



First Quarter Financial Results for FY2015  
(April 1 to June 30, 2015)

July 29, 2015

Sumitomo Dainippon Pharma Co., Ltd.

# FY2015 1Q Financial Results

Billions of yen

	FY2014 1Q	FY2015 1Q	Change			FY2015 2Q		FY2015	
			Value		Percentage (%)	Previous forecasts *	Progress (%)	Previous forecasts *	Progress (%)
				Exchange Impact					
Net sales	89.7	98.1	8.4	7.5	9.3	193.0	50.8	392.0	25.0
Cost of sales	24.1	26.4	2.3	0.8	9.4	51.0	51.7	102.0	25.8
Gross profit	65.7	71.8	6.1	6.7	9.3	142.0	50.5	290.0	24.7
SG&A expenses	57.0	67.3	10.4	6.8	18.2	131.0	51.4	263.0	25.6
SG&A expenses less R&D costs	41.8	47.2	5.5	4.8	13.1	89.5	52.8	176.0	26.8
R&D Costs	15.2	20.1	4.9	2.0	32.2	41.5	48.5	87.0	23.1
Operating income	8.7	4.4	(4.3)	(0.2)	(48.9)	11.0	40.4	27.0	16.5
Ordinary income	9.6	4.7	(4.8)		(50.5)	11.0	43.0	26.5	17.8
Net income attributable to owners of the parent	5.8	5.9	0.2		3.2	8.0	74.3	18.0	33.0
E B I T D A	14.9	9.7				21.5		47.5	

\* Some part of forecasts have been revised.

Exchange Rate:

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

FY2015 1Q : 1US\$ = ¥121.4, 1RMB = ¥19.6

FY2015 : 1US\$ = ¥115.0, 1RMB = ¥18.5

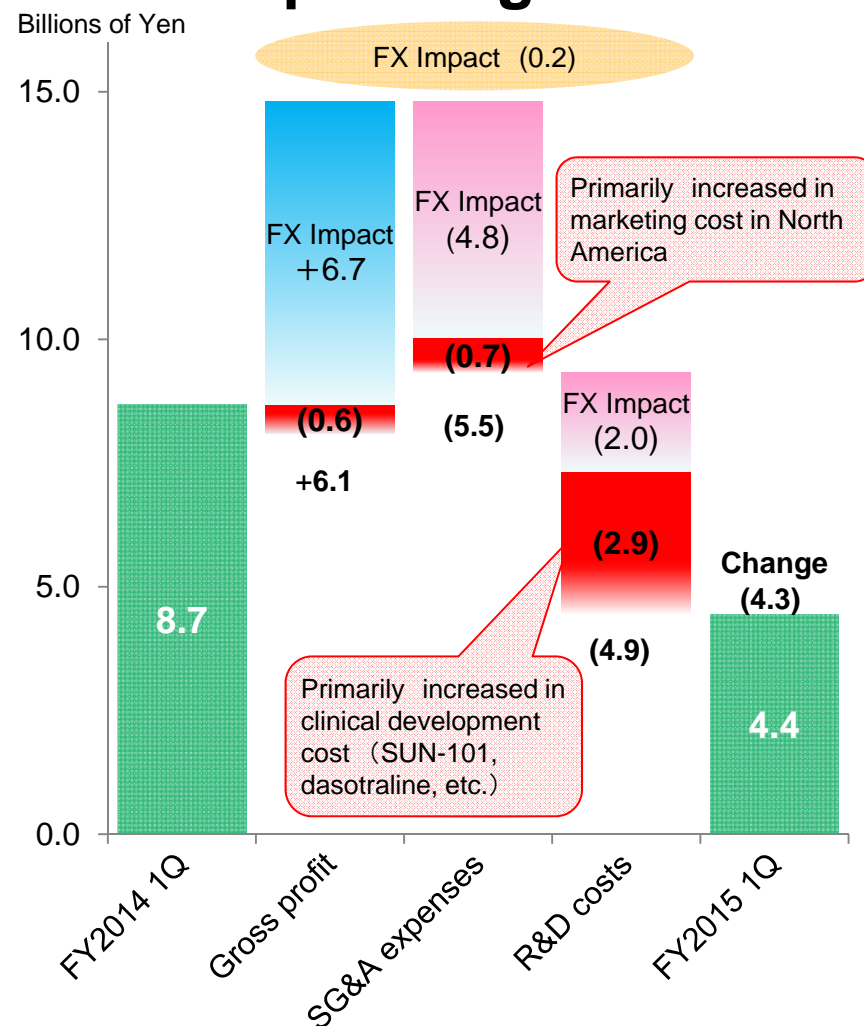
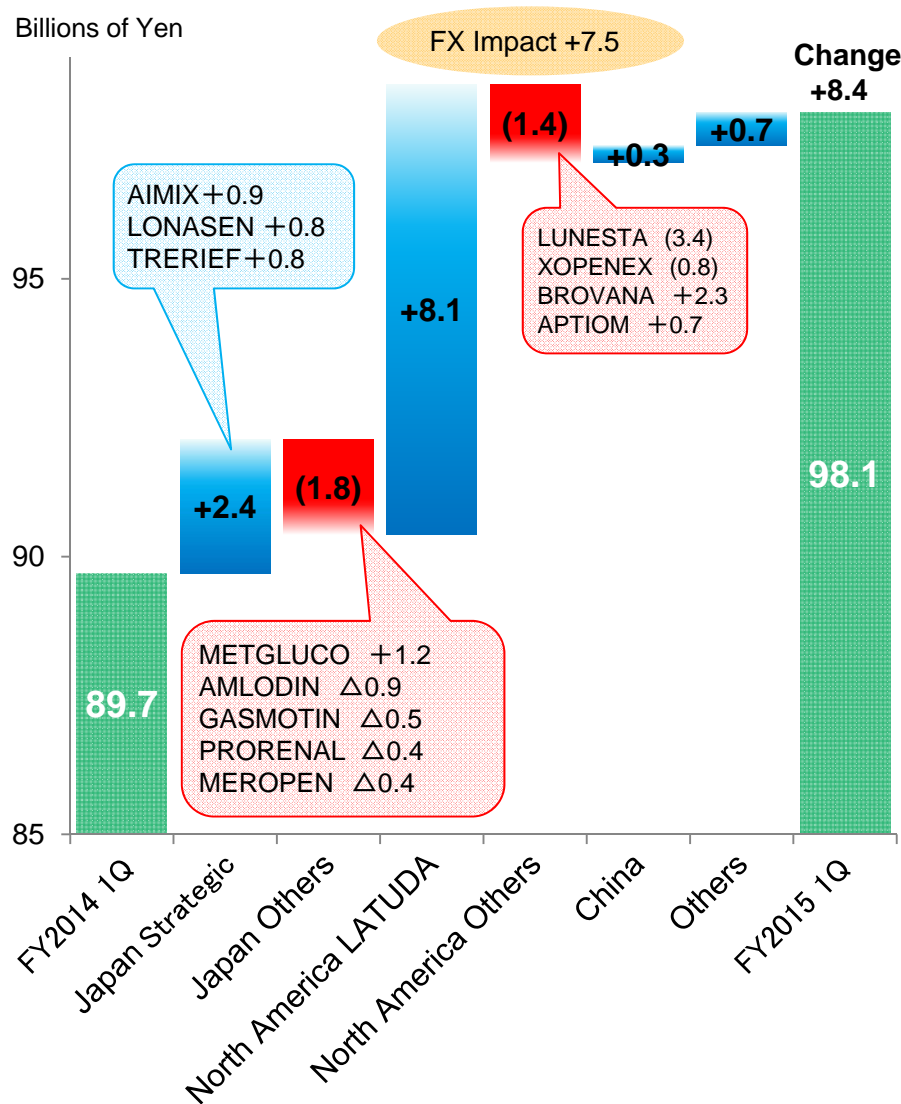
(previous forecast)



# Changes vs. Previous Year

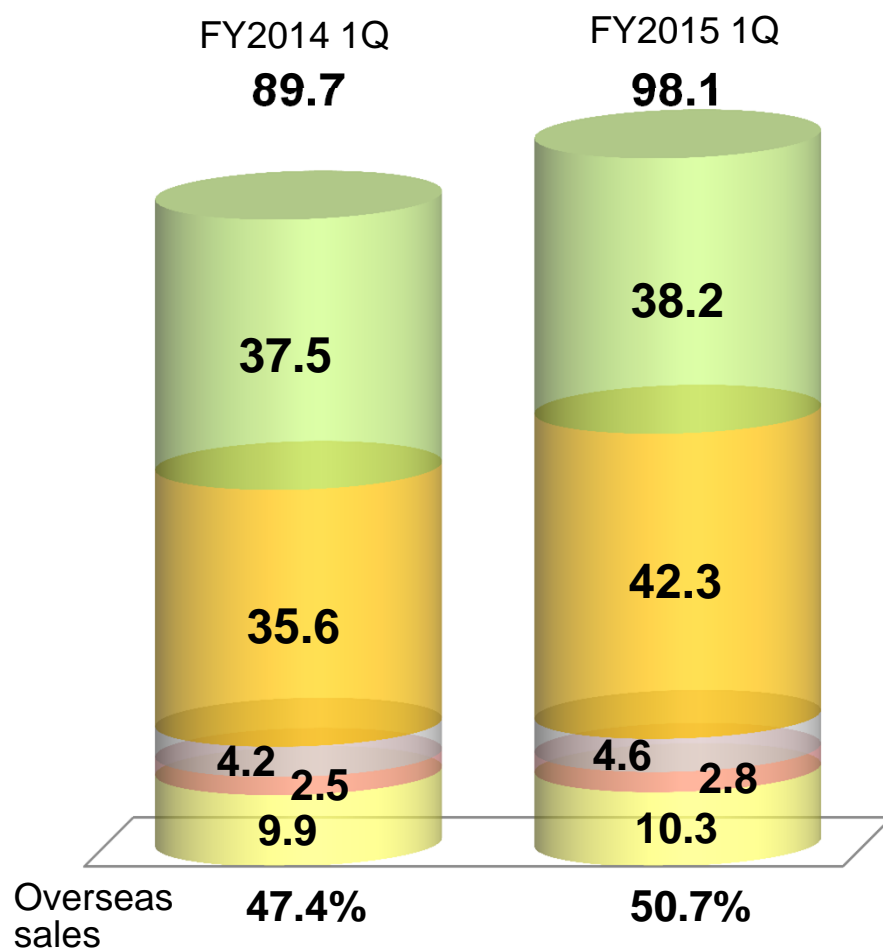
## Sales

## Operating Income



# 1Q Net Sales by Segment

Billions of yen



Exchange Rate:

FY2014 1Q : 1US\$ = ¥ 102.2, 1RMB = ¥16.4

FY2015 1Q : 1US\$ = ¥ 121.4, 1RMB = ¥19.6

	vs. FY2014 1Q Value	1Q %	vs. FY2015 2Q Forecast %
<b>Total</b>	<b>8.4</b>	<b>9.3</b>	<b>50.8</b>

Japan 0.7 1.8 48.5

North America 6.7 18.8 52.9

China 0.3 8.1 47.6

Other Regions 0.3 12.4 76.5

Other Business 0.4 3.9 48.9

**【Japan】** Increase in strategic products and METGLUCO® offset decrease in long-listed products

**【North America】** Growth of LATUDA® and BROVANA®, weak yen made up for drop of LUNESTA®

**【China】** Increased sales due to weak yen

# 1Q Major Products Sales in Japan Billions of yen

	FY2014 1Q	FY2015 1Q	Change		FY2015 2Q	
			Value	Percentage (%)	Previous forecasts	Progress (%)
AIMIX®	2.6	3.5	0.9	35.8	7.8	44.8
AVAPRO®	2.8	2.7	(0.1)	(3.0)	5.8	46.4
LONASEN®	2.3	3.1	0.8	32.4	6.4	48.3
TRERIEF®	2.4	3.3	0.8	35.3	7.0	46.6
Strategic Products Total	10.1	12.5	2.4	24.2	27.0	46.4
SUREPOST®	0.5	0.8	0.4	75.1	1.7	48.1
AmBisome®	0.9	1.0	0.1	8.8	2.4	41.2
REPLAGAL®	2.4	2.8	0.4	15.3	5.4	51.3
METGLUCO®	3.6	4.9	1.2	33.7	8.0	61.0
AMLODIN®	5.1	4.2	(0.9)	(17.4)	8.9	47.4
GASMOTIN®	2.7	2.2	(0.5)	(18.0)	4.4	50.6
PRORENAL®	2.7	2.3	(0.4)	(13.6)	4.7	49.1
MEROPEN®	2.0	1.6	(0.4)	(18.9)	3.6	45.7
Others	7.5	5.8	(1.7)	(22.5)	12.6	45.9
Other Products Total	27.4	25.6	(1.8)	(6.5)	51.7	49.6
<b>Japan Total</b>	<b>37.5</b>	<b>38.2</b>	<b>0.7</b>	<b>1.8</b>	<b>78.7</b>	<b>48.5</b>

# 1Q Major Products Sales in North America & China

	FY2014 1Q	FY2015 1Q	Change	FY2014 1Q	FY2015 1Q	Change		FY2015 2Q		
						Value	Exchange Rate Impact	Previous forecasts *		Yen-based Progress
<b>North America</b>	(Million \$)			(Billion yen)				(Million \$)	(Billion yen)	(%)
LATUDA®	180	<b>218</b>	38	18.4	<b>26.5</b>	8.1	4.2	469	53.9	49.1
APTIOM®	8	<b>13</b>	4	0.9	<b>1.5</b>	0.7	0.2	19	2.2	69.0
BROVANA®	46	<b>58</b>	11	4.7	<b>7.0</b>	2.3	1.1	103	11.8	59.5
Ciclesonide	16	<b>17</b>	1	1.6	<b>2.1</b>	0.5	0.3	26	3.1	66.3
XOPENEX®	24	<b>13</b>	(11)	2.4	<b>1.6</b>	(0.8)	0.3	18	2.1	76.7
LUNESTA®	46	<b>11</b>	(36)	4.7	<b>1.3</b>	(3.4)	0.2	18	2.1	62.1
Industrial property revenues	12	<b>9</b>	(3)	1.3	<b>1.1</b>	(0.1)	0.2	19	2.2	51.5
Others	16	<b>10</b>	(6)	1.6	<b>1.2</b>	(0.4)	0.2	24	2.6	47.3
<b>Total</b>	<b>349</b>	<b>349</b>	<b>(0)</b>	<b>35.6</b>	<b>42.3</b>	<b>6.7</b>	<b>6.7</b>	<b>696</b>	<b>80.0</b>	<b>52.9</b>
<b>China</b>	(Million RMB)			(Billion yen)				(Million RMB)	(Billion yen)	(%)
MEROPEN®	213	<b>193</b>	(21)	3.5	<b>3.8</b>	0.3	0.6	429	7.9	47.7
Others	44	<b>41</b>	(4)	0.7	<b>0.8</b>	0.1	0.1	90	1.7	46.8
<b>Total</b>	<b>257</b>	<b>233</b>	<b>(24)</b>	<b>4.2</b>	<b>4.6</b>	<b>0.3</b>	<b>0.7</b>	<b>519</b>	<b>9.6</b>	<b>47.6</b>

Exchange Rate:

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

FY2015 1Q : 1US\$ = ¥121.4, 1RMB = ¥19.6

FY2015  
(previous forecast) : 1US\$ = ¥115.0, 1RMB = ¥18.5

\* Forecasts of some products have been revised.



# 1Q Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2015 1Q Results	Net sales (Sales to customers)	38.2	42.3	4.6	2.8	87.8	10.3	98.1
	Cost of sales	11.4	3.9	1.0	1.8	18.1	8.3	26.4
	Gross profit	26.8	38.4	3.6	1.0	69.7	2.0	71.8
	SG&A expenses less R&D costs	14.2	28.9	1.9	0.7	45.7	1.6	47.2
	<i>Amortization Included in above ※</i>	-	1.9	-	-	1.9	-	1.9
	<b>Income (loss) of Segment</b>	<b>12.6</b>	<b>9.5</b>	<b>1.6</b>	<b>0.3</b>	<b>24.1</b>	<b>0.5</b>	<b>24.6</b>
	R&D costs					19.9	0.2	20.1
Operating income					4.2	0.3	4.4	
FY2014 1Q Results	Net sales (Sales to customers)	37.5	35.6	4.2	2.5	79.8	9.9	89.7
	Cost of sales	11.2	3.0	0.6	1.4	16.2	7.8	24.1
	Gross profit	26.3	32.6	3.6	1.0	63.6	2.1	65.7
	SG&A expenses less R&D costs	14.4	23.7	1.6	0.5	40.2	1.5	41.8
	<i>Amortization Included in above ※</i>	-	2.6	-	-	2.6	-	2.6
	<b>Income (loss) of Segment</b>	<b>11.9</b>	<b>8.9</b>	<b>2.0</b>	<b>0.5</b>	<b>23.3</b>	<b>0.6</b>	<b>23.9</b>
	R&D costs					15.0	0.2	15.2
Operating income					8.3	0.4	8.7	
Change	Net sales (Sales to customers)	0.7	6.7	0.3	0.3	8.0	0.4	8.4
	SG&A expenses less R&D costs	(0.2)	5.2	0.3	0.1	5.4	0.0	5.5
	<b>Income (loss) of Segment</b>	<b>0.7</b>	<b>0.6</b>	<b>(0.4)</b>	<b>(0.2)</b>	<b>0.7</b>	<b>(0.1)</b>	<b>0.6</b>
	R&D costs					4.9	0.0	4.9
	Operating income					(4.1)	(0.1)	(4.3)

※ Amortization of goodwill and patent rights, etc.

Exchange Rate:

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

FY2015 1Q : 1US\$ = ¥121.4, 1RMB = ¥19.6

# 1Q Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2014 1Q	FY2015 1Q	Change	
			Value	Percentage(%)
Operating Income	8.7	<b>4.4</b>	(4.3)	(48.9)
Non-operating income and expenses	0.9	<b>0.3</b>	(0.6)	
Ordinary income	9.6	<b>4.7</b>	(4.8)	(50.5)
Extraordinary income	1.7	<b>6.0</b>	4.3	
Gain on sales of investment securities	—	<b>6.0</b>		
Compensation income for damage	1.7	—		
Extraordinary loss	0.1	<b>0.2</b>	0.0	
Impairment loss	—	<b>0.2</b>		
Business structure improvement expenses	0.1	—		
Income taxes	5.4	<b>4.6</b>	(0.7)	
Net income attributable to owners of the parent	5.8	<b>5.9</b>	0.2	3.2



# Revised Financial Forecasts for FY2015

(vs. Previous Forecasts)

Billions of yen

	FY2015 2Q			FY2015		
	Previous forecasts	Revised forecasts	Change	Previous forecasts	Revised forecasts	Change
Net sales	193.0	<b>197.5</b>	<b>4.5</b>	392.0	<b>401.0</b>	<b>9.0</b>
Cost of sales	51.0	<b>51.8</b>	<b>0.8</b>	102.0	<b>103.5</b>	<b>1.5</b>
Gross profit	142.0	<b>145.7</b>	<b>3.7</b>	290.0	<b>297.5</b>	<b>7.5</b>
SG&A expenses	131.0	<b>134.7</b>	<b>3.7</b>	263.0	<b>270.5</b>	<b>7.5</b>
SG&A expenses less R&D costs	89.5	<b>92.2</b>	<b>2.7</b>	176.0	<b>181.0</b>	<b>5.0</b>
R&D costs	41.5	<b>42.5</b>	<b>1.0</b>	87.0	<b>89.5</b>	<b>2.5</b>
Operating income	11.0	<b>11.0</b>	—	27.0	<b>27.0</b>	—
Ordinary income	11.0	<b>11.0</b>	—	26.5	<b>26.5</b>	—
Net income attributable to owners of the parent	8.0	<b>8.0</b>	—	18.0	<b>18.0</b>	—
EBITDA	21.5	<b>21.7</b>	<b>0.2</b>	47.5	<b>47.8</b>	<b>0.3</b>

**Forecasts have been revised in line with review of FX rate assumption**

FY2015 Previous forecast : 1US\$ = ¥115.0, 1RMB = ¥18.5

FY2015 Revised forecast : 1US\$ = ¥120.4, 1RMB = ¥19.5

# Revised Forecasts for FY2015 (by Segment)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Revised Forecasts FY2015	Net sales (Sales to customers)	156.7	174.8	19.7	7.4	358.6	42.4	401.0
	Cost of sales	48.0	13.9	3.9	4.3	70.1	33.4	103.5
	Gross profit	108.8	160.9	15.8	3.1	288.6	8.9	297.5
	SG&A expenses less R&D costs	58.1	105.1	8.7	2.5	174.4	6.6	181.0
	<i>Amortization Included in above ※</i>	-	7.8	-	-	7.8	-	7.8
	<b>Income (loss) of Segment</b>	<b>50.7</b>	<b>55.8</b>	<b>7.1</b>	<b>0.6</b>	<b>114.2</b>	<b>2.3</b>	<b>116.5</b>
	R&D costs					88.5	1.0	89.5
	Operating income					25.7	1.3	27.0
Change from Previous Forecasts	Net sales (Sales to customers)	-	8.0	1.0	-	9.0	-	9.0
	SG&A expenses less R&D costs	-	4.6	0.4	-	5.0	-	5.0
	<b>Income (loss) of Segment</b>	<b>-</b>	<b>2.2</b>	<b>0.3</b>	<b>-</b>	<b>2.5</b>	<b>-</b>	<b>2.5</b>
	R&D costs					2.5	-	2.5
	Operating income					-	-	-

※ Amortization of goodwill and patent rights, etc.

Exchange Rate:

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# Development Pipeline (1) (as of July 29, 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	U.S. / 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.				

Revisions since the previous announcement are in red.

※1 A Phase III study completed, development strategy under consideration

※2 A Phase II / III study completed, development strategy under consideration

※3 Phase II/III study

# Development Pipeline (2) (as of July 29, 2015)

## Oncology Area (BBI608, BBI503)

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
BBI608	TBD	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, ※4 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.		※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)

※4 A new study started

Revisions since the previous announcement are in red.

# Development Pipeline (3) (as of July 29, 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				
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				
DSP-7888	TBD	Myelodysplastic syndromes	Japan				
		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				

Revisions since the previous announcement are in red.

# Clinical Development Status

(Major Changes since May 11, 2015)

## dasotraline (SEP-225289)

- Started Phase II / III study for Binge eating disorder (BED) in the U.S.

## BBI608

- Started Phase II study of Phase I / II for Malignant pleural mesothelioma (combination therapy with cisplatin and pemetrexed) in Japan
- Started Phase I study for Solid tumors (combination therapy with ipilimumab, pembrolizumab, or nivolumab) in the U.S.

## BBI503

- Started Phase I study of Phase I / II for Solid tumors (combination therapy with capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, or sunitinib) in the U.S.

## DSP-7888

- Started Phase I study for Solid tumors and Hematologic malignancies in the U.S.

## Newly added

- EPI-589  
Started Phase II study for Parkinson disease and Amyotrophic lateral sclerosis (ALS) in the U.S.

## Completed Study

- EPI-743  
Leigh syndrome: Completed Phase II / III study in Japan  
Development strategy under consideration

# EPI-743, EPI-589 - Clinical development progress

## EPI-743: Leigh syndrome

- Japan : Completed Phase II / III (open label study), observed improvement in NPMDS section 1-3 total score
- U.S. (by Edison) : Completed Phase IIb (placebo controlled study), there were no statistically significant differences in NPMDS section 1-3 total score between the placebo and EPI-743 treatment from the top-line result. Additional data analysis is ongoing.  
⇒ The future development strategy in Japan is under consideration.

## EPI-589: Parkinson disease, Amyotrophic lateral sclerosis (ALS)

- In-licensed the exclusive development and commercial rights in Japan and North America (North America for indications in adults) from Edison Pharmaceuticals, Inc.
- Expected to contribute to the treatment of neurodegenerative indications arising through redox stress based on defects in mitochondrial function
- Started Phase IIa study for Parkinson disease ALS in the U.S. / U.K. and Phase IIa study for ALS in the U.S. by Edison Pharmaceuticals, Inc.
- Sumitomo Dainippon Pharma will develop EPI-589 in Japan and the North America after the Phase IIa studies.

Indications	Parkinson disease	ALS
Area	U.S.	U.S.
Estimated Enrollment	40	20
Study design	Open label	Open label
Primary outcome measures	Biomarker	Biomarker

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# Appendix



# BBI608, BBI503 - Clinical development progress (1)

## Development status of BBI608

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated* <sup>3</sup>
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* <sup>1</sup> (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
<b>Phase II</b>	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin and pemetrexed	D8807005	Feb. 2015
Phase I	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX* <sup>2</sup> , FOLFOX* <sup>2</sup> and bevacizumab, CAPOX* <sup>2</sup> , FOLFIRI* <sup>2</sup> , FOLFIRI* <sup>2</sup> 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	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	BBI608-103HEME	May 2015
Phase I	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
<b>Phase I</b>	<b>U.S.</b>	<b>Solid tumors (Combination therapy)</b>	<b>Iplimumab, pembrolizumab or nivolumab</b>	<b>BBI608-201CIT</b>	<b>Aug. 2015</b>

\* Revisions since the previous announcement are in red.

\*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)

\*3: Study initiated was placed Clinical Trials.gov (as of July 28, 2015)

# BBBI608, BBI503 - Clinical development progress (2)

## Development status of BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated* <sup>2</sup>
Phase II	U.S. / Canada	Solid tumors* <sup>1</sup> (Monotherapy)	—	BBI503-101	Feb. 2012
Phase II	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	—	BBI503-205a	Jan. 2015
Phase II	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	—	BBI503-205b	Feb. 2015
Phase II	Canada	Gastrointestinal stromal tumor (Monotherapy)	—	BBI503-205c	Jan. 2015
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.	Solid tumors (Combination therapy)	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel or sunitinib	BBI503-201	Aug. 2015

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

\*2 : Study initiated was placed Clinical Trials.gov (as of July 28, 2015)

## Development status of BBI608 + BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated* <sup>3</sup>
Phase I	U.S.	Solid tumors (Combination therapy)	—	BBI401-101	Apr. 2015

\*3 : Study initiated was placed Clinical Trials.gov (as of July 28, 2015) 17

\* Revisions since the previous announcement are in red.

# LATUDA<sup>®</sup>(lurasidone) – Clinical development progress

## U.S. (In-house)

Diseases	Development status	Plan
Bipolar maintenance	Phase III	Study was recently completed. The data are currently being analyzed.
MDD with mixed features	Phase III (Completed)	Favorable findings obtained; will be added to the label (Submission planned in FY2015)

## 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
- Approved in: Australia (commercialization partnership with Servier Australia)

# 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.		●		

Added

New Chemical Entities

{ New Indication, etc. }

Revisions since the previous announcement are in red.

# 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)		

□ : 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 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 (allogeneic)		

\* No changes after May 2015.

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# 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.

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