Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for Q3 FY2017
(April 1 to December 31, 2017)

January 30, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma

Financial Results for Q3 FY2017

Financial Results for Q3 FY2017 (Apr.-Dec.)

Billions of yen

	FY2016 Apr.-Dec.	FY2017 Apr.-Dec.	Change			FY2017	
			Value	FX rate impact	%	Previous forecasts	Progress %
Net sales	305.5	364.1	58.6	9.4	19.2	474.0	76.8
Cost of sales	74.3	93.2	18.8	* 8.0	25.3	118.5	78.6
Gross profit	231.2	271.0	39.8	1.4	17.2	355.5	76.2
SG&A expenses	186.9	215.0	28.1	6.3	15.0	283.5	75.8
SG&A expenses less R & D costs	129.8	147.1	17.3	4.5	13.4	194.5	75.6
R&D costs	57.2	67.9	10.7	1.8	18.8	89.0	76.3
Operating income	44.2	55.9	11.7	(4.9)	26.5	72.0	77.7
Ordinary income	49.9	58.0	8.1		16.3	72.0	80.5
Extraordinary income (loss)	(5.2)	(1.9)	3.2			(2.5)	
Net income attributable to owners of the parent	29.6	50.6	21.0		71.1	47.0	107.6
E B I T D A	63.9	72.8	8.9		13.9	92.0	79.2

* Includes an impact [¥7.0B] of change in FX rates on the unrealized profit of inventory

FX rates: Q3 FY2016 Results : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 Results : 1US$ = ¥ 111.7, 1RMB = ¥16.6
FY2017 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

- Increase in net sales and profit year-on-year, good progress on full-year forecast
- Net income increased due to an impact of tax reform in U.S.

Sales of Major Products in Japan

Billions of yen

	FY2016 Apr.-Dec.	FY2017 Apr.-Dec.	Change		FY2017	
			Value	%	Previous forecasts	Progress %
AIMIX®	13.1	14.6	1.5	11.5	17.5	83.2
TRERIEF®	11.7	12.7	1.0	8.4	16.0	79.4
LONASEN®	10.1	10.0	(0.0)	(0.1)	13.2	76.0
METGLUCO®	8.7	8.5	(0.1)	(1.5)	11.3	75.4
REPLAGAL®	8.2	9.0	0.8	10.1	11.3	79.5
Trulicity® *	4.3	11.8	7.5	173.2	14.5	81.4
AVAPRO®	8.1	7.6	(0.4)	(5.3)	8.0	95.4
SUREPOST®	3.3	3.9	0.5	16.1	5.3	72.6
AmBisome®	3.5	3.4	(0.1)	(2.4)	4.5	75.7
Promoted products Total	70.8	81.5	10.7	15.1	101.6	80.2
AMLODIN®	10.2	9.1	(1.1)	(10.8)	10.6	86.0
PRORENAL®	5.2	4.4	(0.8)	(15.6)	5.1	85.9
GASMOTIN®	4.8	4.0	(0.8)	(17.4)	5.0	79.1
MEROPEN®	3.4	2.7	(0.8)	(21.9)	3.3	81.1
Others	14.1	11.3	(2.8)	(19.7)	16.0	70.9
Total	108.6	113.0	4.4	4.0	141.6	79.8

Note: Sales of each product above are shown on an invoice price basis (* Trulicity® is shown on NHI price basis).

- Sales increase is driven by Trulicity®, AIMIX® and TRERIEF® are in steady progress.
- Long listed products continue to be in decreasing trend.

Sales of Major Products in North America & China

	FY2016 Apr.-Dec.	FY2017 Apr.-Dec.	Change	FY2016 Apr.-Dec.	FY2017 Apr.-Dec.	Change			FY2017		
						Value	FX rate impact	%	Forecasts		Yen-based progress
North America	Million $			Billion yen					Million $	Billion yen	%
LATUDA®	911	1,210	299	97.1	135.1	38.0	6.2	39.2	1,618	178.0	75.9
BROVANA®	233	227	(6)	24.8	25.3	0.5	1.2	2.1	313	34.4	73.6
APTIOM®	75	102	27	8.0	11.4	3.4	0.5	42.0	152	16.7	68.2
Ciclesonide	37	13	(24)	3.9	1.4	(2.5)	0.1	(63.6)	13	1.4	102.7
XOPENEX®	38	24	(13)	4.0	2.7	(1.3)	0.1	(32.4)	29	3.2	84.7
New COPD products *	–	3	3	–	0.4	0.4	–	–	6	0.7	54.4
Others	54	136	82	5.7	15.2	9.4	0.7	163.9	158	17.4	87.1
Total	1,347	1,715	368	143.6	191.6	47.9	8.7	33.4	2,289	251.8	76.1
China	Million RMB			Billion yen					Million RMB	Billion yen	%
MEROPEN®	707	801	93	11.3	13.3	2.1	0.6	18.2	1,023	16.9	78.8
Others	104	127	23	1.7	2.1	0.5	0.1	27.6	171	2.8	75.7
Total	811	928	117	12.9	15.4	2.5	0.6	19.4	1,194	19.7	78.4

- UTIBRON™, SEEBRI™, ARCAPTA®, LONHALA™ MAGNAIR™

FX rates: Q3 FY2016 Results : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 Results : 1US$ = ¥ 111.7, 1RMB = ¥16.6
FY2017 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5

- LATUDA® and APTIOM® show steady growth in North America.
- Sales of LONHALA™ MAGNAIR™ will start to contribute in FY2018.

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q3 FY2017 Results	Net sales (Sales to customers)	113.0	191.6	15.4	10.6	330.5	33.6	364.1
	Cost of sales	40.2	18.1	3.4	5.0	66.7	26.5	93.2
	Gross profit	72.8	173.5	12.1	5.6	263.9	7.0	271.0
	SG&A expenses less R&D costs	37.5	95.7	6.4	2.7	142.3	4.8	147.1
	Income (loss) of Segment	35.3	77.8	5.7	2.9	121.6	2.2	123.8
	R&D costs					67.1	0.8	67.9
	Operating income					54.5	1.5	55.9
Q3 FY2016 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
Change	Net sales (Sales to customers)	4.4	47.9	2.5	3.2	58.0	0.6	58.6
	SG&A expenses less R&D costs	(4.7)	21.2	0.4	0.5	17.4	(0.0)	17.3
	Income (loss) of Segment	4.0	15.6	1.1	1.3	22.0	0.4	22.4
	R&D costs					10.7	0.1	10.7
	Operating income					11.3	0.4	11.7

FX rates: Q3 FY2016 : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 : 1US$ = ¥ 111.7, 1RMB = ¥16.6

- Substantial increase in income in North America due to sales growth
- Income in Japan increased partially due to cost reduction

Ordinary income & Net income attributable to owners of the parent

Billions of yen

	Q3 FY2016 Results	Q3 FY2017 Results	Change	
			Value	%
Operating Income	44.2	55.9	11.7	26.5
Non-operating income and expenses	5.6	2.0	(3.4)	
Ordinary income	49.9	58.0	8.1	16.3
Extraordinary income	4.8	–	(4.8)	
Gain on sales of investment securities	4.8	–		
Extraordinary loss	10.0	1.9	(8.1)	
Business structure improvement expenses	10.0	1.9		
Income taxes	15.1	5.5	(9.7)	
Net income attributable to owners of the parent	29.6	50.6	21.0	71.1

FX rates:
Q3 FY2016 : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 : 1US$ = ¥ 111.7, 1RMB = ¥16.6

Financial Forecasts for FY2017

Financial Forecasts for FY2017

Billions of yen

	FY2016 Result (a)	FY2017 Previous forecasts (b)	FY2017 Revised forecasts (c)	Change from previous forecasts (c)-(b)	Change from FY2016 (c)-(a)		
					Value	FX rate impact	%
Net sales	411.6	474.0	474.0	–	62.4	4.3	15.1
Cost of sales	100.1	118.5	118.5	–	18.4	8.5	18.4
Gross profit	311.6	355.5	355.5	–	43.9	(4.2)	14.1
SG&A expenses	258.8	283.5	283.5	–	24.7	2.8	9.5
SG&A expenses less R & D costs	178.0	194.5	194.5	–	16.5	2.0	9.3
R&D costs	80.8	89.0	89.0	–	8.2	0.8	10.1
Operating income	52.8	72.0	72.0	–	19.2	(7.0)	36.5
Ordinary income	54.3	72.0	72.0	–	17.7		32.5
Extraordinary income (loss)	(7.1)	(2.5)	(6.0)	(3.5)	1.1		
Net income attributable to owners of the parent	29.0	47.0	55.0	8.0	26.0		89.7
E B I T D A	72.8	92.0	92.0	–	19.2		26.3

- Figures in ordinary income and upper are unchanged
- Increase in extraordinary loss ¥2.5B→¥6.0B
  (Business structure improvement expenses)
- Income taxes revised down associated with tax reform in U.S.

⇒**Net income attributable to owners of the parent revised upward by ¥8.0B**

FX rates:
FY2016 Result : 1US$ = ¥ 108.4, 1RMB = ¥16.1
FY2017 Forecast : 1US$ = ¥ 110.0, 1RMB = ¥16.5
（Unchanged）

Revision of Dividend Forecast

Dividend Policy (Announced on May 11, 2017)

- Maintain a consistent payment policy but also consider reflecting any improvement in the Company's performance in the dividend payment
- Annual dividend for FY2016 / 2017 : ¥20 per share（Year-end :¥11）
  We propose a special dividend (¥2 per share) because operating income for FY2016 / 2017 is expected to be higher than the 3rd Mid-term Business Plan target of 50 billion yen.

In accordance with the dividend policy and considering earnings forecasts for FY2017, revised year-end dividend (special dividend) forecast with an increase.

Ordinary dividends ¥9 + special dividends ¥2 total ¥11 per share

↓

Ordinary dividends ¥9 + special dividends ¥10 total ¥19 per share

Dividends per share (Yen)	FY2015	FY2016	FY2017		
	Actual	Actual	Previous forecast	Actual	Revised forecast
Interim	9	9	9	9	–
Year-end	9	11	11	–	**19**
Annual total	18	20	20	–	**28**

Clinical Development Status

Clinical Development Status

Development Pipeline (1) (Psychiatry & Neurology Area)

(as of January 30, 2018)

Sumitomo Dainippon Pharma

Revisions since the announcement of October 2017 are shown 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				
		(New usage :pediatric) Epilepsy- Monotherapy/ Adjunctive therapy	Canada				
LATUDA® （SM-13496）	lurasidone hydrochloride	Schizophrenia	China				
		(New usage :pediatric) Bipolar I depression	U.S. / Canada				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
SEP-225289	dasotraline	Adult, Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Binge eating disorder (BED)	U.S.				
		Adult attention-deficit hyperactivity disorder (ADHD)	Japan				
TRERIEF®	zonisamide	(New indication) Parkinsonism in dementia with Lewy bodies (DLB)	Japan				
LONASEN®	blonanserin	(New usage :pediatric) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
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-6745	TBD	Parkinson's disease psychosis	U.S.				
SEP-378608	TBD	Bipolar disorder	U.S.				

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

Development Pipeline (2) (Oncology Area) (as of January 30, 2018)

Sumitomo Dainippon Pharma

No changes since the announcement of October 2017

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
BBI608	napabucasin	Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Canada / Japan				
		Pancreatic cancer (Combination therapy) (Global clinical study)	U.S. / Japan				
		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 ※5				
		Hepatocellular carcinoma (Combination therapy)	Japan				
BBI503	amcasertib	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (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, Pancreatic cancer)
※5／Clinical study for gastrointestinal cancer is conducted only in Canada

Development Pipeline (3) (Oncology & Other Areas)

(as of January 30, 2018)

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the announcement of October 2017 are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-7888	adegramotide/ nelatimotide	Myelodysplastic syndromes (Monotherapy)	Japan			※1	
		Pediatric malignant glioma (Monotherapy)	Japan			※1	
		Glioblastoma (Combination therapy)	U.S. / Canada / Japan, etc.				
		Solid tumors, Hematologic malignancies (Monotherapy / Combination therapy ※3)	U.S. / Canada				
DSP-2033	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Refractory or relapsed patients)	U.S. / Canada, etc				
		Acute myeloid leukemia (AML) (Combination therapy / Newly diagnosed patients)	U.S.				
		Acute myeloid leukemia (AML) (Combination therapy / Newly diagnosed and refractory or relapsed patients)	Japan				
WT4869	TBD	Myelodysplastic syndromes (Monotherapy)	Japan		※2		
		Solid tumors (Monotherapy)	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	U.S.				
		Solid tumors (Monotherapy)	Japan				
TP-0903	TBD	Solid tumors (Monotherapy)	U.S.				
DSP-0509	TBD	Solid tumors (Monotherapy)	U.S.				
DSP-1958 ※4	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT) (Monotherapy)	Japan				

※1／Phase 2 of Phase 1 / 2 study ※2／Phase 1 of Phase 1 / 2 study
※3／Combination therapy is only U.S. ※4／ Development for the use of unapproved or off-labeled drugs

Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
PXL008	imeglimin	Type 2 diabetes	Japan				
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 30, 2017)

- **Lonhala™ Magnair™ (Glycopyrronium bromide)**
  - COPD: Approved in December 2017 in the U.S.
  - Started broad market awareness activities in January 2018 followed by full commercial launch in early FY2018

- **Apomorphine hydrochloride (APL-130277)**
  - U.S.: Completed Phase 3 study (CTH-300 study), preparing for NDA

- **Dasotraline**
  - Japan: Started Phase 1 study for adult ADHD

- **Alvocidib**
  - Japan: Started Phase 1 study for AML (combination therapy / newly diagnosed and refractory or relapsed patients)

- **Newly added**
  - imeglimin: Started Phase 3 study for type 2 diabetes in Japan
  - DSP-0509: Started Phase 1 study for solid tumors in the U.S.

<Reference>

Napabucasin: Results from an investigator-initiated clinical study (SCOOP study) presented at the ASCO-GI in January 2018

- Outline of the study: Phase 1 / 2 study of napabucasin combination with pembrolizumab in colorectal cancer (Clinical Trials.gov No. NCT02851004)
- Sponsor: National Cancer Center Hospital East
- Collaborator: Sumitomo Dainippon Pharma Co., Ltd.

→ The abstract is now available on the website of ASCO-GI (http://abstracts.asco.org/210/AbstView_210_202445.html)

Apomorphine: Phase 3 Topline Data (CTH-300 study)

- **Study design:**
  - ✓ A 12-week, prospective, multi-center, randomized, double-blind, placebo-controlled, Phase 3 study designed to determine the efficacy, safety and tolerability of apomorphine (APL-130277)
  - ✓ L-Dopa responsive 109 Parkinson's disease patients with motor fluctuations ("OFF" episodes)

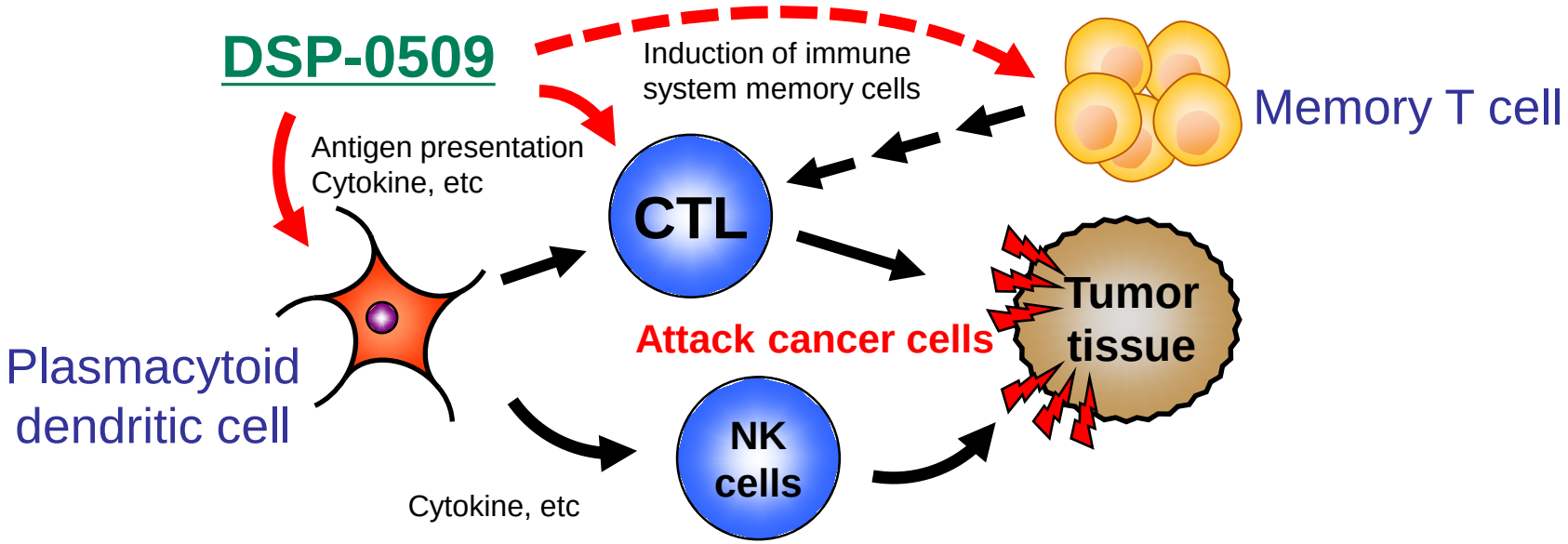
- **Efficacy:** Both primary and secondary endpoints showed significant difference vs placebo.
  - ✓ Primary endpoint: Mean change from pre-dose in MDS-UPDRS Part III Motor Examination at 30 minutes after dosing at the 12-week visit of the Maintenance Treatment Phase (with effects lasting up to 90 minutes post-dose).
  - ✓ Secondary endpoint: Percentage of people (35%) with a patient-rated full ON response within 30 minutes at the 12-week visit of the Maintenance Treatment Phase compared with placebo group (16%).

- **Safety:**
  - ✓ APL-130277 was generally well-tolerated in the study population, and there were no major safety signals or treatment-related adverse events.
  - ✓ The most commonly reported treatment-emergent adverse events during both the titration and maintenance phases were nausea (27.0%), somnolence (14.9%), dizziness (14.2%), yawning (12.8%) and headache (9.2%).

■ **NDA under preparation based on this results**
Plan to submit NDA for OFF episodes associated with Parkinson's disease in spring 2018 in the U.S.

Profile of DSP-0509

- **Target indication :** Solid tumors
- **Origin :** In-house
- **Pharmacological mechanism :** Toll-like receptor (TLR) 7 agonist
- **Development stage :** Phase 1 study in the U.S.
- **Expected profile :**
  - DSP-0509 may promote the cytokine induction and cytotoxic T lymphocyte (CTL) activation mediated by agonistic effect of TLR 7 expressing in plasmacytoid dendritic cell. Furthermore, DSP-0509 is expected to sustain the immune-mediated anti tumor effect by induction of immune system memory cells.

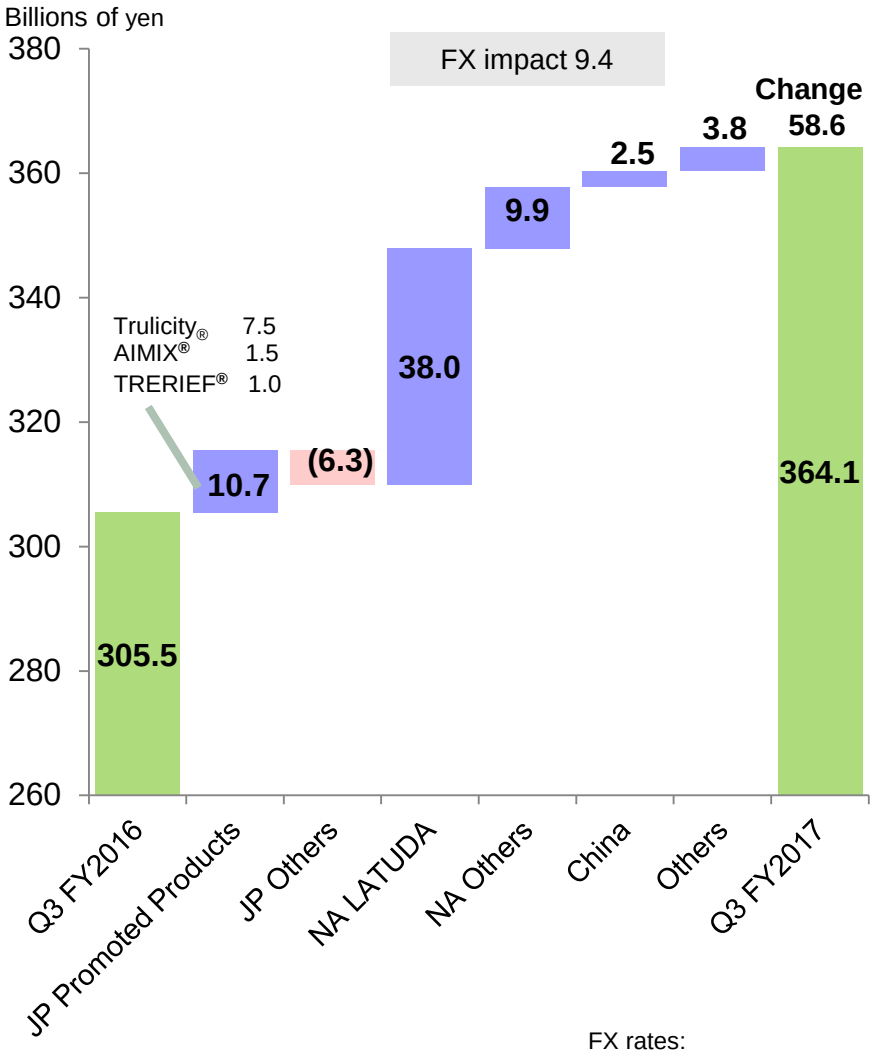


Appendices

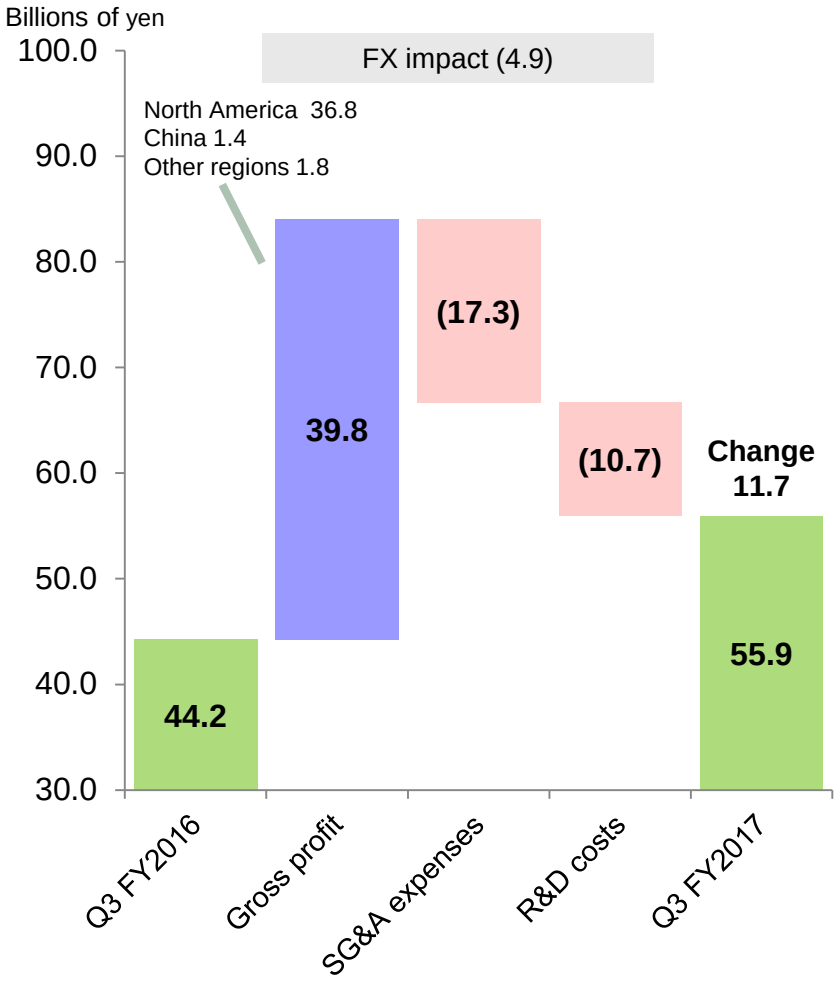
<Contents>

Changes from Q3 FY2017

Sales



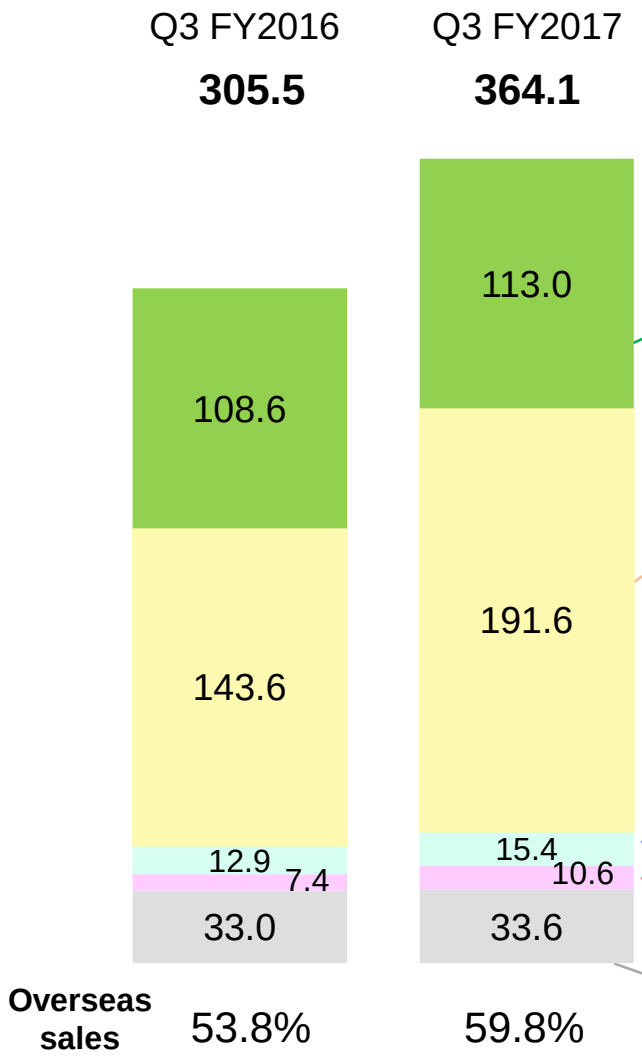
Operating Income



FX rates:
Q3 FY2016 : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 : 1US$ = ¥ 111.7, 1RMB = ¥16.6

Net Sales by Segment

Billions of yen



Changes +58.6 +19.2 % **Progress 76.8 %**

Japan ・Changes +4.4 +4.0 %
- Growth of Trulicity®, solid sales of AIMIX®, TRERIEF®, decrease in long-listed products

・Progress 79.8%

North America
・Changes +47.9 +33.4 %
- Driven by growth of LATUDA® and APTIOM®, divestiture of ciclesonide products

・Progress 76.1%

China ・Changes +2.5 +19.4 %
- Strong sales of MEROPEN®

・Progress 78.4%

Other Regions
・Changes +3.2 +43.2 %
- Increase in export of MEROPEN® partially due to start of export to south east Asia

・Progress 66.6%

Other Business
・Changes +0.6 +1.8 %

・Progress 74.6%

FX rates:
Q3 FY2016 : 1US$ = ¥ 106.6, 1RMB = ¥15.9
Q3 FY2017 : 1US$ = ¥ 111.7, 1RMB = ¥16.6

※ Progress is % to full-year forecast.

Appendix (Clinical Development Status)

Napabucasin – Clinical development progress

(as of January 30, 2018)

Sumitomo Dainippon Pharma

No changes since the announcement of October 2017

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C	June 2016
	U.S. / Japan	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel	CanStem111P	Dec. 2016
Phase 2	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, capecitabine	BBI608-224	Mar. 2012
	U.S. / Canada	Solid tumors※ (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

※／Ovarian cancer, Breast cancer, Melanoma, etc.

Start date is based on Clinical Trials.gov (as of January 29, 2018)

Amcasertib, Napabucasin– Clinical development progress

(as of January 30, 2018)

Sumitomo Dainippon Pharma

No changes since the announcement of October 2017

Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 2	U.S. / Canada	Solid tumors※ (Monotherapy)	―	BBI503-101	Feb. 2012
	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	―	BBI503-205b	Feb. 2015
	Canada	Gastrointestinal stromal tumor (Monotherapy)	―	BBI503-205c	Mar. 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

※／Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

Amcasertib + Napabucasin

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 29, 2018)

LATUDA® (lurasidone) – Clinical development progress

(as of January 30, 2018)

Revisions since the announcement of October 2017 are shown 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/ Partnering)

- Sunovion Pharmaceuticals Europe (SPE) continues to distribute LATUDA® in the U.K., Switzerland, Norway, Finland, Sweden, Denmark and the Netherlands
- SPE granted Angelini exclusive commercialization rights for LATUDA® in 29 European countries and in Turkey in November 2017
  Angelini began to distribute LATUDA® in November 2017 in Italy

Asia, South America, etc. (Partnering)

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

Submission Target of Key Late-stage Pipeline

(as of January 2018)

Area	Products under Development	Submission target			
		FY2017	FY2018	FY2019	FY2020-2022
Psychiatry & Neurology	**SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S.	Submitted in Aug. 2017			
	TRERIEF® **<zonisamide>** (Parkinsonism in Dementia with Lewy Bodies) Japan	Submitted in Aug. 2017			
	APL-130277 <apomorphine > (Parkinson's disease) U.S.	●			
	SEP-225289 <dasotraline> (BED) U.S.		●		
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan		●		
	SM-13496 <lurasidone > (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan			●	
	SB623 (Chronic stroke) U.S.				●
Oncology	**alvocidib** (Acute myeloid leukemia (AML) / Combination therapy) U.S.		● ※		
	BBI608 **<napabucasin>** (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 **<napabucasin>** (Pancreatic cancer / Combination therapy) U.S. / Japan				●
Others	**PXL008** **<imeglimin>** (Type 2 diabetes mellitus) Japan				●

New Chemical Entities | New Indication, etc.

※Premised on the application of accelerated approval program (Plan to consult with the FDA)

Product Launch Plan (as of January 2018)

Sumitomo Dainippon Pharma

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)
		thiotepa (Conditioning treatment prior to HPCT)		napabucasin (Colorectal cancer, Pancreatic cancer)
				amcasertib (Solid tumors)
				DSP-7888 (Solid tumors/ Hematologic malignancies)
				obeticholic acid (NASH)
				DSP-6952 (IBS with constipation, Chronic idiopathic constipation)
				imeglimin (Type 2 diabetes mellitus)
				iPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	UTIBRON™, SEEBRI™ (COPD) (In-licensed)	Lonhala™ Magnair™ (COPD)	dasotraline (BED)	SB623 (Chronic stroke)
		dasotraline (ADHD)	alvocidib (Acute myeloid leukemia)	DSP-2230 (Neuropathic pain)
		apomorphine (Parkinson's disease)		SEP-363856 (Schizophrenia)
				napabucasin (Colorectal cancer, Pancreatic cancer)
				amcasertib (Solid tumors)
				DSP-7888 (Solid tumors/ Hematologic malignancies)
China	LONASEN® (Schizophrenia) (Approved in Feb.2017)	lurasidone (Schizophrenia)		

／Psychiatry & Neurology ／Oncology ／Respiratory ／Others

New Chemical Entities | New Indication , etc.

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows