10th Anniversary

Sumitomo Dainippon Pharma

Financial Results for FY2015 Apr.-Sep.
(Apr. 1 to Sep. 30, 2015)

October 29, 2015

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

Financial Results

for the Six Month Period Ended September 30, 2015

Sumitomo Dainippon Pharma

Financial Results for FY2015 Apr.-Sep.

Billions of yen

	FY2014 Apr.-Sep.	**FY2015 Apr.-Sep.**	Change			FY2015 2Q		FY2015	
			Value	Exchange Impact	Percentage (%)	Previous forecasts	Progress (%)	Previous forecasts July, 29	Progress (%)
Net sales	178.3	**198.9**	20.6	15.4	11.6	197.5	100.7	401.0	49.6
Cost of sales	48.5	**52.1**	3.6	1.6	7.5	51.8	100.6	103.5	50.3
Gross profit	129.8	**146.8**	17.0	13.8	13.1	145.7	100.8	297.5	49.4
SG&A expenses	117.9	**130.0**	12.1	12.7	10.3	134.7	96.5	270.5	48.1
SG&A expenses less R&D costs	84.7	* **89.8**	5.1	8.9	6.0	92.2	97.4	181.0	49.6
R&D costs	33.2	**40.2**	7.0	3.8	21.2	42.5	94.6	89.5	44.9
Operating income	11.9	**16.8**	4.9	1.0	41.0	11.0	153.2	27.0	62.4
Ordinary income	12.7	**17.5**	4.8		37.7	11.0	159.1	26.5	66.0
Net income attributable to owners of the parent	11.8	**13.2**	1.5		12.4	8.0	165.2	18.0	73.4
E B I T D A	22.7	**27.7**	5.0			21.7		47.8	

* 2Q SG&A expenses less R&D costs vs forecast (2.4)
  - Cost reversal due to fair value change of contingent consideration liabilities.

Exchange Rate:
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6
FY2015 2Q : 1US$ = ¥121.9, 1RMB = ¥19.5
FY2015 (previous forecast) : 1US$ = ¥120.4, 1RMB = ¥19.5

2Q Major Products Sales in Japan

Billions of yen

	FY2014 Apr.-Sep.	**FY2015 Apr.-Sep.**	Change		FY2015 Apr.-Sep.	
			Value	Percentage (%)	Previous forecasts	Progress (%)
AIMIX®	5.4	**7.0**	1.6	30.8	7.8	89.8
AVAPRO®	5.6	**5.4**	(0.2)	(3.0)	5.8	93.2
LONASEN®	5.4	**6.3**	0.9	17.2	6.4	98.8
TRERIEF®	5.3	**6.5**	1.2	23.1	7.0	92.5
Strategic Products Total	21.6	**25.2**	3.6	16.8	27.0	93.3
SUREPOST®	1.0	**1.7**	0.6	63.0	1.7	98.1
AmBisome®	2.1	**2.1**	0.0	1.5	2.4	89.3
REPLAGAL®	4.8	**5.2**	0.4	8.0	5.4	96.3
METGLUCO®	7.9	**8.4**	0.5	6.1	8.0	105.1
AMLODIN®	9.9	**8.4**	(1.5)	(15.1)	8.9	94.0
GASMOTIN®	5.3	**4.4**	(1.0)	(18.1)	4.4	98.9
PRORENAL®	5.3	**4.6**	(0.8)	(14.5)	4.7	97.0
MEROPEN®	4.1	**3.3**	(0.7)	(18.1)	3.6	92.6
Others	16.1	**10.8**	(5.4)	(33.3)	12.6	85.4
Other Products Total	56.6	**48.8**	(7.8)	(13.8)	51.7	94.4
Japan Total	78.2	**74.0**	(4.2)	(5.3)	78.7	94.0

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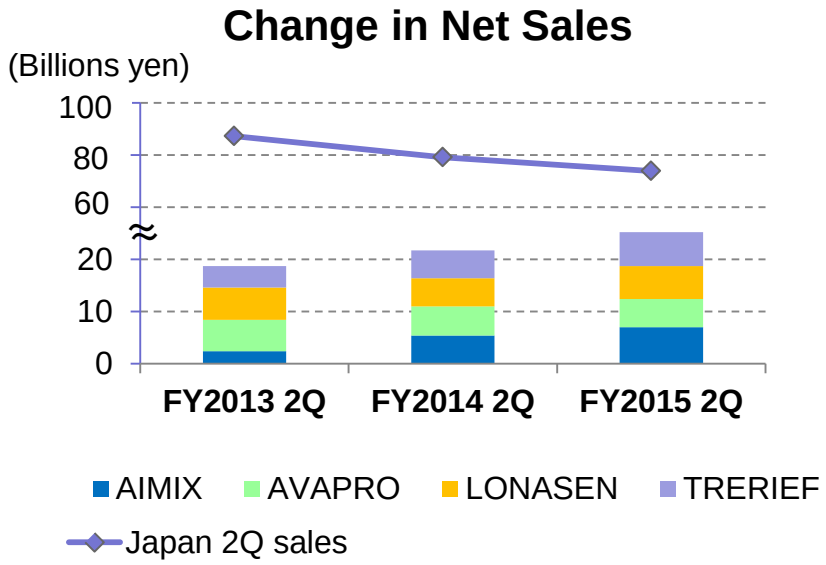
Note: Japan segment sales figures are before reduction of rebates

Topics of FY2015 1H <Japan segment>

- **4 strategic products sales increased by strengthened efforts**
- **Long listed products sales significantly decreased**
- **Launched new two products**



➢ **Trulicity®**

- **Launched in September 2015. Expect expansion in glucagon-like peptide-1 (GLP-1) market**
- **The injector won "Good Design Award 2015" and was selected as one of 2015 Good Design Best 100**
- **Sales target: JPY 20 billion (Peak year)**

➢ **REMITCH®**

- **Started promotion in May 2015**
- **Increase public knowledge and awareness about pruritus in chronic liver disease**

2Q Major Products Sales in North America & China

	FY2014 2Q	**FY2015 2Q**	Change	FY2014 2Q	**FY2015 2Q**	Change		FY2015 2Q		
						Value	Exchange Rate Impact	Previous forecasts		Yen-based Progress
North America	(Million $)			(Billion yen)				(Million $)	(Billion yen)	(%)
LATUDA®	354	**472**	118	36.5	**57.6**	21.1	8.9	469	56.5	101.9
APTIOM®	9	**27**	18	0.9	**3.3**	2.4	0.5	23	2.8	117.7
BROVANA®	93	**120**	27	9.6	**14.6**	5.0	2.3	103	12.4	117.6
Ciclesonide	33	**31**	(2)	3.4	**3.7**	0.4	0.6	26	3.2	116.5
XOPENEX®	50	**29**	(21)	5.1	**3.5**	(1.6)	0.5	18	2.2	160.6
LUNESTA®	69	**22**	(47)	7.1	**2.7**	(4.4)	0.4	18	2.2	123.0
Industrial property revenues	25	**20**	(6)	2.6	**2.4**	(0.2)	0.4	19	2.3	103.9
Others	22	**19**	(2)	2.3	**2.4**	0.1	0.4	20	2.4	98.6
Total	654	**740**	85	67.4	**90.2**	22.7	14.0	696	84.0	107.3
China	(Million RMB)			(Billion yen)				(Million RMB)	(Billion yen)	(%)
MEROPEN®	417	**417**	0	6.9	**8.1**	1.2	1.2	429	8.4	96.4
Others	86	**76**	(11)	1.4	**1.5**	0.0	0.2	90	1.7	86.5
Total	503	**492**	(11)	8.4	**9.6**	1.2	1.4	519	10.1	94.8

Exchange Rate:
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6
FY2015 2Q : 1US$ = ¥121.9, 1RMB = ¥19.5
FY2015 (previous forecast) : 1US$ = ¥120.4, 1RMB = ¥19.5

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Topics of FY2015 1H <North America segment>

◆ Solid expansion of 3 strategic products

➢ LATUDA®

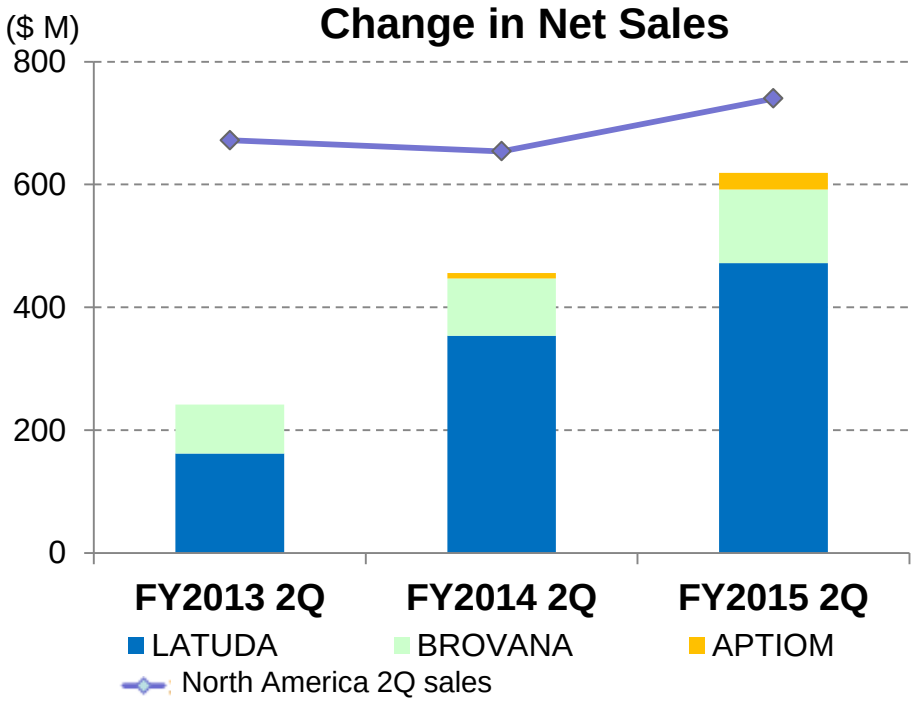
- Achieved the target for 1H of FY2015
- Expanded sales firmly despite the launch of ABILIFY generics and the new drug REXULTI (brexpiprazole)

➢ BROVANA®

- Steady growth ahead of the forecast
- Expanded in home health care and hospital channels

➢ APTIOM®

- Steady growth ahead of the forecast
- Obtained the monotherapy approval in August 2015



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2Q Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2015 2Q Results	Net sales（Sales to customers）	74.0	90.2	9.6	4.7	178.4	20.5	198.9
	Cost of sales	22.7	8.6	1.7	2.6	35.6	16.5	52.1
	Gross profit	51.3	81.6	7.8	2.1	142.8	4.0	146.8
	SG&A expenses less R&D costs	29.3	52.0	4.0	1.3	86.6	3.1	89.8
	Income (loss) of Segment	22.1	29.5	3.8	0.8	56.2	0.9	57.0
	R&D costs					39.8	0.4	40.2
	Operating income					16.4	0.4	16.8
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	48.1	3.3	1.1	81.6	3.1	84.7
	Income (loss) of Segment	26.2	13.7	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
Change	Net sales（Sales to customers）	(4.2)	22.7	1.2	0.2	20.0	0.6	20.6
	SG&A expenses less R&D costs	0.1	4.0	0.7	0.2	5.0	0.0	5.1
	Income (loss) of Segment	(4.1)	15.8	0.1	0.2	12.0	(0.1)	11.9
	R&D costs					7.0	0.0	7.0
	Operating income					5.0	(0.1)	4.9

Exchange Rate:
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6
FY2015 2Q : 1US$ = ¥121.9, 1RMB = ¥19.5

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2Q Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2014 2Q	**FY2015 2Q**	Change	
			Value	Percentage(%)
Operating Income	11.9	**16.8**	4.9	41.0
Non-operating income and expenses	0.8	**0.7**	(0.1)	
Ordinary income	12.7	**17.5**	4.8	37.7
Extraordinary income	10.0	**6.1**	(3.9)	
Gain on sales of investment securities	—	**6.1**		
Gain on sales of property, plant and equipment	8.3	**—**		
Compensation income for damage	1.7	**—**		
Extraordinary loss	0.6	**0.2**	(0.5)	
Impairment loss	—	**0.2**		
Business structure improvement expenses	0.6	**—**		
Income taxes	10.3	**10.2**	(0.1)	
Net income attributable to owners of the parent	11.8	**13.2**	1.5	12.4

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Financial Forecasts for FY2015

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Financial Forecasts for FY2015

Billions of yen

	FY2014 (a)	FY2015 Previous Forecasts (b)	**FY2015 Revised Forecasts (c)**	**Change vs Previous (c)-(b) (d)**	Change vs FY2014 (c)-(a)		
					Value	Exchange Impact	%
Net sales	371.4	401.0	**401.0**	**0.0**	29.6	17.1	8.0
Cost of sales	101.2	103.5	**103.5**	**0.0**	2.3	1.4	2.2
Gross profit	270.1	297.5	**297.5**	**0.0**	27.4	15.7	10.1
SG&A expenses	246.9	270.5	**268.5**	**(2.0)**	21.6	13.9	8.8
SG&A expenses less R&D costs	175.6	181.0	**179.0**	**(2.0)**	3.4	9.6	2.0
R&D costs	71.3	89.5	**89.5**	**0.0**	18.2	4.3	25.5
Operating income	23.3	27.0	**29.0**	**2.0**	5.7	1.8	24.6
Ordinary income	23.3	26.5	**28.5**	**2.0**	5.2		22.2
Net income attributable to owners of the parent	15.4	18.0	**20.0**	**2.0**	4.6		29.5
E B I T D A	43.1	47.8	**49.3**	**1.5**	6.2		14.4

Exchange Rate:
FY2014 : 1US$ = ¥109.8, 1RMB = ¥17.7
FY2015 : 1US$ = ¥120.0, 1RMB = ¥19.0
(Revised forecast)

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Sales Forecast of Major Products (Japan)

Billions of yen

	FY2014	FY2015 Previous Forecasts	FY2015 Revised Forecasts	Change
AIMIX®	12.0	17.5	**15.2**	(2.3)
AVAPRO®	11.4	11.5	**10.8**	(0.7)
LONASEN®	11.5	13.0	**13.0**	–
TRERIEF®	11.6	15.2	**14.0**	(1.2)
Strategic Products Total	46.4	57.2	**53.0**	(4.2)
SUREPOST®	2.4	3.7	**3.7**	–
AmBisome®	4.3	4.9	**4.3**	(0.6)
REPLAGAL®	9.7	11.0	**10.5**	(0.5)
METGLUCO®	17.1	14.0	**14.0**	–
AMLODIN®	19.6	17.0	**16.1**	(0.9)
GASMOTIN®	10.5	8.3	**8.3**	–
PRORENAL®	10.6	9.1	**9.1**	–
MEROPEN®	7.9	6.8	**6.5**	(0.3)
Others	28.1	24.7	**23.9**	(0.8)
Other Products Total	110.1	99.5	**96.4**	(3.1)
Japan total	156.6	156.7	**149.4**	(7.3)

Note: Japan segment sales figures are before reduction of rebates.

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Sales Forecast of Major Products (North America)

	FY2014	FY2015 Previous Forecasts	**FY2015 Revised Forecasts**	Change	FY2014	FY2015 Previous Forecasts	**FY2015 Revised Forecasts**	Change
North America	(Million $)				(Billion yen)			
LATUDA®	752	1,000	**1,000**	—	82.5	120.4	**120.0**	(0.4)
APTIOM®	23	58	**64**	6	2.5	7.0	**7.7**	0.7
BROVANA®	202	218	**244**	26	22.2	26.2	**29.3**	3.1
Ciclesonide	61	52	**57**	5	6.7	6.3	**6.9**	0.6
XOPENEX®	78	22	**54**	32	8.5	2.6	**6.5**	3.9
LUNESTA®	105	32	**35**	3	11.5	3.9	**4.2**	0.3
Others	129	70	**68**	(2)	14.2	8.4	**8.0**	(0.4)
Total	1,350	1,452	**1,522**	70	148.2	174.8	**182.6**	7.8
China	(Million RMB)				(Billion yen)			
MEROPEN®	805	826	**783**	(43)	14.3	16.1	**14.9**	(1.2)
Others	163	185	**154**	(31)	2.9	3.6	**2.9**	(0.7)
Total	968	1,011	**937**	(74)	17.1	19.7	**17.8**	(1.9)

Exchange Rate:
FY2014 Result : 1US$ = ¥109.8, 1RMB = ¥17.7
FY2015 Previous forecast : 1US$ = ¥120.4, 1RMB = ¥19.5
FY2015 Revised forecast : 1US$ = ¥120.0, 1RMB = ¥19.0

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Forecasts for FY2015 (by Segment)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2015 Revised Forecasts	Net sales（Sales to customers）	149.4	182.6	17.8	9.4	359.2	41.8	401.0
	Cost of sales	46.5	15.5	2.6	5.4	70.0	33.5	103.5
	Gross profit	103.0	167.1	15.2	4.0	289.3	8.2	297.5
	SG&A expenses less R&D costs	58.5	103.0	8.5	2.5	172.5	6.5	179.0
	Income (loss) of Segment	44.5	64.1	6.7	1.5	116.8	1.7	118.5
	R&D costs					88.5	1.0	89.5
	Operating income					28.3	0.7	29.0
Change from Previous Forecasts	Net sales（Sales to customers）	(7.3)	7.8	(1.9)	2.0	0.6	(0.6)	-
	SG&A expenses less R&D costs	0.4	(2.1)	(0.2)	-	(1.9)	(0.1)	(2.0)
	Income (loss) of Segment	(6.2)	8.3	(0.4)	0.9	2.6	(0.6)	2.0
	R&D costs					-	-	-
	Operating income					2.6	(0.6)	2.0

Exchange Rate:
FY2015 Previous forecast : 1US$ = ¥120.4, 1RMB = ¥19.5
FY2015 Revised forecast : 1US$ = ¥120.0, 1RMB = ¥19.0

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Clinical Development Status

Development Pipeline (1) (as of October 28, 2015)

Psychiatry & Neurology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
APTIOM® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Japan ※1 / China				
		Bipolar I depression, Bipolar maintenance	Japan				
		(New indication) Bipolar maintenance	U.S. / Europe, etc.				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※2
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				※3
		Binge eating disorder (BED)	U.S.				※3
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
EPI-589	TBD	Parkinson disease	U.S.				
		Amyotrophic lateral sclerosis (ALS)	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.				

※1 A Phase lll study completed, development strategy under consideration
※2 A Phase ll / lll study completed, development strategy under consideration
※3 Phase II/III study

Development Pipeline (2) (as of October 28, 2015)

Oncology Area (BBI608, BBI503)

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
BBI608	napabucasin	Colorectal cancer (Monotherapy) (Global clinical trial)	U.S. / Canada / Japan, etc.	Accrual of new patients has been stopped			
		Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.) (Combination therapy)	U.S. / Canada			※1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			※1	
		Solid tumors (Combination therapy) ※3 Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Hepatocellular carcinoma (Combination therapy)	Japan				
BBI503	TBD	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy) Solid tumors (Combination therapy)	U.S. / Canada		※2		
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
BBI608+BBI503	-	Solid tumors (Combination therapy)	U.S.				

※1 Phase II of Phase I/II study
※2 Phase I of Phase I/II study
※3 A number of tumor type-specific studies
(Gastrointestinal cancer , Hepatocellular carcinoma, Glioblastoma, Pancreatic cancer)

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Revisions since the previous announcement are in red.

Development Pipeline (3) (as of October 28, 2015)

Oncology Area (Excluding BBI608, BBI503)

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				
WT4869	TBD	Myelodysplastic syndromes	Japan		※1		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				
DSP-7888	TBD	Myelodysplastic syndromes	Japan		※1		
		Solid tumors, Hematologic malignancies	U.S.				

※1 Phase I of Phase I/II study

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.				

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				

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Clinical Development Status

(Major Changes since July 29, 2015)

APTIOM®

- Approved for partial-onset seizures (monotherapy) in the U.S. in August 2015

BBI503

- Started Phase l study of Phase l / ll for Solid tumors (combination therapy with capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, or sunitinib) in Canada

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obeticholic acid (DSP-1747) Phase II study top-line results

Study design

- ✓ Randomized, Double-blind, Parallel-group, Placebo-controlled Study of DSP-1747 in Patients with NASH
- ✓ The number of dosed subjects: 200
- ✓ Arms: DSP-1747 10mg/day, 20mg/day, 40mg/day, Placebo
- ✓ Primary endpoint: Improvement of liver pathological findings from baseline to week 72*1

*1 The improvement was defined as: a) No worsening of Kleiner's fibrosis stage, and b) Decrease in NAFLD activity score (NAS) by 2 or more points. Factors of NAS are steatosis, inflammation ,and ballooning.

Study results

- ✓ Efficacy: The percentages of improvement increased dose dependently.
  [Primary analysis with Stratified Cochran-Armitage test with multiple contrast coefficients: p=0.053]

Arms	Placebo	10mg	20mg	40mg
Primary endpoint (ITT)*2	10/50 (20%)	11/50 (22%)	14/50 (28%)	19/50 (38%) *3

*2 The subjects for whom the fibrosis stage or NAS or both at Week 72 were missing were classified as "unimproved"; p value for 40mg is 0.0496 (vs placebo, CMH test stratified by baseline fibrosis stage)

*3 On a complete case analysis, defined as those patients with biopsies available at both baseline and 72 weeks, p value for 40mg (19/37, 51%) vs placebo (10/45, 22%) is 0.006 (CMH test stratified by baseline fibrosis stage)

- ✓ Efficacy: The percentage of improvement in fibrosis stage was similar to placebo group.
- ✓ Safety: Incidences of pruritus as adverse event increased dose dependently.
  (Placebo 8.0%, 10mg 20.0%, 20mg 24.0%, 40mg 50.0%)
  Incidences of reported adverse events of DSP-1747 groups were generally similar to placebo group.

⇒ Additional data analysis ongoing

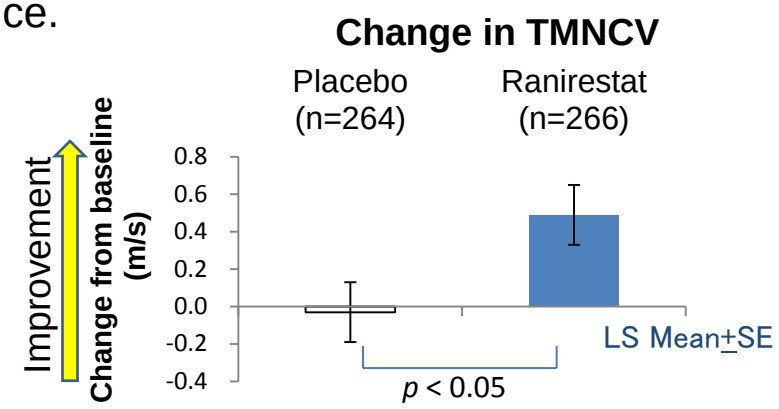
Ranirestat (AS-3201) Phase III study top-line results

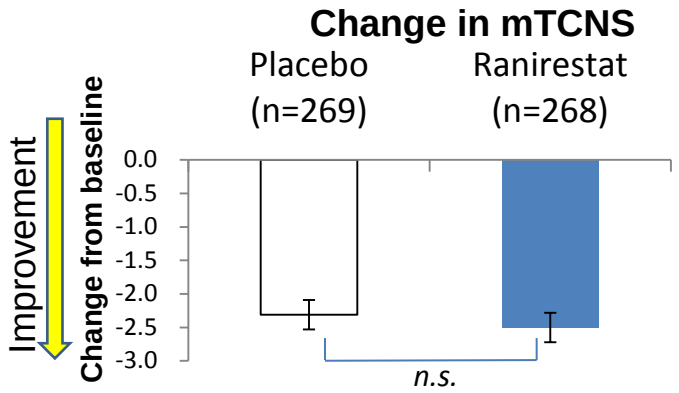
Study design

- ✓ Randomized, double-blind, parallel-group, placebo-controlled study in patients with diabetic neuropathy
- ✓ Arms (the number of dosed subjects): ranirestat 40mg/day (277), Placebo (278)
- ✓ Treatment period: 1 year treatment
- ✓ Co-primary endpoints: Changes in tibial motor nerve conduction velocity (TMNCV) and modified Toronto Clinical Neuropathy Score (mTCNS)

Study results

Efficacy: In comparison with placebo treatment, ranirestat 40 mg/day treatment significantly improved the TMNCV although did not improve the mTCNS with statistical significance.





- ✓ Safety: The incidences of TEAEs and treatment-related TEAEs in 40mg/day treatment group were comparable to those in placebo treatment group, respectively.

Future Plan

- ✓ Additional data analysis ongoing, development strategy under consideration.

Research and development progress

Oncology area

- BBI608 and BBI503 administered to over 1,000 patients in total in over 20 clinical studies.
- BBI608: Data analysis of Phase lll global clinical trial for advanced colorectal cancer (CO.23 study)
  - Analyzing final results including Overall Survival and Biomarker (Number of patients analyzed：195)
- Plan to start new pivotal studies for BBI608 in FY2015 2H

Regenerative medicine / Cell therapy area

- Center for iPS Cell Research and Application,Kyoto University, Hitachi Ltd. and Sumitomo Dainippon Pharma Co., Ltd. started a joint research on development toward application of human iPS cell for Parkinson's disease treatment

  ・This program was accepted for a grant by the Ministry of Economy, Trade and Industry and The Japan Agency for Medical Research and Development in May 2015

  ・The three organizations develop the base technology and the evaluation methods for establishing a production process of dopaminergic neural progenitor cells with a view toward clinical application of human iPS cell-based regenerative medicine technology
- Received a cell line of iPS cells stock from CiRA for regenerative medicine available for clinical studies in August 2015.
  Started to manufacturing a master cell bank
- Plan to build cell processing center in Kobe Biomedical Innovation Cluster (KBIC)

  (Estimated investment amount ¥2.2B)

Event: R&D meeting

- Date: December 9, 2015, Time: 2:00pm-4:00pm(JST)
- Location: Sumitomo Dainippon Pharma Tokyo head office 10th floor

Sumitomo Dainippon Pharma

Corporate Governance Reinforcement Initiative

- **Established "Basic Policy on Corporate Governance" (October 1, 2015)**

  Continuously pursuing the establishment of a yet more effective corporate governance system, aiming for the fuller realization of our Corporate Mission and Management Mission

・Organization

⇒ Continue the organizational structure of a "Company with an Audit & Supervisory Board" Establish the Nomination and Compensation Committee as a consultative body to the Board of Directors

・Strategic Shareholdings

⇒ Not hold any shares of other companies except when such shareholding supports the sustainable enhancement of its corporate value, such as establishment or maintenance of corporate alliances and other types of relationships with important business partners and customers

Nomination and Compensation Committee

- ✓ Consist of three or more members, the majority of which shall be Independent Outside Directors, and the chairperson shall be an Independent Outside Director.
- ✓ Enhance the objectivity and independence of the functions of the Board of Directors in relation to matters such as nomination of candidates for Directors and Audit & Supervisory Board Members, and decisions on compensation of Directors.

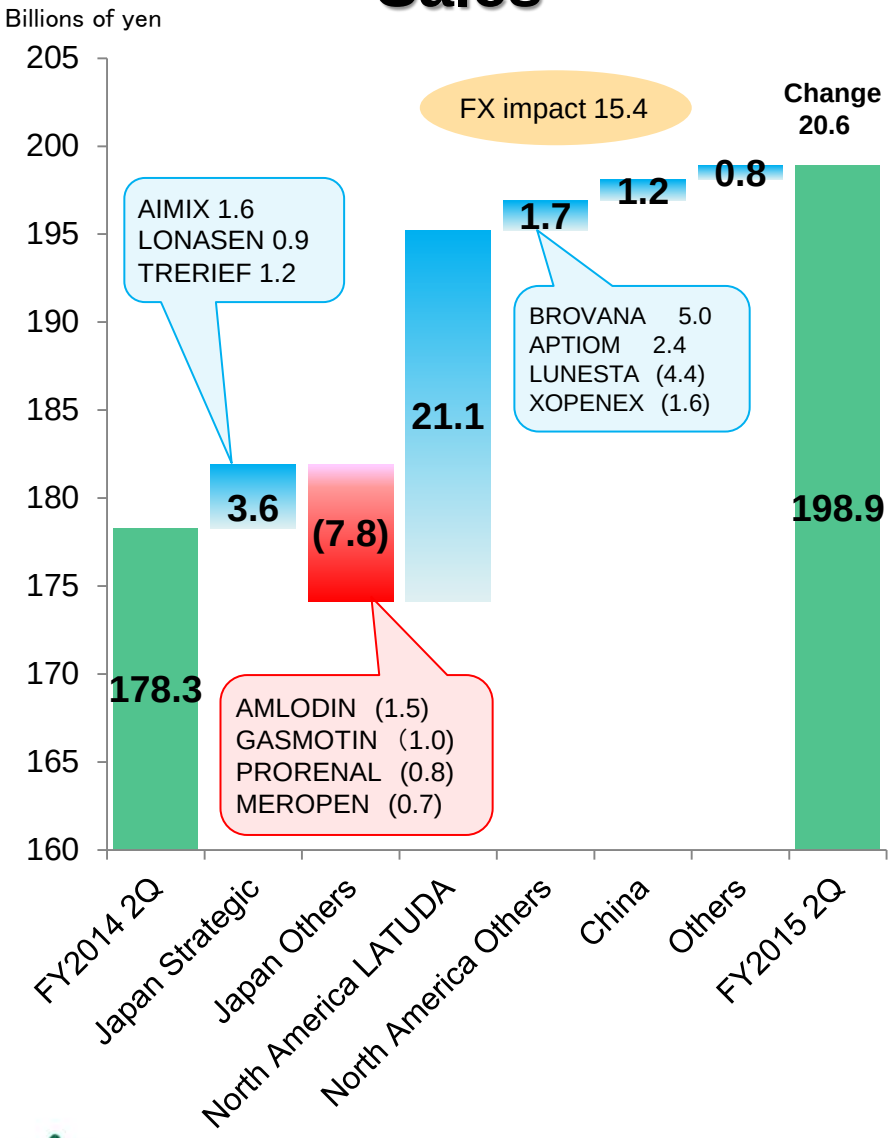
* Submitted the Corporate Governance Report on October 1, 2015 to Tokyo Stock Exchange

- **Strengthening of global compliance**
  - ✓ Establish compliance officer from November 1, 2015 to achieve strengthening of compliance including domestic and oversea group companies

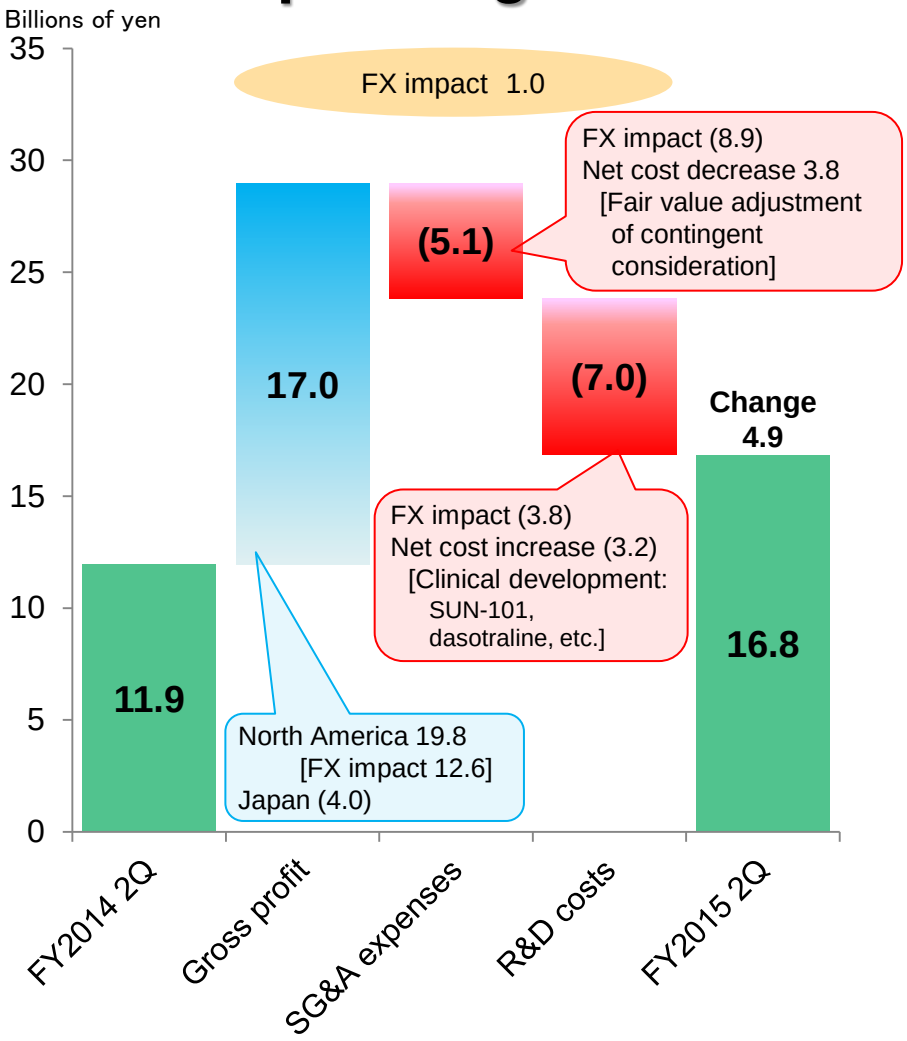
Appendix

2Q Changes vs. Previous Year

Sales



Operating Income

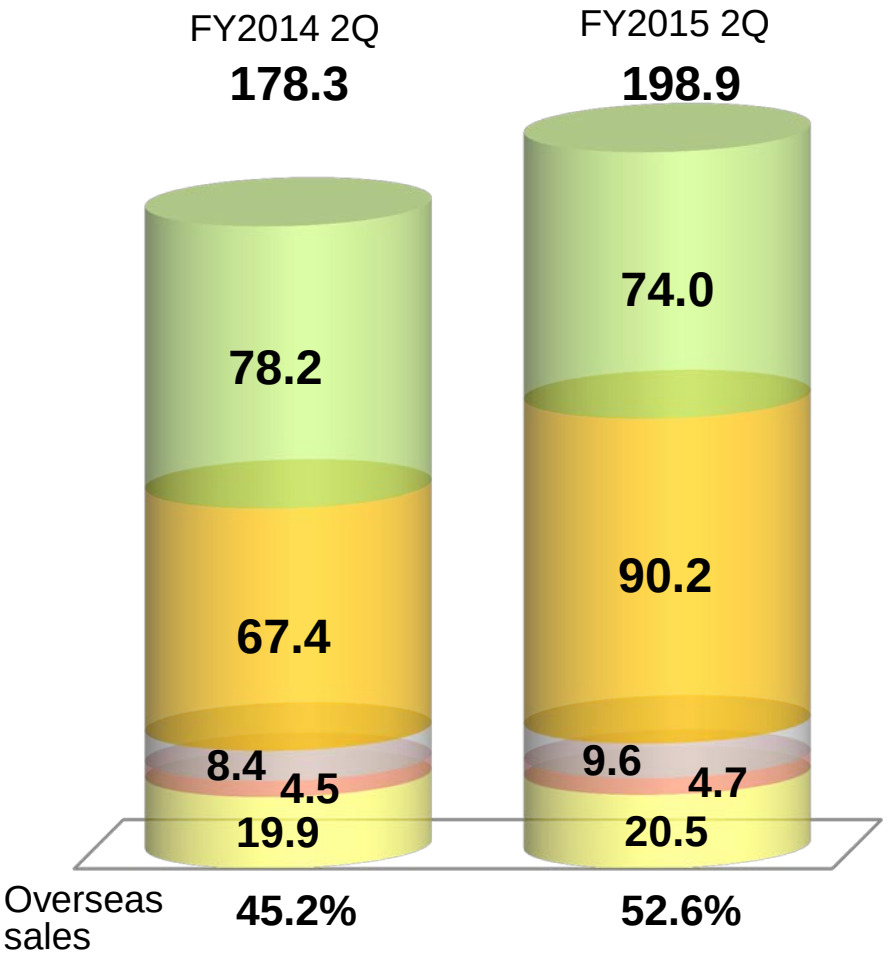


Exchange Rate:
FY2014 2Q : 1US$ = ¥103.0, 1RMB = ¥16.6
FY2015 2Q : 1US$ = ¥121.9, 1RMB = ¥19.5

Sumitomo Dainippon Pharma

FY2015 2Q Net Sales by Segment

Billions of yen



	vs. FY2014 2Q Value	vs. FY2014 2Q %	vs. FY2015 2Q Forecast %
	20.6	**11.6**	**100.7**
Japan	**(4.2)**	**(5.3)**	**94.0**
North America	**22.7**	**33.7**	**107.3**
China	**1.2**	**14.5**	**94.8**
Other Regions	**0.2**	**4.1**	**129.3**
Other Business	**0.6**	**3.3**	**97.3**

Exchange Rate:
FY2014 2Q : 1US$ = ¥ 103.0, 1RMB = ¥16.6
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5

【Japan】 More impact of decrease in long-listed products than growth of strategic products

【North America】 Growth of LATUDA®, BROVANA® and APTIOM® and weaker yen contributed to increased revenue

【China】 Increased sales due to weak yen

Sumitomo Dainippon Pharma

FY2015 2Q Financial Position / Cash Flows

Billions of yen

B/S	as of Mar.31,2015	as of Sep.30,2015	Change
Assets	711.6	726.0	14.4
Current assets	401.7	425.1	23.4
Fixed assets	309.9	301.0	(8.9)
Liabilities	260.6	270.4	9.9
Current liabilities	156.8	190.8	33.9
Long-term liabilities	103.7	79.7	(24.0)
Net assets	451.0	455.6	4.5
Shareholders' equity ratio	63.4%	62.7%	

【Assets】
Cash and time deposits +11.5
Deferred tax assets (current) +12.1
Intangible assets (2.6)
Investment securities (2.0)

【Liabilities】
Income taxes payable +13.0
Total interest-bearing debt (4.7)
Long-term⇒Short-term +22.0 Balance 81.9

C/F	2014 2Q	2015 2Q	Change
Operating CF	21.6	14.3	(7.3)
Investment CF	15.2	28.2	13.0
Financial CF	(8.3)	(8.3)	0.0
Cash / Cash equivalents	106.3	154.5	48.1
Operating funds	172.2	197.6	25.4

(Reference)
Balance as of end of FY2014
Cash / CE 122.8
Operating funds 190.9

BBI608, BBI503 - Clinical development progress (1)

Development status of BBI608

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated
Phase Ⅲ	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	paclitaxel	BBI608-336 (BRIGHTER)	Aug. 2014
Phase Ⅱ	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab or capecitabine	BBI608-224	Mar. 2012
Phase Ⅱ	U.S. / Canada	Solid tumors*1 (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
Phase Ⅱ	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin and pemetrexed	D8807005	Feb. 2015
Phase Ⅰ	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX*2,FOLFOX*2 and bevacizumab, CAPOX*2, FOLFIRI*2, FOLFIRI*2 and bevacizumab, or regorafenib	BBI608-246	Jan. 2014
Phase Ⅰ	U.S.	Hepatocellular carcinoma (Combination therapy)	Sorafenib	BBIHCC-103	Dec. 2014
Phase Ⅰ	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine and nab-paclitaxel, or FOLFIRINOX*2	BBI608-118	Aug. 2014
Phase Ⅰ	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
Phase Ⅰ	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone, bortezomib, imatinib or ibrutinib	BBI608-103HEME	May 2015
Phase Ⅰ	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
Phase Ⅰ	U.S.	Solid tumors (Combination therapy)	Iplimumab, pembrolizmab or nivolumab	BBI608-201CIT	Aug. 2015

∗ Revisions since the previous announcement are in red.

Study initiated was placed Clinical Trials.gov (as of October 27, 2015)

*1：Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.

*2：FOLFOX (Combination with fluorouracil, leucovorin, oxaliplatin)
CAPOX (Combination with capecitabine, oxaliplatin)
FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)
FOLFIRINOX (Combination with fluorouracil, leucovorin, irinotecan, oxaliplatin)

BBI608, BBI503 - Clinical development progress (2)

Development status of BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated
Phase Ⅱ	U.S. / Canada	Solid tumors*1 (Monotherapy)	—	BBI503-101	Feb. 2012
Phase Ⅱ	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	—	BBI503-205a	July 2016
Phase Ⅱ	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	—	BBI503-205b	Feb. 2015
Phase Ⅱ	Canada	Gastrointestinal stromal tumor (Monotherapy)	—	BBI503-205c	July 2016
Phase II	U.S.	Ovarian cancer (Monotherapy)	—	BBI503-205GYN-M	June 2015
Phase Ⅰ	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
Phase Ⅰ	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	Mar. 2015
Phase Ⅰ	U.S. / Canada	Solid tumors (Combination therapy)	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel or sunitinib	BBI503-201	Sep. 2015

*1：Colorectal cancer, Head and neck cancer, Ovarian cancer, etc

Development status of BBI608 + BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated
Phase Ⅰ	U.S.	Solid tumors (Combination therapy)	—	BBI401-101	Apr. 2015

Study initiated was placed Clinical Trials.gov (as of October 27, 2015) ＊ Revisions since the previous announcement are in red.

LATUDA® (lurasidone) – Clinical development progress

U.S. (In-house)

Diseases	Development status	Plan
Bipolar maintenance	**Phase III (Completed)**	**Planning to present findings in December 2015 at academic conference.**
MDD with mixed features	**Phase III (Completed)**	**Favorable findings obtained** **Not planning to submit an sNDA regarding including the findings into the product label.**

Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	Japan	**Phase III (Completed)**	**Development policy under consideration**
Bipolar I depression , Bipolar maintenance		**Phase III**	**FY2017**
Schizophrenia	China	**Phase III**	**FY2015**

Europe (Partnering)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.
- All options for Europe are under consideration including collaboration with a new partner.
- Countries covered by the Agreement: 26 EU member states (excluding the UK), Switzerland, Norway, Turkey and Russia
  Already launched in: Switzerland, the Netherlands, Denmark, Norway, Finland
  Already submitted in: Russia, Turkey

Asia, South America, etc. (Partnering)

- Submitted in: Taiwan, Thailand, Hong Kong, Singapore, Venezuela, Brazil
- Approved in: Australia (commercialization partnership with Servier Australia)

＊ Revisions since the previous announcement are in red.

Target submission date of the Main late Development Pipeline

(Updated July 2015)

Field	Development products	Submission target			
		FY2015	FY2016	FY2017	FY2018
Psychiatry & Neurology Field	SM-13496 <lurasidone hydrochloride> (Schizophrenia) China	●			
	LATUDA® <lurasidone hydrochloride> (Bipolar maintenance) U.S.	●			
	SM-13496 <lurasidone hydrochloride> (Bipolar I depression / Bipolar maintenance) Japan			●	
	AS-3201<ranirestat> (Diabetic neuropathy) Japan		●		
	SEP-225289 <dasotraline> (Adult , Pediatric ADHD) U.S			●	
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan			●	
	TRERIEF® <zonisamide> (Parkinsonism in Dementia with Lewy Bodies) Japan			●	
	SEP-225289 <dasotraline> (BED) U.S				●
Cancer Field	BBI608 (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan			●	
	BBI503 (Solid tumors / Monotherapy) U.S./ Japan			●	
Respiratory Field	SUN-101<glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.		●		

New Chemical Entities | New Indication, etc.

＊No changes after July 2015.

Product Launch Plan (Updated July 2015)

Area	FY2015	FY2016	FY2017	FY2018	FY2019～FY2021
Japan		※ lurasidone (Schizophrenia) ※ EPI-743 (Leigh syndrome)	ranirestat (Diabetic neuropathy) BBI608 (Gastric and Gastro-esophageal junction adenocarcinoma)	lurasidone (Bipolar I depression / Bipolar maintenance) LONASEN® (Schizophrenia / Transdermal patch) TRERIEF® (Parkinsonism in Dementia with Lewy Bodies) BBI503 (Solid tumors)	BBI608 (Colorectal cancer, etc.) DSP-7888 (Solid tumors/ Hematologic cancer) DSP-1747 (NASH) DSP-6952 (IBS with constipation, Chronic idiopathic constipation) iPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	APTIOM® (Epilepsy-monotherapy)	LATUDA® (Bipolar Maintenance)	BBI608 (Gastric and Gastro-esophageal junction adenocarcinoma) SUN-101 (COPD)	dasotraline (ADHD) BBI503 (Solid tumors)	SB623 (Chronic Stroke) DSP-2230 (Neuropathic pain) SEP-363856 (Schizophrenia) dasotraline (BED) BBI608 (Colorectal cancer, etc.) DSP-7888 (Solid tumors/ Hematologic cancer)
China		LONASEN® (Schizophrenia) CALSED® (Small cell lung cancer)		lurasidone (Schizophrenia)	
U.K.		lurasidone (Bipolar disorder)			

∗ No changes after July 2015.

: P&N : liver/ digestive : Oncology : Respiratory

New Chemical Entities New Indication , etc.

※ Development strategy under consideration

Regenerative Medicine/Cell Therapy of Business Plan

(Updated May 2015)

	Partnering	Region (planned)	cell type	Schedule for practical use (Calendar year)					
				2015	2016	2017	2018	2019	2020
Stroke	**SanBio**	North America	Allo MSC	Ph2b			Ph3		Approval Target
AMD (age-related macular degeneration)	**Healios RIKEN**	Japan	Allo iPS cell	Clinical research (autologous / allogeneic)		Investigator initiated clinical trial			Approval Target
Parkinson's disease	**Kyoto Univ 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 Univ, Osaka National Hospital**	global	Allo iPS cell				Clinical research (allogeneic)		

＊No changes after May 2015.

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.