



Financial Results for FY2014  
(The year ended March 31, 2015)

May 12, 2015

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

# Financial Results for FY2014

# Financial Results for FY2014

Billions of yen

	FY2013 Results	FY2014 Results	Comparison to FY2013			FY2014 Forecasts (29 <sup>th</sup> January)	
			Value	Exchange Rate Impact	Percentage (%)	Value	Percentage (%)
Net sales	387.7	371.4	(16.3)	13.6	(4.2)	371.0	100.1
Cost of sales	104.1	101.2	(2.9)	1.3	(2.8)	101.5	99.7
Gross profit	283.6	270.1	(13.4)	12.3	(4.7)	269.5	100.2
SG&A expenses	241.5	246.9	5.4	12.2	2.2	249.5	98.9
SG&A expenses less R&D costs	171.6	175.6	3.9	9.3	2.3	176.0	99.8
R&D Costs	69.8	71.3	1.5	2.9	2.1	73.5	97.0
Operating income	42.1	23.3	(18.9)	0.0	(44.8)	20.0	116.4
Ordinary income	40.6	23.3	(17.3)		(42.6)	20.0	116.7
Extraordinary income (loss)	(5.9)	10.4	16.3				
Net income	20.1	15.4	(4.6)		(23.0)	12.5	123.6
E B I T D A	68.1	43.1	(25.0)		(36.7)	39.5	109.1

Notes: 1. All values are rounded to the nearest 100 million yen.

2. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

Exchange Rate:

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

FY2014 Results : 1US\$ = ¥ 109.8, 1RMB = ¥17.7

# Segment Information for FY2014

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America <sup>※1</sup>	Amortization <sup>※2</sup>	China	Other Regions				
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	91.6	9.4	7.3	2.4	169.4	6.2	175.6	
	<b>Income (loss) of segment</b>	50.6	44.2	(9.4)	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
FY2013 Results	Net sales (Sales to customers)	171.9	145.3	—	11.9	16.7	345.8	41.9	387.7	
	Cost of sales	49.3	15.0	—	2.6	4.4	71.3	32.8	104.1	
	Gross profit	122.7	130.3	—	9.3	12.3	274.6	8.9	283.6	
	SG&A expenses less R&D costs	61.9	78.3	18.2	6.1	0.9	165.4	6.2	171.6	
	<b>Income (loss) of segment</b>	60.8	52.0	(18.2)	3.2	11.4	109.2	2.7	111.9	
	R&D costs							68.9	0.9	69.8
	Operating income							40.4	1.8	42.1
Change	Net sales (Sales to customers)	(15.3)	2.9	—	5.2	(7.9)	(15.1)	(1.2)	(16.3)	
	SG&A expenses less R&D costs	(3.4)	13.4	(8.7)	1.2	1.5	4.0	(0.1)	3.9	
	<b>Income (loss) of segment</b>	(10.3)	(7.9)	8.7	3.1	(10.5)	(16.9)	(0.5)	(17.4)	
	R&D costs							1.5	(0.0)	1.5
	Operating income							(18.4)	(0.5)	(18.9)

※1. Excluding amortization of patent rights and goodwill, etc.

※2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

FY2014 Results : 1US\$ = ¥ 109.8, 1RMB = ¥17.7

# Financial Forecast for FY2015

# Overview of FY2015 Financial Forecast

## ■ Net Sales

- North America: LATUDA<sup>®</sup> growth to \$1B (¥115B) target
- Japan: Business scale sustained by growths of strategic products, compensating for sales decline of long-listed products and METGLUCO<sup>®</sup> erosion by generics

## ■ Expenses

- SG&A: Maintain the previous year's level by offsetting impact of weaker yen by expenses reduction
- R&D: Increase due to active R&D investment focused on development of late-stage pipeline, to minimize impact of approaching LATUDA<sup>®</sup> patent expiry

Target

Sales: 392 billion yen (up 5.6%)

Operating income: 27 billion yen (up 16.0%)

# Financial Forecast for FY2015

Billions of yen

	FY2014 Results	FY2015 Forecast	Comparison to FY2014		
			Value	Exchange Rate Impact	Percentage (%)
Net sales	371.4	<b>392.0</b>	20.6	8.5	5.6
Cost of sales	101.2	<b>102.0</b>	0.8	0.7	0.8
Gross profit	270.1	<b>290.0</b>	19.9	7.8	7.4
SG&A expenses	246.9	<b>263.0</b>	16.1	7.1	6.5
SG&A expenses less R&D costs	175.6	<b>176.0</b>	0.4	4.9	0.2
R&D Costs	71.3	<b>87.0</b>	15.7	2.2	22.0
Operating income	23.3	<b>27.0</b>	3.7	0.6	16.0
Ordinary income	23.3	<b>26.5</b>	3.2	/	13.6
Extraordinary income (loss)	10.4	<b>4.5</b>	(5.9)		
Net income	15.4	<b>18.0</b>	2.6		16.5
E B I T D A	43.1	<b>47.5</b>	4.4		10.2

Notes: 1. All values are rounded to the nearest 100 million yen.

2. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

Exchange Rate:

FY2014 Results : 1US\$ = ¥109.8, 1RMB = ¥17.7

FY2015 Forecast.: 1US\$ = ¥115.0, 1RMB = ¥18.5

# Segment Information for FY2015

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America※1	Amortization ※2	China	Other Regions	Subtotal			
FY2015 Forecast	Net sales (Sales to customers)	156.7	166.8	—	18.7	7.4	349.6	42.4	392.0	
	Cost of sales	48.0	12.7	—	3.6	4.3	68.6	33.4	102.0	
	Gross profit	108.8	154.1	—	15.1	3.1	281.1	8.9	290.0	
	SG&A expenses less R&D costs	58.1	93.0	7.5	8.3	2.5	169.4	6.6	176.0	
	<b>Income (loss) of segment</b>	50.7	61.1	(7.5)	6.8	0.6	111.7	2.3	114.0	
	R&D costs							86.0	1.0	87.0
	Operating income							25.7	1.3	27.0
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	91.6	9.4	7.3	2.4	169.4	6.2	175.6	
	<b>Income (loss) of segment</b>	50.6	44.2	(9.4)	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)	0.1	18.6	—	1.6	(1.4)	18.9	1.7	20.6	
	SG&A expenses less R&D costs	(0.4)	1.4	(1.9)	1.0	0.1	—	0.4	0.4	
	<b>Income (loss) of segment</b>	0.1	16.9	1.9	0.6	(0.2)	19.3	0.1	19.4	
	R&D costs							15.6	0.1	15.7
	Operating income							3.7	—	3.7

※1. Excluding amortization of patent rights and goodwill, etc.

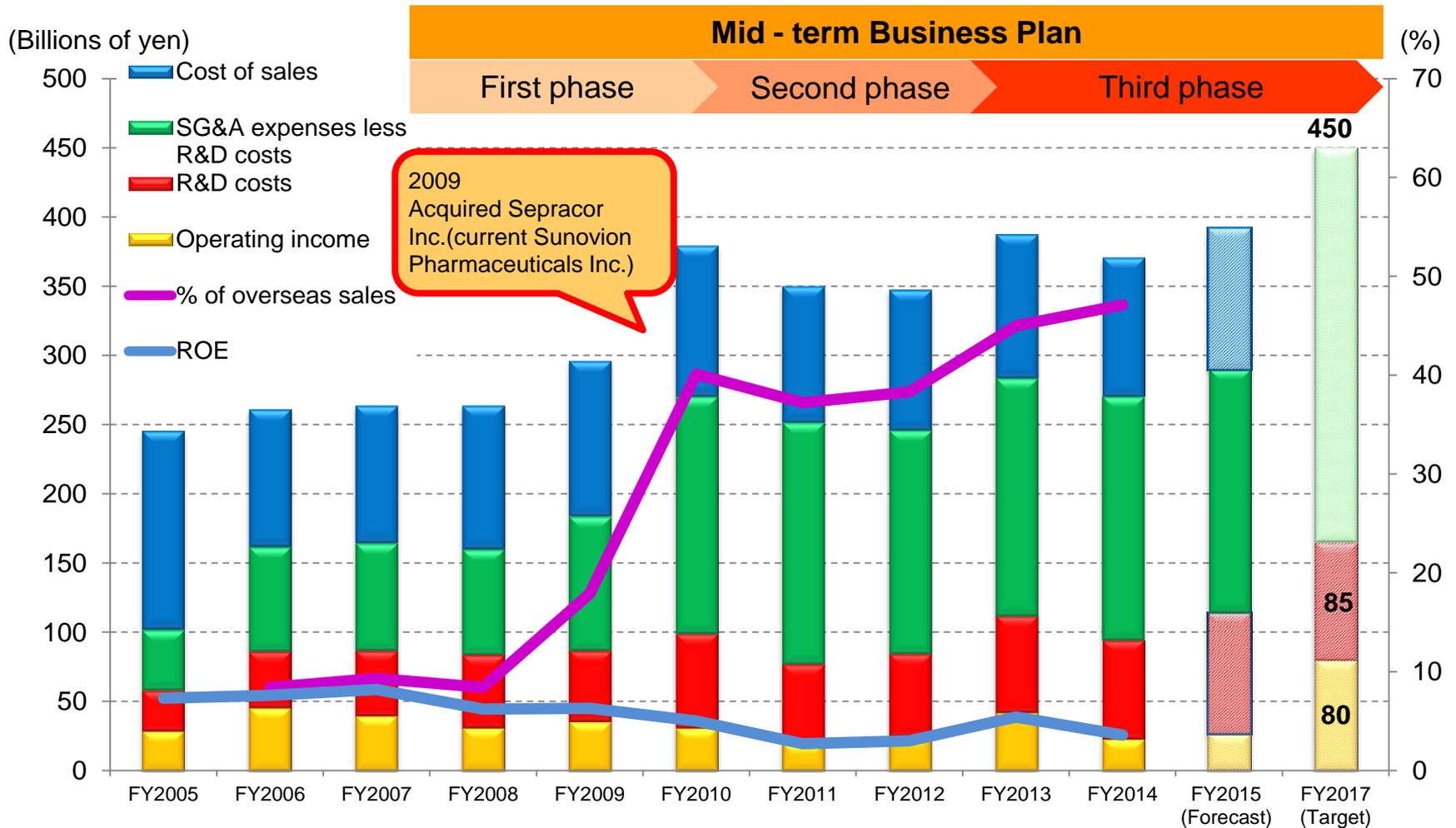
※2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2014 Results : 1US\$ = ¥109.8, 1RMB = ¥17.7

FY2015 Forecast.: 1US\$ = ¥115.0, 1RMB = ¥18.5

# Trend of business results over the past decade



# **FY2015 Strategic issues**

# FY2015 Strategic issues (Japan Business)

- ◆ **Expand AIMIX<sup>®</sup>, LONASEN<sup>®</sup>, TRERIEF<sup>®</sup>**
  - ✓ Concentrate sales resources and promote e-promotion activities
  - ✓ Add 100 medical reps to the psychiatry area to total 330
  
- ◆ **Promotion tie-up of REMITCH<sup>®</sup> (Pruritus in chronic liver disease patients)**
  - ✓ Start promotion in FY2015 following indication addition; strengthen activities in liver area
  - ✓ The first therapeutic medicine of pruritus in chronic liver disease patients
  
- ◆ **Improve sales efficiency in Japan**
  - ✓ Optimize sales cost
  - ✓ Raise efficiency of sales organization in Japan
  - ✓ Promote “Hybrid Marketing”

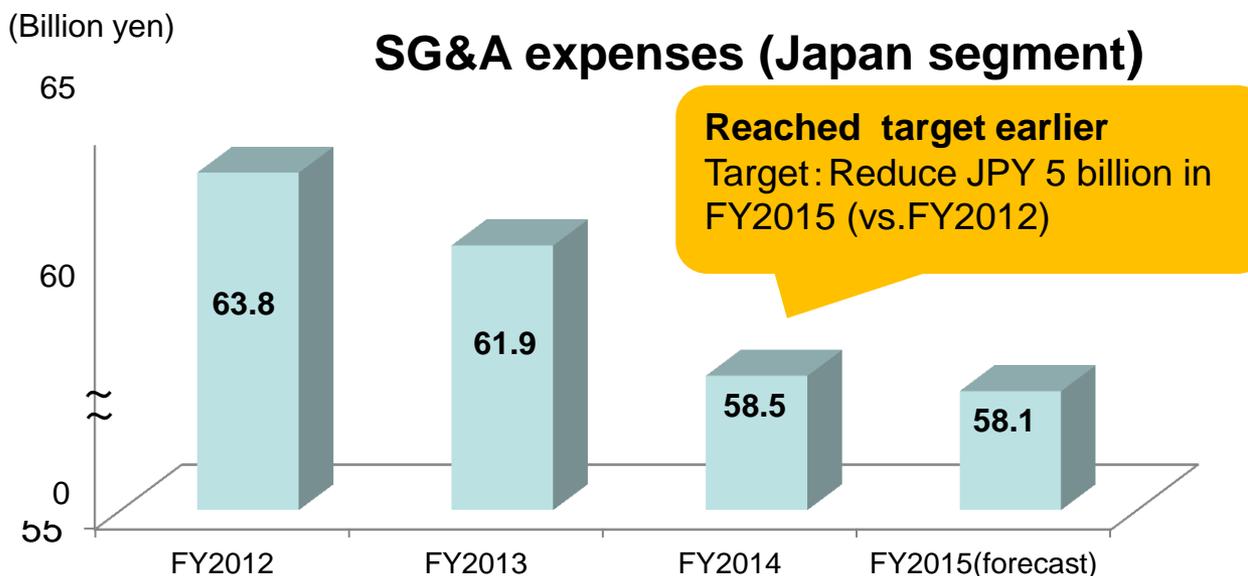
# Strengthen foundation (Japan Business)

## ◆ FY2014: Progress of Streamlining Project

- ✓ Achieved JPY 5 billion reduction in FY2014 (vs. FY2012 actual)
  - Optimized organizations and personnel by improving business operations  
⇒10 units and about 330 employees less (March 31, 2012 vs. March 31, 2015, parent company)
  - Reduced sales promotion expenses
  - Sold some fixed assets (idle assets)
  - Decided realignment of production bases (Productive activities concentrated to Suzuka and Oita)

## ◆ FY2015: Further promotion of Streamlining Project

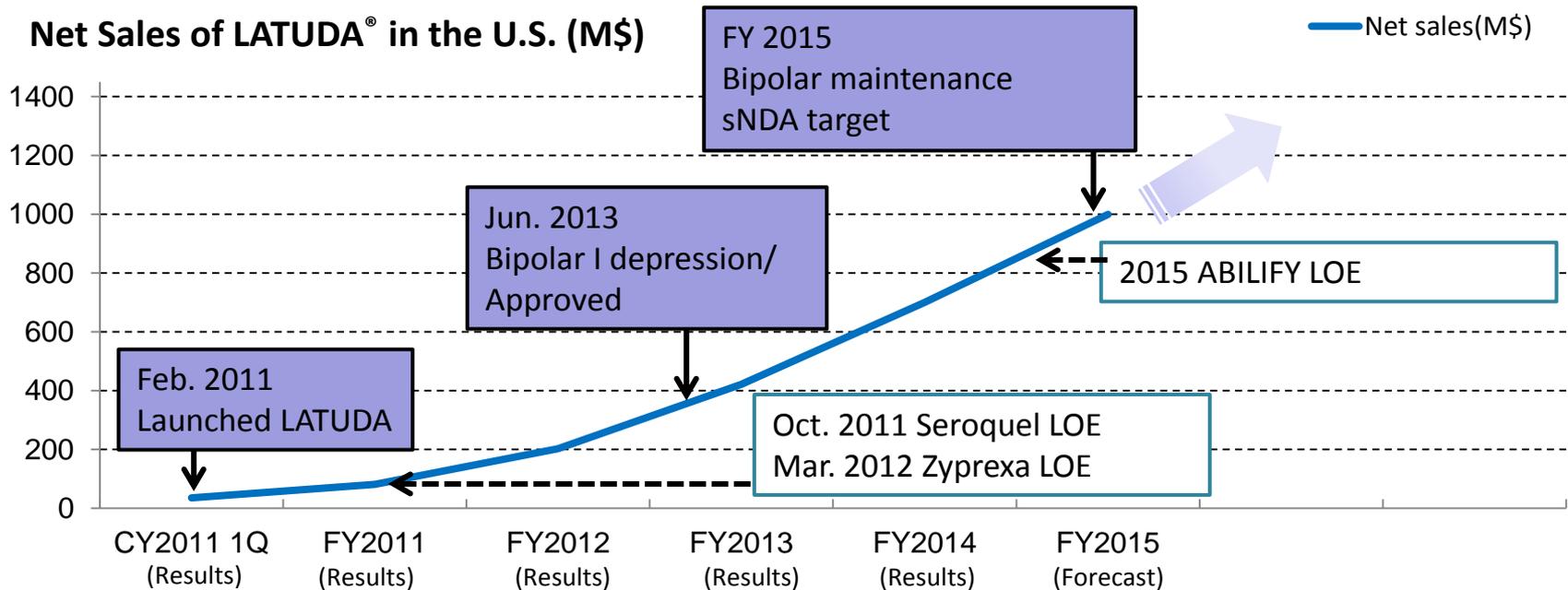
- ✓ Planning further cost reduction in FY2015, including anticipated sales cost increase from promotion tie-up of REMITCH®
  - Enhance sales efficiency in Japan
  - Optimize back office operation
  - Establish zero support system (Integrate admin operation in sales office into head office and branch office) etc.



# FY2015 Strategic issues <North America segment>

## ◆ Expand LATUDA®

- ✓ Direct sales resources efficiently to make LATUDA® a blockbuster (reach \$1B sales) and maximize profit
- ✓ Bipolar maintenance / submission target in FY2015



## ◆ Expand APTIOM®

- ✓ Epilepsy monotherapy / Approval target in the first half of FY2015
- ✓ The percentage of monotherapy in epilepsy treatment: 75%
- ✓ The peak sales target: JPY 50 billion

# FY2015 Strategic issues <R&D promotion>

- ◆ **Prioritize resource allocation in the late-stage pipeline and obtain approval early**
  - ✓ Promote Phase III studies (BBI608, dasotraline, SUN-101, TRERIEF® new indication etc.)
  - ✓ Start new Phase III studies for BBI608 and BBI503
- ◆ **Major clinical studies due for completion during FY2015**
  - ✓ ranirestat : Phase III study
  - ✓ SUN-101: Phase III study
  - ✓ DSP-1747 : Phase II study
  - ✓ BBI608: Data analysis of Phase III global clinical trial for advanced colorectal cancer (CO.23 study)
- ◆ **Promote Regenerative Medicine and Cell Therapy projects**
  - ✓ SB623: Start and promote Phase II b study
  - ✓ Age-related macular degeneration:
    - Sighregen K.K.: Capital increased (March, 2015) and staff increased (April, 2015)  
⇒ Develop commercial-scale manufacturing process of RPE cells, determine dosage form, start preparations for production
  - ✓ Production facilities:
    - Draw up Sumitomo Dainippon Pharma grand design for production, and study construction of new production facilities

# FY2015 Strategic issues <Lurasidone business>

## ◆ Japan

- ✓ Schizophrenia: Phase III study completed
  - ⇒ Assessed the application for approval of manufacturing and marketing would be difficult based on the result of this study.
  - The future development policy is under consideration.
- ✓ Bipolar disorder: Phase III study on going
  - ⇒ The study is continued as planned, J-NDA submission is planned for FY 2017

## ◆ Europe (excluding the U.K.)

- ✓ The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.
- ✓ All options are under consideration including collaboration with a new partner.
  - ⇒ Restructure business in Europe

# FY2015 Strategic issues

## <Strengthen Internal Control>

### ◆ Address to amendment of Companies Act

- ✓ Maintain to be a Company with Board of Company Auditors
- ✓ Revised the Company's "Basic Policy on Internal Control System" (May 2015)
  - <Major points of amendment>
    - Strengthen group-wide internal control (compliance, risk management, etc.)
    - Improve structures to ensure effective audits by the Audit & Supervisory Board Members
- ✓ Continue to measures for strengthening internal control

### ◆ Address to the Corporate Governance Code

- ✓ Under consideration (to be announced around autumn of 2015)

Reference:

#### <General principles of

#### Japan's Corporate Governance Code [Proposal] >

1. Securing the rights and equal treatment of shareholders
2. Appropriate cooperation with stakeholders other than shareholders
3. Ensuring appropriate information disclosure and transparency
4. Responsibilities of the Board
5. Dialogue with Shareholders

# Clinical Development Status

# Development Pipeline (1) (as of May 11, 2015)

## Psychiatry & Neurology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
APTiom® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	U.S. / Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Japan ※1 / China				
		Bipolar I depression, Bipolar maintenance	Japan				
		(New indication) Bipolar maintenance	U.S. / Europe, etc.				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	TBD	Leigh syndrome	Japan				※2
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				

※1 A Phase III study completed, development policy under consideration

※2 Phase II/III study

Revisions since the previous announcement are in red.

# Development Pipeline (2) (as of May 11, 2015)

## Oncology Area (BBI608, BBI503)

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
BBI608	TBD	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)	U.S. / Canada				
		Solid tumors (Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.) (Combination therapy)	U.S. / Canada			※1	
		Solid tumors (Combination therapy) ※3 , Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy) ※4	Japan				
BBI503	TBD	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy)	U.S.			※2	
		Solid tumors (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

(Malignant pleural mesothelioma, Hepatocellular carcinoma)

# Development Pipeline (3) (as of May 11, 2015)

## Oncology Area (Excluding BBI608, BBI503)

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
WT4869	TBD	Myelodysplastic syndromes	Japan		※1		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				
DSP-7888	TBD	Myelodysplastic syndromes	Japan		※1		

※1 Phase I of Phase I/II study

## Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

## Other Areas

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

Revisions since the previous announcement are in red.

# Clinical Development Status

(Major Changes since January 29, 2015)

## TRERIEF® (New indication)

- Started Phase III study for Parkinsonism in Dementia with Lewy Bodies in Japan

## dasotraline (SEP-225289)

- Started Phase II study for Pediatric Attention-Deficit Hyperactivity Disorder (ADHD) in the U.S.

## BBI503

- Started Phase II study for Ovarian cancer (monotherapy) in the U.S.

## BBI608+BBI503

- Started Phase I study for Solid tumors (combination therapy) in the U.S.

## Newly added

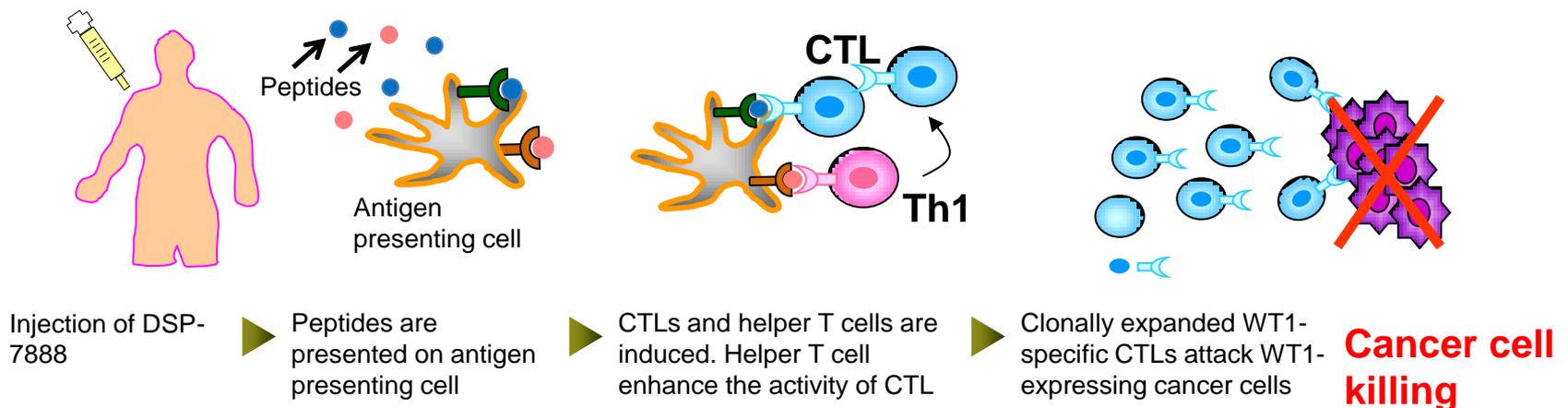
- DSP-7888  
Started Phase I / II study for Myelodysplastic syndromes in Japan

## Completed Study (LATUDA / lurasidone)

- Schizophrenia: Completed Phase III study in Japan  
Development policy under consideration
- MDD with mixed features: Completed Phase III study in U.S. and Europe, etc.  
FDA submission planned for label update

# <Oncology area> Profile of DSP-7888

- Target Indication: Myelodysplastic syndromes
- Origin: In-house
- Pharmacological Mechanism: Induce WT1 (Wilms' tumor 1) -specific cytotoxic T-lymphocytes (CTLs) to attack cancer cells expressing WT1 protein
- Development stage: Phase I of Phase I / II in Japan
- Characteristics:
  - ✓ Novel peptide vaccine containing the peptides which induce WT1-specific CTLs and helper T cells
  - ✓ By adding a helper T cell-inducing peptide, stronger efficacy than killer peptide alone is expected
  - ✓ DSP-7888 is expected to be options for wide range of patients



# BBI608 and BBI503 Data announcement plan

## ◆ Present data at 2015 American Society of Clinical Oncology (ASCO)

- Five presentations have been adopted and the summary will be published on May 13 (US time)
  - BBI608
    - ✓ Phase Ib/II Study of Cancer Stem Cell (CSC) Inhibitor BBI608 combined with Paclitaxel in Advanced Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma (BBI608-201 study)
    - ✓ A phase Ib/II study of cancer stem cell inhibitor BBI608 administered with panitumumab in KRAS wild-type (wt) patients (pts) with metastatic colorectal cancer (mCRC) following progression on anti-EGFR therapy (BBI608-224 study)
    - ✓ A Phase Ib study of BBI608 in combination with FOLFIRI with and without Bevacizumab in patients (pts) with advanced colorectal cancer (CRC) (BBI608-246 study)
    - ✓ (Study protocol) The BRIGHTER trial: A phase III randomized double-blind study of BBI608 + weekly paclitaxel versus placebo (PBO) + weekly paclitaxel in patients (pts) with pretreated advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma (BBI608-BRIGHTER study)
  - BBI503
    - ✓ Phase 1 Extension Study of BBI503, a First-in-Class Cancer Stemness Kinase Inhibitor, in Patients with Advanced Colorectal Cancer (BBI503-101 study)

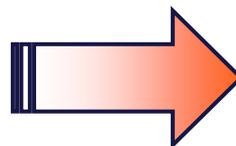
## ◆ Data analysis progress of Phase III global clinical trial for advanced colorectal cancer (CO.23 study)

- Final results including Overall Survival (OS) and Biomarker will be available in 3Q 2015. NCIC-CTG retains publication right.

# Financial strategy & dividend policy

## Financial strategy

- ◆ Loan repayment / Bond retirement
- ◆ Generating cash by asset reduction
- ◆ Utilize leverage



Strategic investment for future growth to R&D, new in-license and M&A

## Dividend policy

Stable dividends in FY2015, later increase in line with performance improvement

	FY2013 (results)	FY2014 (forecast)	FY2015 (forecast)
Dividends per share (yen)	18.00	18.00	18.00
Payout ratio (%)	35.7	46.3	39.7
〈reference〉			
Dividend on equity (%)	1.9	1.7	1.6

## Return On Equity (ROE)

Year	FY2013 (results)	FY2014 (results)	FY2015 (forecast)
Return On Equity (ROE) (%)	5.4	3.6	4.0

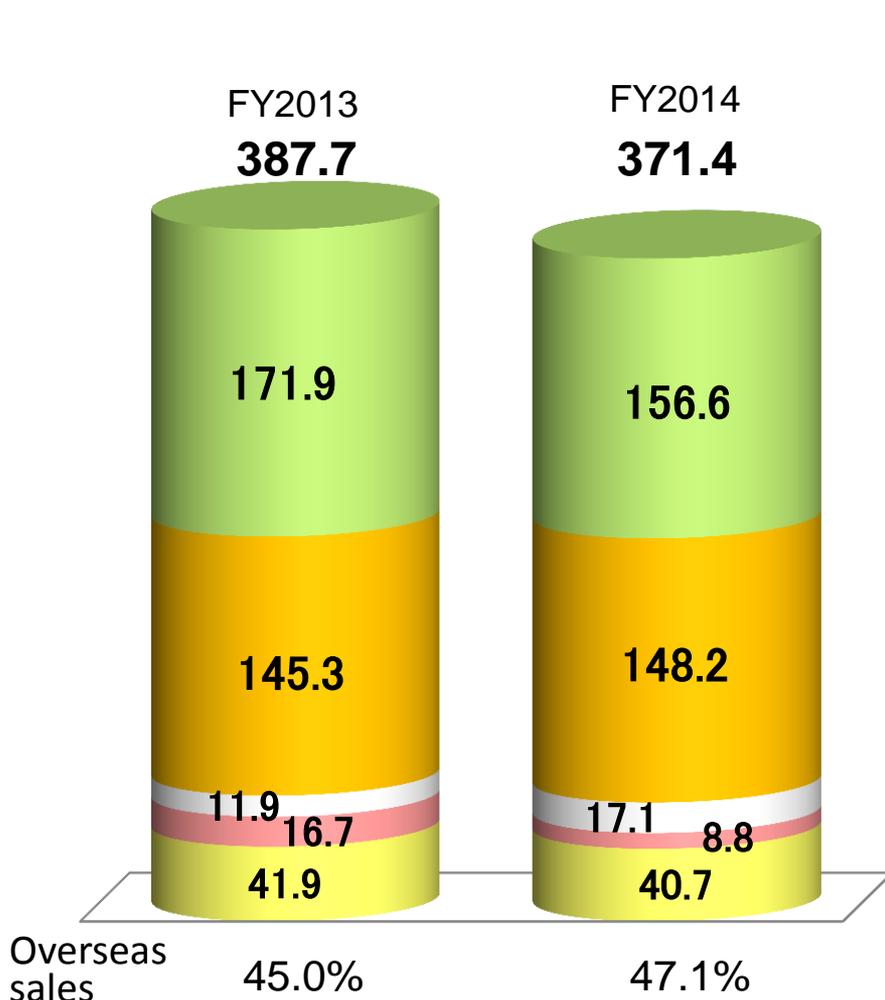
〈reference〉 FY2017 Operating income (target): 80 billion yen, FY2017 ROE (forecast): around 9%

# Appendix

# FY2014

## Net Sales by Segment

Billions of yen



	vs. FY2013	vs. FY2014
	Value	Forecast
		%
	<b>(16.3)</b>	<b>100.1</b>

Japan	<b>(15.3)</b>	<b>(8.9)</b>	<b>98.8</b>
North America	<b>2.9</b>	<b>2.0</b>	<b>101.5</b>
China	<b>5.2</b>	<b>43.7</b>	<b>102.7</b>
Other Regions	<b>(7.9)</b>	<b>(47.4)</b>	<b>99.8</b>
Other Business	<b>(1.2)</b>	<b>(2.8)</b>	<b>99.3</b>

**【Japan】** Effect from NHI price revision and decrease in long-listed products

**【North America】** Growth of LATUDA® and weak yen offset drop in LUNESTA®

**【China】** Strong sales of MEROPEN®

**【Other Regions】** Milestone revenue in FY2013 related to approval of LATUDA® in Europe

Exchange Rate:

FY2013 Results : 1US\$ = ¥ 100.2, 1RMB = ¥16.4

FY2014 Results : 1US\$ = ¥ 109.8, 1RMB = ¥17.7

	FY2013 Results	FY2014 Results	Comparison to FY2013	
			Value	Percentage (%)
AIMIX®	6.9	12.0	5.0	72.7
AVAPRO®	12.1	11.4	(0.7)	(5.8)
LONASEN®	12.6	11.5	(1.1)	(9.0)
TRERIEF®	9.5	11.6	2.1	22.4
Strategic products total	41.1	46.4	5.3	13.0
METGLUCO®	15.8	17.1	1.3	8.4
SUREPOST®	1.7	2.4	0.7	42.3
AmBisome®	4.8	4.3	(0.5)	(9.7)
MIRIPLA®	1.2	0.9	(0.3)	(22.8)
REPLAGAL®	9.8	9.7	(0.1)	(1.2)
New / Specialty products total	33.2	34.4	1.2	3.6
AMLODIN®	27.0	19.6	(7.4)	(27.3)
GASMOTIN®	15.0	10.5	(4.6)	(30.5)
PRORENAL®	13.5	10.6	(3.0)	(21.8)
MEROPEN®	9.8	7.9	(1.9)	(19.8)
Others	32.2	27.2	(5.0)	(15.5)
Other products total	97.6	75.8	(21.8)	(22.4)
<b>Japan total</b>	<b>171.9</b>	<b>156.6</b>	<b>(15.3)</b>	<b>(8.9)</b>

Note: Sales figures before reduction of rebates

## Sales in North America &amp; China

	FY2013 Results	FY2014 Results	Change	FY2013 Results	FY2014 Results	Change		
						Value	Exchange Rate Impact	Percentage (%)
<b>North America</b>	(Million \$)			(Billion yen)				
LATUDA®	421	<b>752</b>	331	42.2	<b>82.5</b>	40.3	7.2	95.6
BROVANA®	168	<b>202</b>	34	16.8	<b>22.2</b>	5.3	1.9	31.8
LUNESTA®	579	<b>105</b>	(474)	58.0	<b>11.5</b>	(46.5)	1.0	(80.1)
XOPENEX®	121	<b>78</b>	(43)	12.1	<b>8.5</b>	(3.6)	0.7	(29.5)
Ciclesonide	81	<b>61</b>	(20)	8.2	<b>6.7</b>	(1.4)	0.6	(17.6)
APTIOM®	—	<b>23</b>	23	—	<b>2.5</b>	2.5	—	—
Industrial property revenues	41	<b>90</b>	49	4.1	<b>9.9</b>	5.8	0.4	142.4
Others	40	<b>39</b>	(0)	4.0	<b>4.3</b>	0.4	0.4	9.1
<b>Total</b>	<b>1,450</b>	<b>1,350</b>	<b>(100)</b>	<b>145.3</b>	<b>148.2</b>	<b>2.9</b>	<b>12.3</b>	<b>2.0</b>
<b>China</b>	(Million RMB)			(Billion yen)				
MEROPEN®	597	<b>805</b>	208	9.8	<b>14.3</b>	4.5	1.1	45.7
Others	131	<b>163</b>	32	2.1	<b>2.9</b>	0.7	0.2	34.7
<b>Total</b>	<b>727</b>	<b>968</b>	<b>241</b>	<b>11.9</b>	<b>17.1</b>	<b>5.2</b>	<b>1.3</b>	<b>43.7</b>

# FY2014 Segment Breakdown for North America

< Excluding amortization of patent rights and goodwill, etc. >

	FY2013 Results	FY2014 Results	Change	FY2013 Results	FY2014 Results	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
Net sales	1,450	<b>1,350</b>	(100)	145.3	<b>148.2</b>	2.9	12.3
Cost of sales	149	<b>113</b>	(37)	15.0	<b>12.4</b>	(2.6)	1.0
Gross profit	1,301	<b>1,237</b>	(64)	130.3	<b>135.8</b>	5.5	11.3
SG&A expenses	782	<b>835</b>	54	78.3	<b>91.6</b>	13.4	7.9
Income (loss) of segment	519	<b>402</b>	(118)	52.0	<b>44.2</b>	(7.9)	3.3

< Impact from amortization of patent rights and goodwill, etc. >

	FY2013 Results	FY2014 Results	Change	FY2013 Results	FY2014 Results	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
SG&A expenses	181	<b>86</b>	(95)	18.2	<b>9.4</b>	(8.7)	0.8
Income (loss) of segment	(181)	<b>(86)</b>	95	(18.2)	<b>(9.4)</b>	8.7	(0.8)

**FY2014**

# Ordinary income & Net income

Billions of yen

	FY2013 Results	FY2014 Results	Change	
			Value	Percentage(%)
Operating income	42.1	23.3	(18.9)	(44.8)
Non-operating income and expenses	(1.5)	0.1	1.6	
Ordinary income	40.6	23.3	(17.3)	(42.6)
Extraordinary income	4.1	17.7	13.6	
Gain on sales of property, plant and equipment	—	16.0	16.0	
Compensation income for damage	—	1.7	1.7	
Gain on sales of investment securities	2.8	—	(2.8)	
Fair value adjustment of contingent consideration	1.3	—	(1.3)	
Extraordinary loss	10.0	7.3	(2.7)	
Impairment loss	7.6	5.3	(2.3)	
Business structure improvement expenses	2.3	2.0	(0.4)	
Income taxes	14.6	18.3	3.7	
Net income	20.1	15.4	(4.6)	(23.0)

【Gain on sales of PP&E】 Sales of idle real estate

【Impairment loss】 Reorganization of production sites

【Business structure improvement expenses】 Optimization of personnel

⇒ Measures for strengthening business foundation

FY2014

# Financial Position / Cash Flows

Billions of yen

B/S	as of Mar.31,2014	as of Mar.31,2015	Change
Assets	659.0	711.6	52.6
Current assets	359.6	401.7	42.1
Fixed assets	299.4	309.9	10.5
Liabilities	260.5	260.6	0.1
Current liabilities	131.2	156.8	25.6
Long-term liabilities	129.3	103.7	(25.6)
Net assets	398.5	451.0	52.5

Shareholders' equity ratio            60.5%            63.4%

C/F	FY2013	FY2014	Change
Operating CF	49.9	30.3	(19.7)
Investment CF	(26.2)	23.5	49.7
Financial CF	(27.2)	(15.7)	11.4
Cash / Cash equivalents	73.9	122.8	48.9

Operating funds                    146.5                    190.9                    44.5

## 【Assets】

Marketable securities +29.3

PP&E (7.5)

Intangible assets +17.1

## 【Liabilities】

Bonds payable

    Long-term⇒Short-term +30.0

Total interest-bearing debt (8.5)

Balance 86.5

## 【Net Assets】

Foreign currency translation adj. +41.4

Retained earnings +7.8

## 【Reasons for increase in Cash / CE】

Increase in collection of accounts  
receivable

Sale of idle real estate  
Impact of FX fluctuation

	FY2014 Results	FY2015 Forecast	Comparison to FY2014	
			Value	Percentage (%)
AIMIX®	12.0	17.5	5.5	46.3
AVAPRO®	11.4	11.5	0.1	1.1
LONASEN®	11.5	13.0	1.5	13.4
TRERIEF®	11.6	15.2	3.6	30.7
Strategic products total	46.4	57.2	10.8	23.2
SUREPOST®	2.4	3.7	1.3	54.0
AmBisome®	4.3	4.9	0.6	13.5
MIRIPLA®	0.9	1.0	0.1	12.6
REPLAGAL®	9.7	11.0	1.3	13.4
New / Specialty products total	17.3	20.6	3.3	19.0
METGLUCO®	17.1	14.0	(3.1)	(18.0)
AMLODIN®	19.6	17.0	(2.6)	(13.5)
GASMOTIN®	10.5	8.3	(2.2)	(20.6)
PRORENAL®	10.6	9.1	(1.5)	(14.1)
MEROPEN®	7.9	6.8	(1.1)	(13.4)
Others	27.2	23.7	(3.5)	(12.9)
Other products total	92.8	78.9	(13.9)	(15.0)
<b>Japan total</b>	156.6	156.7	0.1	0.1

Note: Sales figures before reduction of rebates

# FY2015

## Sales Forecast in North America & China

	FY2014 Results	FY2015 Forecast	Change	FY2014 Results	FY2015 Forecast	Change		
						Value	Exchange Rate Impact	Percentage (%)
<b>North America</b>	(Million \$)			(Billion yen)				
LATUDA®	752	<b>1,000</b>	248	82.5	<b>115.0</b>	32.5	5.2	39.4
APTIOM®	23	<b>54</b>	31	2.5	<b>6.2</b>	3.7	0.3	143.8
BROVANA®	202	<b>218</b>	16	22.2	<b>25.1</b>	2.9	1.1	13.1
Ciclesonide	61	<b>52</b>	(9)	6.7	<b>6.0</b>	(0.7)	0.3	(11.0)
XOPENEX®	78	<b>22</b>	(56)	8.5	<b>2.5</b>	(6.0)	0.1	(70.3)
LUNESTA®	105	<b>32</b>	(73)	11.5	<b>3.7</b>	(7.8)	0.2	(68.1)
Others	129	<b>72</b>	(57)	14.2	<b>8.4</b>	(5.9)	0.4	(41.3)
<b>Total</b>	<b>1,350</b>	<b>1,450</b>	<b>100</b>	<b>148.2</b>	<b>166.8</b>	<b>18.6</b>	<b>7.6</b>	<b>12.6</b>
<b>China</b>	(Million RMB)			(Billion yen)				
MEROPEN®	805	<b>826</b>	21	14.3	<b>15.3</b>	1.0	0.7	7.3
Others	163	<b>185</b>	22	2.9	<b>3.4</b>	0.5	0.1	17.8
<b>Total</b>	<b>968</b>	<b>1,011</b>	<b>43</b>	<b>17.1</b>	<b>18.7</b>	<b>1.6</b>	<b>0.8</b>	<b>9.1</b>

Exchange Rate:

FY2014 Results : 1US\$ = ¥ 109.8, 1RMB = ¥17.7

FY2015 Forecast.: 1US\$ = ¥ 115.0, 1RMB = ¥18.5

# FY2015

## Ordinary income & Net income

Billions of yen

	FY2014 Results	FY2015 Forecast	Change	
			Value	Percentage(%)
Operating income	23.3	27.0	3.7	16.0
Non-operating income and expenses	0.1	(0.5)	(0.6)	
Ordinary income	23.3	26.5	3.2	13.6
Extraordinary income	17.7	4.5	(13.2)	
Gain on sales of property, plant and equipment	16.0	—	(16.0)	
Compensation income for damage	1.7	—	(1.7)	
Gain on sales of investment securities	—	4.5	4.5	
Extraordinary loss	7.3	—	(7.3)	
Impairment loss	5.3	—	(5.3)	
Business structure improvement expenses	2.0	—	(2.0)	
Income taxes	18.3	13.0	(5.3)	
Net income	15.4	18.0	2.6	16.5

# BBI608, BBI503 - Clinical development progress (1)

## Development status of BBI608

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated <sup>*3</sup>
Phase III	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	paclitaxel	BBI608-336 (BRIGHTER)	Aug. 2014
Phase II	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, or capecitabine	BBI608-224	Mar. 2012
Phase II	U.S. / Canada	Solid tumors <sup>*1</sup> (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
Phase I	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX <sup>*2</sup> , FOLFOX <sup>*2</sup> and bevacizumab, CAPOX <sup>*2</sup> , FOLFIRI <sup>*2</sup> , FOLFIRI <sup>*2</sup> and bevacizumab, or regorafenib	BBI608-246	Jan. 2014
Phase I	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
Phase I	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine and nab-paclitaxel	BBI608-118	Aug. 2014
Phase I	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
Phase I	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin and pemetrexed	D8807005	Feb. 2015
Phase I	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone	BBI608-103HEME	Apr. 2015
Phase I	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015

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

\*2: FOLFOX (Combination with fluorouracil, leucovorin, oxaliplatin)

CAPOX (Combination with capecitabine, oxaliplatin)

FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)

\*3: Study initiated was placed Clinical Trials.gov (as of May 7, 2015)

\* No changes after January 2015

# BBBI608, BBI503 - Clinical development progress (2)

## Development status of BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated* <sup>2</sup>
Phase II	U.S. / Canada	Solid tumors* <sup>1</sup> (Monotherapy)	—	BBI503-101	Feb. 2012
Phase II	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	—	BBI503-205a	Jan. 2015
Phase II	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	—	BBI503-205b	Feb. 2015
Phase II	Canada	Gastrointestinal stromal tumor (Monotherapy)	—	BBI503-205c	Jan. 2015
Phase II	U.S.	Ovarian cancer (Monotherapy)	—	BBI503-205GYN-M	May 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

\*1: Colorectal cancer, Head and neck cancer, Ovarian cancer, etc

\*2: Study initiated was placed Clinical Trials.gov (as of May 7, 2015)

## Development status of BBI608 + BBI503

Development stage	Development location	Proposed indication	Combination products	Study number	Study initiated* <sup>3</sup>
Phase I	U.S.	Solid tumors (Combination therapy)	—	BBI401-101	Apr. 2015

\*3: Study initiated was placed Clinical Trials.gov (as of May 7, 2015)

Revisions since the previous announcement are in red.

# LATUDA® (lurasidone) – Clinical development progress

## U.S. (In-house)

Indication, Proposed indication	Development status	Plan
Bipolar maintenance	Phase III	Submission planned in FY2015
MDD with mixed features (No new indication)	Phase III (Completed)	Favorable findings obtained; will be added to the label (Submission planned in FY2015)

## Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	Japan	Phase III (Completed)	Development policy under consideration
Bipolar I depression , Bipolar maintenance		Phase III	FY2017
Schizophrenia	China	Phase III	FY2015

## Europe (Partnering)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.
- All options for Europe are under consideration including collaboration with a new partner.
- Countries covered by the Agreement: 26 EU member states (excluding the UK), Switzerland, Norway, Turkey and Russia  
 Already launched in: Switzerland, the Netherlands, Denmark, Norway, Finland  
 Already submitted in: Russia, Turkey

## Asia, South America, etc. (Partnering)

- Submitted in: Taiwan, Thailand, Hong Kong, Singapore, Venezuela
- Approved in: Australia (alliance under negotiation)

# Target submission date of the Main late Development Pipeline

(Updated May 2015)

Field	Development products	Submission target		
		FY2015	FY2016	FY2017
Psychiatry & Neurology Field	SM-13496 <lurasidone hydrochloride> (Schizophrenia) China	●		
	LATUDA® <lurasidone hydrochloride> (Bipolar maintenance) U.S.	●		
	SM-13496 <lurasidone hydrochloride> (Bipolar I depression / Bipolar maintenance) Japan			●
	EPI-743 (Leigh syndrome) Japan	●		
	AS-3201 <ranirestat> (Diabetic neuropathy) Japan		●	
	SEP-225289 <dasotraline> (Adult , Pediatric ADHD) U.S			●
	LONASEN® <blonanserin> ( Schizophrenia / Transdermal patch ) Japan			●
	TRERIEF® <zonisamide> ( Parkinsonism in Dementia with Lewy Bodies ) Japan			●
Cancer Field	BBI608 (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan			●
	BBI503 (Solid cancer / Monotherapy) U.S./ Japan			●
Respiratory Field	SUN-101 <glycopyrrolate bromide> (Chronic obstructive pulmonary disease) U.S.		●	

Added  
Added

New Chemical Entities

New Indication, etc.

Revisions since the previous announcement are in red.

# Product Launch Plan (Updated May 2015)

Area	FY2015	FY2016	FY2017	FY2018	FY2019~FY2021
Japan		<div style="border: 1px solid black; padding: 2px;">※ Iurasidone (Schizophrenia)</div> <div style="border: 1px solid black; padding: 2px;">EPI-743 (Leigh syndrome)</div>	<div style="border: 1px solid black; padding: 2px;">ranirestat (Diabetic neuropathy)</div> <div style="border: 1px solid black; padding: 2px;">BBI608 (Gastric and Gastroesophageal junction adenocarcinoma)</div>	<div style="border: 1px dashed black; padding: 2px;">Iurasidone (Bipolar depression / Bipolar maintenance)</div> <div style="border: 1px dashed black; padding: 2px;">LONASEN® (Schizophrenia / Transdermal patch)</div> <div style="border: 1px dashed black; padding: 2px;">TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)</div> <div style="border: 1px solid black; padding: 2px;">BBI503 (Solid tumors)</div>	<div style="border: 1px solid black; padding: 2px;">BBI608 (Colorectal cancer, etc.)</div> <div style="border: 1px solid black; padding: 2px;">DSP-7888 (Solid cancer/ Hematologic cancer)</div> <div style="border: 1px solid black; padding: 2px;">DSP-1747 (NASH)</div> <div style="border: 1px solid black; padding: 2px;">DSP-6952 (IBS with constipation, Chronic idiopathic constipation)</div> <div style="border: 1px solid black; padding: 2px;">iPS cell-derived RPE cells (Age-related macular degeneration)</div>
U.S.	<div style="border: 1px dashed black; padding: 2px;">APTiom® (Epilepsy-monotherapy)</div>	<div style="border: 1px dashed black; padding: 2px;">LATUDA® (Bipolar Maintenance)</div>	<div style="border: 1px solid black; padding: 2px;">BBI608 (Gastric and Gastroesophageal junction adenocarcinoma)</div> <div style="border: 1px solid black; padding: 2px;">SUN-101 (COPD)</div>	<div style="border: 1px solid black; padding: 2px;">dasotraline (ADHD)</div> <div style="border: 1px solid black; padding: 2px;">BBI503 (Solid tumors)</div>	<div style="border: 1px solid black; padding: 2px;">SB623 (Chronic Stroke)</div> <div style="border: 1px solid black; padding: 2px;">DSP-2230 (Neuropathic pain)</div> <div style="border: 1px solid black; padding: 2px;">SEP-363856 (Schizophrenia)</div> <div style="border: 1px solid black; padding: 2px;">BBI608 (Colorectal cancer, etc.)</div> <div style="border: 1px solid black; padding: 2px;">DSP-7888 (Solid cancer/ Hematologic cancer)</div>
China		<div style="border: 1px solid black; padding: 2px;">LONASEN® (Schizophrenia)</div> <div style="border: 1px solid black; padding: 2px;">CALSED® (Small cell lung cancer)</div>		<div style="border: 1px solid black; padding: 2px;">Iurasidone (Schizophrenia)</div>	
U.K.			<div style="border: 1px dashed black; padding: 2px;">Iurasidone (Bipolar disorder)</div>		

: P&N  
 : Oncology  
 : liver/ digestive  
 : Respiratory

New Chemical Entities
New Indication, etc.

※ Development policy under consideration

# Regenerative Medicine/Cell Therapy of Business Plan

(Updated May 2015)

	Partnering	Region (planned)	cell type	Schedule for practical use (Calendar year)					
				2015	2016	2017	2018	2019	2020
Stroke	SanBio	North America	Allo MSC	Ph2b			Ph3		Approval Target
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell	Clinical research (autologous / allogenic)			Investigator initiated clinical trial		Approval Target
Parkinson's disease	Kyoto Uni CiRA	global	Allo iPS cell	Clinical research (autologous)			Investigator or corporate initiated clinical trial		
Retinitis pigmentosa	RIKEN	global	Allo iPS cell				Investigator initiated clinical trial		
Spinal Cord Injury	Keio Uni, Osaka National Hospital	global	Allo iPS cell				Clinical research (allogenic)		

# 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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