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# **Top Management Presentation**

Financial Results for 2Q FY2014 (April 1 – September 30, 2014)

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**President and CEO** 

**November 4, 2014** 

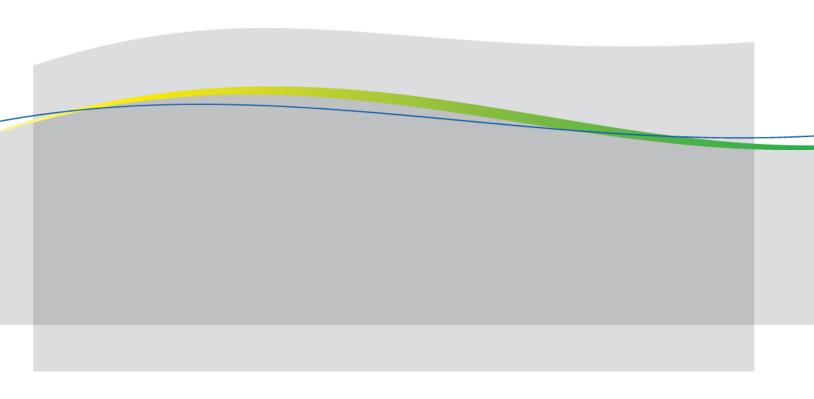
# **Today's Topics**



- ♦ FY2014 2Q Results
- FY2014 revised consolidated forecast
- Business Update
- Optimization of Business Operation
   Structure in Japan
- R&D Update



# FY2014 2Q Results



# **Overview of FY2014 2Q Results**



#### **Consolidated Statement of Profit or Loss**

#### **Daiichi Sankyo Group**

JPY Bn

JPY Br

			JPT DN
	FY2013 2Q Result	FY2014 2Q Result	YoY
Revenue	516.8	525.4	+8.6
Cost of sales	174.1	176.1	+2.1
R&D expenses	94.8	88.8	-6.0
SG&A expenses	195.2	191.6	-3.5
(Loss on restructuring/ General expenses	(16.5)	(6.9)	(-9.6)
Operating Profit	52.7	68.8	+16.1
Profit before tax	43.9	65.4	+21.5
Profit attributable to owners of the Company	33.5	50.3	+16.8

				JPY Bn
	FY2013 2Q Result	FY2014 2Q Result	YoY	Revised Plan*
Revenue	429.1	429.6	+0.1%	920.0
Cost of sales	129.3	130.8	+1.5	280.0
R&D expenses	90.1	84.9	-5.2	182.0
SG&A expenses	159.7	155.2	-4.5	338.0
(Loss on restructuring/ General expenses	(13.2)	(4.7)	(-8.5)	-
Operating Profit	50.1	58.7	+17.2%	100.0
Profit before tax	50.2	60.7	+20.8% +1 <b>0.5</b>	120.0
Profit attributable to owners of the Company	35.2	35.5	+0.8%	78.0 <b>65.0</b>

\*Figures do not include Ranbaxy, which will not be consolidated, post its merger with Sun Pharma.

Currency Rate
 USD/JPY
 98.86
 103.05

 EUR/JPY
 130.01
 138.91

 INR/JPY
 1.74
 1.72

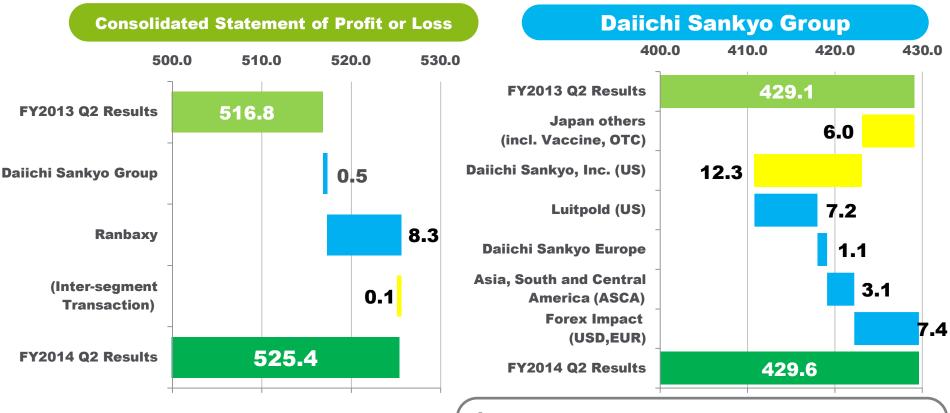
### FY2014 2Q Revenue (JPY Bn)

**Positive Factors** 

**Negative Factors** 



#### **Decline in Japan and Daiichi Sankyo Inc.** offsetted by growth of Luitopold and ASCA



#### Japan

Positive: Nexium +8.1 Memary +2.4 Pralia +2.0 Tenelia +3.1 Negative: Loxonin -5.3 Cravit -1.5 Mevalotin -2.8

Vaccines Business -5.0

**Global** (including Forex impact)

Daiichi Sankyo Inc.: Olmesartan -9.6 Luitpold: Venofer +2.5 Injectafer +2.7 Daiichi Sankyo Europe : Olmesartan +4.2

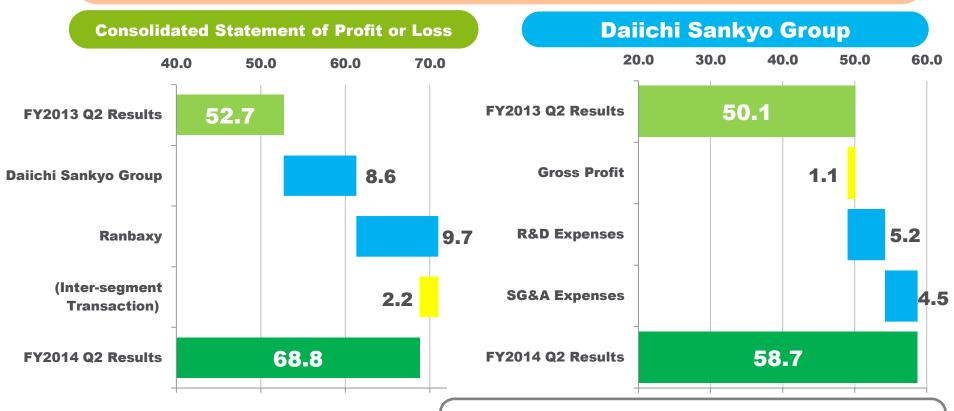
# **FY2014 2Q Operating Profit**

**Positive Factors** 

Negative Factors



Operating profit increase reflected decreases in SG&A expenses and R&D expenses



**R&D Expenses -5.2** (Forex Impact /USD·EUR +16)

SG& A Espenses -4.5 (Forex Impact /USD·EUR +35)

·Gains from sales of fixed assets -2.2 and loss on restructuring in Daiichi Sankvo Europe GmbH +10.8 booked in FY2013 2Q

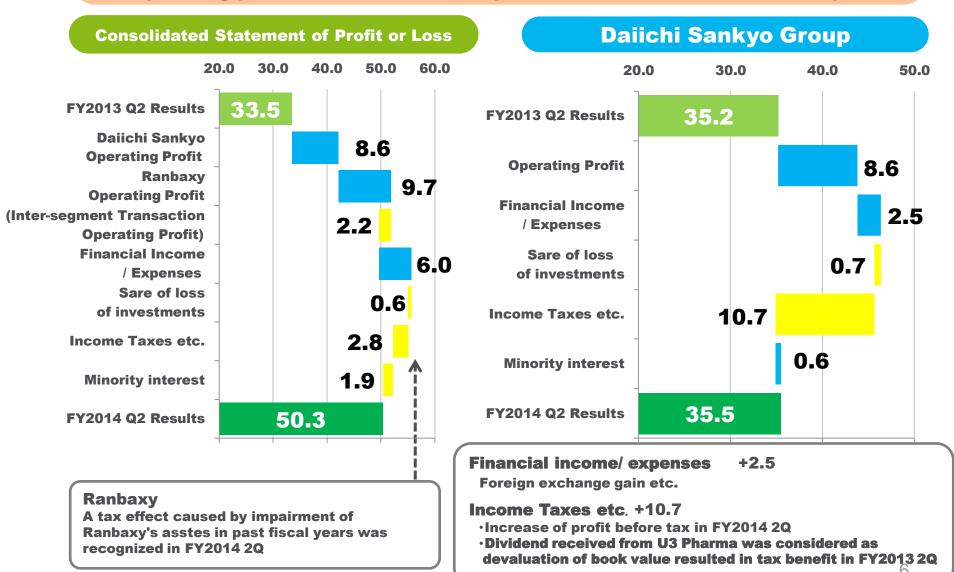
# FY2013 1Q Profit attributable to owners of the Company (

(JPY Bn)

Positive Negative Factors Factors



Profit (attributable to owners of the Company) increase owing to the operating profit increase and an improvement in financial income/expenses





# FY2014 revised consolidated forecast

### FY2014 revised consolidated forecast



**JPY Bn** 

	FY 2013 Forecast (July)	FY 2013 Revised Forecast (October)	change
Revenue	920.0	900.0	-20.0
Cost of sales	285.0	280.0	-5.0
R&D expenses	182.0	182.0	0
SG&A expenses	333.0	338.0	+5.0
Operating Profit	120.0	100.0	-20.0
Profit before tax	120.0	100.0	-20.0
Profit attributable to owners of the Company	78.0	65.0	-13.0

Currency Rate	USD/JPY	100	104.02
	EUR/JPY	140	139.46

Forecast for Q3 and Q4 USD/JPY:105 EUR/JPY:140

### **Summary of the revised FY2014 forecast**



Revenue

Sales growth of mainstay products in Japan at a rate below initial forecasts,

Sales decline of long listed products at a greater rate than initially forecasted as a result of expansion in prescriptions of generic products, Intensified price competition for the core product Olmesartan in the US, in light of these circumstances, the forecast for revenue has been revised downward by JPY20.0 bn. from the previous forecast to JPY900.0 bn.

# Operating Profit

A profit decrease in line with the downward revision to the revenue forecast as well as personnel-related expenses associated with the execution of work to optimize the business operation structure in Japan are projected to occur,

On the other hand, work will be carried out to make further cost reductions in order to secure operating profit of JPY100.0 bn.

**Profit** 

In light of the above, the forecast for profit before tax has been revised downward by JPY20.0 bn. from the previous forecast to JPY100.0 bn., and the forecast for profit (attributable to owners of the Company) has been revised downward by JPY13.0 bn. to JPY65.0 bn.



# **Business Update**

# **Major Products in Japan**



**JPY Bn** 

		2013Q2 Result	2014Q2 Result	YoY	Revised Forecast (Oct.)	Change	To Plan
Olmetec	anti-hypertension	37.6	37.8	+0.3	79.0		48%
Nexium	anti-ulcer (Proton Pump Inhibitor)	24.0	32.1	+8.1	67.0		48%
Loxonin	analgesic and anti- inflammatory	30.7	25.4	-5.3	48.0	-4.0	53%
Memary	treatment for Alzheimer	14.4	16.8	+2.4	39.0	-11.0	43%
Cravit	antibacterial	15.7	14.2	-1.5	27.0	-2.0	53%
Rezaltas	anti-hypertension	9.0	9.0	+0	18.0	-4.0	50%
Artist	anti-hypertension	11.1	9.4	-1.6	18.0	-3.0	<b>52</b> %
Mevalotin	anti-hyperlipidemia	11.1	8.3	-2.8	16.0	-1.0	<b>52</b> %
Omnipaque	contrast medium	10.0	8.6	-1.4	17.0	+2.0	51%
Pralia	osteoporosis	0.9	3.0	+2.0	7.0	-5.0	43%
Ranmark	treatment for bone metastasis	3.4	4.7	+1.2	10.0		47%

### **Initiatives for Mainstay Products in Japan**





#### **Olmetec**

- Use home blood pressure data
- Emphasize appeal of excellent antihypertensive effect and consistency
- Keep No. 1 ARB share



#### **Nexium**

- In 3<sup>rd</sup> year after launch, gain overwhelming market share through strong partnership with AstraZeneca
- Promote switching from other drugs (combination with low-dose aspirin, etc.)

# **Initiatives for Mainstay Products in Japan**





#### **Memary**

- Emphasize appeal of advancement suppression effects from combination with Donepezil
- Steadily spread orally disintegrating (OD) tablet
- Secure new prescriptions and provide continuous education on disease by clarifying symptoms Memary® is effective for



#### **Pralia**

- Emphasize appeal of strong efficacy in increasing bone density and reducing bone fracture risk
- Emphasize appeal of ease of twice-yearly administration
- Thoroughly ensure proper usage with data of year following market launch



#### **Effient**

- Differentiate from competitor drugs by emphasizing appeal of speed and stability
  - Achieve early spread in use at PCI institutions, and expand sales to general practitioners in anticipation of rapid sales growth following lifting of restrictions on long-term prescribing

# **Major Business Units**



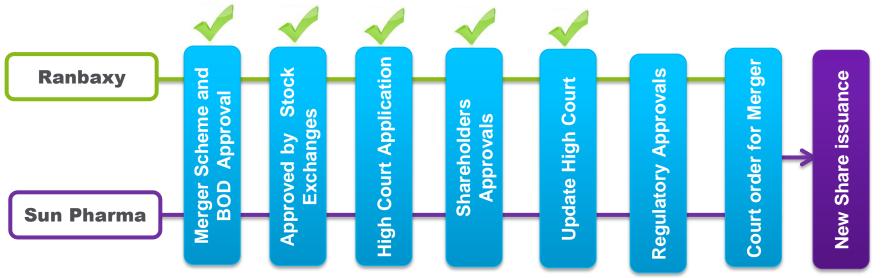
JPY Bn

						JPY Bn
	FY2013Q2 Result	FY2014Q2 Result	YoY	Revised Forecast (Oct.)	Change	To plan
Japan Company + Vaccine business	227.6	222.6	-4.9	480.0	-28.0	46%
Daiichi Sankyo Healthcare	23.0	22.7	-0.3	48.0		47%
Daiichi Sankyo Inc.	86.5	78.1	-8.4	161.0	-3.0	49%
Olmesartan	56.8	47.2	-9.6	98.0	-7.0	48%
Welchol	21.0	21.8	+0.8	44.0	+3.0	50%
Effient (alliance revenue)	7.6	8.5	+0.8	-		-
Luitpold	18.3	26.8	+8.5	53.0	+3.0	51%
Venofer	11.7	14.2	+2.5	26.0	+7.0	55%
Injectafer	0.2	2.9	+2.7	7.0	-3.0	42%
Daiichi Sankyo Europe	40.4	44.5	+4.1	84.0	+3.0	53%
Olmesartan	31.2	35.4	+4.2	66.0	+3.0	54%
Efient (alliance revenue)	2.3	2.3	+0.1	-		-
Asia, South and Central America (ASCA)	26.9	30.0	+3.1	64.0	+5.0	47%
Ranbaxy Group	88.4	96.4	+8.0	-		-

# **Merger of Ranbaxy with Sun Pharma**



- Agreements for a merger of Ranbaxy with Sun Pharma on April 6, 2014
- ◆ Approved at the respective general shareholders' meetings of Ranbaxy and Sun Pharma by September 30, 2014
  - The final examinations by the relevant authorities are currently in progress
  - Daiichi Sankyo will obtain an equity stake of approximately 9% in the merged entity via a share swap





# **Optimization of Business Operation Structure in Japan**

# Optimization of Business Operation Structure in Japan



- Background
  - Improve SG&A ratio that is higher than industry standard
  - Handle Olmesartan patent period expiration\*



Optimization of Business Operation Structure in Japan

- Aims
  - Strengthen business foundation to enable investment for sustainable growth
  - Enhance self-sustaining business operation
  - Switch to low-cost structure (simplify and streamline)

<sup>\*</sup> Schedule for patent period expiration US: Oct. 2016, Europe/Japan: Feb. 2017

# **Optimization of**





#### Reform business operation in each unit

- Self-sustaining business operation in each Japan business
- Greater efficiency through reduction of indirect operations and concentration of operations
- Expediting of decision making through simplified organization

#### Reconstruct supply chain

- Reconstruct Japan operations with 2 companies:
   Daiichi Sankyo Chemical Pharma Co., Ltd. (API production function)
   Daiichi Sankyo Propharma Co., Ltd. (dosage forms production and logistics functions)
- Transfer Akita plant to Alfresa Pharma Corporation

#### Personnel measures

- Review distribution of all Group employees in Japan and implement workforce resizing
- Carry out employee assignments and transfers inside and outside Group in line with function transfers, reorganizing, etc.



# **R&D** Update

# **Progress in R&D pipeline**

# Daiichi-Sankyo

### Major change from 1Q FY2014 announcement

Generic Name Dev. Code	Target indication	region	Ph-1	Ph-2	Ph-3	Filed	Approved
Edoxaban	Prevention of stroke and systemic embolism in patients with NVAF	JP					•
Euoxaban	Treatment of DVT and prevention of recurrent VTE	JP					•
Mirogabalin	Fibromyalgia	<b>US·EU</b>					
DS-5565	Diabetic neuropathic pain Posthepetic neuralgia	JP·Asia		3	sta	o be rted in 22014	
CHS-0214 (etanercept biosimilar)	Rheumatoid Arthritis	JP	-		*		
CL-108	Acute Pain	US/EU		In- licens	*		
Quizartinib* AC220	Acute Myeloid Leukemia	US/EU		M&A	*		
DS-6051	Solid cancer	US	*				

<sup>\*</sup>After completion of TOB for Ambit (10 Oct, 2014 started)



# **CL-108: Hydrocodone combination**



- In-license product from Charleston Laboratories Inc.\*
- Exclusive license for commercialization in US and EU
- Hydrocodone\*\*·acetaminophen·promethazine (immediate release) combination
  - To be used for managed care for patients with from mid to severe acute pain
  - Decrease in Opioid Induced Nausea & Vomiting (OINV)
  - To address unmet medical needs on treatment with opioid
- NDA: scheduled for FY2015
   Launch: scheduled for FY2016

<sup>\*</sup> Charleston Laboratories, Inc., privately held and located in Jupiter, Florida, is a specialty pharmaceutical company focused on the research and development of novel pain products that prevent or significantly reduce nausea and vomiting

<sup>\*\*</sup> Hydrocodone: Opioid type pain reliever, prescription volume of which is about 130 M per year in the US. Nausea observed in 30% of patients and vomiting observed in 15% is well recognized as an unfavorable effect associated with treatment with opioid drug.

# AC220 / Quizartinib



- Acquired Ambit Bioscience by TOB
- MOA:FLT3(Fms-Like Tyrosine Kinase 3)-ITD\*inhibitor (\*ITD:Internal Tandem Duplication)
- Target indication: FLT3-ITD mutation positive acute myeloid leukemia (AML)
  - FLT3-ITD mutation is observed in 30 % of patients with AML, resulted in poor clinical outcome
    - → potential therapeutics for severe diseases with high unmet medical needs
  - Fast track designation by FDA
  - Phase 3 study for 2<sup>nd</sup> line is ongoing based on the favorable Phase 2 results with low doses regimen
  - Approval in US/EU is expected in 2018 (2<sup>nd</sup> line) and 2020 (1<sup>st</sup> line)

### **Major R&D Pipeline**

#### As of October 2014



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	DS-1040 (Acute ischemic stroke / TAFIa inhibitor)	CS-3150 (JP) (Hypertensive / DM nephropathy / MR antagonist) DS-8500 (JP) (Diabetes / GPR119 agonist)	Prasugrel (JP) (CS-747 / ischemic stroke / antiplatelet agent) Prasugrel (US) (CS-747 / sickle Cell Disease / antiplatelet agent)	Edoxaban (US/EU/Others) (DU-176b / AF / oral factor Xa inhibitor)  Edoxaban (US/EU/Others) (DU-176b / VTE / oral factor Xa inhibitor)
Oncology	U3-1565 (US/JP) (Anti-HB-EGF antibody)  DS-7423 (US/JP) (PI3K / mTOR inhibitor)  DS-3078 (US/EU) (mTOR inhibitor)  DS-3032 (US) (MDM2 inhibitor)  PLX7486 (US) (Fms / Trk inhibitor)  DS-8895 (JP) (Anti-EPHA2 antibody)  DS-8273 (US) (Anti-DR5 antibody)  PLX8394 (US) (BRAF inhibitor)  DS-6051 (US) (NTRK / ROS1 inhibitor)	Patritumab (US/EU) (U3-1287 / anti-HER3 antibody)  Vemurafenib (US/EU) (PLX4032 / BRAF inhibitor)  PLX3397 (US) (Fms / Kit/Flt3-ITD inhibitor)	Tivantinib (US/EU) (ARQ 197 / HCC / Met inhibitor)  Denosumab (JP) (AMG 162 / breast cancer adjuvant / anti-RANKL antibody)  Nimotuzumab (JP) (DE-766 / gastric cancer / anti-EGFR antibody)  Vemurafenib (US)* (PLX4032 / melanoma adjuvant / BRAF inhibitor	
Others	PLX5622 (Rheumatoid arthritis / FMS kinase inhibitor)  DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor)  DS-3801 (Chronic obstipation / GPR 38 agonist)  DS-1971 (Chronic pain)	Mirogabalin (JP) (DS-5565 / chronic pain / α2δ ligand)  SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system)  Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota)  Ioforminol (JP) (GE-145 / X-ray contrast media / angiography)	Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / α2δ ligand)  Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone)  Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body)  Hydromorphone (JP) (DS-7113 / narcotic analgesic / opioid μ-receptor regulator)  CHS-0214 (JP) (Etanercept BS / rheumatoid arthritis / TNFα / rhibitor)  CL-108 (US) (Acute pain / opioid μ-receptor regulator)	

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