



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows

# **Financial Results for Q1 FY2017**

## **(April 1 to June 30, 2017)**

---

July 28, 2017

Sumitomo Dainippon Pharma Co., Ltd.

# Financial Results for Q1 FY2017

# Financial Results for Q1 FY2017

Billions of yen

	Q1 FY2016 Results	Q1 FY2017 Results	Change			Q2 FY2017 (Apr.-Sep.)		FY2017	
			Value		%	Previous forecasts	Progress %	Previous forecasts	Progress %
				FX rate impact					
Net sales	103.5	116.3	12.8	1.5	12.4	220.0	52.9	450.0	25.8
Cost of sales	23.9	29.5	5.6	* 1.9	23.4	57.5	51.3	116.0	25.4
Gross profit	79.6	86.8	7.2	(0.3)	9.1	162.5	53.4	334.0	26.0
SG&A expenses	65.0	67.0	2.0	1.1	3.1	136.0	49.3	279.0	24.0
SG&A expenses less R&D costs	45.7	47.1	1.4	0.8	3.2	95.5	49.3	194.0	24.3
R&D Costs	19.3	19.9	0.6	0.3	3.1	40.5	49.2	85.0	23.5
Operating income	14.6	19.7	5.2	(1.4)	35.6	26.5	74.5	55.0	35.9
Ordinary income	12.7	19.8	7.2		56.4	26.5	74.9	55.0	36.1
Extraordinary income (loss)	—	—	—			—	—	(2.5)	
Net income attributable to owners of the parent	8.4	14.4	6.0		72.2	18.0	80.1	36.0	40.0
<b>E B I T D A</b>	17.4	24.7	7.3		42.2			75.0	

\* Includes an impact [¥1.6B] of change in FX rates on the unrealized profit of inventory

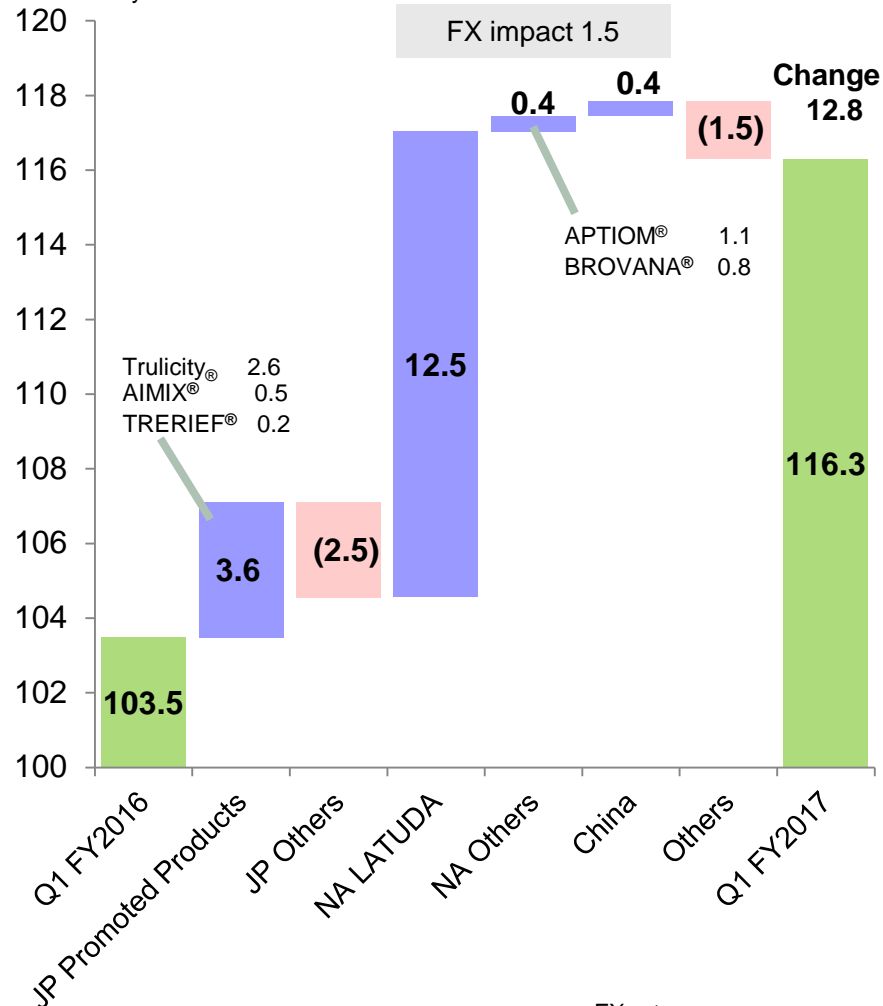
FX rates:

Q1 FY2016 Results : 1US\$ = ¥ 108.1, 1RMB = ¥16.5  
 Q1 FY2017 Results : 1US\$ = ¥ 111.1, 1RMB = ¥16.2  
 FY2017 Forecasts : 1US\$ = ¥ 110.0, 1RMB = ¥16.5

# Changes from Q1 FY2016

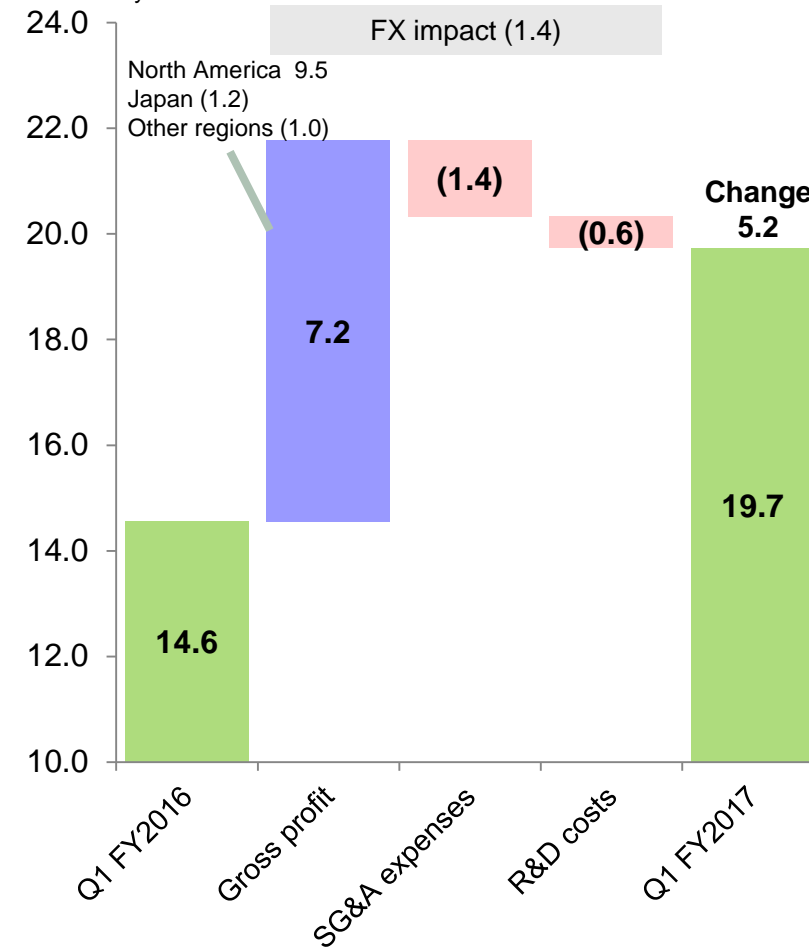
## Sales

Billions of yen



## Operating Income

Billions of yen



FX rates:

Q1 FY2016 : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Q1 FY2017 : 1US\$ = ¥ 111.1, 1RMB = ¥16.2

# Sales of Major Products in Japan

Billions of yen

	Q1 FY2016 Results	Q1 FY2017 Results	Change		Q2 FY2017 (Apr.-Sep.)	
			Value	%	Forecasts	Progress %
AIMIX®	4.2	4.7	0.5	13.2	8.6	55.0
TRERIEF®	3.9	4.1	0.2	5.6	8.1	50.5
LONASEN®	3.5	3.4	(0.1)	(2.5)	6.7	50.3
METGLUCO®	2.9	2.9	(0.0)	(1.6)	5.6	51.3
REPLAGAL®	2.7	2.9	0.3	10.1	5.6	52.2
Trulicity® *	0.7	3.4	2.6	354.4	5.0	67.6
AVAPRO®	2.7	2.6	(0.1)	(4.0)	4.7	55.6
SUREPOST®	1.1	1.2	0.1	12.0	2.5	49.7
AmBisome®	1.0	1.1	0.1	5.9	2.2	49.6
Promoted products Total	22.7	26.3	3.6	16.0	49.0	53.7
AMLODIN®	3.6	3.1	(0.5)	(13.1)	5.6	55.6
PRORENAL®	1.8	1.5	(0.3)	(17.4)	2.8	53.9
GASMOTIN®	1.7	1.4	(0.3)	(19.8)	2.6	52.2
MEROPEN®	1.2	0.9	(0.3)	(22.5)	2.2	40.7
Others	5.1	3.9	(1.2)	(22.9)	8.4	46.6
<b>Total</b>	<b>36.0</b>	<b>37.1</b>	<b>1.1</b>	<b>3.0</b>	<b>70.6</b>	<b>52.5</b>

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

# Sales of Major Products in North America & China

	Q1 FY2016 Results	Q1 FY2017 Results	Change	Q1 FY2016 Results	Q1 FY2017 Results	Change			Q2 FY2017 (Apr.-Sep.)		
						Value	FX rate impact	%	Previous forecasts		Yen- based progress
<b>North America</b>	Million \$			Billion yen			Million \$	Billion yen	%		
LATUDA®	291	395	104	31.5	43.9	12.5	1.2	39.6	708	77.9	56.4
BROVANA®	71	75	5	7.6	8.4	0.8	0.2	9.9	156	17.2	48.7
APTIOM®	23	31	9	2.4	3.5	1.1	0.1	43.2	68	7.4	47.2
Ciclesonide	13	10	(3)	1.4	1.1	(0.2)	0.0	(18.3)	22	2.4	46.2
XOPENEX®	12	8	(4)	1.3	0.9	(0.4)	0.0	(30.6)	21	2.3	39.6
New COPD products *	—	1	1	—	0.1	0.1	—	—	4	0.5	23.6
Others	29	19	(9)	3.1	2.2	(0.9)	0.1	(29.9)	31	3.4	63.6
<b>Total</b>	<b>438</b>	<b>541</b>	<b>104</b>	<b>47.3</b>	<b>60.2</b>	<b>12.9</b>	<b>1.6</b>	<b>27.2</b>	<b>1,010</b>	<b>111.1</b>	<b>54.2</b>
<b>China</b>	Million RMB			Billion yen			Million RMB	Billion yen	%		
MEROPEN®	257	277	20	4.2	4.5	0.2	(0.1)	5.7	518	8.5	52.8
Others	33	44	10	0.6	0.7	0.2	(0.0)	27.5	71	1.2	59.0
<b>Total</b>	<b>291</b>	<b>320</b>	<b>30</b>	<b>4.8</b>	<b>5.2</b>	<b>0.4</b>	<b>(0.1)</b>	<b>8.2</b>	<b>589</b>	<b>9.7</b>	<b>53.6</b>

\* UTIBRON™, SEEBRI™, ARCAPTA®, SUN-101 (NDA filed)

FX rates:

Q1 FY2016 Results : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Q1 FY2017 Results : 1US\$ = ¥ 111.1, 1RMB = ¥16.2

FY2017 Forecasts: 1US\$ = ¥ 110.0, 1RMB = ¥16.5

# Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q1 FY2017 Results	Net sales (Sales to customers)	37.1	60.2	5.2	2.6	105.1	11.2	116.3
	Cost of sales	13.0	5.2	1.2	1.3	20.7	8.9	29.5
	Gross profit	24.2	55.0	4.0	1.3	84.4	2.3	86.8
	SG&A expenses less R&D costs	12.2	30.8	1.7	0.9	45.5	1.6	47.1
	Income (loss) of Segment	12.0	24.2	2.3	0.5	38.9	0.8	39.7
	R&D costs					19.7	0.2	19.9
	Operating income					19.2	0.5	19.7
Q1 FY2016 Results	Net sales (Sales to customers)	36.0	47.3	4.8	4.3	92.4	11.1	103.5
	Cost of sales	10.7	1.8	0.6	2.0	15.1	8.9	23.9
	Gross profit	25.3	45.5	4.2	2.3	77.4	2.2	79.6
	SG&A expenses less R&D costs	14.2	27.4	1.8	0.7	44.1	1.6	45.7
	Income (loss) of Segment	11.1	18.1	2.5	1.6	33.3	0.6	33.9
	R&D costs					19.1	0.2	19.3
	Operating income					14.2	0.4	14.6
Change	Net sales (Sales to customers)	1.1	12.9	0.4	(1.7)	12.7	0.2	12.8
	SG&A expenses less R&D costs	(2.0)	3.4	(0.0)	0.1	1.5	(0.0)	1.4
	Income (loss) of Segment	0.8	6.1	(0.2)	(1.1)	5.6	0.1	5.8
	R&D costs					0.6	(0.0)	0.6
	Operating income					5.0	0.1	5.2

FX rates:

Q1 FY2016 : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Q1 FY2017 : 1US\$ = ¥ 111.1, 1RMB = ¥16.2

# Financial Forecasts for FY2017



# Financial Forecasts for FY2017

Billions of yen

	Q2 FY2017			FY2017		
	Previous forecasts	Revised forecasts	Change	Previous forecasts	Revised forecasts	Change
Net sales	220.0	234.5	14.5	450.0	464.0	14.0
Cost of sales	57.5	57.5	–	116.0	117.0	1.0
Gross profit	162.5	177.0	14.5	334.0	347.0	13.0
SG&A expenses	136.0	136.0	–	279.0	282.0	3.0
SG&A expenses less R&D costs	95.5	95.5	–	194.0	194.0	–
R&D Costs	40.5	40.5	–	85.0	88.0	3.0
Operating income	26.5	41.0	14.5	55.0	65.0	10.0
Ordinary income	26.5	41.0	14.5	55.0	65.0	10.0
Extraordinary income (loss)	–	–	–	(2.5)	(2.5)	–
Net income attributable to owners of the parent	18.0	28.5	10.5	36.0	44.0	8.0
EBITDA	36.0	50.5	14.5	75.0	85.0	10.0

### Revised forecasts in North America segment

- Ciclesonide divestiture in 2<sup>nd</sup> half → 1<sup>st</sup> half
- Revised North America sales upward  
LATUDA® ¥158.4B → ¥169.2B (FY2017)

### Revised R&D costs

- Revised upward in 2<sup>nd</sup> half - Estimated in-licensing cost

FX rates:

 FY2017: 1US\$ = ¥ 110.0, 1RMB = ¥16.5  
(No change)

# Clinical Development Status

# Clinical Development Status Development Pipeline (1) (Psychiatry & Neurology Area) (as of July 28, 2017)



Revisions since the previous announcement are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
APTIOM®	eslicarbazine acetate	(New indication) Epilepsy- Monotherapy	Canada				
		(New usage :pediatric) Epilepsy- Monotherapy / adjunctive therapy	U.S.				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	China				
		(New usage :pediatric) Bipolar I depression	U.S. / Canada				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
LONASEN®	blonanserin	(New usage :pediatric) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Adult, Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Binge eating disorder (BED)	U.S.				
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-1200	TBD	Treatment-resistant depression	U.S.				
DSP-6745	TBD	Parkinson's disease psychosis	U.S.				
SEP-378608	TBD	Bipolar depression	U.S.				

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

## Development Pipeline (2) (Oncology Area) (as of July 28, 2017)

Revisions since the previous announcement are shown in red.

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 , etc.				
		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) ※ <sup>3</sup>	U.S. / Canada			※ <sup>1</sup>	
		Malignant pleural mesothelioma (Combination therapy)	Japan			※ <sup>1</sup>	
		Solid tumors (Combination therapy) ※ <sup>4</sup> Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada ※ <sup>5</sup>				
		Hepatocellular carcinoma (Combination therapy)	Japan				
BBI503	amcasertib	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※ <sup>1</sup>	
		Solid tumors (Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy)	U.S		※ <sup>2</sup>		
		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.				

※<sup>1</sup>/Phase 2 of Phase 1 / 2 study ※<sup>2</sup>/Phase 1 of Phase 1 / 2 study ※<sup>3</sup>/Glioblastoma's development is only Canada

※<sup>4</sup>/Multiple studies for different tumor types (Gastrointestinal cancer, Hepatocellular carcinoma, Pancreatic cancer)

※<sup>5</sup>/Clinical study for gastrointestinal cancer is conducted only in Canada

**Oncology Area (Excluding napabucasin, amcasertib)**

Revisions since the previous announcement are shown in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-7888	adegramotide/ relatimotide	Myelodysplastic syndromes (Monotherapy)	Japan			※1	
		Pediatric malignant glioma (Monotherapy)	Japan			※1	
		Glioblastoma (Combination therapy)	U.S. / Canada / Japan , etc.				
		Solid tumors, Hematologic malignancies (Monotherapy)	U.S. / Canada				
alvocidib	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven)	U.S. / Canada				
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-1958 ※3	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/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 May 11, 2017)

## Glycopyrronium bromide (SUN-101)

- ✓ Received Complete Response Letter (CRL) from FDA (May 2017)  
Resubmitted NDA in response to CRL (June 2017)
- ✓ Target to obtain approval and launch in FY2017 (PDUFA date: December 15, 2017)

## LATUDA®

- ✓ Submitted sNDA for pediatric bipolar I depression in the U.S. and Canada (May 2017)

## Napabucasin

- ✓ Started Phase 3 study (CanStem111P study) for pancreatic cancer (combination therapy) in Japan in addition to the U.S.
- ✓ Deleted Phase 3 study (BRIGHTER study) for gastric and gastro-esophageal junction adenocarcinoma (combination therapy) subsequently to unblinding the study
- ✓ Deleted Phase 3 study (CanStem43L study) for non-small cell lung cancer (combination therapy) due to the discontinuation of the study

## Amcasertib

- ✓ Deleted Phase 2 study for renal cell and urothelial carcinoma (monotherapy) due to the discontinuation of the study

## DSP-7888

- ✓ Started Phase 2 study for glioblastoma (combination therapy) in Canada and Japan, etc. in addition to the U.S.

## Alvocidib

- ✓ Started Phase 2 study for acute myeloid leukemia (combination therapy) in Canada in addition to the U.S.

## Newly added

- ✓ SEP-378608: Started Phase 1 study for bipolar depression in the U.S.
  - Novel CNS-active molecule identified using SmartCube® systems of PsychoGenics Inc.

# Appendices

## <Contents>

Financial Results for Q1 FY2017

P.15 Net Sales by Segment

Clinical Development Status

P.16 Napabucasin - Clinical development progress

P.17 Amcasertib, Napabucasin– Clinical development progress

P.18 LATUDA<sup>®</sup> (lurasidone) – Clinical development progress

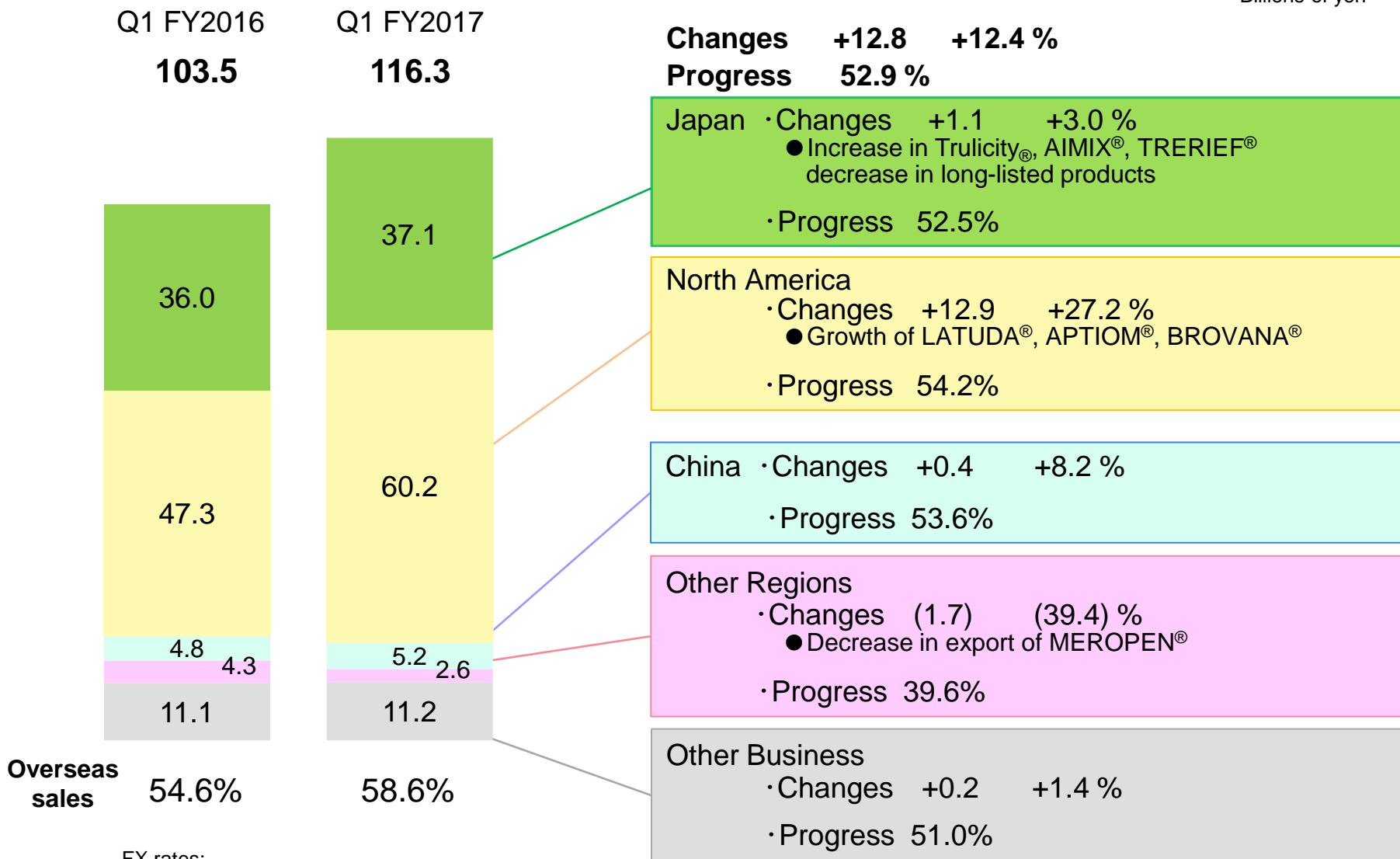
P.19 Submission Target of Key Late-stage Pipeline

P.20 Product Launch Plan

P.21 Regenerative Medicine / Cell Therapy Business Plan

# Net Sales by Segment

Billions of yen



FX rates:

Q1 FY2016 : 1US\$ = ¥ 108.1, 1RMB = ¥16.5

Q1 FY2017 : 1US\$ = ¥ 111.1, 1RMB = ¥16.2

※ Progress is % to 1H forecast



# Appendix (Clinical Development Status) Napabucasin – Clinical development progress



(as of July 28, 2017)

Revisions since the previous announcement are shown in red.

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan, etc	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*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 July 27, 2017)

**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	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

\*1/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 July 27, 2017)

## Japan / China (In-house)

Revisions since the previous announcement are shown in red.

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<sup>®</sup> in EU and Switzerland was transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ SPE started commercializing LATUDA<sup>®</sup> 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 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 July 2017)

Area	Products under Development	Submission target			
		FY2017	FY2018	FY2019	FY2020-2022
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> (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 <napabucasin> (Pancreatic cancer / Combination therapy) U.S. / Japan				●

New Chemical Entities

New Indication, etc.

# Product Launch Plan (as of July 2017)

Area	FY2017	FY2018	FY2019	FY2020 - FY2022	
Japan		<div style="border: 1px dashed black; padding: 5px;">TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)</div> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">thiotepa (Conditioning treatment prior to HPCT)</div>	<div style="border: 1px dashed black; padding: 5px;">LONASEN® (Schizophrenia / Transdermal patch)</div>	<div style="border: 1px solid black; padding: 5px;">lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance)</div>	<div style="border: 1px solid black; padding: 5px;">obeticholic acid (NASH)</div>
				<div style="border: 1px solid black; padding: 5px;">napabucasin (Colorectal cancer, Pancreatic cancer)</div>	<div style="border: 1px solid black; padding: 5px;">DSP-6952 (IBS with constipation, Chronic idiopathic constipation)</div>
				<div style="border: 1px solid black; padding: 5px;">amcasertib (Solid tumors)</div>	<div style="border: 1px solid black; padding: 5px;">iPS cell-derived RPE cells (Age-related macular degeneration)</div>
				<div style="border: 1px solid black; padding: 5px;">DSP-7888 (Solid tumors/ Hematologic malignancies)</div>	
U.S.	<div style="border: 1px solid black; padding: 5px; background-color: #90EE90;">glycopyrronium (COPD)</div>	<div style="border: 1px solid black; padding: 5px;">dasotraline (ADHD)</div>	<div style="border: 1px solid black; padding: 5px;">dasotraline (BED)</div>	<div style="border: 1px solid black; padding: 5px;">SB623 (Chronic stroke)</div>	<div style="border: 1px solid black; padding: 5px;">napabucasin (Colorectal cancer, Pancreatic cancer)</div>
	<div style="border: 1px solid black; padding: 5px; background-color: #90EE90;">UTIBRON™, SEEBRI™ (COPD) (In-licensed)</div>	<div style="border: 1px solid black; padding: 5px;">apomorphine (Parkinson's disease)</div>	<div style="border: 1px solid black; padding: 5px;">alvocidib (Acute myeloid leukemia)</div>	<div style="border: 1px solid black; padding: 5px;">DSP-2230 (Neuropathic pain)</div>	<div style="border: 1px solid black; padding: 5px;">amcasertib (Solid tumors)</div>
				<div style="border: 1px solid black; padding: 5px;">SEP-363856 (Schizophrenia)</div>	<div style="border: 1px solid black; padding: 5px;">DSP-7888 (Solid tumors/ Hematologic malignancies)</div>
China	<div style="border: 1px solid black; padding: 5px;">LONASEN® (Schizophrenia) (Approved on Feb.2017)</div>	<div style="border: 1px solid black; padding: 5px;">lurasidone (Schizophrenia)</div>			

  / Psychiatry & Neurology  
   / Oncology  
   / Liver / Digestive  
   / Respiratory

  New Chemical Entities  
   New Indication, etc.

# Appendix (Clinical Development Status) Regenerative Medicine / Cell Therapy Business Plan (as of July 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			Approval Target	
						Phase 3		
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell	Clinical research	Investigator or corporate initiated clinical study			Approval Target
Parkinson's disease (Designated as a "SAKIGAKE" Product in Feb. 2017)	Kyoto Univ CiRA	Global	Allo iPS cell		Investigator-initiated 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.

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



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows