



For Immediate Release

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### **Correction to the Documents for Top Management Presentation**

**TOKYO, Japan (November 6, 2014)** – With regard to the above, we wish to inform that there were typo errors in the document, which was filed on November 4, 2014 at 11:30, as follows.

#### **Correction**

- (1) Page20 Progress in R&D pipeline CL-108 region  
Page23 Major R&D Pipeline CL-108 region  
Before: US/EU  
After : US
  
- (2) Page20 Progress in R&D pipeline DS-6051 region  
Page23 Major R&D Pipeline DS-6051 region  
Before: JP  
After : US
  
- (3) Page21 CL-108: Hydrocodone combination the second line  
Before: Exclusive license for commercialization in US/EU  
After : Exclusive license for commercialization in US

More information regarding Daiichi Sankyo's FY2014 Q2 financial results can be found at the following link:  
[http://www.daiichisankyo.com/media\\_investors/investor\\_relations/quarterly\\_results/index.html](http://www.daiichisankyo.com/media_investors/investor_relations/quarterly_results/index.html)

# **Top Management Presentation**

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

**Joji Nakayama**  
President and CEO

**November 4, 2014**

## **Today's Topics**

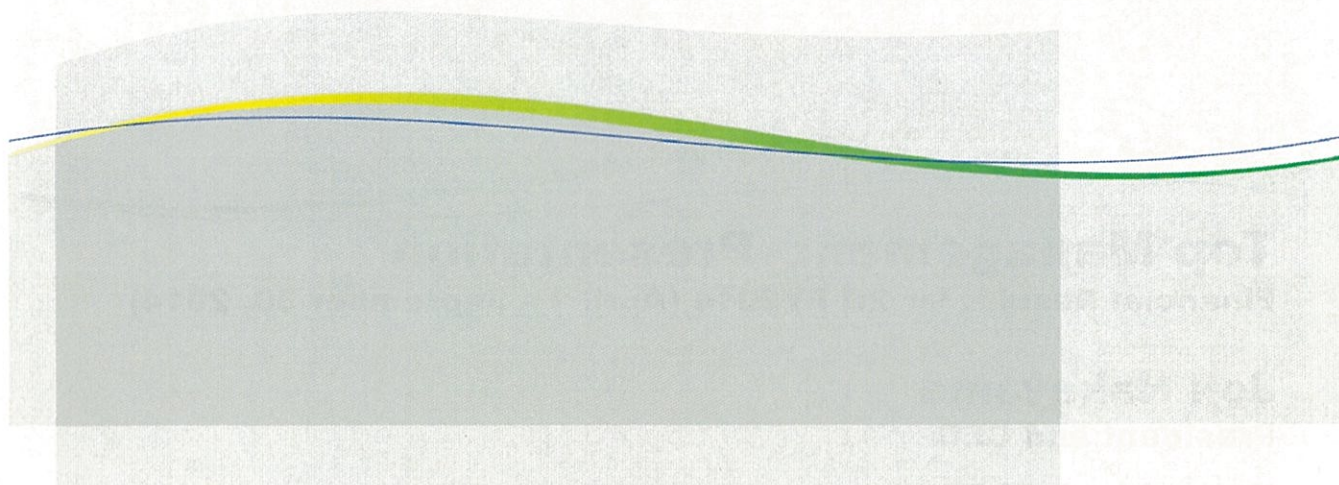


- ◆ **FY2014 2Q Results**
- ◆ **FY2014 revised consolidated forecast**
- ◆ **Business Update**
- ◆ **Optimization of Business Operation Structure in Japan**
- ◆ **R&D Update**





# FY2014 2Q Results



## Overview of FY2014 2Q Results



### Consolidated Statement of Profit or Loss

|  | JPY Bn              |                     |        |
|--|---------------------|---------------------|--------|
|  | FY2013<br>2Q Result | FY2014<br>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/<br>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<br>to owners of the<br>Company | 33.5                | 50.3                | +16.8  |

### Daiichi Sankyo Group

|  | JPY Bn              |                     |                 |                  |
|--|---------------------|---------------------|-----------------|------------------|
|  | FY2013<br>2Q Result | FY2014<br>2Q Result | YoY             | Revised<br>Plan* |
| Revenue  | 429.1               | 429.6               | +0.1%<br>+0.5   | 920.0<br>900.0   |
| 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/<br>General expenses)       | (13.2)              | (4.7)               | (-8.5)          | -                |
| Operating Profit                                   | 50.1                | 58.7                | +17.2%<br>+8.6  | 120.0<br>100.0   |
| Profit before tax                                  | 50.2                | 60.7                | +20.8%<br>+10.5 | 120.0<br>100.0   |
| Profit attributable<br>to owners of the<br>Company | 35.2                | 35.5                | +0.8%<br>+0.3   | 78.0<br>65.0     |

|                  |         |        |        |
|------------------|---------|--------|--------|
| Currency<br>Rate | USD/JPY | 98.86  | 103.05 |
|                  | EUR/JPY | 130.01 | 138.91 |
|                  | INR/JPY | 1.74   | 1.72   |

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



# FY2014 2Q Revenue (JPY Bn)

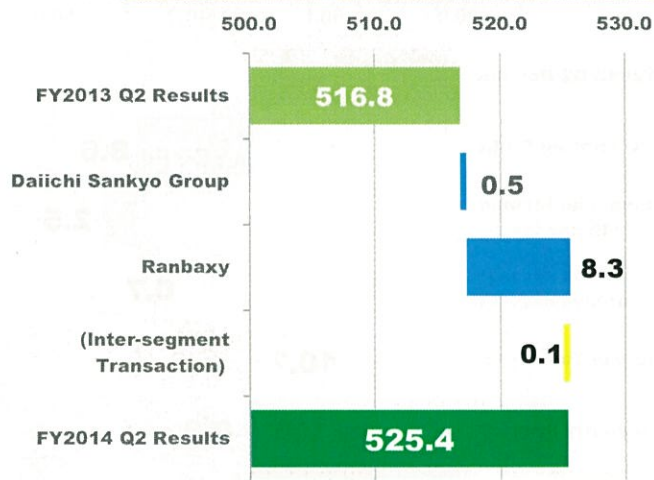
Positive  
Factors

Negative  
Factors

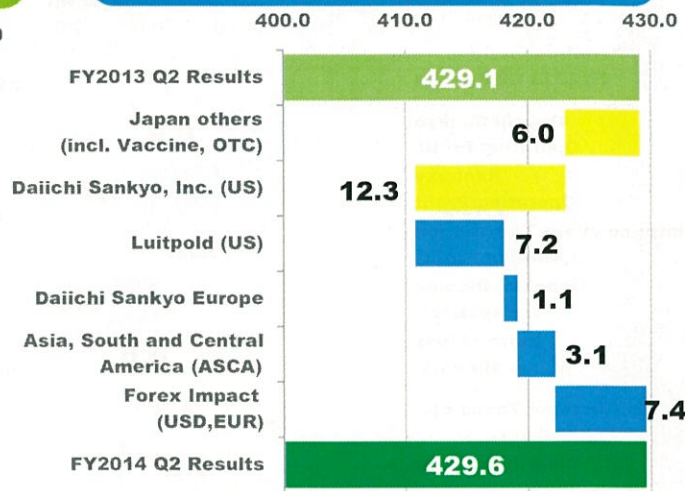


Decline in Japan and Daiichi Sankyo Inc.  
offsetted by growth of Luitopold and ASCA

## Consolidated Statement of Profit or Loss



## Daiichi Sankyo Group



### 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

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# FY2014 2Q Operating Profit (JPY Bn)

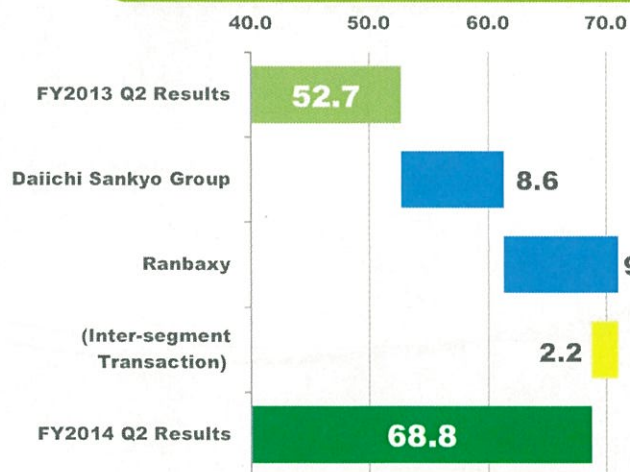
Positive  
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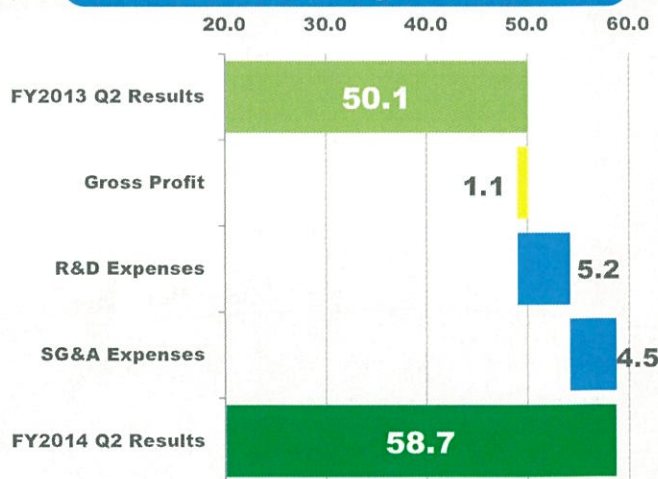


Operating profit increase reflected  
decreases in SG&A expenses and R&D expenses

## Consolidated Statement of Profit or Loss



## Daiichi Sankyo Group



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

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

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

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# FY2013 1Q Profit attributable to owners of the Company

(JPY Bn)

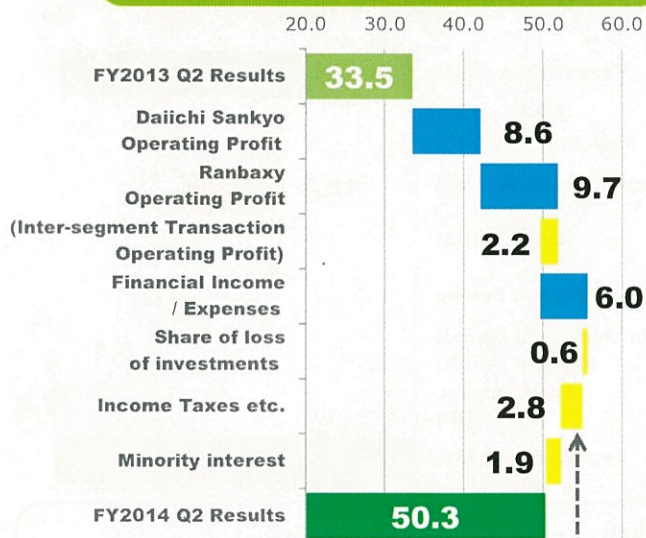
Positive Factors

Negative Factors



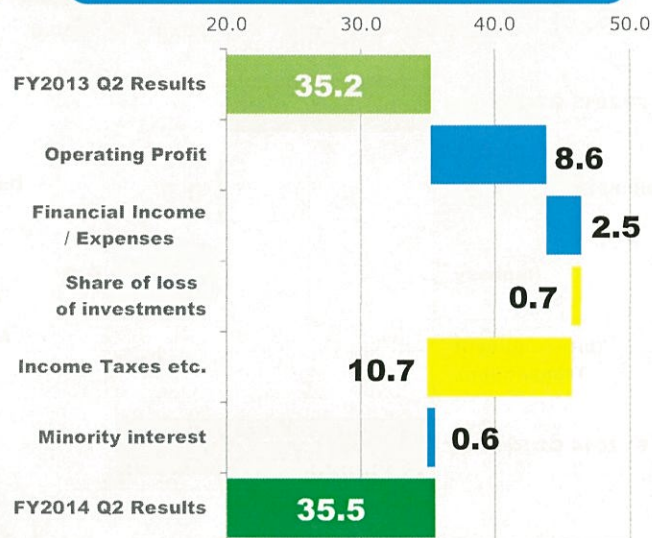
Profit (attributable to owners of the Company) increase owing to the operating profit increase and an improvement in financial income/expenses

## Consolidated Statement of Profit or Loss



**Ranbaxy**  
A tax effect caused by impairment of Ranbaxy's assets in past fiscal years was recognized in FY2014 2Q

## Daiichi Sankyo Group



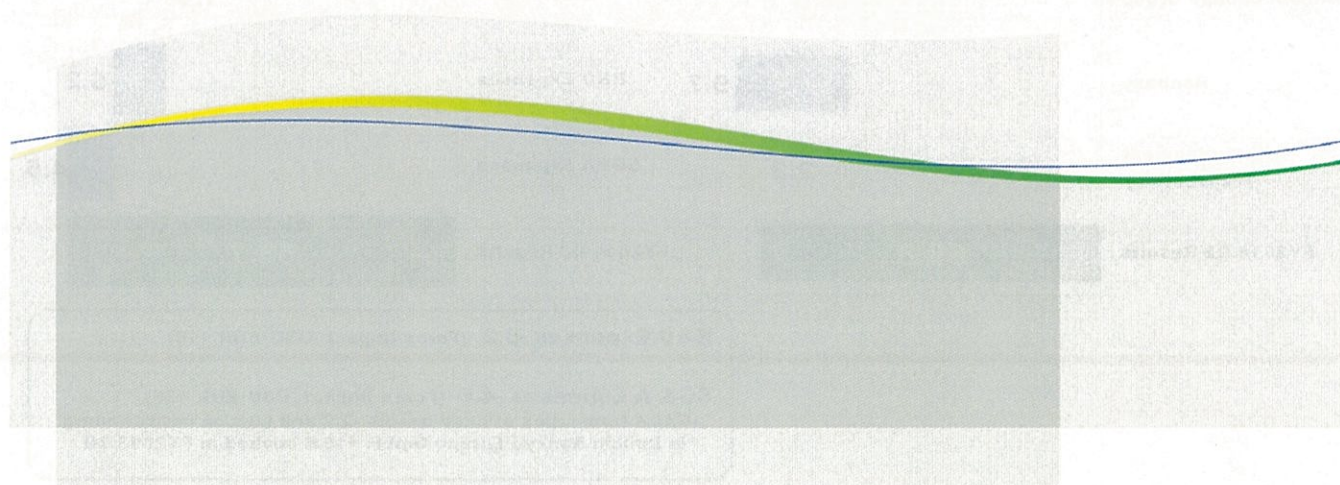
Financial income/ expenses +2.5  
Foreign exchange gain etc.

Income Taxes etc. +10.7

- Increase of profit before tax in FY2014 2Q
- Dividend received from U3 Pharma was considered as devaluation of book value resulted in tax benefit in FY2013 2Q



## FY2014 revised consolidated forecast





# FY2014 revised consolidated forecast



JPY Bn

|   | FY 2013<br>Forecast<br>(July) | FY 2013<br>Revised Forecast<br>(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<br>owners of the Company | 78.0                          | 65.0                                     | -13.0  |

|                  |         |     |        |
|------------------|---------|-----|--------|
| Currency<br>Rate | USD/JPY | 100 | 104.02 |
|                  | EUR/JPY | 140 | 139.46 |

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

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## 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.

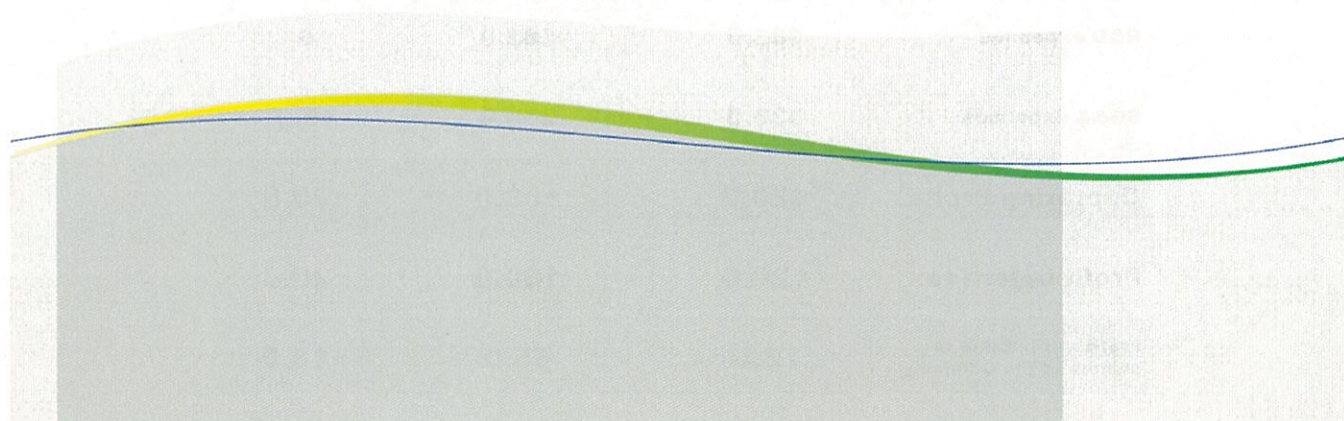
### Profit

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.

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# Business Update



## Major Products in Japan

JPY Bn

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



## Initiatives for Mainstay Products in Japan



### Olmotec

- 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.)

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## 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

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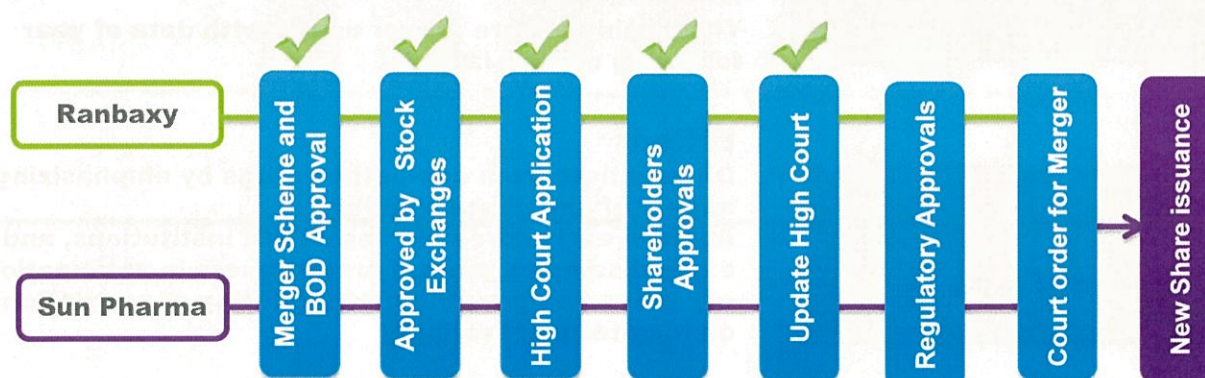
# Major Business Units

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

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## Merger of Ranbaxy with Sun Pharma

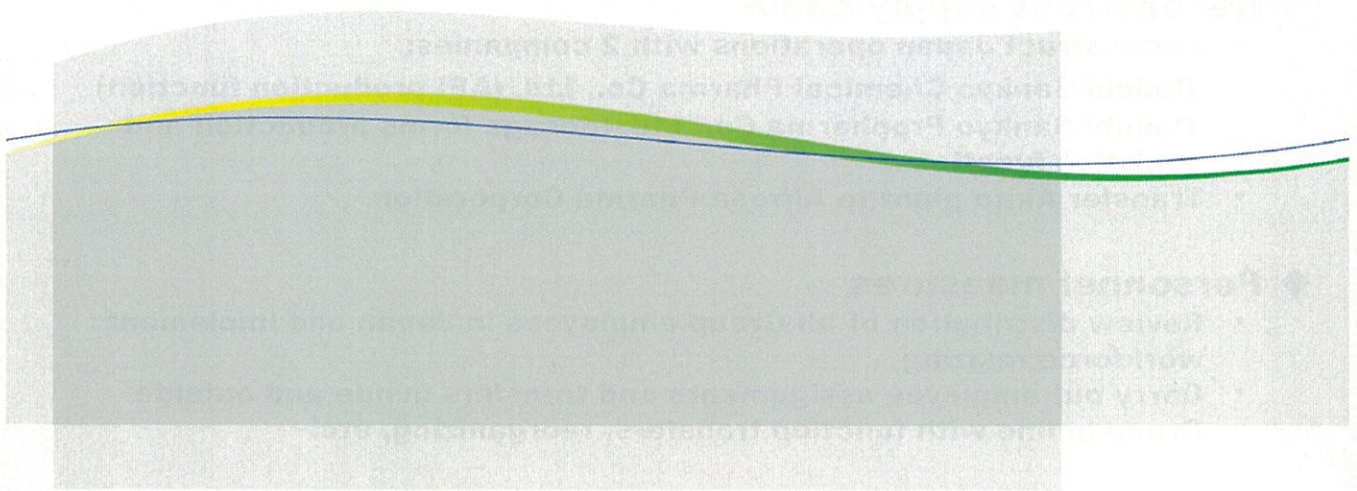
- ◆ Agreements for a merger of Ranbaxy with Sun Pharma on April 6, 2014
- ◆ Approved at the respective general shareholders' meetings of Ranbaxy and Sun Pharma by September 30, 2014
  - The final examinations by the relevant authorities are currently in progress
  - Daiichi Sankyo will obtain an equity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



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# 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)

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



# Optimization of Business Operation Structure in Japan



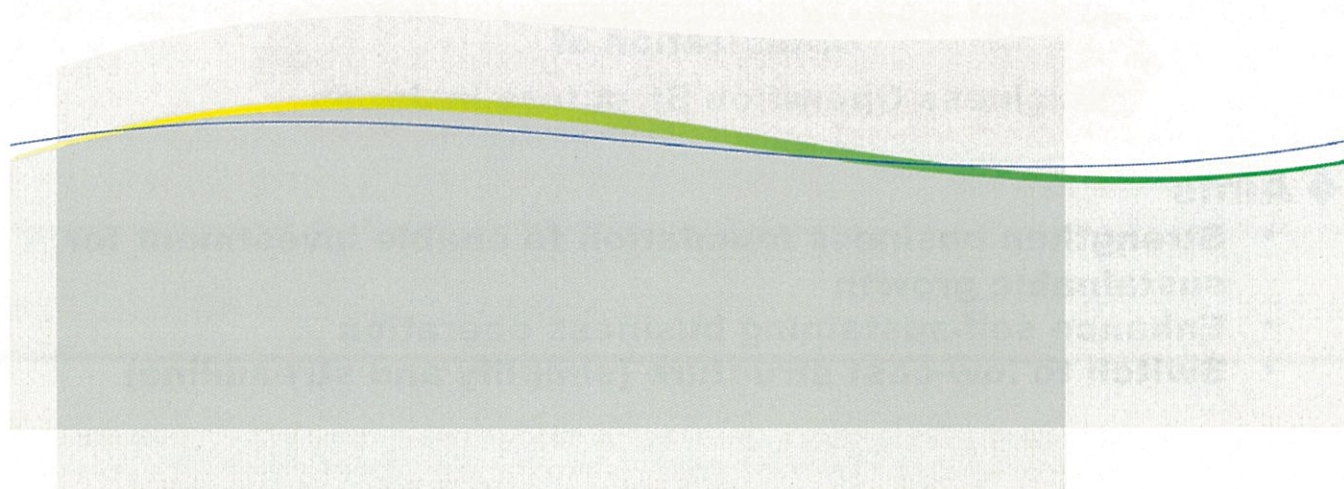
- ◆ **Reform business operation in each unit**
  - Self-sustaining business operation in each Japan business
  - Greater efficiency through reduction of indirect operations and concentration of operations
  - Expediting of decision making through simplified organization
- ◆ **Reconstruct supply chain**
  - 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.

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Daiichi-Sankyo

## R&D Update





# Progress in R&D pipeline

Major change from 1Q FY2014 announcement



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

\*After completion of TOB for Ambit (10 Oct, 2014 started)

● :Stage-up  
★ :New pipeline

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## CL-108: Hydrocodone combination



- ◆ In-license product from Charleston Laboratories Inc.\*
- ◆ Exclusive license for commercialization in US
- ◆ 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

\* 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

\*\* 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.

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- ◆ 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)

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## Major R&D Pipeline

As of October 2014



| Therapeutic area                 | Phase 1  | Phase 2  | Phase 3   | Application   |
|----------------------------------|--|--|---|---|
| <b>Cardiovascular-Metabolics</b> | <ul style="list-style-type: none"> <li>■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor)</li> </ul>  | <ul style="list-style-type: none"> <li>■ CS-3150 (JP) (Hypertensive / DM nephropathy / MR antagonist)</li> <li>■ DS-8500 (JP) (Diabetes / GPR119 agonist)</li> </ul>   | <ul style="list-style-type: none"> <li>■ Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent)</li> <li>■ Prasugrel (US) (CS-747 / sickle Cell Disease / anti-platelet agent)</li> </ul>  | <ul style="list-style-type: none"> <li>■ Edoxaban (US/EU/Others) (DU-176b / AF / oral factor Xa inhibitor)</li> <li>■ Edoxaban (US/EU/Others) (DU-176b / VTE / oral factor Xa inhibitor)</li> </ul> |
| <b>Oncology</b>                  | <ul style="list-style-type: none"> <li>■ U3-1565 (US/JP) (Anti-HB-EGF antibody)</li> <li>■ DS-7423 (US/JP) (PI3K / mTOR inhibitor)</li> <li>■ DS-3078 (US/EU) (mTOR inhibitor)</li> <li>■ DS-3032 (US) (MDM2 inhibitor)</li> <li>■ PLX7486 (US) (Fms / Trk inhibitor)</li> <li>■ DS-8895 (JP) (Anti-EPHA2 antibody)</li> <li>■ DS-8273 (US) (Anti-DR5 antibody)</li> <li>■ PLX8394 (US) (BRAF inhibitor)</li> <li>■ <u>DS-6051 (US)</u> (NTRK / ROS1 inhibitor)</li> </ul> | <ul style="list-style-type: none"> <li>■ Patritumab (US/EU) (U3-1287 / anti-HER3 antibody)</li> <li>■ Vemurafenib (US/EU) (PLX4032 / BRAF inhibitor)</li> <li>■ PLX3397 (US) (Fms / 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)* (PLX4032 / melanoma adjuvant / BRAF inhibitor)</li> </ul>  |   |
| <b>Others</b>                    | <ul style="list-style-type: none"> <li>■ PLX5622 (Rheumatoid arthritis / FMS kinase inhibitor)</li> <li>■ DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor)</li> <li>■ DS-3801 (Chronic obstruction / GPR 38 agonist)</li> <li>■ DS-1971 (Chronic pain)</li> </ul>   | <ul style="list-style-type: none"> <li>■ Mirogabalin (JP) (DS-5565 / chronic pain / α2δ ligand)</li> <li>■ SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system)</li> <li>■ Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota)</li> <li>■ Ioforninol (JP) (GE-145 / X-ray contrast media / angiography)</li> </ul> | <ul style="list-style-type: none"> <li>■ <u>Mirogabalin (US/EU)</u> (DS-5565 / Fibromyalgia / α2δ ligand)</li> <li>■ Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone)</li> <li>■ Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL antibody)</li> <li>■ Hydromorphone (JP) (DS-7113 / narcotic analgesic / opioid μ-receptor regulator)</li> <li>■ <u>CHS-0214 (JP)</u> (Etanercept RS / rheumatoid arthritis / TNFα inhibitor)</li> <li>■ <u>CL-108 (US)</u> (Acute pain / opioid μ-receptor regulator)</li> </ul> |   |

Underlined: stage-up project after the 1Q financial announcement on July 31, 2014

\*: newly cited in line with Roche's description

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