R&D costs	171.6	162.0	**173.5**	11.5	4.5	7.1
R&D costs	69.8	70.0	**72.0**	2.0	1.6	2.9
Operating income	42.1	20.0	**20.0**	—	0.0	—
Ordinary income	40.6	19.0	**19.5**	0.5		2.6
Net income	20.1	12.0	**14.0**	2.0		16.7
EBITDA	68.1	38.0	**39.0**	1.0		2.6

Exchange Rate:

FY2013 : 1US$ = ¥100.2, 1RMB= ¥16.4

FY2014 Previous forecast : 1US$ = ¥100.6, 1RMB = ¥16.1

FY2014 Revised forecast : 1US$ = ¥105.0, 1RMB = ¥17.0

Sumitomo Dainippon Pharma

Sales by Product in Japan Segment

Billions of yen

	FY2013	FY2014 Previous Forecasts	FY2014 Revised Forecasts	Change
AIMIX®	6.9	12.8	**12.8**	—
AVAPRO®	12.1	11.6	**11.6**	—
LONASEN®	12.6	13.5	**12.3**	(1.2)
TRERIEF®	9.5	11.7	**12.1**	0.4
Strategic products total	41.1	49.6	**48.8**	(0.8)
METGLUCO®	15.8	16.1	**17.1**	1.0
SUREPOST®	1.7	3.2	**2.5**	(0.7)
AmBisome®	4.8	5.4	**4.9**	(0.5)
MIRIPLA®	1.2	1.0	**1.0**	—
REPLAGAL®	9.8	10.8	**10.0**	(0.8)
New / Specialty products total	33.2	36.5	**35.5**	(1.0)
AMLODIN®	27.0	20.0	**19.7**	(0.3)
GASMOTIN®	15.0	10.5	**10.5**	—
PRORENAL®	13.5	10.5	**10.5**	—
MEROPEN®	9.8	8.1	**8.1**	—
Others	32.2	27.8	**26.9**	(0.9)
Japan total	171.9	163.0	**160.0**	(3.0)

Note: Sales figures are before reduction of rebates.

Sales by Product in North America and China Segments

	FY2013	FY2014 Previous Forecasts	**FY2014 Revised Forecasts**	Change	FY2013	FY2014 Previous Forecasts	**FY2014 Revised Forecasts**	Change
North America	(Million $)				(Billion yen)			
LATUDA®	421	716	**749**	33	42.2	72.0	**78.7**	6.7
BROVANA®	168	207	**207**	—	16.8	20.8	**21.8**	1.0
LUNESTA®	579	85	**88**	3	58.0	8.5	**9.3**	0.8
XOPENEX®	121	68	**62**	(6)	12.1	6.8	**6.6**	(0.2)
Ciclesonide	81	59	**54**	(5)	8.2	5.9	**5.6**	(0.3)
APTIOM®	—	35	**35**	—	—	3.5	**3.6**	0.1
Industrial property revenues	41	33	**87**	54	4.1	3.3	**9.1**	5.8
Others	40	32	**41**	9	4.0	3.2	**4.3**	1.1
Total	1,450	1,233	**1,324**	91	145.3	124.0	**139.0**	15.0
China	(Million RMB)				(Billion yen)			
MEROPEN®	597	807	**823**	16	9.8	13.0	**14.0**	1.0
Others	131	155	**159**	4	2.1	2.5	**2.7**	0.2
Total	727	963	**982**	19	11.9	15.5	**16.7**	1.2

Exchange Rate:
FY2014 Previous forecast : 1US$ = ¥100.6, 1RMB = ¥16.1
FY2014 Revised forecast : 1US$ = ¥105.0, 1RMB = ¥17.0

Sumitomo Dainippon Pharma

Revised Forecasts for FY2014 (by Segment)

Billions of yen

		Pharmaceuticals Business						Other Business	Total
		Japan	North America※1	Amortization※2	China	Other Regions	Subtotal		
FY2014 Revised Forecasts	Net sales（Sales to customers）	160.0	139.0	—	16.7	8.3	324.0	42.0	366.0
	Cost of sales	48.1	11.0	—	3.3	5.1	67.5	33.0	100.5
	Gross profit	112.0	128.0	—	13.4	3.2	256.6	8.9	265.5
	SG&A expenses less R&D costs	59.5	89.0	9.4	6.8	2.4	167.1	6.4	173.5
	Income (loss) of Segment	52.5	39.0	(9.4)	6.6	0.8	89.5	2.5	92.0
	R&D costs						71.0	1.0	72.0
	Operating income						18.5	1.5	20.0
FY2014 Previous Forecasts	Net sales（Sales to customers）	163.0	124.0	—	15.5	7.8	310.3	41.7	352.0
	Cost of sales	49.2	11.2	—	3.1	4.4	67.9	32.1	100.0
	Gross profit	113.9	112.8	—	12.4	3.4	242.5	9.5	252.0
	SG&A expenses less R&D costs	59.9	78.8	8.3	6.5	2.0	155.5	6.5	162.0
	Income (loss) of Segment	54.0	34.0	(8.3)	5.9	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
Change	Net sales（Sales to customers）	(3.0)	15.0	—	1.2	0.5	13.7	0.3	14.0
	SG&A expenses less R&D costs	(0.4)	10.2	1.1	0.3	0.4	11.6	(0.1)	11.5
	Income (loss) of Segment	(1.5)	5.0	(1.1)	0.7	(0.6)	2.5	(0.5)	2.0
	R&D costs						2.0	—	2.0
	Operating income						0.5	(0.5)	—

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

Exchange Rate:
FY2014 Previous forecast : 1US$ = ¥100.6, 1RMB = ¥16.1
FY2014 Revised forecast : 1US$ = ¥105.0, 1RMB = ¥17.0

Towards Sustainable Growth

Sumitomo Dainippon Pharma

Towards achieving the goals of 3rd MTBP

Significant upward revision of LATUDA® sales

+

Thanks to weak yen

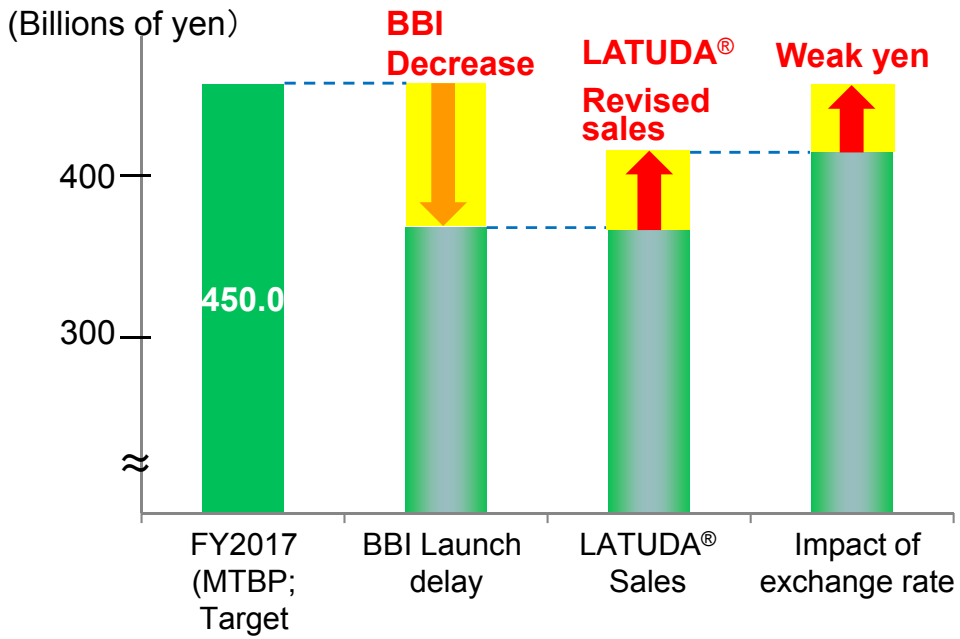
MTBP Goals (Net sales: 450.0 billion yen, Operating income: 80.0 billion yen) not to be changed

	FY2017 (Goals)
Net Sales	450.0
Operating income	80.0
Exchange rate	80.0 yen/$

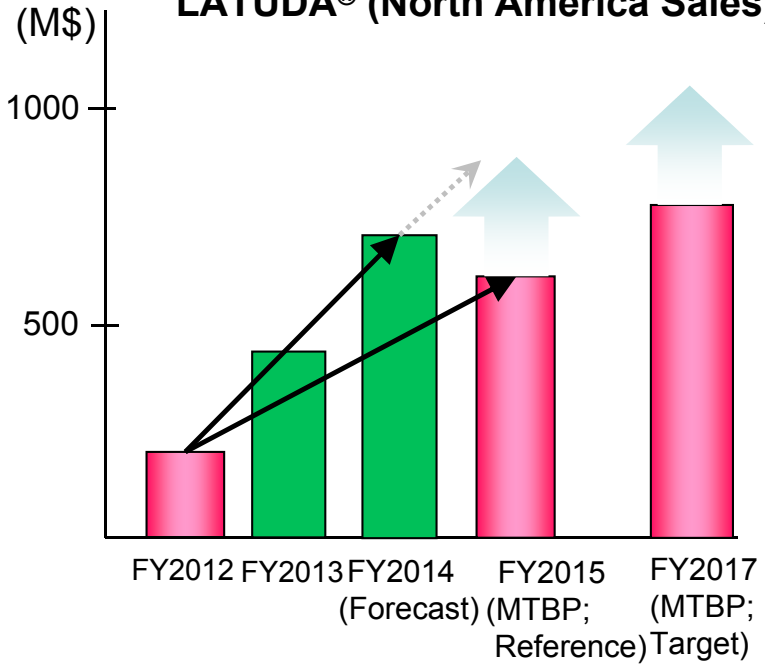
(Billions of yen)

	FY2017 (Goals)
No Change	450.0
No Change	80.0
Change	100.0yen/$

FY2017 Net Sales goal

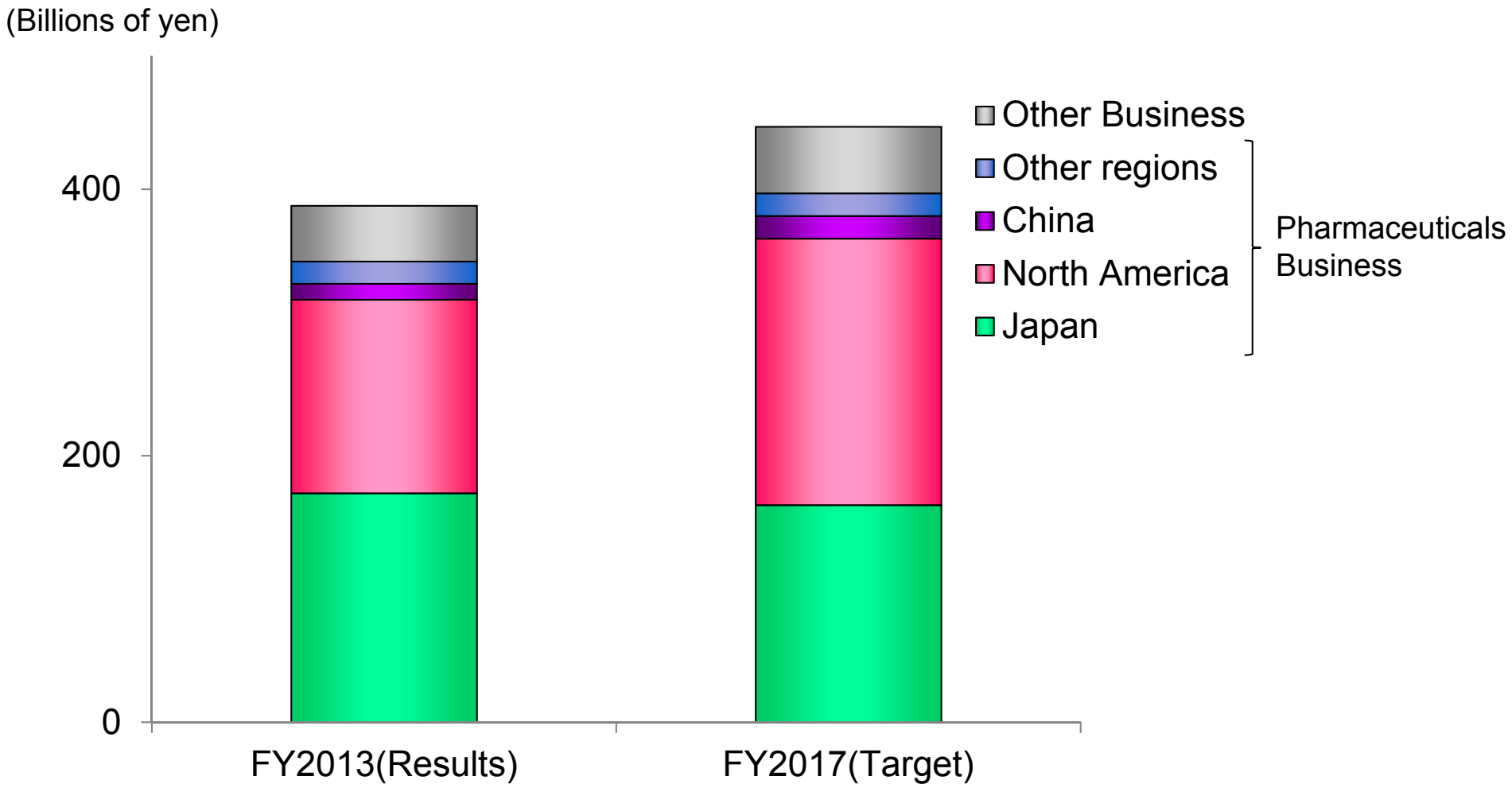


LATUDA® (North America Sales)



3rd MTBP: Regional Strategy

North America: Grow LATUDA®
Japan: Expand new products to offset revenue drop of long-listed brands



Sumitomo Dainippon Pharma

Product Launch Plan

FY2013～FY2015

Japan

- SUREPOST®<repaglinide> (Type 2 diabetes/ Combination therapies with DPP-4 inhibitors)

U.S.

- LATUDA® <lurasidone hydrochloride> (Bipolar Maintenance)
- APTIOM® <eslicarbazepine acetate> (Epilepsy-monotherapy)

China

- LONASEN® <blonanserin> (Schizophrenia)
- CALSED® <amurubicin hydrochloride> (Small cell lung cancer)

U.K.

FY2016～FY2017

Japan

- SM-13496<lurasidone hydrochloride> (Schizophrenia)
- EPI-743 (Leigh syndrome)
- AS-3201<ranirestat> (Diabetic neuropathy/ neuropathy)
- BBI608 (Gastric cancer/Gastro-esophageal junction adenocarcinoma)

U.S.

- BBI608 (Gastric cancer/Gastro-esophageal junction adenocarcinoma)
- SUN-101<glycopyrrolate bromide> (COPD)

China

- SM-13496<lurasidone hydrochloride> (Schizophrenia)

U.K.

- SM-13496<lurasidone hydrochloride> (Bipolar disorder)

FY2018～FY2021 (not all)

Japan

- SM-13496 <lurasidone hydrochloride> (Bipolar depression)
- LONASEN® <blonanserin> (Schizophrenia/ Transdermal patch)
- DSP-1747< obeticholic acid > (NASH)
- DSP-6952 (IBS with constipation, Chronic idiopathic constipation)
- BBI608 (Colorectal cancer, etc.)
- BBI503 (Solid tumors)
- WT4869 (Hematologic cancer/ Solid cancer)
- iPS cell-derived RPE cells (HLS001) (Age-related macular degeneration)

Overseas

- SEP-225289 <dasotraline> (ADHD)
- SB623 (Chronic Stroke)
- DSP-2230 (Neuropathic pain)
- SEP-363856 (Schizophrenia)
- BBI608 (Colorectal cancer, etc.)
- BBI503 (Solid tumors)
- WT2725 (Solid cancer/ Hematologic cancer)

Sumitomo Dainippon Pharma

: P&N
: Oncology
: Diabetes
: Respiratory
: liver/ digestive
New Chemical Entities
New Indication etc.

LATUDA® Patent expiries measures

Expansion of R&D to offset LATUDA's loss of exclusivity and sustainable growth

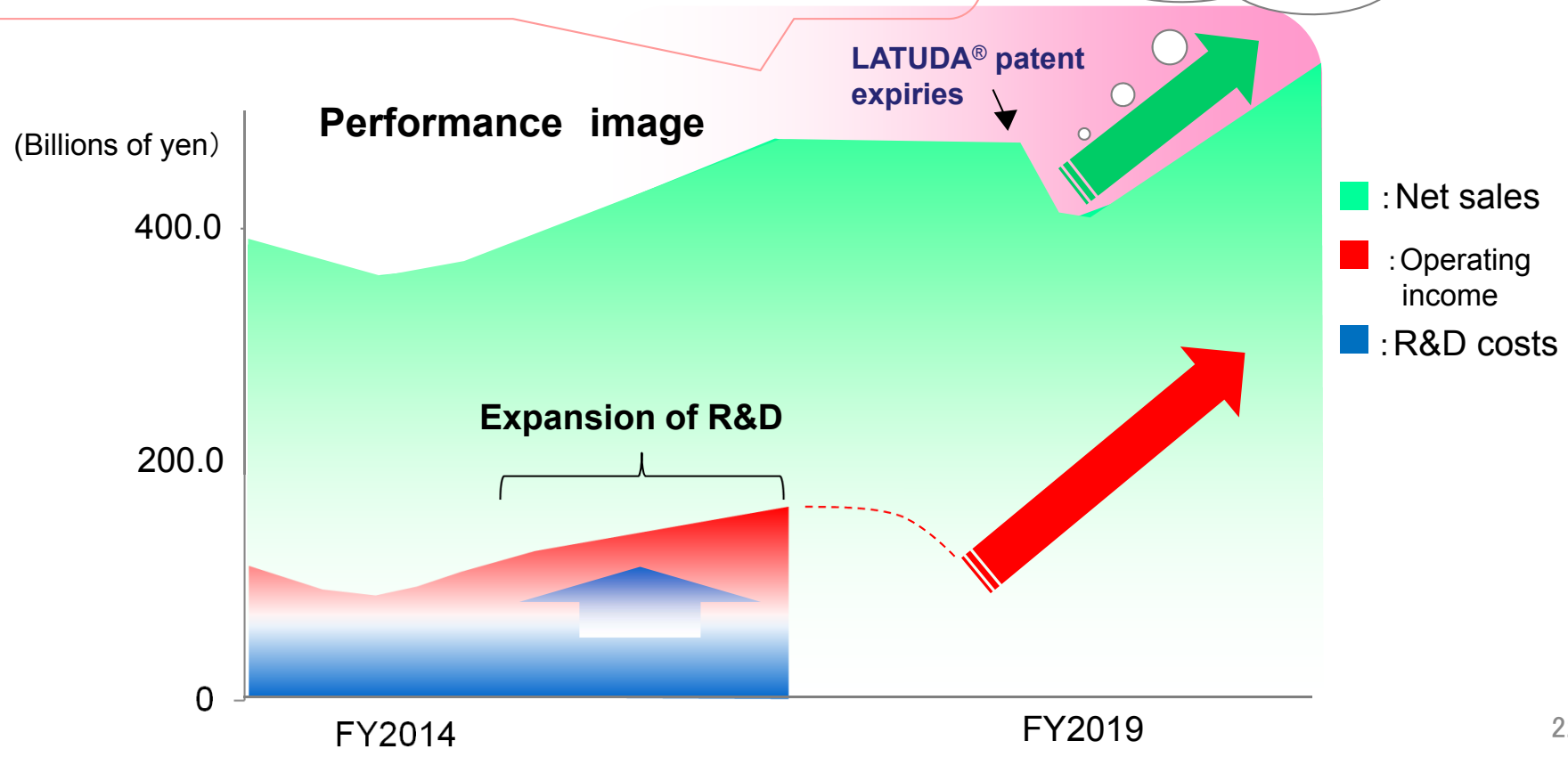
- ✓ Accelerate development in late-stage pipeline in North America and Japan
- ✓ Proactively promote in-license and M&A

Main Launch Products

North America BBI608,BBI503,SUN-101,SEP-225289,SB623, etc.

Japan BBI608,BBI503, lurasidone, ranirestat, DSP-1747, etc.

Work to exceed forecasts by in-license and M&A



Clinical Development Status

Sumitomo Dainippon Pharma

Development Pipeline (1) (as of October 30, 2014)

Psychiatry & Neurology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA® (SM-13496)	lurasidone hydrochloride	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	(New indication) Epilepsy- Monotherapy	U.S. / Canada				
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				※1
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				

Revisions since the previous announcement are in red.

※1 Phase II/III study

Development Pipeline (2) (as of October 30, 2014)

Oncology Area

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.	Accrual of new patients has been stopped			
		Gastric cancer, Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy)	U.S. / Canada			※1	
		Hepatocellular carcinoma (Combination therapy)	U.S.		※2		
		Gastrointestinal cancer (Combination therapy)	U.S. / Canada				
		Pancreatic cancer (Combination therapy)	U.S.				
BBI503	TBD	Solid tumors (Monotherapy)	U.S. / Canada			※1	
		Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)	Canada				
		Hepatocellular carcinoma (Combination therapy)	U.S.		※2		
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic cancers	U.S.				
		Solid tumors	Japan				

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 October 30, 2014)

Respiratory Area

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 Area

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 Areas

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				

Approved

Revisions since the previous announcement are in red.

Sumitomo Dainippon Pharma

Clinical Development Status
(Major Changes since July 30, 2014)

METGLUCO®

- Approved in Japan for pediatric usage (August 2014)

APTIOM®

- Submitted in the U.S. for epilepsy (monotherapy) (October 2014)

SEP-225289

- Started Phase III for Adult Attention-Deficit Hyperactivity Disorder (ADHD) in the U.S.
- Started Phase I for Pediatric Attention-Deficit Hyperactivity Disorder (ADHD) in the U.S.

LONASEN® (New formulation: Transdermal patch)

- Started Phase III for schizophrenia in Japan

BBI608

- Japan sites added to Phase III global clinical trial for Gastric cancer, Gastro-esophageal junction adenocarcinoma (combination therapy with paclitaxel)
- Started Phase I of Phase I / II for Hepatocellular carcinoma (combination therapy with sorafenib) in the U.S.
- Started Phase I for Pancreatic cancer (combination therapy with gemcitabine and nab-paclitaxel) in the U.S.

BBI503

- Started Phase I of Phase I / II for Hepatocellular carcinoma (combination therapy with sorafenib) in the U.S.

Newly added

- SB623 (U.S.：Phase II)
- DSP-3748 (U.S.：Phase I)

Discontinued

- DSP-3025 (Japan：Phase I)

Target submission date 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/ Canada.	Submitted in Oct. 2014			
	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			●	
	SEP-225289 <dasotraline> (Adult , Pediatric ADHD) U.S				●
Cancer Field	BBI608 (Gastric cancer, Gastro-esophageal junction adenocarcinoma／Combination therapy) U.S./ Japan				●
	BBI503 (Solid cancer／ Monotherapy) U.S./ Japan				●
Respiratory Field	SUN-101<glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.			●	

Sumitomo Dainippon Pharma

New Chemical Entities | New Indication etc.

Development Status of Oncology area (BBI608, BBI503)

Sumitomo Dainippon Pharma

BBI608: Data Analysis schedule of Phase III Clinical Study of BBI608 in Adult Patients With Advanced Colorectal Cancer (CO.23 study)

- **Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014**
  - Randomized, double-blind, placebo-controlled study of BBI608 in patients with advanced colorectal cancer who have failed all available therapies
  - Global sponsor: NCIC-CTG
  - Locations: U.S. / Canada / Japan / etc.
  - The protocol-defined first interim analysis of the initial 97 patients enrolled into the CO.23 study has been completed. DSMC recommended that further enrollment of new patients be stopped and all study drug be discontinued because while there is no safety concern, the futility analysis, based on DCR (disease control rate), met protocol defined criteria for stopping.

- Data analysis of the approximately 280 patients (who have been enrolled in this study) in progress
- Analysis plan (by NCIC-CTG)

✓ By 2014 : disease control rate (DCR), progression-free survival (PFS), patient background, etc.

✓ By 1H 2015 : Overall survival (OS), Biomarker

➡ Development plan of colorectal cancer (monotherapy) will be considered based on the result of this clinical study.

*NCIC-CTG retains the publication right of the data.

BBI608 - Clinical development status

U.S., Canada, Japan, etc.

- **Gastric cancer/ Gastro-esophageal junction adenocarcinoma (Combination therapy)**
  Phase III in progress (initiated in 1Q 2014)
  - ✓ Japan sites added in Phase III global clinical study (initiated in 3Q 2014)

Target submission date
North America and Japan
FY2017

U.S., Canada

- **Colorectal cancer (Combination with Cetuximab, Panitumumab, or Capecitabine)**
  Phase II in progress (initiated in 1Q 2012)
- **Solid tumors (Combination with paclitaxel)**
  Phase II of Phase I / II in progress (initiated in 2Q 2013)
  Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.
- **Gastrointestinal cancer (Combination with FOLFOX[*1],FOLFOX[*1] and Bevacizumab, CAPOX[*2], FOLFIRI[*3], FOLFIRI[*3] and Bevacizumab, or Regorafenib)**
  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)

U.S.

- **Hepatocellular carcinoma (Combination therapy with sorafenib)**
  Phase I of Phase I / II in progress (initiated in 3Q 2014)
- **Pancreatic cancer (Combination therapy with gemcitabine and nab-paclitaxel)**
  Phase I in progress (initiated in 3Q 2014)

Revisions since the previous announcement are in red.

Phase III Clinical Study of BBI608 in Gastric and Gastro-Esophageal Junction Adenocarcinoma (BRIGHTER) (BBI608-336 study)

ClinicalTrials.gov (NCT02178956)

- A phase III clinical trial of BBI608 plus weekly paclitaxel vs. placebo plus weekly paclitaxel in adult patients with advanced of BBI608 in patients with gastric cancer and gastro-esophageal junction adenocarcinoma, previously treated
- Study Design：randomized, double-blind, multi-center, phase III study
  - ✓ BBI608 (480mg bid) + weekly paclitaxel (80 mg/m^2 i.v.)
  - ✓ Placebo + weekly paclitaxel (80 mg/m^2 i.v.)
- Primary Objective：Overall Survival (OS)
- Secondary Objectives：Progression Free Survival (PFS), Objective Response Rate (ORR), Disease Control Rate (DCR), etc.
- Estimated Enrollment: 680
- Locations: U.S. / Canada / Japan / etc.

Sumitomo Dainippon Pharma

BBI503 - Clinical development status

U.S., Canada

- **Solid tumors (Monotherapy)**
  Phase II of Phase I / II in progress (initiated in 2Q 2014)
  Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

Target submission date
North America and Japan
FY2017 (Cancer type: TBD)

Canada

- **Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)**
  Phase II in progress (initiated in 2Q 2014)

U.S.

- **Hepatocellular carcinoma (Combination therapy with sorafenib)**
  Phase I of Phase I / II in progress (initiated in 3Q 2014)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

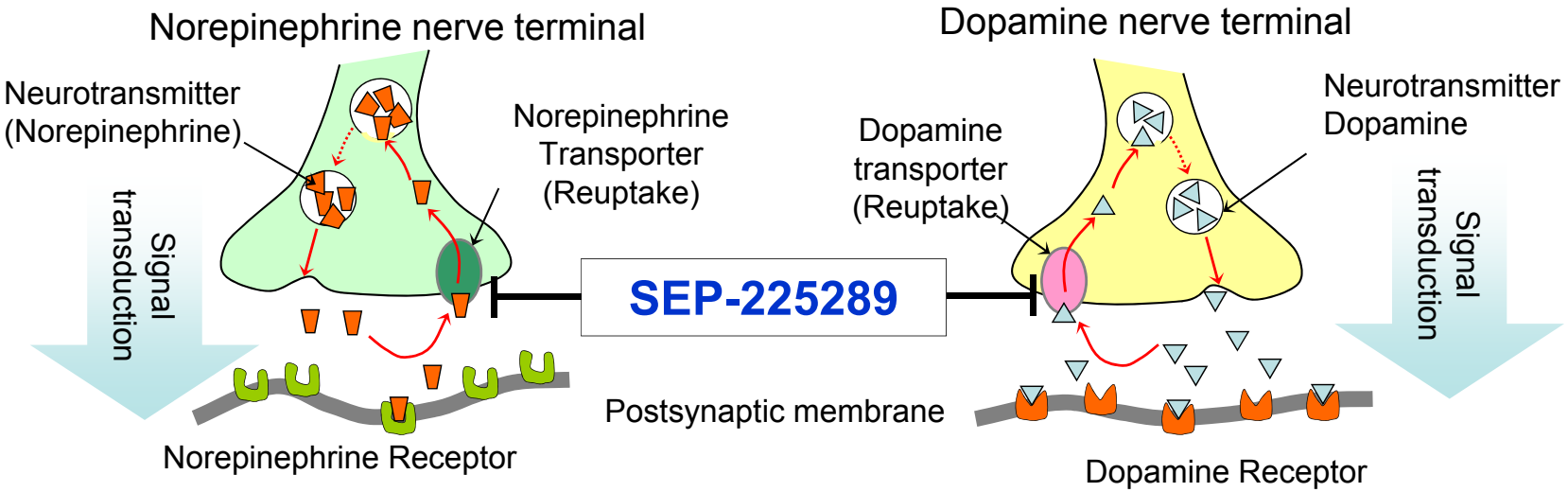
Progress of Psychiatry & Neurology area (SEP-225289, DSP-3748)

Sumitomo Dainippon Pharma

SEP-225289: Started of Phase III Clinical Study of Adult Attention-deficit hyperactivity disorder (ADHD)

- Phase III of SEP-225289 in adult subjects with attention-deficit hyperactivity disorder (ADHD)
- Study Design：multi-center, double-blind, randomized (SEP-225289 4mg, 6mg. placebo)
- Primary Objective：ADHD Rating Scale Ver. IV
- Secondary Objectives：CGI-S：Clinical Global Impressions-Severity of Illness scale, etc.
- Estimated Enrollment: 600
- Locations: U.S.

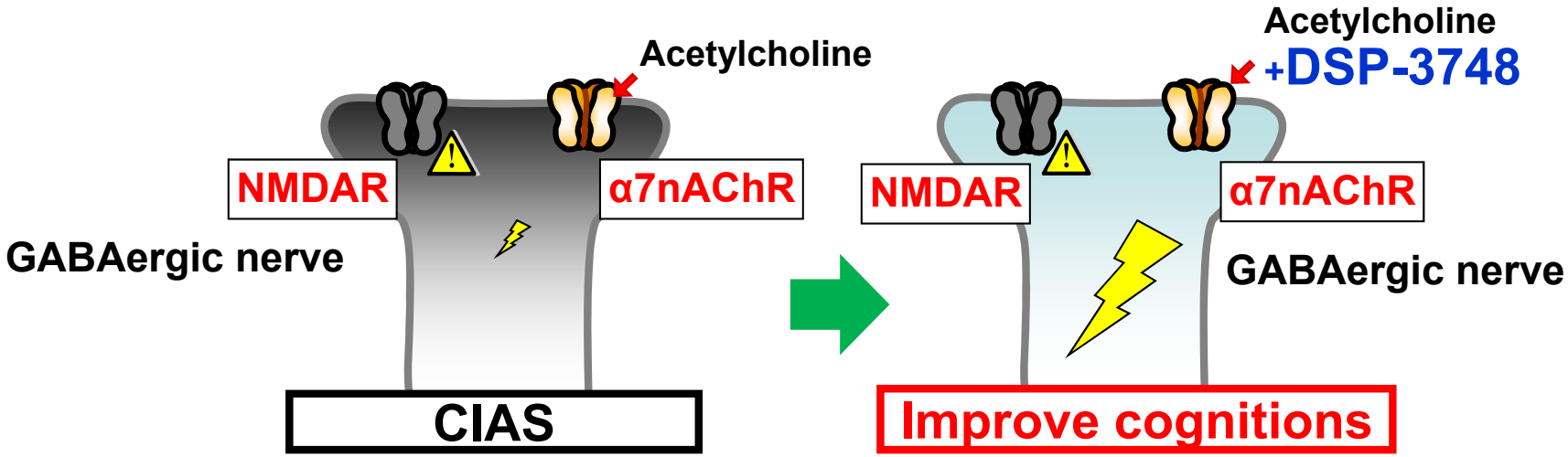
Pharmacological Mechanism: Dopamine and Norepinephrine Reuptake Inhibitor (DNRI)



Sumitomo Dainippon Pharma

Profile of DSP-3748

- Target Indication: Cognitive Impairment Associated with Schizophrenia (CIAS), Adjunctive therapy
- Origin: In-house
- Pharmacological Mechanism: Positive allosteric modulator (PAM) for α7 type nicotinic acetylcholine receptor (α7nAChR)
- Development stage: Phase I in the U.S.
- Characteristics:
  - ✓ Adjunctive therapy with antipsychotics for the treatment of CIAS by enhancing the ACh transmission via α7nAChR
  - ✓ DSP-3748 may have superiority to Orthosteric agonists (competitors) because PAM may not desensitize the target molecule



NMDAR: N-methyl-D-aspartic acid receptor

Sumitomo Dainippon Pharma

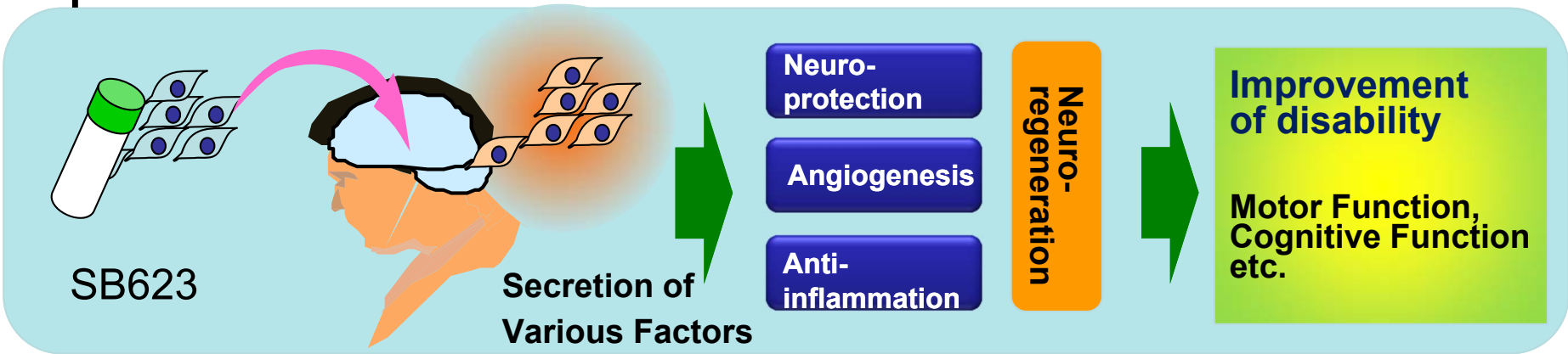
Progress of
Regenerative Medicine / Cell Therapy

Sumitomo Dainippon Pharma

SB623: Joint development and license agreement in North America

- Target Indication: Chronic stroke
- License: Joint development and license agreement for exclusive marketing rights in North America in September 2014
- Origin: SanBio, Inc.
- Pharmacological Mechanism: SB623 cells secrete various trophic factors that exert to promote regeneration and activation of the central nervous
- Development stage: Phase II in the U.S.
- Characteristics:
  - ✓ SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors
  - ✓ Expect to function by secreting proteins that aid the regenerative process
  - ✓ In preclinical and clinical studies to date, SB623 has shown beneficial results on Chronic stroke disability with no serious adverse events which are associated with SB623
  - ✓ Unlike autologous cell therapy, which requires individualized cell preparation at the health care institution, SB623 enables delivery of uniform quality products to a large number of stroke patients

Expected Mode of Action



Regenerative Medicine/Cell Therapy of Business Plan

	Partnering	Region	cell type	Schedule for practical use
				2014 / 2015 / 2016 / 2017 / 2018 / 2019 / 2020
Stroke※1	**SanBio**	North America	Allo MSC	Ph1/2 → Ph2b → Ph3 → Launch
AMD※1 (age-related macular degeneration)	**Healios RIKEN**	Japan	Allo iPS cell	Clinical research (autologous) → Investigator initiated clinical trial → Launch
Parkinson's disease※2	**Kyoto Uni CiRA**	global	Allo iPS cell	Clinical research (autologous) → Investigator or corporate initiated clinical trial
Retinitis pigmentosa	**RIKEN**	global	Allo iPS cell	Investigator initiated clinical trial
Spinal Cord Injury	**Keio Uni, Osaka National Hospital**	global	Allo iPS cell	Clinical research (allogenic)

※1 : Schedule change in October 2014

※2 : Newly added in October 2014 (Started joint research in May 2014)

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.

Sumitomo Dainippon Pharma