10th Anniversary

Sumitomo Dainippon Pharma

Financial Results for the Nine Month Period Ended December 31, 2015 (Apr. 1 to Dec. 31, 2015)

January 27, 2016

Sumitomo Dainippon Pharma Co., Ltd.

Financial Results for FY2015 Apr.-Dec.

Billions of yen

	FY2014 Apr.-Dec.	**FY2015 Apr.-Dec.**	Change			FY2015	
			Value		Percentage (%)	Previous forecasts Oct. 28	Progress (%)
				Exchange Impact			
Net sales	279.1	**304.5**	25.4	18.5	9.1	401.0	75.9
Cost of sales	75.1	**79.1**	4.0	1.8	5.3	103.5	76.4
Gross profit	204.0	**225.5**	21.4	16.7	10.5	297.5	75.8
SG&A expenses	181.2	**194.4**	13.2	15.0	7.3	268.5	72.4
SG&A expenses less R&D costs	130.0	**135.4**	5.4	10.5	4.1	179.0	75.7
R&D costs	51.2	**59.0**	7.8	4.6	15.2	89.5	65.9
Operating income	22.8	**31.1**	8.3	1.6	36.2	29.0	107.2
Ordinary income	22.5	**31.1**	8.6		38.3	28.5	109.2
Net income attributable to owners of the parent	19.0	**23.3**	4.4		22.9	20.0	116.7
E B I T D A	37.3	**46.6**	9.2			49.3	

Exchange Rate:
FY2014 3Q : 1US$ = ¥106.7, 1RMB = ¥17.3
FY2015 3Q : 1US$ = ¥121.8, 1RMB = ¥19.3
FY2015(forecast) : 1US$ = ¥120.0, 1RMB = ¥19.0

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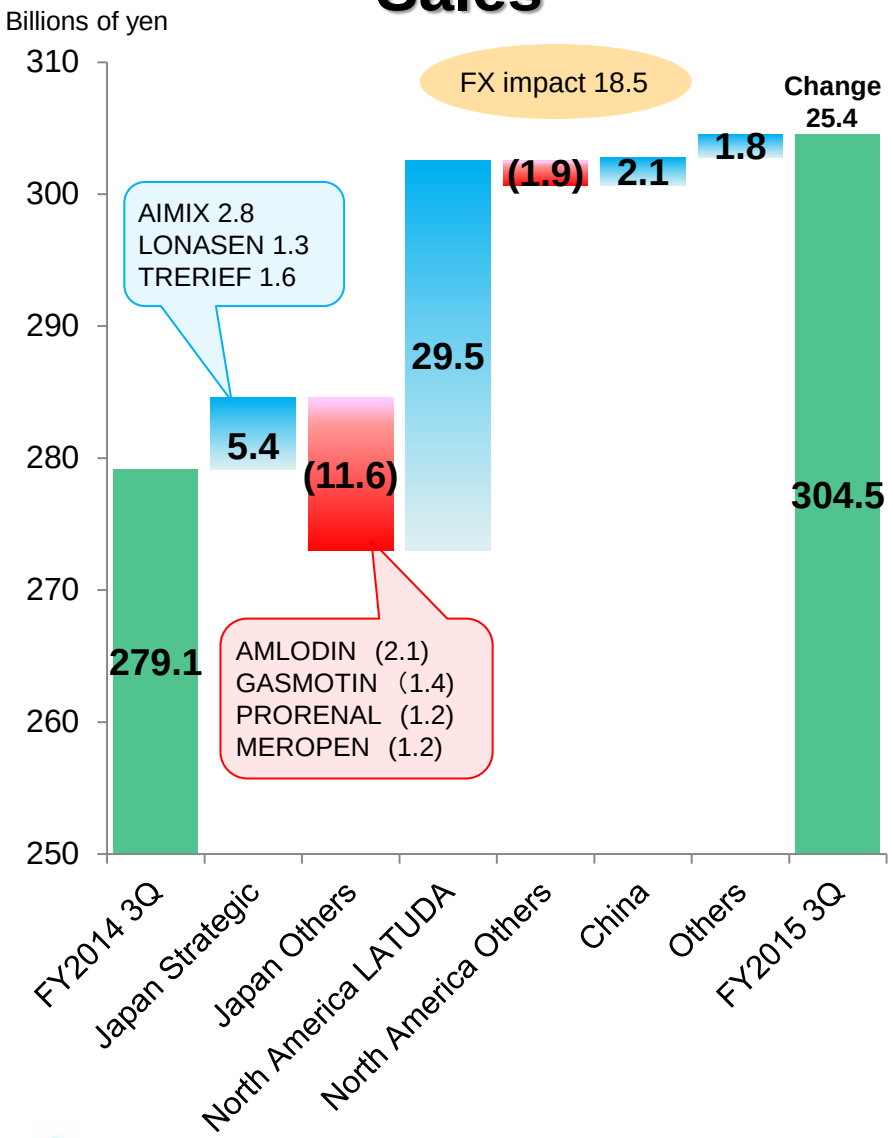
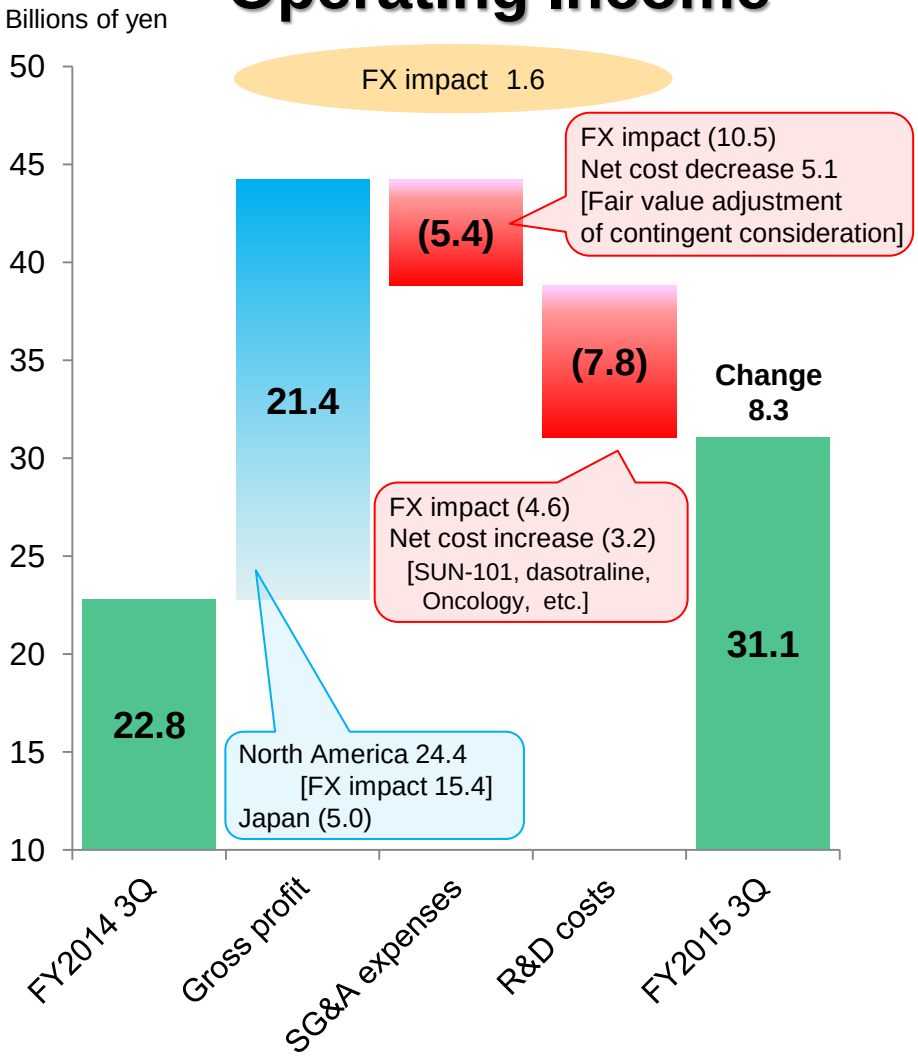
3Q Changes vs. Previous Year

Sales



Operating Income



Exchange Rate:

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FY2015 3Q	: 1US$ = ¥121.8, 1RMB = ¥19.3

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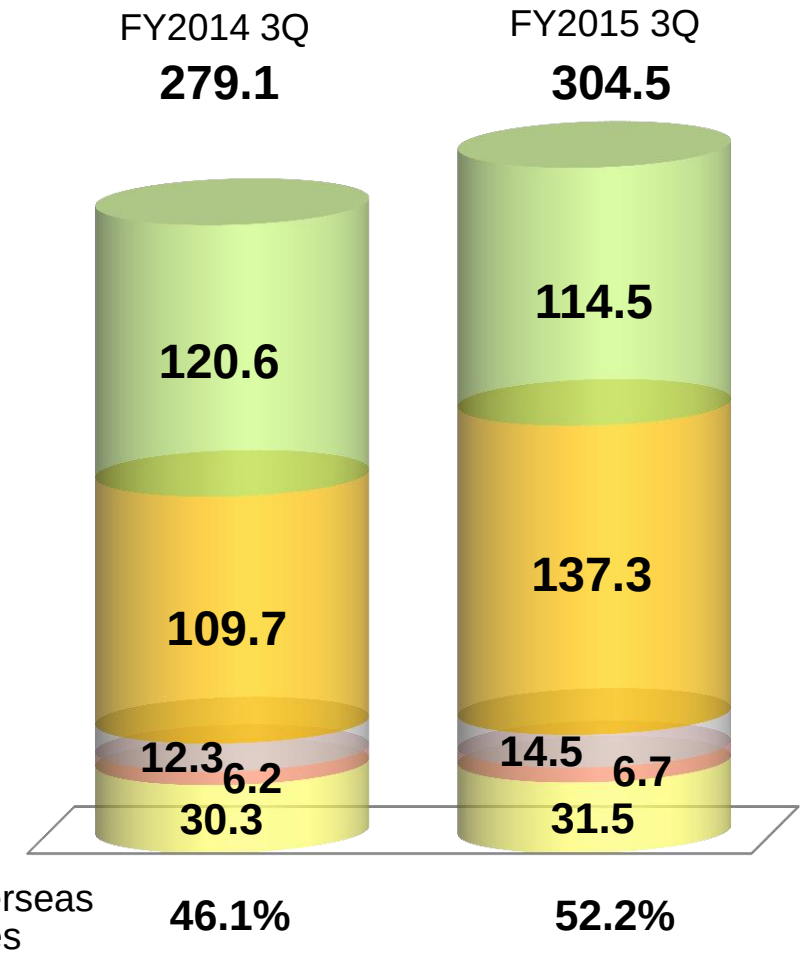
FY2015 3Q Net Sales by Segment

Billions of yen



	FY2014 3Q	vs. FY2014 3Q Value	vs. FY2014 3Q %	vs. FY2015 Forecast %
	279.1	**304.5**	**25.4**	**9.1**	**75.9**
Japan	**120.6**	**114.5**	**(6.1)**	**(5.1)**	**76.6**
North America	**109.7**	**137.3**	**27.6**	**25.2**	**75.2**
China	**12.3**	**14.5**	**2.1**	**17.4**	**81.2**
Other Regions	**6.2**	**6.7**	**0.5**	**8.6**	**71.6**
Other Business	**30.3**	**31.5**	**1.2**	**4.1**	**75.4**

Exchange Rate:
FY2014 3Q : 1US$ = ¥ 106.7, 1RMB = ¥17.3
FY2015 3Q : 1US$ = ¥ 121.8, 1RMB = ¥19.3

【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】 MEROPEN® and weak yen contributed to increased revenue

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3Q Major Products Sales in Japan

Billions of yen

	FY2014 Apr.-Dec.	**FY2015 Apr.-Dec.**	Change		FY2015	
			Value	Percentage (%)	Previous forecasts	Progress (%)
AIMIX®	9.1	**11.9**	2.8	30.6	15.2	78.4
AVAPRO®	8.7	**8.4**	(0.2)	(2.6)	10.8	78.2
LONASEN®	8.5	**9.8**	1.3	14.7	13.0	75.3
TRERIEF®	8.5	**10.1**	1.6	19.1	14.0	72.4
Strategic Products Total	34.8	**40.3**	5.4	15.6	53.0	76.0
SUREPOST®	1.7	**2.7**	1.0	57.3	3.7	72.1
AmBisome®	3.4	**3.3**	(0.1)	(2.0)	4.3	76.9
REPLAGAL®	7.5	**7.9**	0.3	4.3	10.5	74.8
METGLUCO®	12.7	**12.0**	(0.7)	(5.7)	14.0	85.8
AMLODIN®	15.0	**12.9**	(2.1)	(13.9)	16.1	80.3
GASMOTIN®	8.1	**6.7**	(1.4)	(17.3)	8.3	80.5
PRORENAL®	8.2	**6.9**	(1.2)	(14.8)	9.1	76.3
MEROPEN®	6.2	**5.0**	(1.2)	(19.1)	6.5	76.8
Others	23.1	**16.8**	(6.2)	(27.0)	23.9	70.5
Other Products Total	85.8	**74.2**	(11.6)	(13.5)	96.4	77.0
Japan Total	120.6	**114.5**	(6.1)	(5.1)	149.4	76.6

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Note: Japan segment sales figures are before reduction of rebates

3Q Major Products Sales in North America & China

	FY2014 3Q	**FY2015 3Q**	Change	FY2014 3Q	**FY2015 3Q**	Change		FY2015		
						Value	Exchange Rate Impact	Previous forecasts		Yen-based Progress
North America	(Million $)			(Billion yen)				(Million $)	(Billion yen)	(%)
LATUDA®	555	**729**	174	59.3	**88.8**	29.5	11.0	1,000	120.0	74.0
APTIOM®	15	**44**	30	1.6	**5.4**	3.8	0.6	64	7.7	70.1
BROVANA®	146	**182**	36	15.6	**22.2**	6.5	2.7	244	29.3	75.6
Ciclesonide	51	**46**	(5)	5.4	**5.6**	0.2	0.7	57	6.9	80.9
XOPENEX®	64	**42**	(22)	6.8	**5.1**	(1.7)	0.6	54	6.5	79.2
LUNESTA®	90	**30**	(60)	9.6	**3.6**	(6.0)	0.4	35	4.2	86.1
Others	107	**54**	(53)	11.4	**6.6**	(4.8)	0.8	68	8.0	82.9
Total	1,028	**1,128**	100	109.7	**137.3**	27.6	16.9	1,522	182.6	75.2
China	(Million RMB)			(Billion yen)				(Million RMB)	(Billion yen)	(%)
MEROPEN®	591	**632**	41	10.2	**12.2**	2.0	1.3	783	14.9	81.7
Others	122	**118**	(4)	2.1	**2.3**	0.2	0.2	154	2.9	78.7
Total	713	**750**	37	12.3	**14.5**	2.1	1.5	937	17.8	81.2

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FY2015 (forecast) : 1US$ = ¥120.0, 1RMB = ¥19.0

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3Q Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2015 3Q Results	Net sales（Sales to customers）	114.5	137.3	14.5	6.7	273.0	31.5	304.5
	Cost of sales	35.0	12.3	2.6	3.8	53.7	25.3	79.1
	Gross profit	79.5	125.0	11.8	3.0	219.3	6.1	225.5
	SG&A expenses less R&D costs	44.1	78.6	6.2	1.9	130.7	4.7	135.4
	Income (loss) of Segment	35.4	46.4	5.7	1.1	88.6	1.4	90.0
	R&D costs					58.3	0.6	59.0
	Operating income					30.3	0.8	31.1
FY2014 3Q Results	Net sales（Sales to customers）	120.6	109.7	12.3	6.2	248.9	30.3	279.1
	Cost of sales	36.3	9.1	2.1	3.7	51.2	23.9	75.1
	Gross profit	84.5	100.6	10.2	2.5	197.8	6.2	204.0
	SG&A expenses less R&D costs	43.7	74.2	5.7	1.8	125.4	4.6	130.0
	Income (loss) of Segment	40.8	26.4	4.5	0.7	72.4	1.7	74.0
	R&D costs					50.6	0.6	51.2
	Operating income					21.8	1.0	22.8
Change	Net sales（Sales to customers）	(6.1)	27.6	2.1	0.5	24.1	1.2	25.4
	SG&A expenses less R&D costs	0.4	4.4	0.5	0.1	5.3	0.1	5.4
	Income (loss) of Segment	(5.3)	20.0	1.2	0.3	16.3	(0.2)	16.0
	R&D costs					7.8	(0.0)	7.8
	Operating income					8.5	(0.2)	8.3

Exchange Rate:
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FY2015 3Q : 1US$ = ¥121.8, 1RMB = ¥19.3

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3Q Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2014 3Q	**FY2015 3Q**	Change	
			Value	Percentage(%)
Operating Income	22.8	**31.1**	8.3	36.2
Non-operating income and expenses	(0.3)	**0.0**	0.4	
Ordinary income	22.5	**31.1**	8.6	38.3
Extraordinary income	17.7	**6.1**	(11.6)	
Gain on sales of investment securities	—	**6.1**		
Gain on sales of property, plant and equipment	16.0	**—**		
Compensation income for damage	1.7	**—**		
Extraordinary loss	5.9	**0.3**	(5.7)	
Impairment loss	5.1	**0.3**		
Business structure improvement expenses	0.8	**—**		
Income taxes	15.3	**13.6**	(1.7)	
Net income attributable to owners of the parent	19.0	**23.3**	4.4	22.9

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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	**403.0**	**2.0**	31.6	17.2	8.5
Cost of sales	101.2	103.5	**104.5**	**1.0**	3.3	1.4	3.2
Gross profit	270.1	297.5	**298.5**	**1.0**	28.4	15.8	10.5
SG&A expenses	246.9	268.5	**265.5**	**(3.0)**	18.6	13.8	7.5
SG&A expenses less R&D costs	175.6	179.0	**179.0**	**-**	3.4	9.6	2.0
R&D costs	71.3	89.5	**86.5**	**(3.0)**	15.2	4.2	21.3
Operating income	23.3	29.0	**33.0**	**4.0**	9.7	2.0	41.8
Ordinary income	23.3	28.5	**32.5**	**4.0**	9.2		39.3
Net income attributable to owners of the parent	15.4	20.0	**23.0**	**3.0**	7.6		48.9
E B I T D A	43.1	49.3	**53.3**	**4.0**	10.2		23.7

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

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Development Pipeline (1) (as of January 27, 2016)

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	China				
		Schizophrenia	Japan ※1				
		Bipolar I depression, Bipolar maintenance	Japan				
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 Preparing for the new Phase lll study
※2 A Phase ll / lll study completed, development strategy under consideration
※3 Phase II/III study

Revisions since the previous announcement are in red.

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Development Pipeline (2) (as of January 27, 2016)

Oncology Area (napabucasin, 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) (Global clinical trial)	U.S.				
		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				
		Solid tumors (Combination therapy) ※4	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)	U.S		※2		
		Solid tumors (Combination therapy)	U.S. / Canada				
		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 number of tumor type-specific studies (Hepatocellular carcinoma, Colorectal cancer)

Revisions since the previous announcement are in red.

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Development Pipeline (3) (as of January 27, 2016)

Oncology Area (Excluding napabucasin, 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				
DSP-7888	TBD	Myelodysplastic syndromes	Japan		※1		
		Solid tumors, Hematologic malignancies	U.S.				
WT4869	TBD	Myelodysplastic syndromes	Japan	※2			
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				

※1 Phase II of Phase I/II study
※2 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				

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Clinical Development Status

(Major Changes since October 28, 2015)

LATUDA®

- Submitted for schizophrenia in China in December 2015

Napabucasin (BBI608)

- Started Phase lll global clinical trial for Colorectal cancer (combination therapy with FOLFIRI, or FOLFIRI and bevacizumab) in the U.S.
- Started Phase l study for Colorectal cancer (combination therapy with FOLFIRI and bevacizumab) in Japan

DSP-7888

- Started Phase ll study of Phase l / ll for Myelodysplastic syndromes in Japan

Completed study

- LATUDA®
  Bipolar maintenance: Deleted due to completion of Phase lll study in the U.S. and Europe, etc.

Napabucasin presentation
Gastrointestinal Cancers Symposium (ASCO-GI 2016, U.S.)

- Presented 3 posters at the ASCO-GI in January 2016

✓ **Phase I study in colorectal cancer (combination therapy with FOLFIRI, or FOLFIRI and bevacizumab) (BBI608-246)**

✓ **Phase I study in pancreatic cancer (combination therapy with gemcitabine and nab-paclitaxel) (BBI608-118)**

✓ **Phase I / II study in pancreatic cancer (combination therapy with paclitaxel) (BBI608-201)**

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Napabucasin presentation

Gastrointestinal Cancers Symposium (ASCO-GI 2016, U.S.)

Phase I study in colorectal cancer (combination therapy with FOLFIRI, or FOLFIRI and bevacizumab) (BBI608-246)

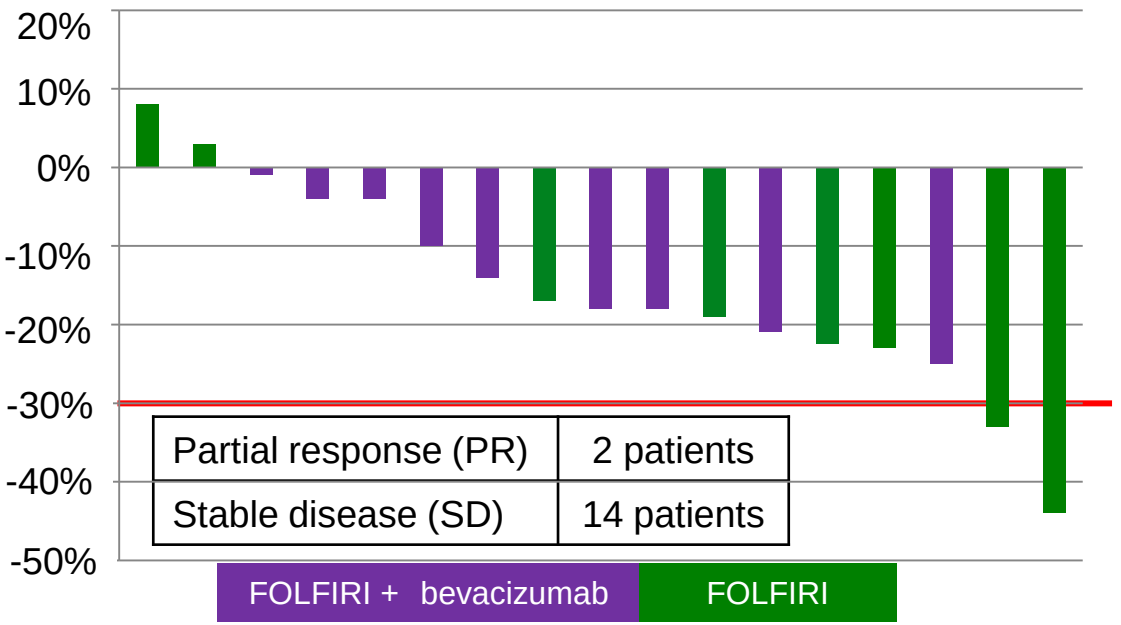
- **Study design**
  Open label, multi-center
- **Objectives**
  Safety, tolerability and preliminary anti-cancer activity (combination with FOLFIRI, or FOLFIRI and bevacizumab)

* FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)

- **Signs of anti-cancer activity** (Colorectal cancer 17patients)

Disease control rate (DCR)	94% (16 patients)

%Change in target lesions (Best response)



Hubbard JM, et al. *J Clin Oncol 34, 2016,* ASCO-GI 2016 (Abstract 569)

This study showed signs of anti-cancer activity with no dose limiting toxicity or new adverse events.

Appendix

Napabucasin, BBI503 - Clinical development progress (1)

Development status of napabucasin

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 Ⅲ	U.S.	Colorectal cancer (Combination therapy)	FOLFIRI*2, or FOLFIRI*2 and bevacizumab	BB608-303CRC	To be posted
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, regorafenib, or irinotecan	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
Phase Ⅰ	Japan	Colorectal cancer (Combination therapy)	FOLFIRI*2 and bevacizumab	D8809001	Dec. 2015

Study initiated was placed Clinical Trials.gov (as of January 26, 2016)

＊ Revisions since the announcement of October 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)

Napabucasin, 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 napabucasin + 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 January 26, 2016)

＊ No changes after the announcement of October 2015

LATUDA® (lurasidone) – Clinical development progress

Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	China	**Submitted**	–
Schizophrenia※	Japan	**Phase III**	**FY2019**
Bipolar I depression , Bipolar maintenance		**Phase III**	**FY2019**

※ Preparing for the new Phase III study

Europe (In-house & 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.
  ⇒The termination of the agreement and the transfer of the rights (effective January 31st, 2016)
- Future business plan in Europe
  - ✓ The Marketing Authorization (MA) for LATUDA® in EU and Switzerland will be transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ After the transfer of the MA, SPE will commercialize LATUDA® in Switzerland, the Netherlands and the Nordic region.
  - ✓ For countries other than the UK, Switzerland, the Netherlands, and the Nordic region, we will continuously seek a licensing partner.

(Reference)
Countries covered by the Agreement: 26 EU member states (excluding the UK), Switzerland, Norway, Turkey and Russia
Launched in: Switzerland, the Netherlands, Denmark, Norway, Finland
Submitted in: Russia, Turkey

Asia, South America, etc. (Partnering)

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

＊ Revisions since the announcement of October 2015

Target submission date of the Main late Development Pipeline

(Updated January 2016)

Field	Development products	Submission target			
		FY2015	FY2016	FY2017	FY2018
Psychiatry & Neurology Field	SM-13496 <lurasidone hydrochloride> (Schizophrenia) China	Submitted in Dec. 2015			
	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 <napabucasin> (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan			●	
	BBI503 (Solid tumors) U.S./ Japan				●
Respiratory Field	SUN-101<glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.		●		

Up-date

New Chemical Entities　　New Indication, etc.

＊ Revisions since the announcement of October 2015

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Product Launch Plan (Updated December 2015)

Area	FY2015 (Launched)	FY2016	FY2017	FY2018	FY2019～FY2021	
Japan	REMITCH® (Pruritus (chronic liver disease) (Promotion) Trulicity® (GLP-1 recepter agonist) (Marketing)	※ EPI-743 (Leigh syndrome)	ranirestat (Diabetic neuropathy) napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	LONASEN® (Schizophrenia / Transdermal patch) TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	Lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance) napabucasin (Colorectal cancer, etc.) BBI503 (Solid tumors) 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)		napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma) SUN-101 (COPD)	dasotraline (ADHD)	SB623 (Chronic stroke) DSP-2230 (Neuropathic pain) SEP-363856 (Schizophrenia) dasotraline (BED)	napabucasin (Colorectal cancer, etc.) BBI503 (Solid tumors) DSP-7888 (Solid tumors/ Hematologic cancer)
China		LONASEN® (Schizophrenia) CALSED® (Small cell lung cancer)		lurasidone (Schizophrenia)		

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: P&N
: Oncology
: Liver/ Digestive
: Respiratory

New Chemical Entities
New Indication , etc.

※ Development strategy under consideration

＊No changes after R&D meeting in December 2015.

Regenerative Medicine/Cell Therapy of Business Plan

(Updated December 2015)

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year)					
				2015	2016	2017	2018	2019	2020
Chronic 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 or 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)		

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＊No changes after R&D meeting in December 2015.

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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Innovation today, healthier tomorrows