Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for FY2015 (The year ended March 31, 2016)

May 12, 2016

Masayo Tada, President and CEO
Sumitomo Dainippon Pharma Co., Ltd.

10th Anniversary

Sumitomo Dainippon Pharma

Financial Results for FY2015

Financial Results for FY2015

Billions of yen

	FY2014 Results	FY2015 Results	Change			FY2015 Forecasts 27th Jan.	
			Value	FX rate impact	%	Value	Achieved %
Net sales	371.4	403.2	31.8	17.1	8.6	403.0	100.1
Cost of sales	101.2	104.5	3.2	1.5	3.2	104.5	100.0
Gross profit	270.1	298.7	28.6	15.6	10.6	298.5	100.1
SG&A expenses	246.9	261.8	14.9	14.1	6.1	265.5	98.6
SG&A expenses less R&D costs	175.6	179.8	4.2	9.5	2.4	179.0	100.4
R&D Costs	71.3	82.0	10.7	4.6	15.0	86.5	94.8
Operating income	23.3	36.9	13.7	1.5	58.7	33.0	111.9
Ordinary income	23.3	35.2	11.9		51.0	32.5	108.4
Extraordinary income (loss)	10.4	4.3	(6.1)				
Net income attributable to owners of the parent	15.4	24.7	9.2		59.9	23.0	107.4
E B I T D A	43.1	55.8	12.7		29.4	53.3	

Exchange rates:
FY2014 Results : 1US$ = ¥ 109.8, 1RMB = ¥17.7
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9

Sales of Major Products in Japan

Billions of yen

	FY2014 Results	FY2015 Results	Change	
			Value	%
AIMIX®	12.0	14.9	3.0	25.0
AVAPRO®	11.4	10.8	(0.5)	(4.6)
LONASEN®	11.5	12.6	1.1	10.0
TRERIEF®	11.6	13.1	1.5	12.7
Strategic Products Total	46.4	51.5	5.1	10.9
SUREPOST®	2.4	3.6	1.2	48.3
AmBisome®	4.3	4.3	0.0	0.6
REPLAGAL®	9.7	10.2	0.5	5.3
METGLUCO®	17.1	14.7	(2.4)	(13.8)
AMLODIN®	19.6	16.4	(3.2)	(16.3)
GASMOTIN®	10.5	8.4	(2.1)	(19.8)
PRORENAL®	10.6	8.7	(1.9)	(17.8)
MEROPEN®	7.9	6.2	(1.7)	(21.1)
Others	28.1	22.4	(5.7)	(20.1)
Other Products Total	110.1	95.0	(15.2)	(13.8)
Japan Total	156.6	146.5	(10.1)	(6.4)

Note: Sales of each products above are shown by gross sales basis.

Sales of Major Products in North America & China

	FY2014 Results	FY2015 Results	Change	FY2014 Results	FY2015 Results	Change		
						Value	FX rate impact	%
North America	Million $			Billion yen				
LATUDA®	752	1,002	250	82.5	120.4	37.9	10.4	45.9
APTIOM®	23	64	40	2.5	7.6	5.1	0.7	200.0
BROVANA®	202	249	47	22.2	29.9	7.7	2.6	34.9
Ciclesonide	61	58	(3)	6.7	7.0	0.3	0.6	4.5
XOPENEX®	78	56	(22)	8.5	6.7	(1.8)	0.6	(21.6)
LUNESTA®	105	38	(67)	11.5	4.6	(6.9)	0.4	(60.1)
Others	129	72	(57)	14.2	8.7	(5.5)	0.8	(38.9)
Total	1,350	1,539	189	148.2	184.9	36.7	16.0	24.8
China	Million RMB			Billion yen				
MEROPEN®	805	826	21	14.3	15.6	1.3	0.9	9.2
Others	163	148	(15)	2.9	2.8	(0.1)	0.2	(3.0)
Total	968	974	6	17.1	18.4	1.2	1.1	7.2

Exchange rates:
FY2014 Results : 1US$ = ¥ 109.8, 1RMB = ¥17.7
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2015 Results	Net sales (Sales to customers)	146.5	184.9	18.4	11.2	360.9	42.3	403.2
	Cost of sales	45.8	16.0	2.8	6.1	70.6	33.8	104.5
	Gross profit	100.8	168.9	15.6	5.1	290.4	8.3	298.7
	SG&A expenses less R&D costs	59.3	103.8	7.6	2.6	173.3	6.5	179.8
	Income (loss) of Segment	41.5	65.2	8.0	2.4	117.1	1.8	119.0
	R&D costs					81.1	0.9	82.0
	Operating income					36.0	0.9	36.9
FY2014 Results	Net sales (Sales to customers)	156.6	148.2	17.1	8.8	330.7	40.7	371.4
	Cost of sales	47.6	12.4	3.6	5.5	69.1	32.2	101.2
	Gross profit	109.1	135.8	13.6	3.3	261.8	8.4	270.1
	SG&A expenses less R&D costs	58.5	101.1	7.3	2.4	169.4	6.2	175.6
	Income (loss) of Segment	50.6	34.7	6.2	0.8	92.4	2.2	94.6
	R&D costs					70.4	0.9	71.3
	Operating income					22.0	1.3	23.3
Change	Net sales (Sales to customers)	(10.1)	36.7	1.2	2.4	30.3	1.6	31.8
	SG&A expenses less R&D costs	0.8	2.7	0.3	0.2	3.9	0.3	4.2
	Income (loss) of Segment	(9.0)	30.4	1.7	1.6	24.8	(0.4)	24.4
	R&D costs					10.7	0.0	10.7
	Operating income					14.0	(0.4)	13.7

Exchange rates:
FY2014 Results : 1US$ = ¥ 109.8, 1RMB = ¥17.7
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9

Financial Forecasts for FY2016

Major activities for FY2016

➢ Japan

- Net Sales：

  Expanding the sales of strategic products (AIMIX®・LONASEN®・TRERIEF®) and new products（Trulicity®・REMITCH®） to minimize the decline in revenue due to NHI price revisions and drop in sales of long-listed products

- SG&A expenses less R&D cost：

  Optimizing SG&A expenses and the business management structure

➢ North America

- Net Sales：

  Further boosting LATUDA® sales beyond the $1billion mark and fostering growth of APTIOM® and BROVANA®, and maximizing sales of new products (to be in-licensed in FY 2016) early on

- SG&A expenses less R&D cost：

  Establishing efficient sales organizations for oncology products and for new products

➢ R&D

- Accelerating development of napabucasin and other products in later phases

Target： Net Sales ¥ 410 billion (1.7% UP vs FY2015)
Operating income ¥ 40 billion (8.3% UP vs FY2015)

Financial Forecasts for FY2016

Billions of yen

	FY2015 Results	FY2016 Forecasts	Change		
			Value		%
				FX rate impact	
Net sales	403.2	410.0	6.8	(20.3)	1.7
Cost of sales	104.5	99.5	(5.0)	(7.0)	(4.8)
Gross profit	298.7	310.5	11.8	(13.3)	3.9
SG&A expenses	261.8	270.5	8.7	(15.5)	3.3
SG&A expenses less R&D costs	179.8	186.0	6.2	(11.3)	3.5
R&D costs	82.0	84.5	2.5	(4.2)	3.0
Operating income	36.9	40.0	3.1	2.2	8.3
Ordinary income	35.2	40.0	4.8		13.6
Extraordinary income (loss)	4.3	2.5	(1.8)		
Net income attributable to owners of the parent	24.7	25.0	0.3		1.2
E B I T D A	55.8	61.0	5.2		9.4

Exchange rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 Forecasts	Net sales (Sales to customers)	137.6	200.7	16.0	11.8	366.1	43.9	410.0
	Cost of sales	45.4	11.0	2.8	5.0	64.2	35.3	99.5
	Gross profit	92.2	189.7	13.2	6.8	301.9	8.6	310.5
	SG&A expenses less R&D costs	57.8	110.0	8.1	3.5	179.4	6.6	186.0
	Income (loss) of Segment	34.4	79.7	5.1	3.3	122.5	2.0	124.5
	R&D costs					83.5	1.0	84.5
	Operating income					39.0	1.0	40.0
FY2015 Results	Net sales (Sales to customers)	146.5	184.9	18.4	11.2	360.9	42.3	403.2
	Cost of sales	45.8	16.0	2.8	6.1	70.6	33.8	104.5
	Gross profit	100.8	168.9	15.6	5.1	290.4	8.3	298.7
	SG&A expenses less R&D costs	59.3	103.8	7.6	2.6	173.3	6.5	179.8
	Income (loss) of Segment	41.5	65.2	8.0	2.4	117.1	1.8	119.0
	R&D costs					81.1	0.9	82.0
	Operating income					36.0	0.9	36.9
Change	Net sales (Sales to customers)	(8.9)	15.8	(2.4)	0.6	5.2	1.6	6.8
	SG&A expenses less R&D costs	(1.5)	6.2	0.5	0.9	6.1	0.1	6.2
	Income (loss) of Segment	(7.1)	14.5	(2.9)	0.9	5.4	0.2	5.5
	R&D costs					2.4	0.1	2.5
	Operating income					3.0	0.1	3.1

Exchange rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

Clinical Development Status

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

Glycopyrronium bromide (SUN-101)

- ✓ Completed Phase lll studies, preparing for the NDA in the U.S.

Lurasidone hydrochloride

- ✓ Started new Phase lll study for Schizophrenia in Japan

DSP-2230

- ✓ Started Phase l study for Neuropathic pain in Japan

DSP-7888

- ✓ Started Phase l study of Phase l / ll for Pediatric malignant glioma in Japan

Newly added

- ✓ **DSP-1200**
  Started Phase l study for Treatment-resistant depression in the U.S.

Discontinued

- ✓ ranirestat (Japan: Phase lll)
- ✓ amurubicin hydrochloride (China: Submitted)

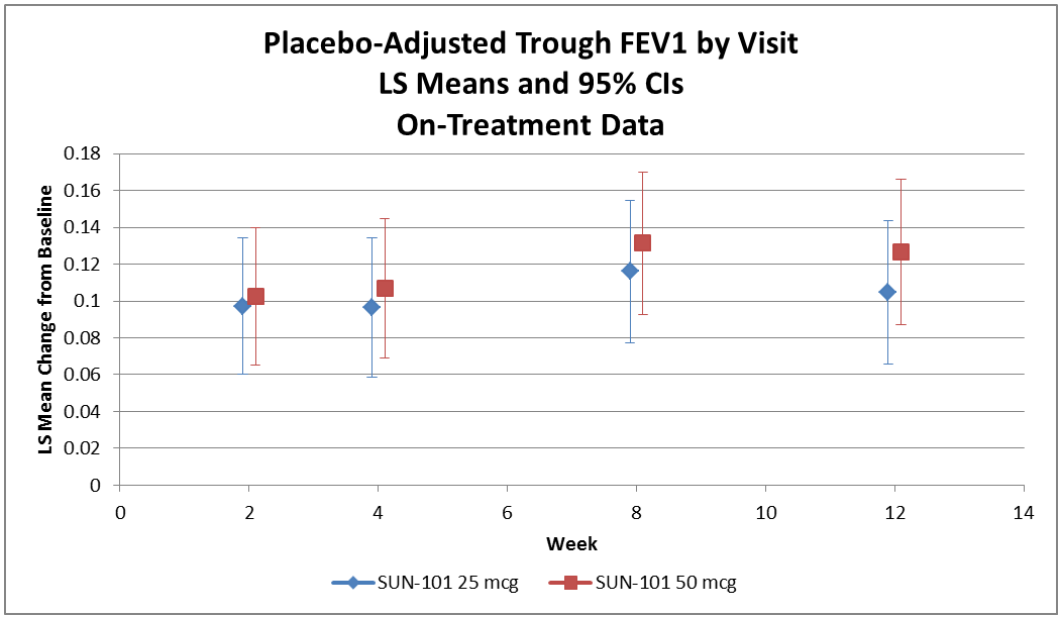
Glycopyrronium bromide (SUN-101) Top Line Results

➢ Study Design

- ✓Phase lll , 12-week, randomized, double-blind, placebo-controlled, parallel-group, studies in patients with COPD
- ✓Enrolled Patients: 1,294 (GOLDEN-3 and GOLDEN-4 studies)
- ✓Primary endpoint: Change from baseline in trough FEV_1 at end of treatment (week 12)

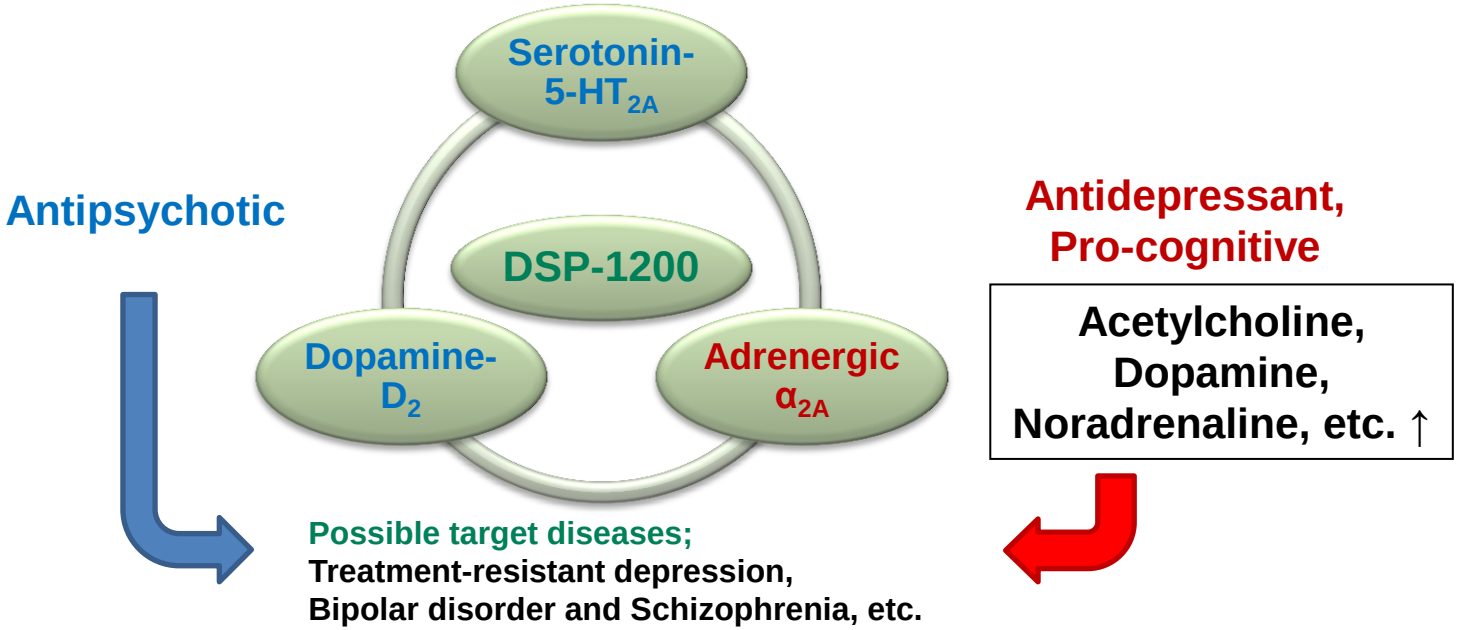
➢ Study Results

- ✓Efficacy： There were statistically significant improvements in the primary endpoint in both studies
- ✓Safety： SUN-101 was well tolerated



Profile of DSP-1200

- **Target Indication：** Treatment-resistant depression
- **Origin：** In-house
- **Pharmacological mechanism：** Dopamine D_2, serotonin 5-HT_{2A}, and adrenergic α_{2A} receptors antagonist
- **Development stage：** Phase I study in the U.S.
- **Characteristics：**
  - ✓ DSP-1200 is expected to enhance acetylcholine, dopamine, and noradrenaline release in prefrontal cortex, which would provide improvement of depressive symptoms and cognitive function.
  - ✓ DSP-1200 may have fewer safety concerns compared with marketed antipsychotics, because it has low or negligible affinities for receptors associated with safety profile.



FY2016 R&D top priorities

- **Submit NDA for glycopyrronium bromide (SUN-101) in the U.S.**
- **Promote development of focus therapeutic areas**
  - **Psychiatry & Neurology area**
    - ✓ Dasotraline (SEP-225289) : pivotal studies
      Adult attention-deficit hyperactivity disorder (ADHD) (Adult / Pediatric)
      Binge eating disorder (BED)
    - ✓ Lurasidone hydrochloride : new Phase lll study for Schizophrenia in Japan
  - **Oncology area**
    - ✓ Napabucasin (BBI608) : pivotal studies
      - Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy with paclitaxel / BRIGHTER)
      - Colorectal cancer (combination therapy with FOLFIRI, FOLFIRI + bevacizumab / 303CRC)
      - Start new pivotal studies (Pancreatic cancer and Non-small cell lung cancer)
    - ✓ Amcasertib (BBI503) : Start a new pivotal study
    - ✓ DSP-7888: Promote development in the U.S. and Japan
- **Promote development and commercialization of Regenerative medicine / Cell therapy**
  - Creation of Cell processing center In Kobe-City, Hyogo
- **Promote in-licensing and M&A**
  - New in-licensing (execution of an agreement expected in FY2016)

American Society of Clinical Oncology presentation (ASCO 2016, U.S.)

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- Seven posters to be presented at the ASCO in June 2016
  - The abstracts will be published on May 18 (US time)

Napabucasin (BBI608)

- ✓ Phase 1b extension study of cancer stemness inhibitor Napabucasin administered in combination with FOLFIRI +/- Bevacizumab (Bev) in patients (pts) with advanced colorectal cancer (CRC) (BBI608-246)
- ✓ A Phase Ib/II Study of Cancer Stemness Inhibitor Napabucasin Combined with Weekly Paclitaxel in Advanced Triple Negative Breast Cancer (BBI608-201)
- ✓ A Phase Ib/II Study of Cancer Stemness Inhibitor Napabucasin Combined with Weekly Paclitaxel in Advanced Non-Small Cell Lung Cancer (BBI608-201)
- ✓ A Phase Ib/II Study of Cancer Stemness Inhibitor Napabucasin Combined with Weekly Paclitaxel in Platinum Resistant Ovarian Cancer (BBI608-201)
- ✓ A Phase Ib extension study of cancer stemness inhibitor Napabucasin in combination with Gemcitabine and nab-Paclitaxel (nab-PTX) in patients (pts) with metastatic pancreatic cancer (BBI608-118)
- ✓ The BRIGHTER trial: A phase III randomized double-blind study of Napabucasin + weekly paclitaxel *versus* placebo (PBO) + weekly paclitaxel in patients (pts) with pretreated advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma

Amcasertib (BBI503)

- ✓ Phase I Extension Clinical Study of BBI503, a First-in-Class Cancer Stemness Kinase Inhibitor, in Adult Patients with Advanced Head and Neck Cancer (BBI503-101)

Napabucasin (BBI608) CO.23 study Top Line Results

Sumitomo Dainippon Pharma

- A Phase III Randomized Study of BBI608 and Best Supportive Care Versus Placebo and Best Supportive Care in Patients With Pretreated Advanced Colorectal Carcinoma
- Enrollment (planned)：650 patients
- Primary endpoint: Overall Survival (OS)
- Global Sponsor: Canadian Cancer Trials Group (CCTG; previously known as NCIC-CTG)

NOTE: The study is not statistically powered for detecting projected difference in overall survival, the primary endpoint of this study, as the accrual of enrollment was prematurely stopped in May 2014.

Results

- **Final Data analysis was obtained in May 2016.**
- **Among all randomized patients (n=282), there was no statistical difference in the median overall survival between napabucasin and placebo arms.**
- **In pre-specified subset analysis, napabucasin treatment significantly improved OS in patients with high p-Stat3 expression.**
- **Detailed results of full data will be submitted for presentation at an upcoming scientific congress by CCTG.**

Target submission date of key late-stage pipeline
(Updated May 2016)

Area	Development	Submission target			
		FY2016	FY2017	FY2018	FY2019 or later
Psychiatry & Neurology	**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.			●	
	SM-13496 <lurasidone hydrochloride> (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				●
Respiratory	**SUN-101 <glycopyrronium bromide>** (Chronic obstructive pulmonary disease) U.S.	●			

New Chemical Entities | New Indication, etc.

The 3rd MTBP & Measures for Subsequent Growth

Factors for changes in FY2017 Business Goals

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Changes in the business environment since October 2014

	Japan	Overseas
Positive factor	**New launches through alliances** ・REMITCH® ・Trulicity®	**Weaker yen** **(Current assumption : ¥110)** **(Previous assumption : ¥100)**
	Streamlining	**Profit improvement in North America**
Negative factor	**・Sluggish sales of strategic products, etc.** **・Accelerated decline of long-listed product sales due to the MHLW's initiative to promote the use of generic drugs**	**Change of Lurasidone business structure in Europe**
	Delayed new launches ・lurasidone, etc.	**New in-license in North America**

Changes in FY2017 Business Goals

3rd MTBP Changes in FY2017 business goals

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Original goals in February 2013 → **Revision in October 2014** → **Latest revision**

(billions of yen)

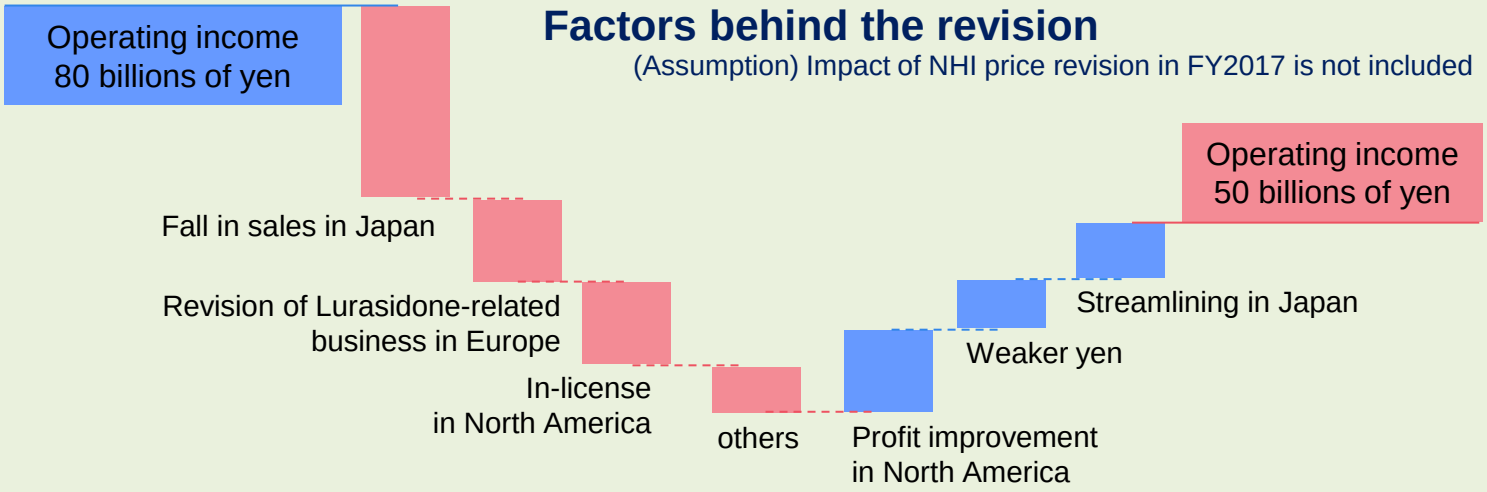
Business Goals	FY2017	Revision	FY2017	Revision	FY2017
Net Sales	450		450		440
Operating income	80		80		50
R&D costs	80		85		85
EBITDA	110		110		75
Exchange rate	80.0 yen/$		100.0 yen/$		110.0 yen/$

ROE forecast 6%

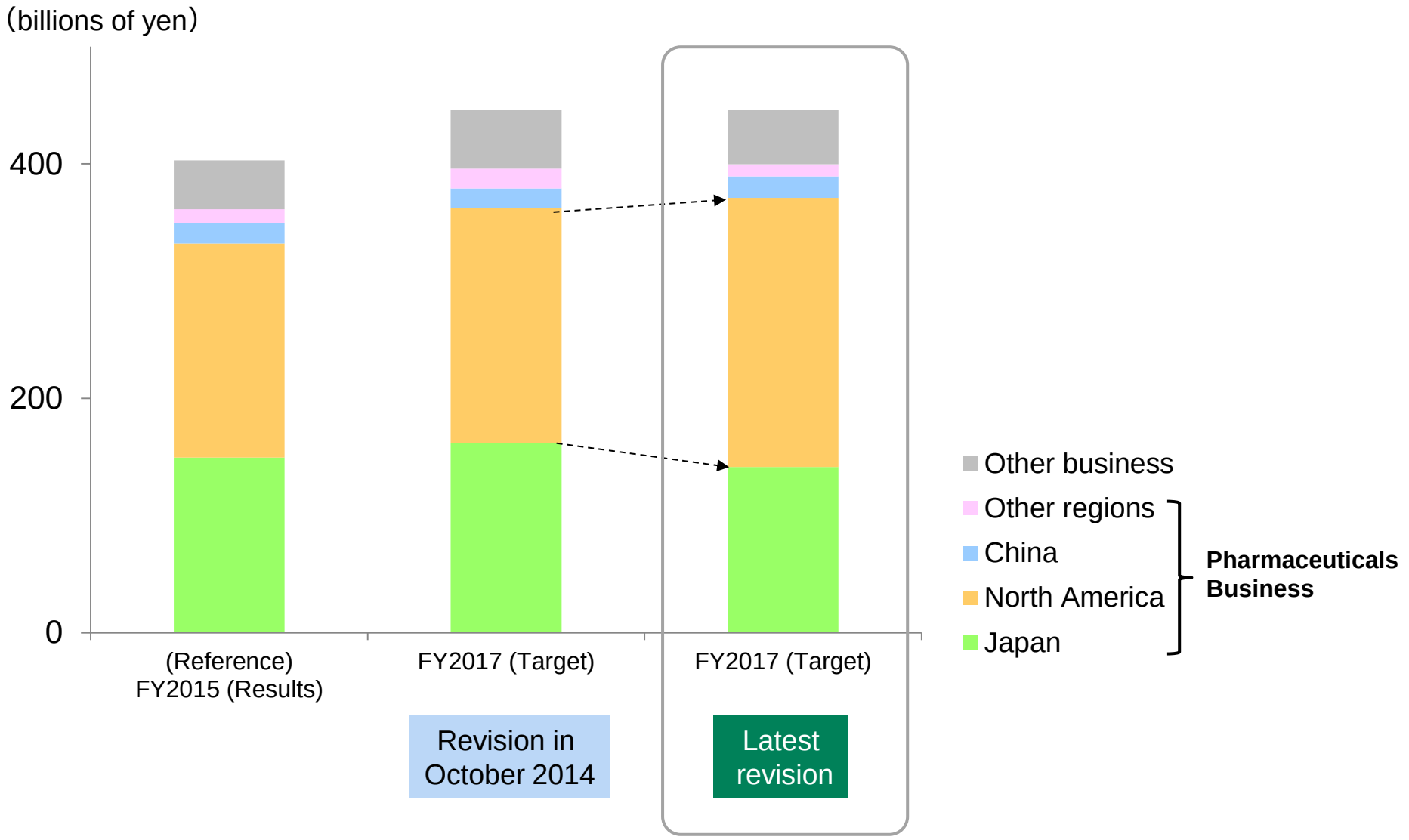
- Positive factors :
  - LATUDA® sales revised up in North America
  - Weaker yen
- Negative factors :
  - Napabucasin launch delayed

Factors behind the revision

(Assumption) Impact of NHI price revision in FY2017 is not included



3rd MTBP Sales targets by region



Measures for growth after the 3rd MTBP (1)

Products strategies

Sales maximization of strategic products

North America： LATUDA® (FY2017 peak sales), APTIOM® , BROVANA®, New In-license (Plan to launch in FY2016)

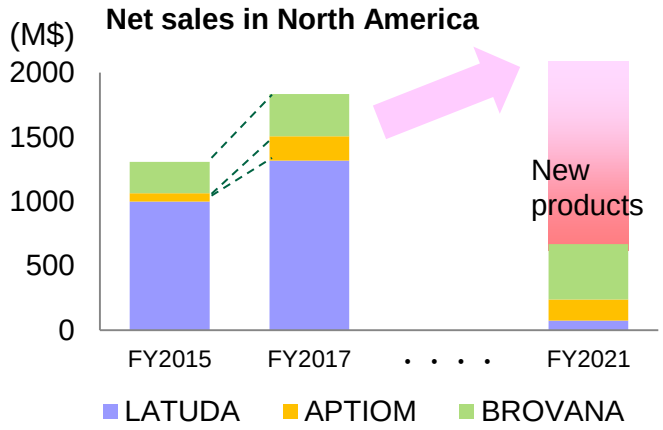
Japan： Trulicity®, REMITCH®, TRERIEF® , etc.

Launch and early maximization of sales of late development pipeline

Oncology area： napabucasin, etc.

The other areas：dasotraline, SUN-101, etc.

New in-licenses



Expected sales of key late-stage products (peak sales)

- ✓ Napabucasin : 100 billion yen or more
- ✓ Dasotraline : about 50 billion yen
- ✓ SUN-101 : about 50 billion yen

Measures for growth after the 3rd MTBP (2)

Financial / investment strategies

Proactive R&D investments **(around 20% of net sales)**
New in-licenses and M&As **(up to 150-200 billion yen)**
Adequate dividends **(dividend policy: stable payment, dividend hikes as profits grow)**

Strengthening foundations / Carrying out structural reform

Japan **Optimizing the business management structure**

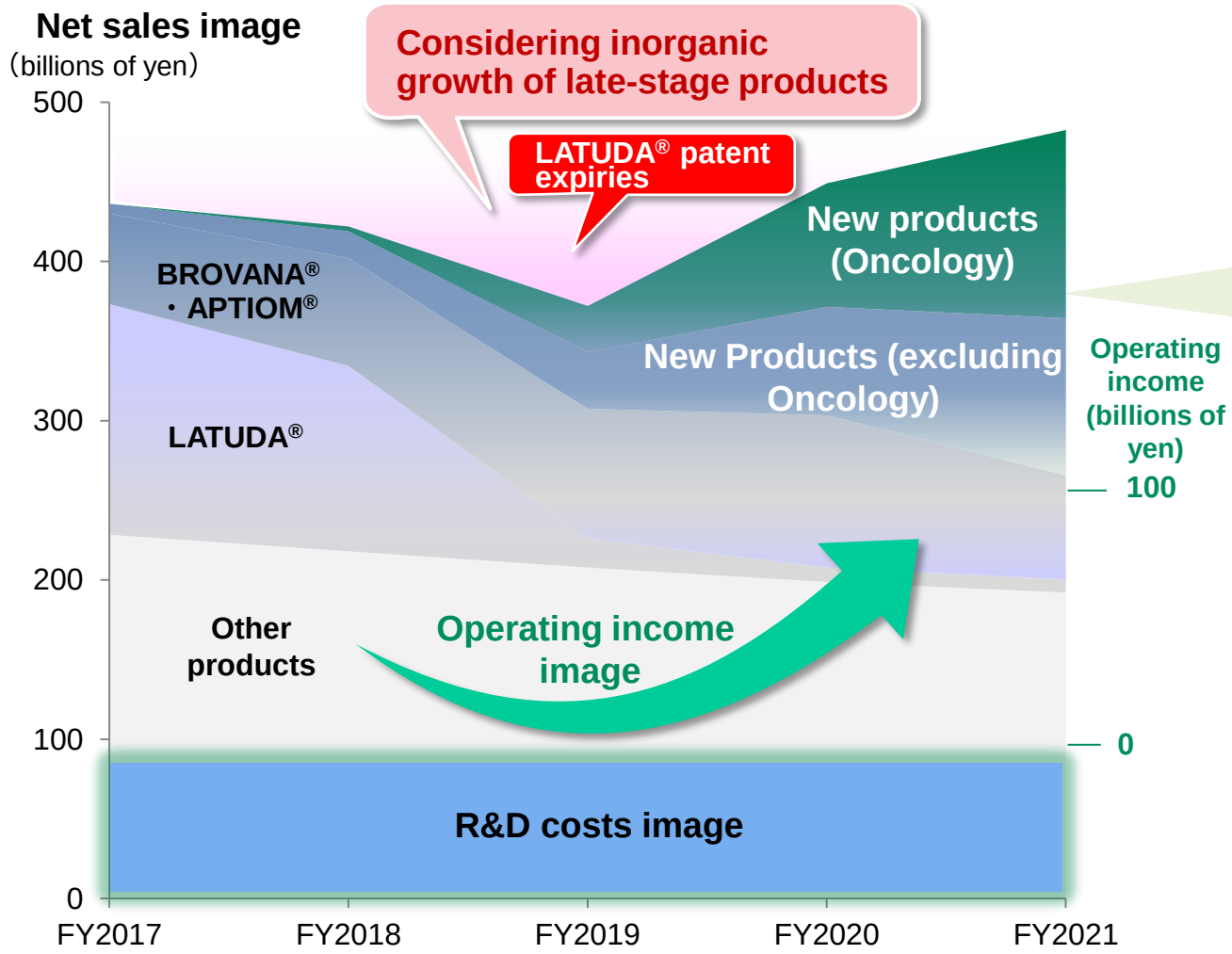
North America **Maximizing profits from LATUDA® and building efficient sales organization for new products**

Cost reduction

- Trimming SG&A expenses both in Japan and North America existing businesses to prevent increase in total SG&A expenses (except amortization of goodwill and patent rights, etc.) despite the increase due to the launch of napabucasin, dasotraline, SUN-101 and new in-licensed products
- Reorganization of production sites：Consolidating the current four plants into two plants

Performance forecast after the 3rd MTBP

Drop expected in FY2019 as LATUDA® loses its exclusivity in North America. Shooting for early recovery after FY2020 through launches and growth of late-stage products.



Main launch products (planned)

Oncology area

Napabucasin
(Japan and North America)
Amcasertib
(Japan and North America)

The other areas

SUN-101 (North America)
Dasotraline (North America)
SB623 (North America)
New In-licensed product
(North America)
Lurasidone (Japan)
DSP-1747 (Japan)

(Assumption) Two NHI price revisions (FY2018, FY2020)

Appendices

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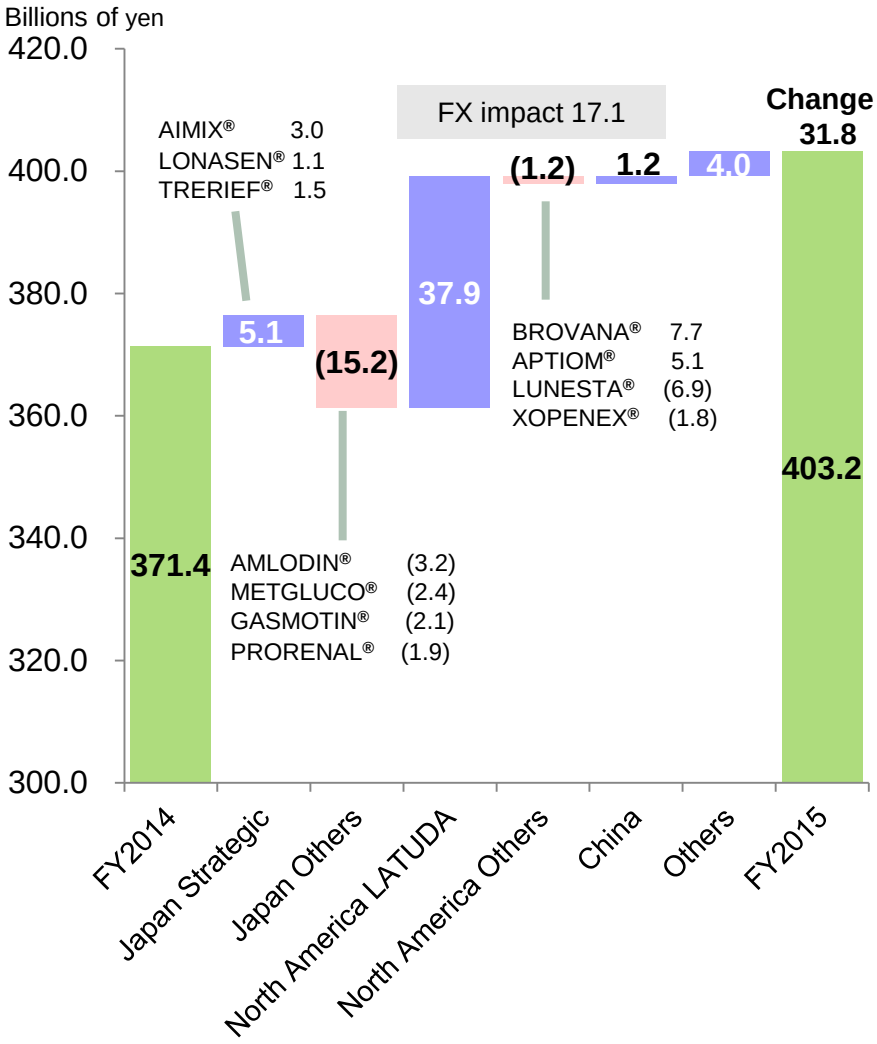
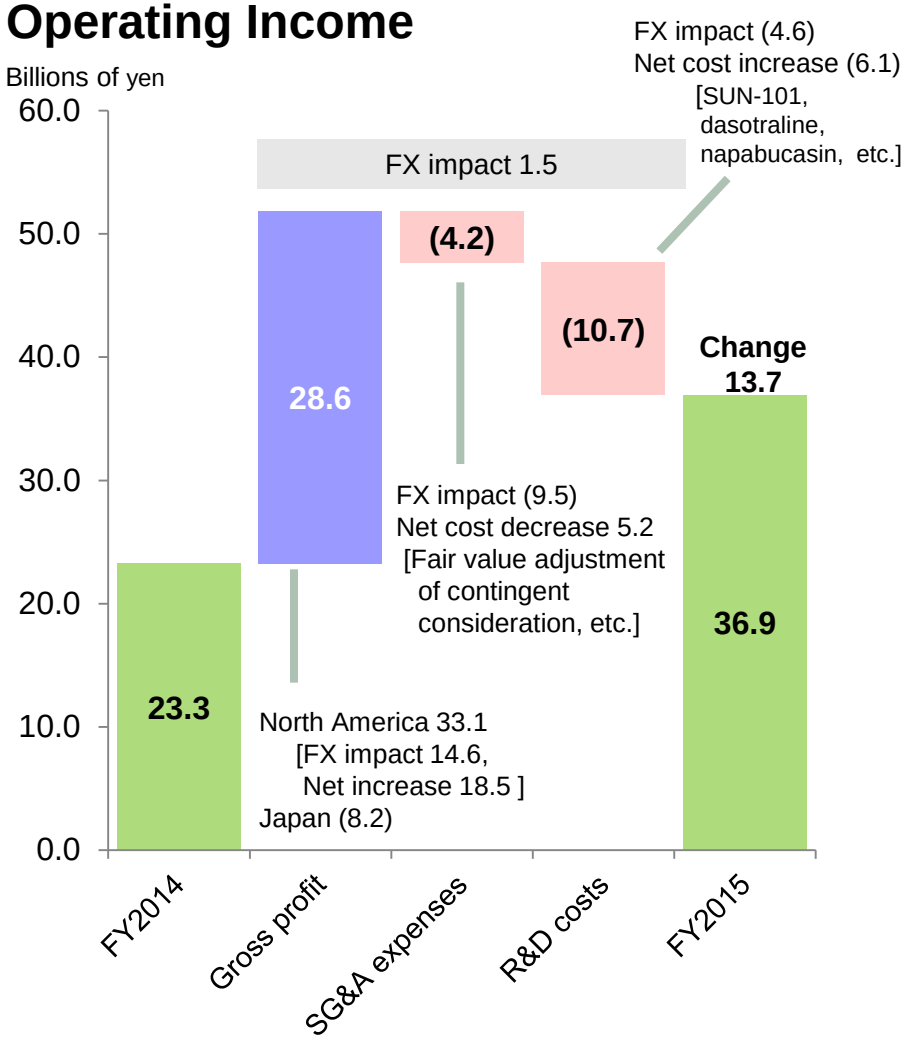
Change from FY2014

Sales



Operating Income



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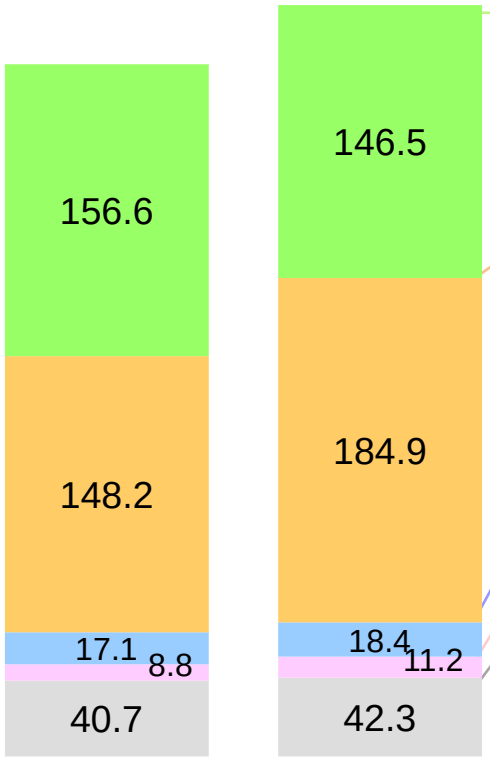
Net Sales by Segment

Billions of yen



	FY2014	FY2015	vs. FY2014 Value	vs. FY2014 %	Achieved % to Forecasts
	371.4	**403.2**	**31.8**	**8.6 %**	**100.1%**
Japan			(10.1)	(6.4) %	98.1 %
North America			36.7	24.8 %	101.2 %
China			1.2	7.2 %	103.2 %
Other Regions			2.4	27.4 %	98.1 %
Other Business			1.6	3.9 %	101.2 %
Overseas sales	47.1%	53.3%			

【Japan】Decrease in long-listed products sales
【North America】Growth of LATUDA®, BROVANA® and APTIOM® and weaker yen
【China】Increased sales due to weaker yen, unchanged in RMB basis
【Other Regions】Increase in export of MEROPEN®

Exchange rates:
FY2014 Results : 1US$ = ¥ 109.8, 1RMB = ¥17.7
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9

Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2014 Results	FY2015 Results	Change	
			Value	%
Operating Income	23.3	36.9	13.7	58.7
Non-operating income and expenses	0.1	(1.7)	(1.8)	
Ordinary income	23.3	35.2	11.9	51.0
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	7.3	1.8	(5.5)	
Business structure improvement expenses	2.0	0.6		
Loss on disposal of property, plant and equipment	–	0.6		
Impairment loss	5.3	0.6		
Income taxes	18.3	14.9	(3.4)	
Net income attributable to owners of the parent	15.4	24.7	9.2	59.9

Exchange rates:
FY2014 Results : 1US$ = ¥ 109.8, 1RMB = ¥17.7
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9

Financial Position / Cash Flows

Billions of yen

B/S	As of March 31, 2015	As of March 31, 2016	Change
Assets	711.6	707.7	(3.9)
Current assets	401.7	421.6	19.9
Fixed assets	309.9	286.1	(23.8)
Liabilities	260.6	261.2	0.7
Current liabilities	156.8	179.7	22.9
Long-term liabilities	103.7	81.5	(22.2)
Net assets	451.0	446.5	(4.5)
Shareholders' equity ratio	63.4%	63.1%	

【Assets】

Cash and time deposits	24.4
Marketable securities	(30.3)
Deferred tax assets (current)	25.1
Intangible assets	(17.3)

【Liabilities】

Income taxes payable	23.1
Total interest-bearing debt	(35.5)
Long-term ⇒Short-term	22.0
Balance	51.0

C/F	FY2014	FY2015	Change
Operating CF	30.3	49.4	19.2
Investment CF	23.4	15.9	(7.6)
Financial CF	(15.7)	(42.6)	(26.9)
Cash / Cash equivalents	122.8	135.6	12.8
Operating funds	190.9	184.4	(6.6)

【Financial CF】

Redemption of bonds in FY2015	(30.0)

Sales of Major Products in Japan

Billions of yen

	FY2015 Results	FY2016 Forecasts	Change	
			Value	%
AIMIX®	14.9	16.1	1.2	7.7
AVAPRO®	10.8	9.3	(1.5)	(14.3)
LONASEN®	12.6	13.8	1.2	9.5
TRERIEF®	13.1	14.5	1.4	10.6
Strategic Products Total	51.5	53.7	2.2	4.3
SUREPOST®	3.6	4.6	1.0	29.1
AmBisome®	4.3	4.3	(0.0)	(0.9)
REPLAGAL®	10.2	10.5	0.3	2.8
METGLUCO®	14.7	9.8	(4.9)	(33.4)
AMLODIN®	16.4	12.2	(4.2)	(25.8)
GASMOTIN®	8.4	6.0	(2.4)	(28.4)
PRORENAL®	8.7	7.0	(1.7)	(19.6)
MEROPEN®	6.2	4.5	(1.7)	(27.4)
Others	22.4	25.0	2.6	11.4
Other Products Total	95.0	83.9	(11.1)	(11.7)
Japan Total	146.5	137.6	(8.9)	(6.1)

Note: Sales of each products above are shown by gross sales basis.

Sales of Major Products in North America & China

	FY2015 Results	FY2016 Forecasts	Change	FY2015 Results	FY2016 Forecasts	Change		
						Value	FX rate impact	%
North America	Million $			Billion yen				
LATUDA®	1,002	1,152	150	120.4	126.7	6.3	(11.7)	5.3
APTIOM®	64	124	60	7.6	13.7	6.1	(1.3)	79.3
BROVANA®	249	286	37	29.9	31.5	1.6	(2.9)	5.4
Ciclesonide	58	55	(3)	7.0	6.1	(0.9)	(0.6)	(13.1)
XOPENEX®	56	43	(13)	6.7	4.7	(2.0)	(0.4)	(29.6)
LUNESTA®	38	26	(12)	4.6	2.9	(1.7)	(0.3)	(36.9)
Others	72	139	67	8.7	15.1	6.4	(1.4)	73.5
Total	1,539	1,825	286	184.9	200.7	15.8	(18.5)	8.5
China	Million RMB			Billion yen				
MEROPEN®	826	805	(21)	15.6	13.7	(1.9)	(1.5)	(12.0)
Others	148	138	(10)	2.8	2.3	(0.5)	(0.3)	(17.8)
Total	974	943	(31)	18.4	16.0	(2.4)	(1.8)	(12.9)

Exchange rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

Development Pipeline (1) (as of May 11, 2016)

Sumitomo Dainippon Pharma

Psychiatry & Neurology Area

Revisions since the previous announcement are in red.

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				
		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
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. / Japan				
SEP-363856	TBD	Schizophrenia	U.S.				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				
DSP-1200	TBD	Treatment-resistant depression	U.S.				

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

Development Pipeline (2) (as of May 11, 2016)

Sumitomo Dainippon Pharma

Oncology Area (napabucasin, amcasertib)

Revisions since the previous announcement are in red.

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	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	-	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)

Development Pipeline (3) (as of May 11, 2016)

Sumitomo Dainippon Pharma

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-7888	TBD	Myelodysplastic syndromes	Japan			※1	
		Solid tumors, Hematologic malignancies	U.S.				
		Pediatric malignant glioma	Japan		※2		
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	glycopyrronium 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				

Napabucasin – Clinical development progress

Sumitomo Dainippon Pharma

Revisions since the announcement of January 2016

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, FOLFIRI and bevacizumab	BB608-303CRC (CanStem303C)	June 2016
Phase II	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, 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 + pemetrexed	D8807005	Feb. 2015
Phase I	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, 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 + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin	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, 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, pembrolizumab, nivolumab	BBI608-201CIT	Aug. 2015
Phase I	Japan	Colorectal cancer (Combination therapy)	FOLFIRI + bevacizumab	D8809001	Dec. 2015

Study initiated was placed Clinical Trials.gov (as of May 10, 2016)

*1／Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.

Napabucasin , Amcasertib– Clinical development progress

Sumitomo Dainippon Pharma

Amcasertib

No changes after the announcement of January 2016

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, sunitinib	BBI503-201	Sep. 2015

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

Napabcasin + Amcasertib

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 May 10, 2016)

LATUDA® (lurasidone) – Clinical development progress

Revisions since the announcement of January 2016

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

Europe (In-house)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe was terminated in 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 will start 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: Russia, Turkey

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

Asia, South America, etc. (Partnering)

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

Product Launch Plan (Updated May 2016)

Sumitomo Dainippon Pharma

Area	FY2016	FY2017	FY2018	FY2019	FY2020 - FY2022
Japan		napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	LONASEN® (Schizophrenia / Transdermal patch) TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	amucasertib (Solid tumors)	lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance) napabucasin (Colorectal cancer,Pancreatic cancer, NSCLC, etc.) DSP-7888 (Solid tumors/ Hematologic cancer) obeticholic acid (NASH) DSP-6952 (IBS with constipation, Chronic idiopathic constipation) iPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	New in-licensed product (In-license)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma) glycopyrronium bromide (COPD)	dasotraline (ADHD)	dasotraline (BED) amucasertib (Solid tumors)	SB623 (Chronic stroke) DSP-2230 (Neuropathic pain) SEP-363856 (Schizophrenia) napabucasin (Colorectal cancer,Pancreatic cancer, NSCLC, etc.) 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 of Business Plan
(Updated May 2016)

Sumitomo Dainippon Pharma

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year) 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** → **Investigator or corporate 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**		

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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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Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows