

# Results Briefing

Results for Q3 FY2015 (April 1 – December 31, 2015)

DAIICHI SANKYO CO., LTD

Joji Nakayama  
President and CEO

January 29, 2016

- ◆ FY2015 Q3 YTD Results
- ◆ FY2015 Revised Consolidated Forecast
- ◆ Major Management Topics
  - Edoxaban Update in Japan and EU
  - R&D Update

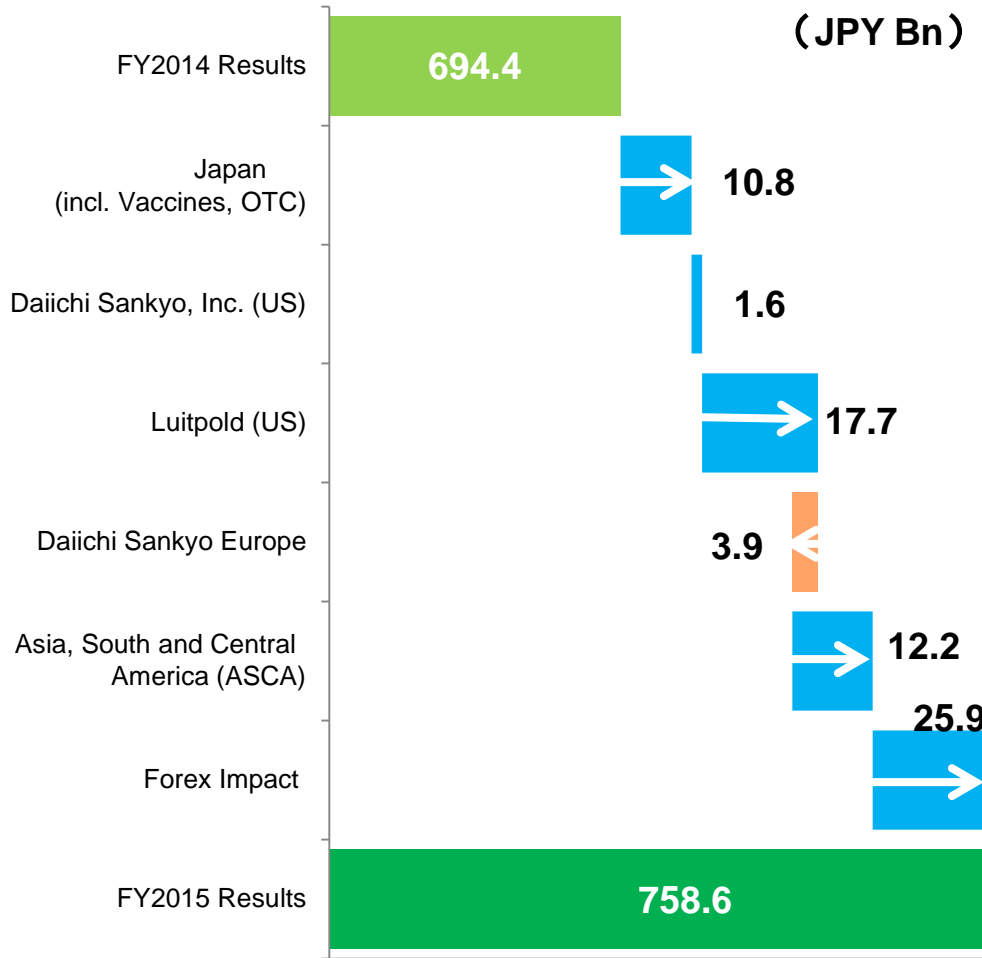
# FY2015 Q3 YTD Results

# Overview of FY2015 Q3 YTD Results (JPY Bn)

	FY2014 Q3 YTD Results * <sup>1</sup>	FY2015 Q3 YTD Results	YoY	
Revenue	694.4	758.6	<div>+9.2%</div> +64.2	
Cost of Sales	220.9	237.7	+16.8	
SG&A Expenses	237.8	232.3	-5.5	
R&D Expenses	135.7	138.1	+2.4	
Operating Profit	100.0	150.4	<div>+50.4%</div> +50.4	
Profit before Tax	107.5	145.4	+38.0	
Profit attributable to owners of the Company	68.9	110.7	<div>+60.6%</div> +41.8	
Currency Rate	USD/JPY	106.88	121.70	+14.82
	EUR/JPY	140.31	134.37	-5.94

\*1 FY2014 Q3 Results have been restated and indicated as only the values for continuing operations.

**Increased by 64.2 JPY Bn**  
**Decline in Daiichi Sankyo Europe**  
**offsetted by growth of Japan, Luitpold and ASCA with Forex**



## Japan

Positive:	Lixana	+7.5	Teneria	+6.4
	Nexium	+6.2	Memary	+5.2
	Pralia	+3.9	Efient	+2.8
	Olmetec	+2.1	Ranmark	+1.8
Negative:	Cravit	-8.4	Inavir	-5.6
	Artist	-2.0	Mevalotin	-1.8

## Global (excl. Forex Impact)

Daiichi Sankyo Inc. :	Olmesartan	+0.7
	Welchol	-2.0
	Effient	+1.3
	Movantic	+1.1
Luitpold :	Venofer	-1.4
	Injectafer	+6.2
Daiichi Sankyo Europe :	Olmesartan	-3.8
	Lixiana	+0.7
ASCA :	Olmesartan	+1.1

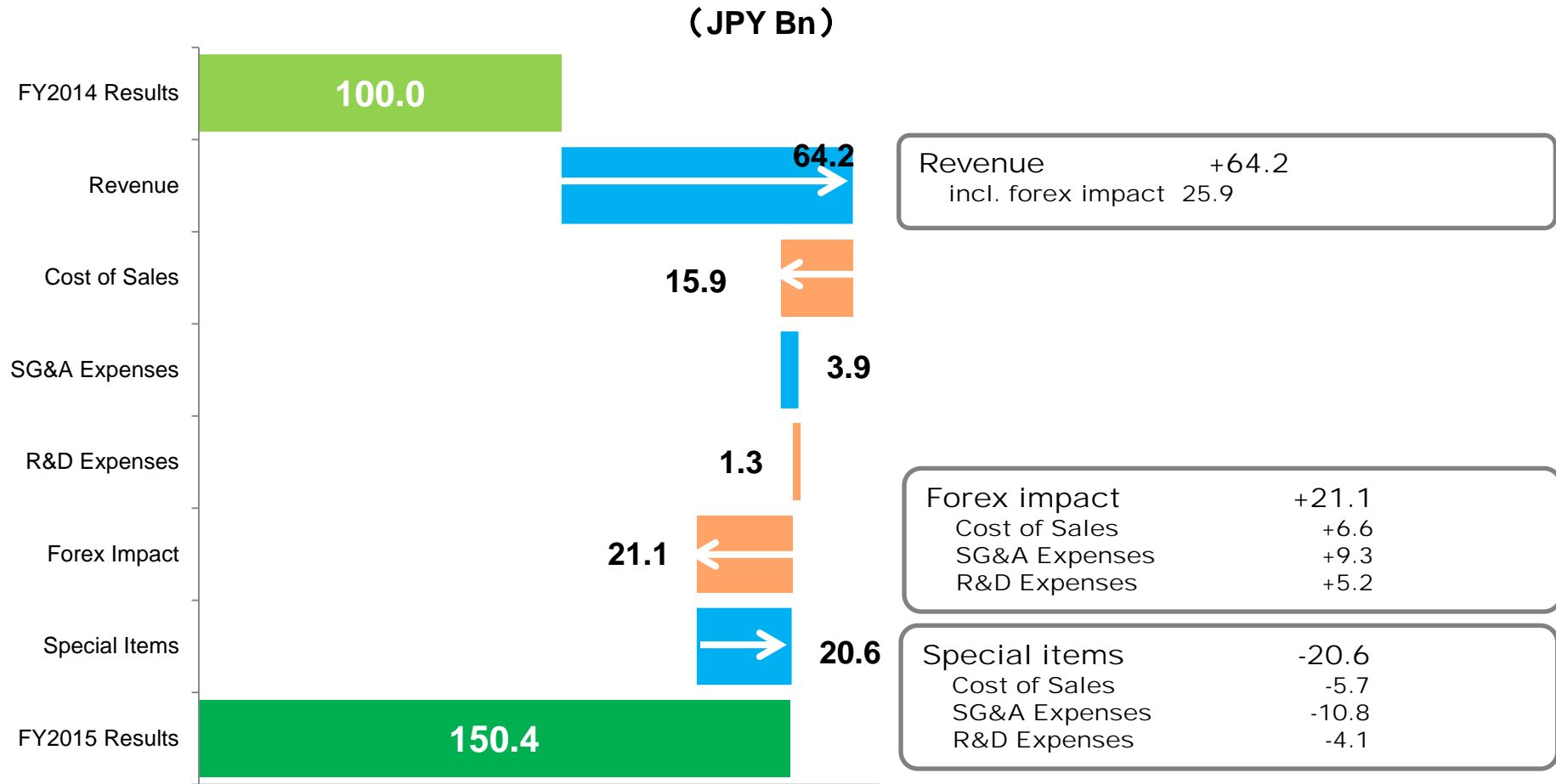
# Operating Profit

Positive  
Factors

Negative  
Factors



**Increased by 50.4 JPY Bn**  
**due to increased revenue, decreased SG&A expenses and special items**  
**absorbing increased other costs**



# Special Items

(JPY Bn)

	FY2014 Q3 YTD Results		FY2015 Q3 YTD Results		YoY
Cost of Sales	Restructuring costs in Japan	2.2	Gain on sales of subsidiary	-2.4	-5.7
			Gain on sales of fixed assets-	1.1	
SG&A Expenses	Settlement expenses with US Department of Justice	4.6			-10.8
	Restructuring costs in Japan	7.1	Restructuring costs in US	6.1	
	Gain on sales of fixed assets	-2.9	Gain on sales of fixed assets	-8.2	
R&D Expenses	Restructuring costs in Japan	4.4	Restructuring costs in R&D	0.3	-4.1
Total		15.4		-5.3	-20.6

- : Cost decrease items

# Profit attributable to owners of the Company

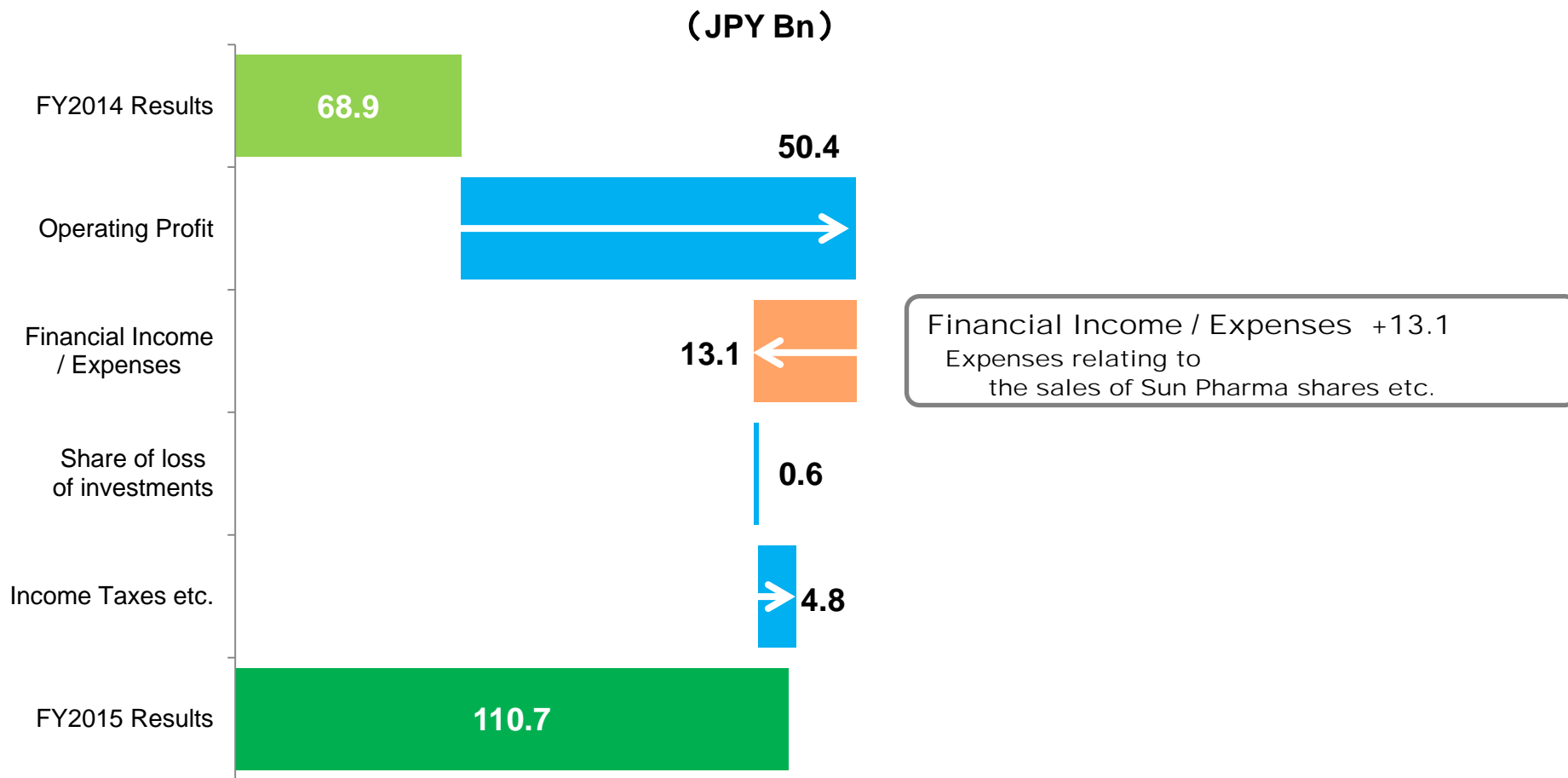
Positive  
Factors

Negative  
Factors



**Increased by 41.8 JPY Bn due to increased operating profit**

**Expenses relating to the sales of the Sun Pharma shares etc. are booked as financial expenses**





# Major Business Units

(JPY Bn)

	FY2014 Q3 YTD Results	FY2015 Q3 YTD Results	YoY	vs. Forecast (%)
Japan	367.8	377.5	+9.6	76.9%
Daiichi Sankyo Healthcare	37.0	39.9	+2.9	81.3%
Daiichi Sankyo Inc.	126.2	145.5	+19.3	82.7%
Olmesartan	76.9	88.4	+11.5	87.5%
Welchol	35.1	37.7	+2.5	80.2%
Effient	13.1	16.4	+3.3	-
Savaysa	-	0.3	+0.3	14.5%
Movantik	-	1.3	+1.3	-
Luitpold	42.9	69.0	+26.1	80.3%
Venofer	22.8	24.4	+1.6	81.3%
Injectafer	5.1	12.9	+7.8	75.7%
Daiichi Sankyo Europe	64.6	58.1	-6.5	76.4%
Olmesartan	50.2	44.4	-5.8	76.5%
Efient	3.7	3.3	-0.4	-
Lixiana	-	0.7	+0.7	38.5%
Asia, South and Central America (ASCA)	48.9	62.6	+13.7	71.1%

# Major Products in Japan

(JPY Bn)

		FY2014 Q3 YTD Results	FY2015 Q3 YTD Results	YoY	vs. Forecast (%)
Olmetec	anti-hypertension	58.4	60.5	+2.1	76.6%
Nexium	anti-ulcer (Proton Pump Inhibitor)	55.7	62.0	+6.2	80.5%
Memary	treatment for Alzheimer	27.5	32.7	+5.2	69.6%
Loxonin	analgesic and anti-inflammatory	38.7	38.2	-0.4	86.9%
Cravit	antibacterial	23.0	14.6	-8.4	85.8%
Rezaltas	anti-hypertension	14.1	14.1	+0.0	74.2%
Artist	Treatment for hypertension, angina pectoris and chronic heart failure	14.1	12.1	-2.0	71.2%
Omnipaque	contrast medium	13.3	13.2	-0.1	82.6%
Mevalotin	anti-hyperlipidemia	12.6	10.8	-1.8	77.0%
Ranmark	treatment for bone metastasis	7.6	9.4	+1.8	71.9%
Inavir	anti-influenza	8.2	2.5	-5.6	21.1%
Urief	treatment for dysuria	8.7	9.0	+0.3	82.2%
Pralia	osteoporosis	5.1	9.0	+3.9	90.3%
Lixiana	anticoagulant	2.1	9.6	+7.5	87.2%
Efient	antiplatelet	0.5	3.3	+2.8	65.6%
Teneria	treatment for type 2 diabetes	5.5	11.9	+6.4	-

# FY2015 Revised Consolidated Forecast

# FY2015 Revised Consolidated Forecast

(JPY Bn)

	FY 2015 Forecast (as of Oct.)	FY 2015 Revised Forecast (as of Jan.)	vs. Forecast (as of Oct.)	<b><u>Major factors</u></b>
Revenue	980.0	980.0	0	
Cost of Sales	314.0	316.0	+2.0	Shift of product mix
SG&A Expenses	354.0	337.0	-17.0	Efficient cost expense
R&D Expenses	192.0	197.0	+5.0	Restructuring cost in R&D
Operating Profit	120.0	130.0	+10.0	Foreign-currency valuation losses in the emerging countries' markets
Profit before tax	115.0	120.0	+5.0	
Profit attributable to owners of the Company	75.0	75.0	0	Reversal of deferred tax assets related to a change in the tax rate etc.

Currency Rate	USD/JPY	120.90	121.28
	EUR/JPY	132.53	133.27

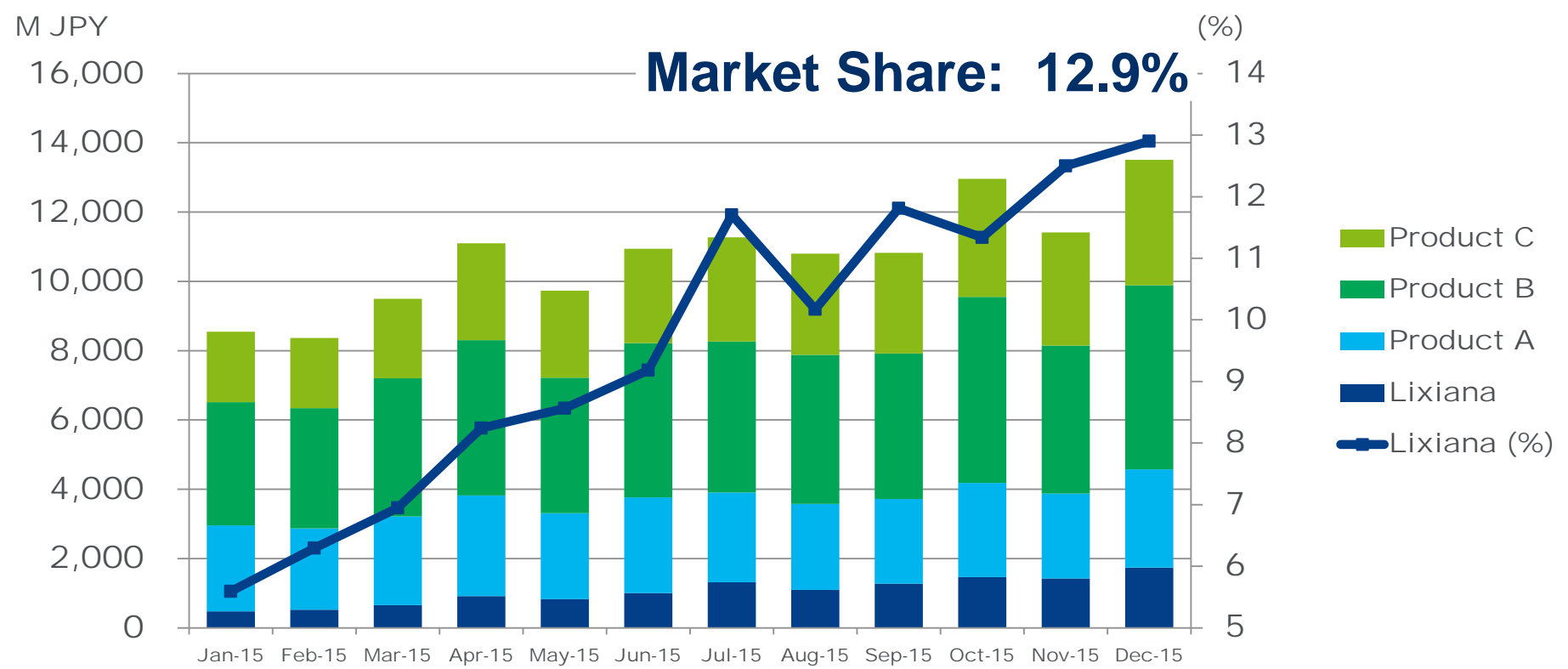
Forecast for Q4  
USD/JPY:120 EUR/JPY:130

# Major Management Topics

- Edoxaban Update in Japan and EU
- R&D Update



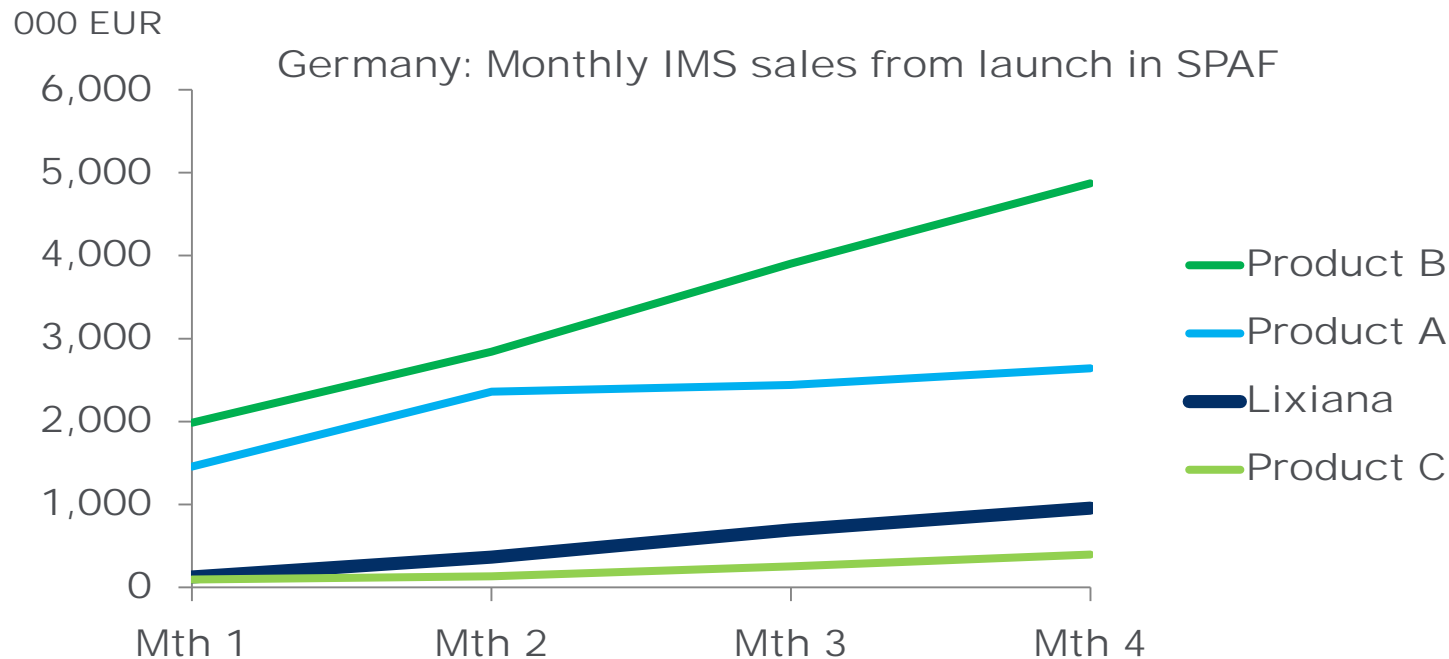
## Impressive Market Share Growth



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## Successful Step by Step Launches

- ◆ Launched in Switzerland, UK, Germany, Ireland and Netherlands



# Major Management Topics

- Edoxaban Update in Japan and EU
- R&D Update



## CHS-0214: Achieved Primary Endpoints in Phase **3** Study

### ◆ **CHS-0214:** Etanercept biosimilar

### ◆ **Patients:** Subjects with rheumatoid arthritis and inadequate response to treatment with methotrexate

### ◆ **Primary endpoint:**

- Efficacy
- Safety



**CHS-0214 demonstrated  
similarity to Enbrel®**

### ◆ **Schedule:**

- Targeted for the first launch of etanercept biosimilar in Japan
- J-NDA submission in FY2016
- Approval and Launch in FY2017

## Accelerate Global Development

### ◆ Quizartinib: FLT3-ITD inhibitor

- **Second-line treatment for Acute Myeloid Leukemia (QuANTUM-R Phase 3 study)**
  - ✓ US and EU: on track
  - ✓ Asia: has started recruitment
- **First-line treatment for Acute Myeloid Leukemia**
  - ✓ Global phase 3 study in the planning phase
- Japan: Phase 1 study started

## Clinical Entries of New Biologics

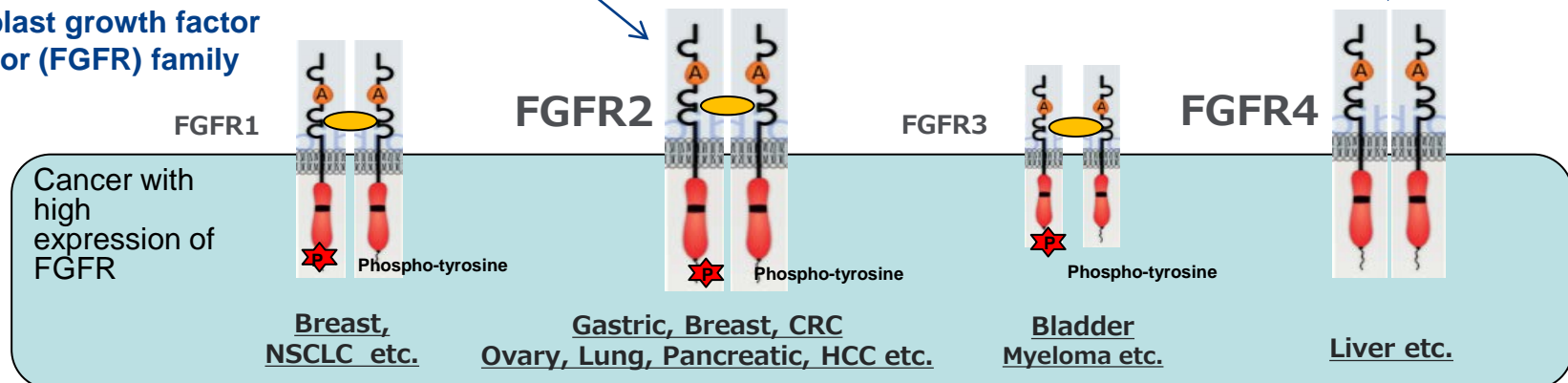
### ◆ DS-1123: Anti-FGFR2 antibody

- High expression of FGFR2 is observed in gastric cancer etc.
- Started phase 1 in Japan

### ◆ U3-1784: Anti-FGFR4 antibody

- High expression of FGFR4 is observed in hepatic cancer etc.
- Started phase 1 in EU

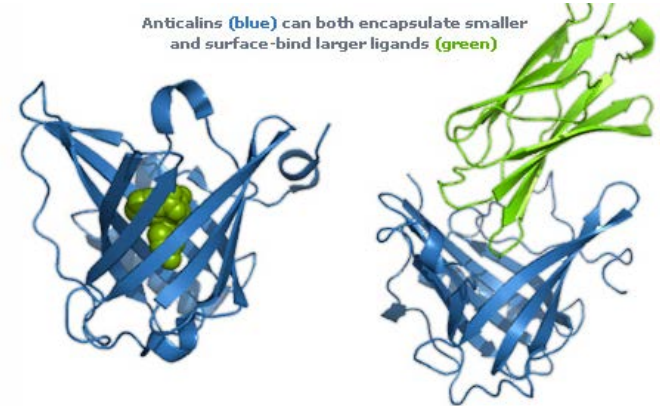
Fibroblast growth factor receptor (FGFR) family



## Value Creation by Combination of Innovative Technologies

### ◆ Anticalin®

- In-licensed technology from Pieris (US)
- An alternative to antibody with molecular weight of 1/10
- Low immunogenicity as compared to antibody
- Can be produced by microorganism in large volume with low cost



<http://www.pieris.com/anticalin-technology/overview>

### ◆ Albumod™ platform

- In-licensed technology from Affibody AB (Sweden)
- Extending circulatory half-life of biologics

### ◆ Selected PCSK9 as a target molecule

### ◆ Started phase 1 study of DS-9001, anti-PCSK9 Anticalin-Albumod

# Anticipating Major R&D Milestone

【Milestone event for regulatory submission and approval】

Product	Event		Anticipated time
CL-108	Treatment of Pain and Opioid-Induced Nausea and Vomiting (US)	NDA	FY2015 Q4
Denosumab	Rheumatoid Arthritis Phase 3 (JP)	TLR*	FY2015 Q4
Prasugrel	Ischemic Cerebrovascular Disease Phase 3 (JP)	TLR	FY2016 H1

TLR\*: Top Line Result

【Publication for results of major clinical studies at academic conference】

Product	Studied to be publishsed in detail	
CHS-0214 (etanercept BS)	Rheumatoid Arthritis	Phase 3 (JP)
CL-108	Bunionectomy Surgery	Phase 3 (US)
Patritumab	Head & Neck Cancer	Phase 1b (EU)
DS-8500	Type 2 Diabetes Mellitus	Phase 2a (JP)

# Major R&D Pipeline

As of January 2016

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	<ul style="list-style-type: none"> <li>■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor)</li> <li>■ DS-2330 (Hyperphosphatemia)</li> <li>■ DS-9231/TS23 (Thrombosis / <math>\alpha 2</math>-PI inactivating antibody)</li> <li>■ <b>DS-9001</b> (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)</li> </ul>	<ul style="list-style-type: none"> <li>■ CS-3150 (JP) (Hypertension · DM nephropathy / MR antagonist)</li> <li>■ DS-8500 (JP/US) (Diabetes / GPR119 agonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)</li> </ul>	<ul style="list-style-type: none"> <li>■ Edoxaban (ASCA etc.) (DU-176b / AF / oral factor Xa inhibitor)</li> <li>■ Edoxaban (ASCA etc.) (DU-176b / VTE / oral factor Xa inhibitor)</li> </ul>
Oncology	<ul style="list-style-type: none"> <li>■ DS-3032 (US/JP) (MDM2 inhibitor)</li> <li>■ PLX7486 (US) (FMS / TRK inhibitor)</li> <li>■ PLX8394 (US) (BRAF inhibitor)</li> <li>■ DS-6051 (US) (NTRK/ROS1 inhibitor)</li> <li>■ PLX9486 (US) (KIT inhibitor)</li> <li>■ DS-8895 (JP) (Anti-EPHA2 antibody)</li> <li>■ DS-8273 (US) (Anti-DR5 antibody)</li> <li>■ DS-5573 (JP) (Anti-B7-H3 antibody)</li> <li>■ DS-8201 (JP) (Anti-HER2 ADC)</li> <li>■ <b>U3-1784 (EU)</b> (Anti-FGFR4 antibody)</li> <li>■ <b>DS-1123 (JP)</b> (Anti-FGFR2 antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ Patritumab (US/EU) (U3-1287 / Anti-HER3 antibody)</li> <li>■ Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor)</li> <li>■ Denosumab (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody)</li> <li>■ Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody)</li> <li>■ Vemurafenib (US/EU) (PLX4032 / Melanoma Adjuvant / BRAF inhibitor)</li> <li>■ <b>Quizartinib (US/EU/Asia)</b> (AC220 / AML / FLT3-ITD inhibitor)</li> <li>■ Pexidartinib (US/EU) (PLX3397/TGCT / CSF-1R/KIT/FLT3-ITD inhibitor)</li> </ul>	
Others	<ul style="list-style-type: none"> <li>■ DS-1971 (Chronic pain)</li> <li>■ DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)</li> <li>■ DS-7080 (US) (AMD / Angiogenesis inhibitor)</li> <li>■ <b>DS-2969</b> (<i>Clostridium difficile</i> infection / GyrB inhibitor)</li> <li>■ VN-0102/JVC-001 (JP) (MMR vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ Laninamivir (US/EU) (CS-8958 / Anti-influenza / out-licensing with Biota)</li> </ul>	<ul style="list-style-type: none"> <li>■ Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / <math>\alpha 2\delta</math> ligand)</li> <li>■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ <math>\alpha 2\delta</math> ligand)</li> <li>■ Mirogabalin (JP/Asia) (DS-5565 / PHN / <math>\alpha 2\delta</math> ligand)</li> <li>■ Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL anti-body)</li> <li>■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid <math>\mu</math>-receptor regulator)</li> <li>■ <b>CHS-0214 (JP)</b> (Etanercept BS / Rheumatoid arthritis / TNF<math>\alpha</math> inhibitor)</li> <li>■ CL-108 (US) (Acute pain / Opioid <math>\mu</math>-receptor regulator)</li> <li>■ VN-0105 (JP) (DPT-IPV/Hib vaccine)</li> <li>■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 /prefilled i.d. vaccine for seasonal flu)</li> <li>■ VN-101 (JP) (Cell-culture H5N1 Influenza vaccine)</li> </ul>

◆ **Date:** **March 31, 2016, Thursday**

● For media representatives PM1:30-PM3:00

● For investors and securities analysts PM4:00-PM5:30

\*On-demand broadcasting will be available on later day

◆ **Location:** **Daiichi Sankyo Co., Ltd.**  
**Nihonbashi HQ**

◆ **Speaker:** **Joji Nakayama, president and CEO**

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