Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for 3Q FY2016
(April 1 to December 31, 2016)

January 27, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma

Financial Results for 3Q FY2016

Financial Results for FY2016 Apr.-Dec.

Billions of yen

	FY2015 Apr.-Dec.	FY2016 Apr.-Dec.	Change			FY2016	
			Value	FX rate impact	%	Previous forecasts	Progress %
Net sales	304.5	305.5	1.0	(23.1)	0.3	398.0	76.8
Cost of sales	79.1	74.3	(4.7)	* (6.8)	(6.0)	95.5	77.8
Gross profit	225.5	231.2	5.7	(16.0)	2.5	302.5	76.4
SG&A expenses	194.4	186.9	(7.5)	(16.2)	(3.8)	256.5	72.9
SG&A expenses less R & D costs	135.4	129.8	(5.7)	(11.4)	(4.2)	173.5	74.8
R&D Costs	59.0	57.2	(1.8)	(4.7)	(3.0)	83.0	68.9
Operating income	31.1	44.2	13.2	0.2	42.3	46.0	96.2
Ordinary income	31.1	49.9	18.7		60.2	44.0	113.3
Extraordinary income (loss)	5.8	(5.2)	(11.0)			(3.0)	
Net income attributable to owners of the parent	23.3	29.6	6.2		26.7	25.0	118.3
E B I T D A	46.6	63.9	17.4		37.3	63.0	

* The number includes downward impact on cost of sales because unrealized profit of inventory on FY2015 FX rate realized in this period with stronger yen.

FX rates:
FY2015 3Q Results : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q Results : 1US$ = ¥ 106.6, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.0

Sales of Major Products in Japan

Billions of yen

	FY2015 Apr.-Dec.	FY2016 Apr.-Dec.	Change		FY2016	
			Value	%	Previous forecasts	Progress %
AIMIX®	11.9	13.1	1.1	9.6	16.1	81.1
LONASEN®	9.8	10.1	0.3	2.7	13.8	72.8
TRERIEF®	10.1	11.7	1.6	15.7	14.5	80.9
Strategic Products Total	31.8	34.8	3.0	9.4	44.4	78.5
REPLAGAL®	7.9	8.2	0.3	3.9	10.5	77.7
AmBisome®	3.3	3.5	0.2	5.5	4.3	81.1
AVAPRO®	8.4	8.1	(0.4)	(4.6)	10.0	80.5
SUREPOST®	2.7	3.3	0.6	24.3	4.6	72.1
METGLUCO®	12.0	8.7	(3.4)	(27.9)	10.8	80.1
AMLODIN®	12.9	10.2	(2.7)	(21.0)	12.2	83.7
PRORENAL®	6.9	5.2	(1.8)	(25.3)	7.0	74.2
GASMOTIN®	6.7	4.8	(1.9)	(28.3)	6.0	79.8
MEROPEN®	5.0	3.4	(1.6)	(31.3)	4.5	76.2
Others	16.8	18.4	1.6	9.5	24.7	74.7
Other Products Total	82.7	73.7	(8.9)	(10.8)	94.6	77.9
Japan Total	114.5	108.6	(5.9)	(5.2)	139.0	78.1

Note: Sales of each product above are shown by invoice price sales basis.

Sales of Major Products in North America & China

	FY2015 Apr.-Dec.	FY2016 Apr.-Dec.	Change	FY2015 Apr.-Dec.	FY2016 Apr.-Dec.	Change			FY2016		
						Value	rate	FX rate impact	Previous forecasts		Yen-based Progress
North America	Million $			Billion yen			%	Billion yen	Million $	Billion yen	%
LATUDA®	729	911	181	88.8	97.1	8.3	9.3	(13.8)	1,210	127.1	76.4
APTIOM®	44	75	31	5.4	8.0	2.6	48.6	(1.1)	117	12.3	65.2
BROVANA®	182	233	51	22.2	24.8	2.7	12.0	(3.5)	286	30.0	82.7
Ciclesonide	46	37	△9	5.6	3.9	(1.6)	(29.3)	(0.6)	49	5.1	77.4
XOPENEX®	42	38	△5	5.1	4.0	(1.1)	(22.1)	(0.6)	52	5.5	72.9
LUNESTA®	30	△7	△37	3.6	(0.8)	(4.4)	–	0.1	7	0.7	–
Others	54	61	7	6.6	6.5	(0.1)	(1.5)	(0.9)	69	7.3	89.5
Total	1,128	1,347	219	137.3	143.6	6.3	4.6	(20.4)	1,790	188.0	76.4
China	Million RMB			Billion yen			%	Billion yen	Million RMB	Billion yen	%
MEROPEN®	632	707	75	12.2	11.3	(0.9)	(7.4)	(2.4)	902	14.4	78.3
Others	118	104	(14)	2.3	1.7	(0.6)	(27.3)	(0.3)	148	2.4	69.2
Total	750	811	61	14.5	12.9	(1.5)	(10.5)	(2.7)	1,050	16.8	77.0

FX rates:
FY2015 3Q Results : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q Results : 1US$ = ¥ 106.6, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 105.0, 1RMB = ¥16.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 3Q Results	Net sales (Sales to customers)	108.6	143.6	12.9	7.4	272.5	33.0	305.5
	Cost of sales	35.1	7.0	2.3	3.6	48.0	26.3	74.3
	Gross profit	73.5	136.6	10.6	3.8	224.6	6.6	231.2
	SG&A expenses less R&D costs	42.2	74.5	6.0	2.2	124.9	4.8	129.8
	Income (loss) of Segment	31.2	62.1	4.6	1.6	99.6	1.8	101.4
	R&D costs					56.5	0.7	57.2
	Operating income					43.1	1.1	44.2
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
Change	Net sales (Sales to customers)	(5.9)	6.3	(1.5)	0.7	(0.5)	1.5	1.0
	SG&A expenses less R&D costs	(1.9)	(4.1)	(0.2)	0.4	(5.8)	0.1	(5.7)
	Income (loss) of Segment	(4.2)	15.7	(1.0)	0.5	11.0	0.4	11.4
	R&D costs					(1.9)	0.1	(1.8)
	Operating income					12.8	0.3	13.2

FX rates:
FY2015 3Q : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q : 1US$ = ¥ 106.6, 1RMB = ¥15.9

Ordinary income & Net income attributable to owners of the parent

Billions of yen

	FY2015 3Q Results	FY2016 3Q Results	Change	
			Value	%
Operating Income	31.1	44.2	13.2	42.3
Non-operating income and expenses	0.0	5.6	5.6	
Ordinary income	31.1	49.9	18.7	60.2
Extraordinary income	6.1	4.8	(1.3)	
Gain on sales of investment securities	6.1	4.8		
Extraordinary loss	0.3	10.0	9.7	
Business structure improvement expenses	–	10.0		
Impairment loss	0.3	–		
Income taxes	13.6	15.1	1.5	
Net income attributable to owners of the parent	23.3	29.6	6.2	26.7

FX rates:
FY2015 3Q : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q : 1US$ = ¥ 106.6, 1RMB = ¥15.9

Valuations and accounting procedures following the acquisition of Cynapsus

Valuation of assets and accounting procedures associated with the acquisition are as follows.

Millions of US$

	Before Purchase price allocation	After Purchase price Allocation	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible assets)	–	669	669	Capitalize (amortize after launch)
Other assets & liabilities (Net)	(57)	(74)	(17)	License fee payable in future and other liabilities
Goodwill	–	12	12	Amortization for 20 years
Total acquisition cost	(57)	607	664	

Acquisition of Tolero Pharmaceutical, Inc.

Acquisition of Tolero was completed on January 25, 2017 (U.S. pacific standard time). Valuation of the asset and accounting procedures will be disclosed in the FY2016 earnings announcement.

Financial Forecasts for FY2016

Financial Forecasts for FY2016

Billions of yen

	FY2015 Result (a)	FY2016 Previous forecasts (b)	FY2016 Revised Forecasts (c)	Change from previous forecasts (c)-(b)		Change from FY2015 (c)-(a)		
				Value	FX rate impact	Value	FX rate impact	%
Net sales	403.2	398.0	404.0	6.0	5.4	0.8	(24.9)	0.2
Cost of sales	104.5	95.5	98.5	3.0	1.9	(6.0)	(8.7)	(5.7)
Gross profit	298.7	302.5	305.5	3.0	3.5	6.8	(16.2)	2.3
SG&A expenses	261.8	256.5	259.5	3.0	4.3	(2.3)	(18.4)	(0.9)
SG&A expenses less R&D costs	179.8	173.5	178.5	5.0	3.1	(1.3)	(13.5)	(0.7)
R&D Costs	82.0	83.0	81.0	(2.0)	1.2	(1.0)	(4.9)	(1.3)
Operating income	36.9	46.0	46.0	–	(0.7)	9.1	2.2	24.6
Ordinary income	35.2	44.0	46.0	2.0		10.8		30.6
Extraordinary income (loss)	4.3	(3.0)	(5.0)	(2.0)		(9.3)		
Net income attributable to owners of the parent	24.7	25.0	26.0	1.0		1.3		5.3
E B I T D A	55.8	63.0	65.5	2.5		9.7		17.4

FX rates:

FY2015 Result : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Previous Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0
FY2016 Revised Forecast : 1US$ = ¥ 108.0, 1RMB = ¥16.0

Clinical Development Status

Clinical Development Status

Development Pipeline (1) (Psychiatry & Neurology Area)

(as of January 27, 2017)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
APTIOM®	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® （SM-13496）	lurasidone hydrochloride	Schizophrenia	China				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				※2
		Binge eating disorder (BED)	U.S.				※2
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
EPI-589	TBD	Parkinson's disease	U.S.				
		Amyotrophic lateral sclerosis (ALS)	U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
		Parkinson's disease psychosis	U.S.				
		Schizophrenia	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				
DSP-1200	TBD	Treatment-resistant depression	U.S.				
DSP-6745	TBD	Parkinson's disease psychosis	U.S.				

※1／A Phase 2 / 3 study completed, development strategy under consideration ※2／Phase 2 / 3 study

Development Pipeline (2) (Oncology Area) (as of January 27, 2017)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
BBI608	napabucasin	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical study)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Canada / Japan				
		Non-small cell lung cancer (Combination therapy) (Global clinical study)	U.S.				
		Pancreatic cancer (Combination therapy) (Global clinical study)	U.S.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Ovarian cancer, Breast cancer, Melanoma, Glioblastoma, etc.) (Combination therapy) ※3	U.S. / Canada			※1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			※1	
		Solid tumors (Combination therapy) ※4 Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy) ※5	Japan				
BBI503	amcasertib	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	napabucasin amcasertib	Solid tumors (Combination therapy)	U.S.				

※1／Phase 2 of Phase 1 / 2 study ※2／Phase 1 of Phase 1 / 2 study ※3／Glioblastoma's development is only Canada.
※4／Multiple studies for different tumor types (Gastrointestinal cancer , Hepatocellular carcinoma, Pancreatic cancer)
※5／Multiple studies for different tumor types (Hepatocellular carcinoma)

Development Pipeline (3) (Oncology & Others Area)

(as of January 27, 2017)

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-7888	TBD	Myelodysplastic syndromes	Japan			※1	
		Pediatric malignant gliomas	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				
DSP-1958 ※3	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT)	Japan				
alvocidib	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven)	U.S.				
TP-0903	TBD	Solid tumors	U.S.				

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study　※3／Development for the use of unapproved or off-labeled drugs

Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
SUN-101	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

Clinical Development Status (Major Changes since October 27, 2016)

Dasotraline

- ✓ Topline results from Phase 3 study of adult ADHD and Phase 2/3 study of BED announced in January 2017

Napabucasin (BBI608)

- ✓ Started global Phase 3 study for pancreatic cancer (combination therapy with gemcitabine and nab-paclitaxel) in the U.S.
- ✓ Started Phase 2 of Phase 1/2 study for glioblastoma (combination therapy with temozolomide) in Canada

Newly added

- ✓ **Alvocidib**
  - Newly added through the acquisition of Tolero in January 2017
  - Phase 2 study for acute myeloid leukemia (AML) in the U.S.
- ✓ **TP-0903**
  - Newly added through the acquisition of Tolero in January 2017
  - Phase 1 study for solid tumors in the U.S.
- ✓ **DSP-6745**
  - Phase 1 study for Parkinson's disease psychosis in the U.S.

Upcoming Event: R&D meeting

- Date: February 28, 2017, Time: 10:00am-12:00
- Location: Sumitomo Dainippon Pharma Tokyo Head Office 10th floor

Development Progress of Dasotraline

- **Topline results from adult ADHD Phase 3 study (SEP360-301)**
  - ✓ Study Design: 8-week, double-blind, placebo-controlled study (4mg, 6mg)
    Primary endpoint: Change from baseline at Week 8 in ADHD symptoms as measured by ADHD RS IV with adult prompts total score
    Secondary endpoint: Clinical Global Impression-Severity of Illness Scale at Week 8
  - ✓ Study Results:
    - Efficacy: Dasotraline 4 mg/day and 6 mg/day were not statistically superior to placebo on the primary endpoint, but 6 mg/day showed a trend to greater improvement and statistically significant improvement on the secondary endpoint
    - Safety: Adverse events were consistent with completed studies

- **Topline results from adult BED Phase 2/3 study (SEP360-221)**
  - ✓ Study Design: 12-week, double-blind, placebo-controlled study (4 to 8 mg)
  - ✓ Study Results:
    - Efficacy: Dasotraline was statistically superior to placebo on the primary endpoint and key secondary endpoints
    - Safety: Adverse events were consistent with completed studies

- **Future Plan**
  - ✓ Adult and Pediatric ADHD: Plan to submit NDA in FY2017
  - ✓ BED: Plan to submit NDA in FY2018

Napabucasin Presentation
(Gastrointestinal Cancers Symposium (ASCO-GI 2017))

- **Presented results of Phase 1b/2 studies in colorectal cancer (2 posters) at the ASCO-GI in January 2017（Announced in the press release on January 23, 2017)**
  - BBI608-246 study: Combination therapy with FOLFIRI, or FOLFIRI and bevacizumab (open label)
  - BBI608-224 study: Combination therapy with panitumumab (open label)

● BBI608-246 study

➢Study Results :

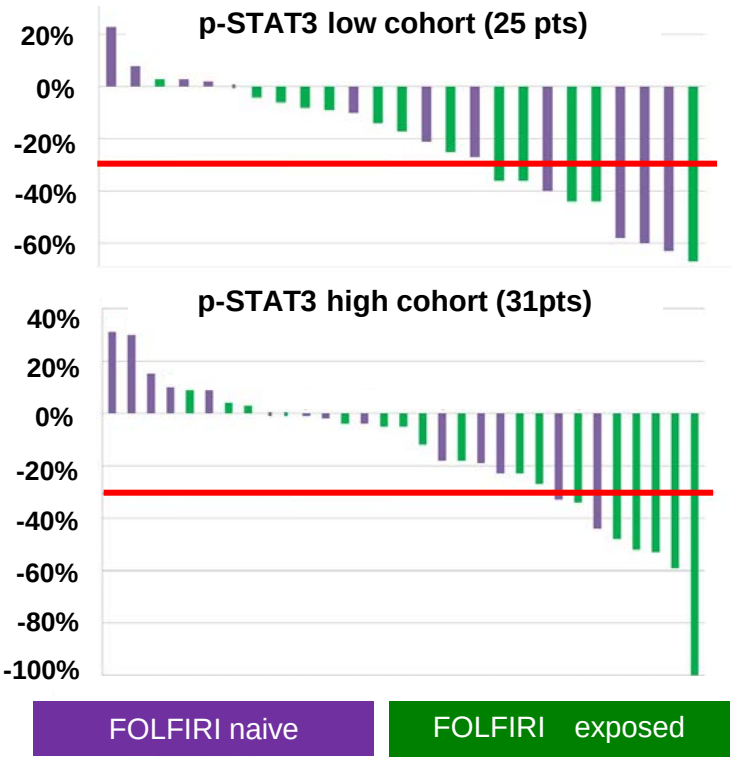
✓ Napabucasin showed signs of anti-cancer activity regardless of FOLFIRI-pretreatment or p-STAT3 status.

(56 evaluable patients)

Subset	Disease control rate (DCR)	overall response rate (ORR)
Evaluable 56 pts	88% (49/56 pts)	29% (16/56 pts) (1 pt achieving CR)
FOLFIRI naïve	93% (28/30 pts)	33% (10/30 pts)
FOLFIRI exposed	81% (21/26 pts)	23% (6/26 pts)
p-STAT3 low	92% (23/25 pts)	32% (8/25 pts)
p-STAT3 high	84% (26/31 pts)	26% (8/31 pts)

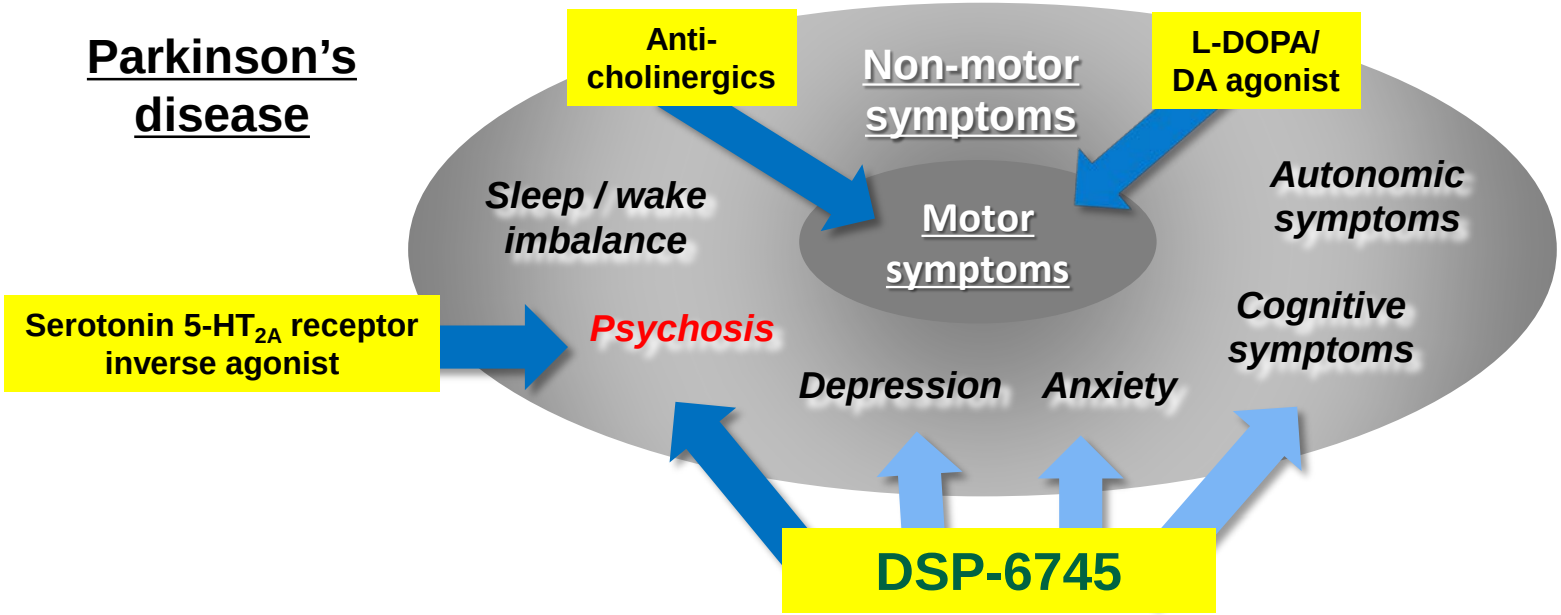
* FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)

Percentage Change in target lesions (Best response)



Profile of DSP-6745

- **Target Indication:** Parkinson's disease psychosis
- **Origin:** In-house
- **Mechanism of Action:** Serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors dual antagonist
- **Development stage:** Phase 1 study in the U.S.
- **Characteristics:**
  - Antagonist effects at serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors are expected to provide broad therapeutic opportunities for patients with Parkinson's disease non-motor symptoms, especially with psychosis.
  - Negligible affinity for dopamine D_2 receptors may have less safety concern about exacerbation of motor symptoms.



Appendices

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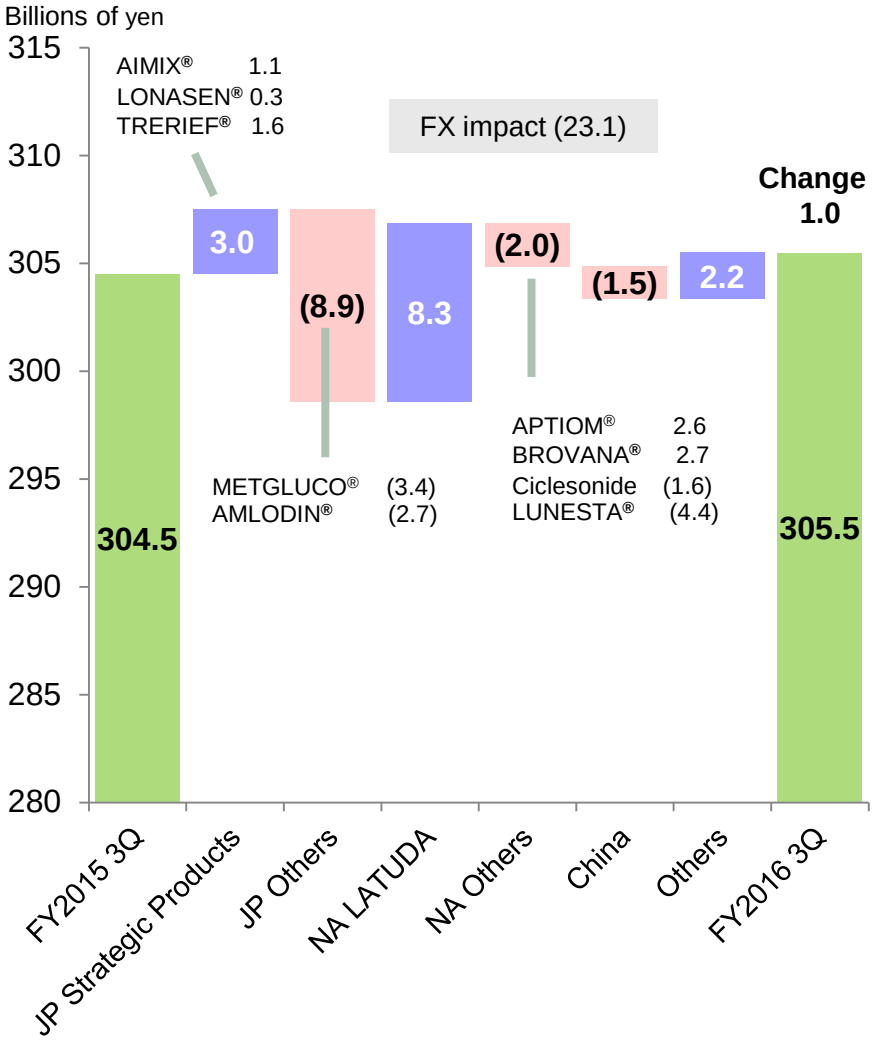
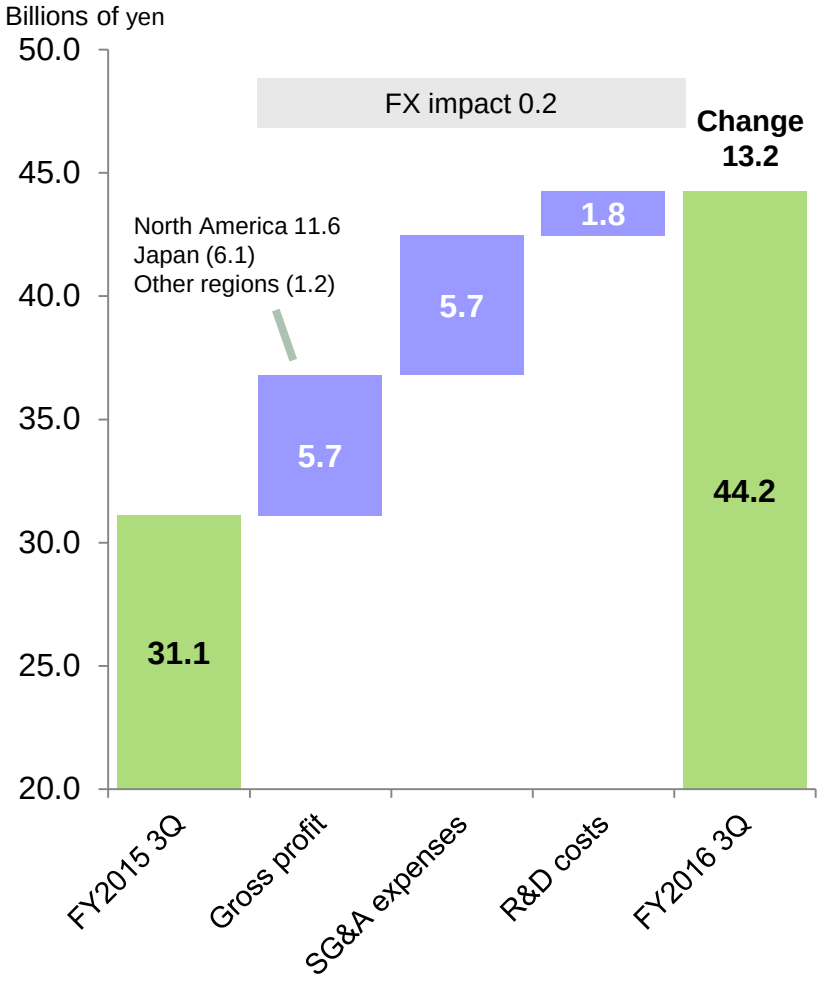
Changes from FY2015 3Q

Sales



Operating Income



FX rates:
FY2015 3Q : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q : 1US$ = ¥ 106.6, 1RMB = ¥15.9

Net Sales by Segment

Billions of yen

Changes +1.0 +0.3 %
Progress 76.8 %

Japan ・Changes (5.9) (5.2) %
- NHI drug price revision (5.9)
  Increase in strategic products, decrease in long-listed products

・Progress 78.1 %

North America
・Changes +6.3 +4.6 %
- Growth of LATUDA®, APTIOM® and BROVANA® offset impact of yen appreciation (20.4)

・Progress 76.4 %

China ・Changes (1.5) (10.5) %
- Decrease due to FX impact (2.7) despite increase in MEROPEN®

・Progress 77.0 %

Other Regions
・Changes +0.7 +9.8 %
- Increase in export of MEROPEN® and others

・Progress 68.4 %

Other Business
・Changes +1.5 +4.8 %
・Progress 76.0 %

FX rates:
FY2015 3Q : 1US$ = ¥ 121.8, 1RMB = ¥19.3
FY2016 3Q : 1US$ = ¥ 106.6, 1RMB = ¥15.9

＊Progress is % to previous full-year forecasts.

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 Revised Forecasts	Net sales (Sales to customers)	139.5	193.5	16.8	10.8	360.6	43.4	404.0
	Cost of sales	46.0	9.5	3.1	5.1	63.7	34.8	98.5
	Gross profit	93.5	184.0	13.7	5.7	296.9	8.6	305.5
	SG&A expenses less R&D costs	57.3	103.8	7.7	3.1	171.9	6.6	178.5
	Income (loss) of Segment	36.2	80.2	6.0	2.6	125.0	2.0	127.0
	R&D costs					80.0	1.0	81.0
	Operating income					45.0	1.0	46.0
FY2016 Previous forecasts	Net sales (Sales to customers)	139.0	188.0	16.8	10.8	354.6	43.4	398.0
	Cost of sales	46.0	6.5	3.1	5.1	60.7	34.8	95.5
	Gross profit	93.0	181.5	13.7	5.7	293.9	8.6	302.5
	SG&A expenses less R&D costs	57.5	98.6	7.7	3.1	166.9	6.6	173.5
	Income (loss) of Segment	35.5	82.9	6.0	2.6	127.0	2.0	129.0
	R&D costs					82.0	1.0	83.0
	Operating income					45.0	1.0	46.0
Change	Net sales (Sales to customers)	0.5	5.5	—	—	6.0	—	6.0
	SG&A expenses less R&D costs	(0.2)	5.2	—	—	5.0	—	5.0
	Income (loss) of Segment	0.7	(2.7)	—	—	(2.0)	—	(2.0)
	R&D costs	—	—	—	—	(2.0)	—	(2.0)
	Operating income	—	—	—	—	—	—	—

FX rates:
FY2016 Previous Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0
FY2016 Revised Forecast : 1US$ = ¥ 108.0, 1RMB = ¥16.0

Appendix (Clinical Development Status)

Napabucasin – Clinical development progress

(as of January 27, 2017)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	paclitaxel	BRIGHTER	Aug. 2014
	U.S. / Canada / Japan	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C	June 2016
	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel	CanStem111P	Dec. 2016
	U.S.	Non-small cell lung cancer (Combination therapy)	Paclitaxel	CanStem43L	Nov. 2016
Phase 2	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, capecitabine	BBI608-224	Mar. 2012
	U.S. / Canada	Solid tumors*1 (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin + pemetrexed	D8807005	Feb. 2015
	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
Phase 1	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, irinotecan	BBI608-246	Jan. 2014
	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin	BBI608-118	Aug. 2014
	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone, bortezomib, imatinib, ibrutinib	BBI608-103HEME	May 2015
	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
	U.S.	Solid tumors (Combination therapy)	iplimumab, pembrolizumab, nivolumab	BBI608-201CIT	Aug. 2015

*1／Ovarian cancer, Breast cancer, Melanoma, etc.

Start date is based on Clinical Trials.gov (as of January 26, 2017)

Amcasertib, Napabucasin– Clinical development progress

(as of January 27, 2017)

Sumitomo Dainippon Pharma

Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 2	U.S. / Canada	Solid tumors*1 (Monotherapy)	―	BBI503-101	Feb. 2012
	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	―	BBI503-205a	Jan. 2017
	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	―	BBI503-205b	Feb. 2015
	Canada	Gastrointestinal stromal tumor (Monotherapy)	―	BBI503-205c	Jan. 2017
	U.S.	Ovarian cancer (Monotherapy)	―	BBI503-205GYN-M	June 2015
Phase 1	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	Mar. 2015
	U.S. / Canada	Solid tumors (Combination therapy)	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	BBI503-201	Sep. 2015

*1／Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

Napabucasin + Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 1	U.S.	Solid tumors (Combination therapy)	―	BBI401-101	Apr. 2015

Start date is based on Clinical Trials.gov
(as of January 26, 2017)

LATUDA® (lurasidone) – Clinical development progress

Revisions since the previous announcement are in red.

Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	China	Submitted	—
Schizophrenia	Japan	Phase 3	FY2019
Bipolar I depression , Bipolar maintenance		Phase 3	FY2019

Europe (In-house)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe was terminated on January 31st, 2016.
- The Marketing Authorization (MA) for LATUDA® in EU and Switzerland was transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ SPE started commercializing LATUDA® in May 2016 in the countries where the product has already been launched.
  - ✓ For other countries, we will continuously seek a licensing partner.

  (Reference)

  MA Submitted in: Turkey

  Approved in: Russia

  Launched in: UK, Switzerland, Denmark, Norway, the Netherlands, Finland, and Sweden

Asia, South America, etc. (Partnering)

- MA Submitted in: Venezuela, Brazil (submitted by Daiichisankyo)
- Approved in: Singapore, Thailand, Hong Kong (obtained by DKSH)
- Launched in: Australia (commercialization partnership with Servier Australia),
  Taiwan (commercialization partnership with Standard Chem. & Pharm.)

Target submission date of key late-stage pipeline

(Updated January 2017)

Area	Development	Submission target			
		FY2016	FY2017	FY2018	FY2019 or later
Respiratory	**SUN-101 <glycopyrronium>** (Chronic obstructive pulmonary disease) U.S.	July 2016 Submitted			
Psychiatry & Neurology	**SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S.		●		
	APL-130277 <apomorphine > (Parkinson's disease) U.S.		●		
	TRERIEF® **<zonisamide>** (Parkinsonism in Dementia with Lewy Bodies) Japan		●		
	SEP-225289 <dasotraline> (BED) U.S.			●	
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan			●	
	SM-13496 <lurasidone > (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan				●
Oncology	**BBI608 <napabucasin>** (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan			●	
	BBI608 <napabucasin> (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 <napabucasin> (Pancreatic cancer / Combination therapy) U.S.				●

New Chemical Entities | New Indication, etc.

Product Launch Plan (Updated January 2017)

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Area	FY2017	FY2018	FY2019	FY2020 - FY2022	
Japan		TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	LONASEN® (Schizophrenia / Transdermal patch)	lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance)	obeticholic acid (NASH)
		thiotepa (Conditioning treatment prior to HPCT)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	napabucasin (Colorectal cancer, etc.)	DSP-6952 (IBS with constipation, Chronic idiopathic constipation)
				amcasertib (Solid tumors)	iPS cell-derived RPE cells (Age-related macular degeneration)
				DSP-7888 (Solid tumors/ Hematologic cancer)	
U.S.	glycopyrronium (COPD)	dasotraline (ADHD)	dasotraline (BED)	SB623 (Chronic stroke)	napabucasin (Colorectal cancer, Pancreatic cancer, NSCLC)
	UTIBRON, SEEBRI (COPD) (In-licensed)	apomorphine (Parkinson's disease)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	DSP-2230 (Neuropathic pain)	amcasertib (Solid tumors)
			alvocidib (Acute myeloid leukemia)	SEP-363856 (Schizophrenia)	DSP-7888 (Solid tumors/ Hematologic cancer)
China	LONASEN® (Schizophrenia)	lurasidone (Schizophrenia)			

Psychiatry & Neurology / Oncology / Liver / Digestive / Respiratory

New Chemical Entities | New Indication , etc.

Regenerative Medicine / Cell Therapy Business Plan

(Updated January 2017)

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year) 2017	2018	2019	2020-2022
Chronic Stroke	**SanBio**	North America	Allo MSC	**Phase 2b**		**Phase 3**	**Approval Target**
AMD (age-related macular degeneration)	**Healios RIKEN**	Japan	Allo iPS cell	**Clinical research** ※ **Investigator or corporate initiated clinical study**			**Approval Target**
Parkinson's disease	**Kyoto Univ CiRA**	Global	Allo iPS cell	**Clinical research or clinical study**			
Retinitis pigmentosa	**RIKEN**	Global	Allo iPS cell		**Clinical research**		
Spinal Cord Injury	**Keio Univ Osaka National Hospital**	Global	Allo iPS cell		**Clinical research**		

※ Start of clinical studies originally scheduled in 2017 may be delayed due to changes in non-clinical study plans.

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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Innovation today, healthier tomorrows