

# Results Briefing

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Results for Q3 FY2011  
(April 1 – December 31, 2011)

Manabu Sakai  
Executive Officer,  
Global Corporate Finance Officer

January 31, 2012 4:45pm~5:30pm



Products	Injectafer® (USA) Treatment of Iron Deficiency Anemia	Oct 3 NDA
	NEXIUM® (Japan) Proton Pump Inhibitor	Oct 24 Application for additional indication  "prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with aspirin at low doses"
	ARQ 092 AKT inhibitor	Nov 10 License agreement
	Rotarix® (Japan) Rotavirus vaccine	Nov 21 Launch (Co-promotion)
	Methylthioninium Chloride Solution for Injection (Japan) Injection for Methaemoglobinaemia	Nov 25 License agreement
Business Operation	Daiichi Sankyo	
	Nov 1	Established New Vaccine Research Unit
	Nov 8	Established DAIICHI SANKYO (CHINA) HOLDINGS CO., LTD.

## Ranbaxy

Nov 30 Approval and launch of Atorvastatin

Dec 21 Ranbaxy signed a consent decree with the U.S. FDA

- Ranbaxy has committed to further strengthen procedures and policies to ensure data integrity and to comply with current good manufacturing practices
- Ranbaxy also announced that it intends to make a provision of \$500 million in connection with the investigation by the U.S. Department of Justice, which the company believes will be sufficient to resolve all potential civil and criminal liability.

Jan 26 Consent decree with the U.S. FDA has been filed with the U.S. District Court for the District of Maryland

# Financial Overview

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Consolidated Income Statement

	FY2010 Q3 Results	FY2011 Q3 Results	FY2011	
			Revised Forecast	Progress
Net Sales	748.1	696.4	940.0	74%
Cost of Sales	213.1	200.5	273.0	73%
SG&A Expenses	414.4	404.0	567.0	71%
R&D Expenses	142.3	128.8	185.0	70%
Other Expenses	272.0	275.2	382.0	72%
Operating Income	120.6	91.9	100.0	92%
Ordinary Income	130.6	86.4	77.0	112%
Net Income	79.7	17.5	15.0	117%

Currency Rate	USD/JPY	86.53	79.00	78.50
	EUR/JPY	113.31	110.62	107.00
	INR/JPY	1.96	1.79	1.73

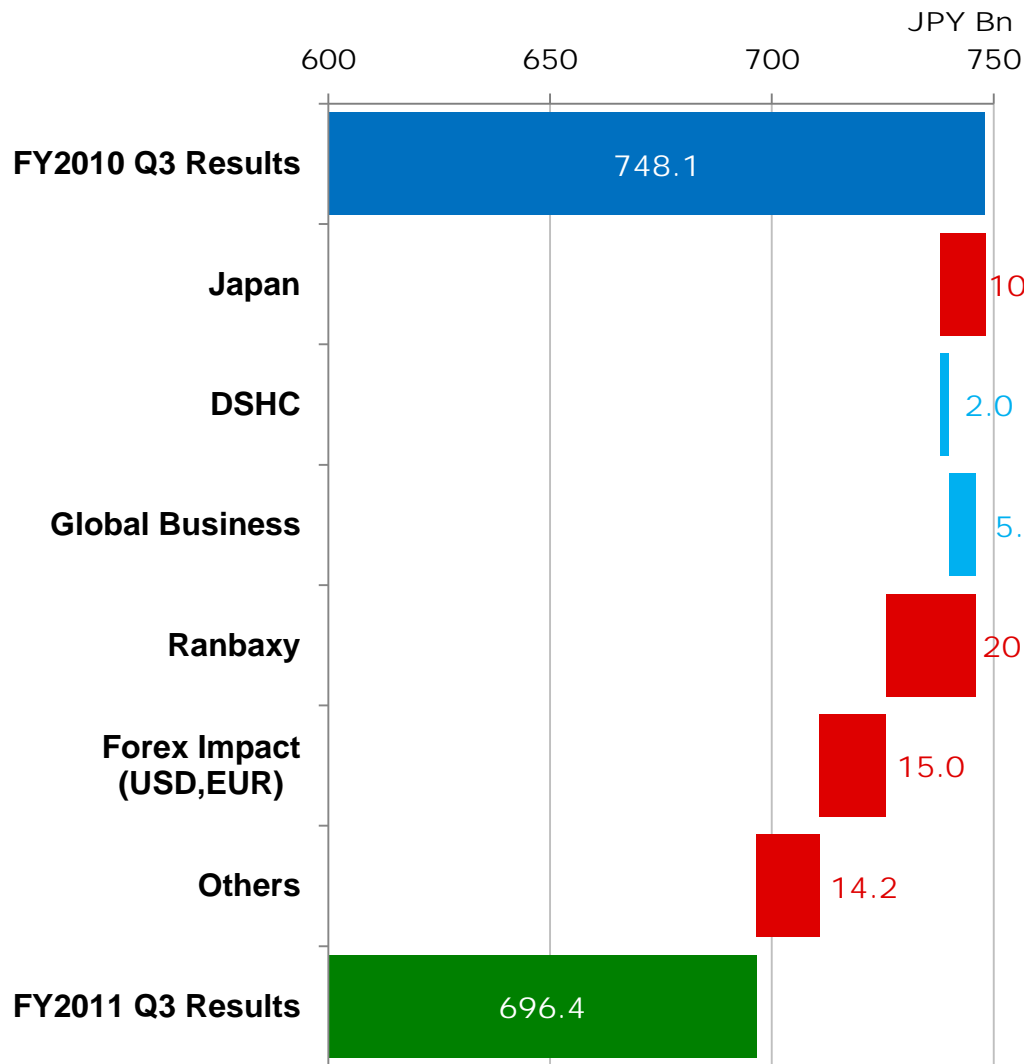
Ranbaxy Laboratories Limited

Note : Figures of Ranbaxy are pre-adjusted before consolidation

FY2010 (Jan-Sep) Results	FY2011 (Jan-Sep) Results	FY2011 (Jan-Dec)	
		Plan	Progress
134.2	114.5	162.0	71%
58.7	59.0		
48.9	47.8		
9.2	7.0		
39.7	40.8		
26.6	7.8		
34.7	0.5		
26.7	4.7		

JPY Bn

Net Sales factors



**Japan**

- Contribution of New products +10.2,
- Rezaltas +6.7, Loxonin+5.8, ActHib+7.0
- Return of sales rights -21.0
- Olmetec/Calblock -2.5
- Mevalotin -4.0
- Influenza Vaccine -6.1

**Daiichi Sankyo Healthcare (DSHC)**

- Loxonin S, Lulu series

**Global Business**

- Daiichi Sankyo Inc. (DSI) +1.4
- Effient +3.5
- Olmesartan -2.4
- Daiichi Sankyo Europe GmbH (DSE) +2.9
- Olmesartan +2.9
- Asia, South and Central America (ASCA) +0.9
- Luitpold Pharmaceuticals, Inc. (LPI) +0.8
- Venofer +2.1

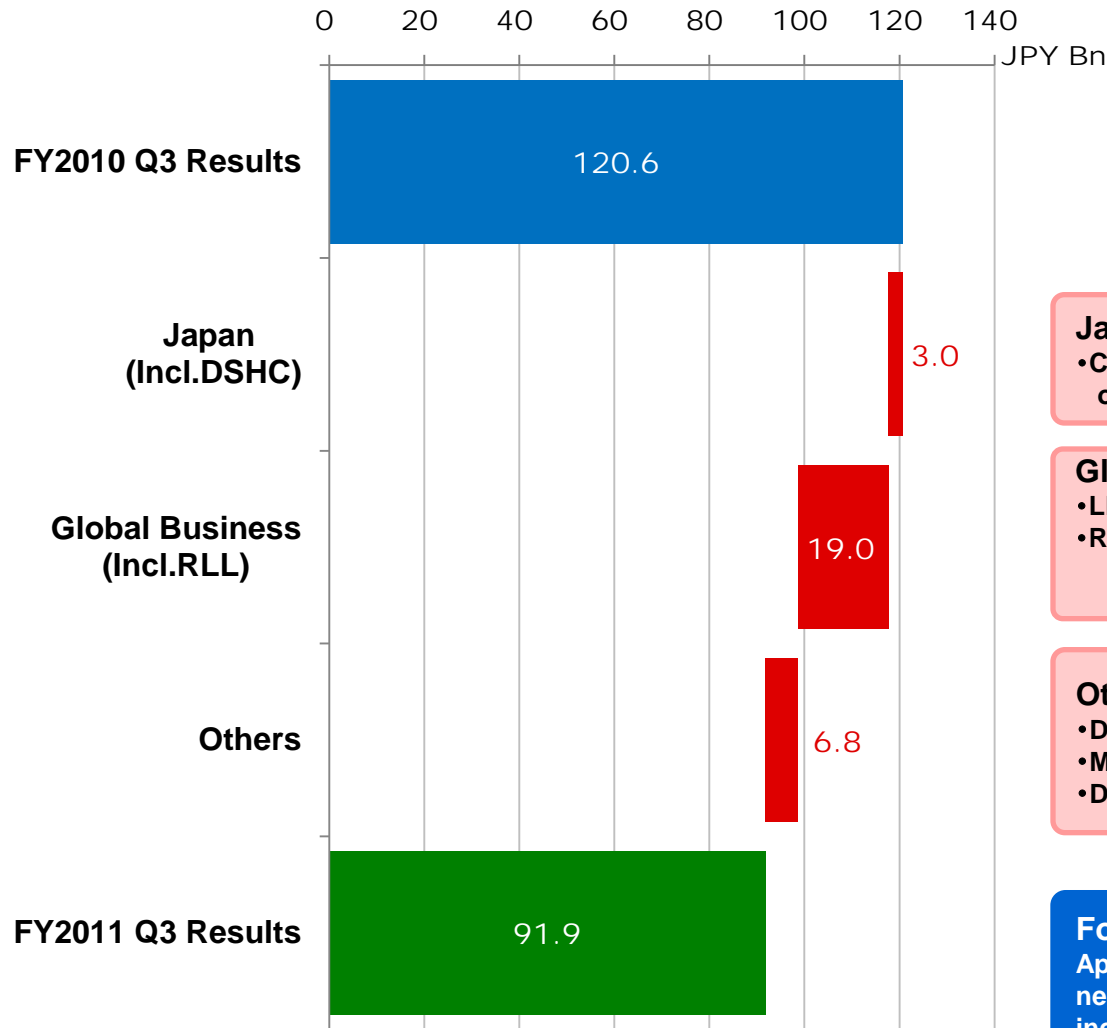
**Ranbaxy (RLL)** (Incl. forex impact -11.0)

- Positive Factors: Growth in India, Contribution of Donepezil
- Negative Factors: Expansion of Valacyclovir (FY2010), Lump-sum income of Tamsulosin (FY2010)

**Others**

- Positive Factors: Plexxikon
- Negative Factors: Decrease in export / royalty of Levofloxacin, Milestone income of Denosumab (FY2010)

Operating Income factors



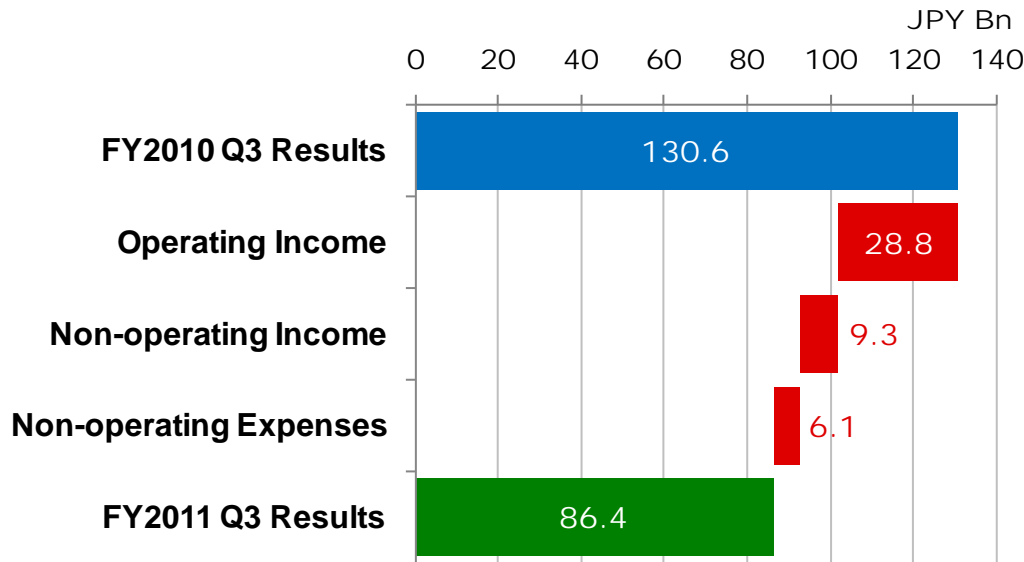
**Japan (Incl. DSHC)**  
 • Contribution of new products could not fully off-set negative impact of sales right returns

**Global Business (Incl. RLL)**  
 • LPI Factory Issue etc.  
 • Ranbaxy  
 Expansion of Valacyclovir (FY2010)  
 Lump-sum income of Tamsulosin (FY2010)

**Others**  
 • Decrease in R&D expenses  
 • Milestone income of Denosumab (FY2010)  
 • Decrease in export (Levofloxacin etc.)

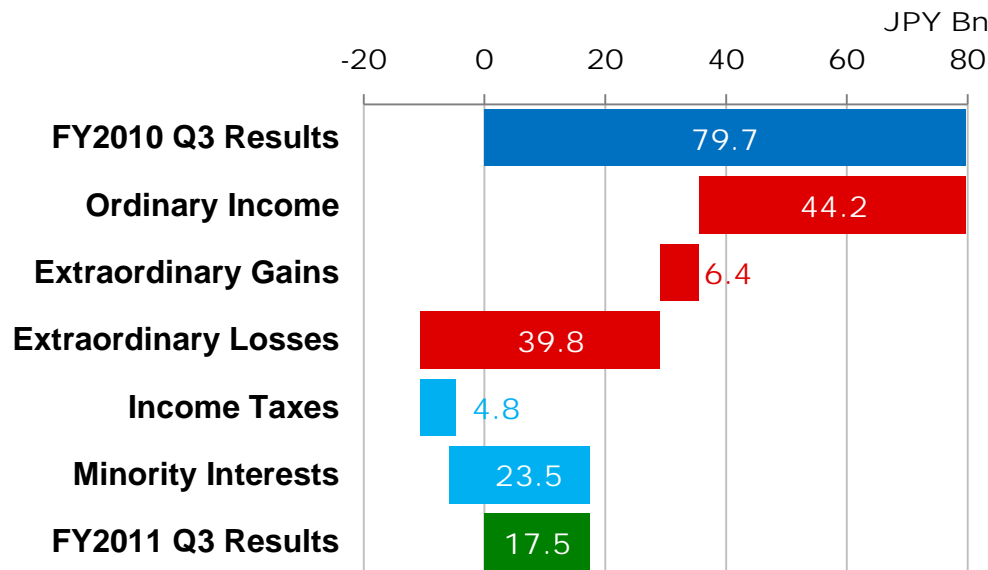
**Forex Impact**  
 Appreciation of JPY to USD, EUR and INR negatively affected the FY2011 Q3 operating income by -2.0

Ordinary Income factors



**Non-operating income / Expenses**  
 • Increase in forex losses and loss on valuation of derivatives of Ranbaxy

Net Income factors



**Extraordinary Gains**  
 • Decreases in;  
 gain on sales of non-current assets  
 gain on sales of affiliates' stock  
 gain on sales of investment securities

**Extraordinary Losses**  
 • Provision for settlement expenses (40.3 Bn)

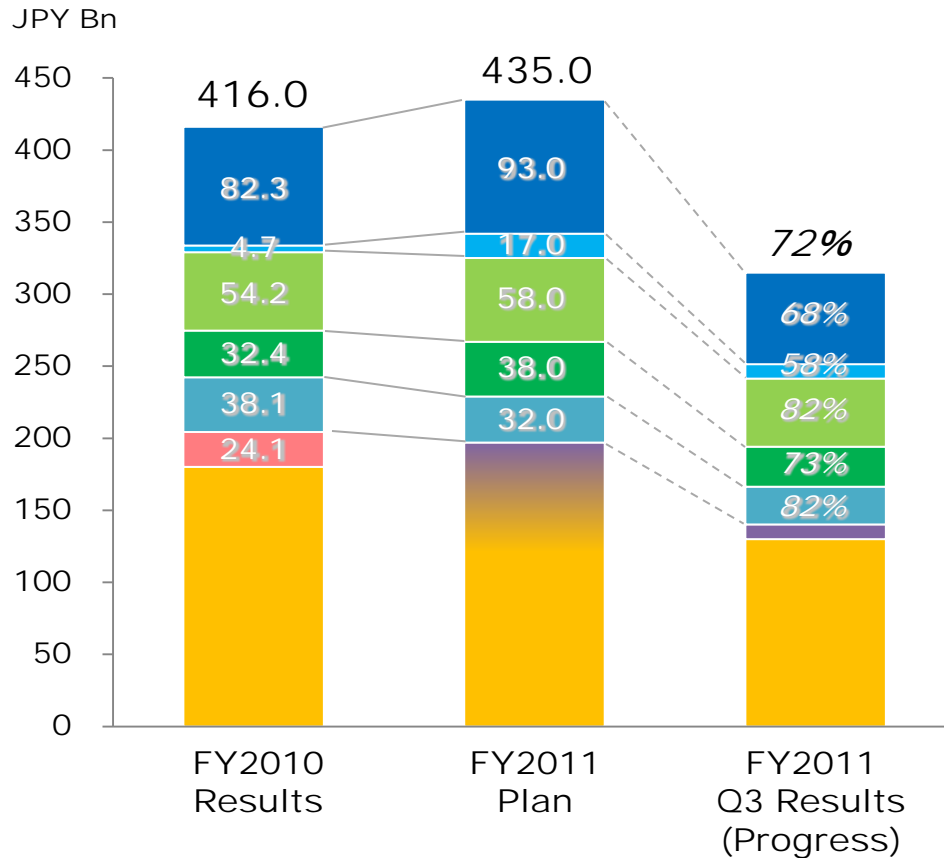
**Minority Interests**  
 • Minority interests on provision for settlement expenses



		FY2010 Results	FY2011		
			Plan	Q3 Results	Progress
Japan Company (domestic sales)	JPY Bn	416.0	435.0	314.9	72%
Daiichi Sankyo Healthcare (OTC)	JPY Bn	44.8	49.0	36.1	74%
Daiichi Sankyo, Inc. (US)	USD Mn	1,522	1,566	1,196	76%
Luitpold Pharmaceuticals, Inc. (US)	USD Mn	629	590	470	80%
Daiichi Sankyo Europe GmbH	EUR Mn	587	670	462	69%
Asia, South and Central America (ASCA)	JPY Bn	27.4	30.0	20.7	69%
Ranbaxy Laboratories Limited	INR Bn	89	85	64	75%

※2011 Plan are those announced at the beginning of the fiscal year (May 2011)

## Japan Company (domestic sales)

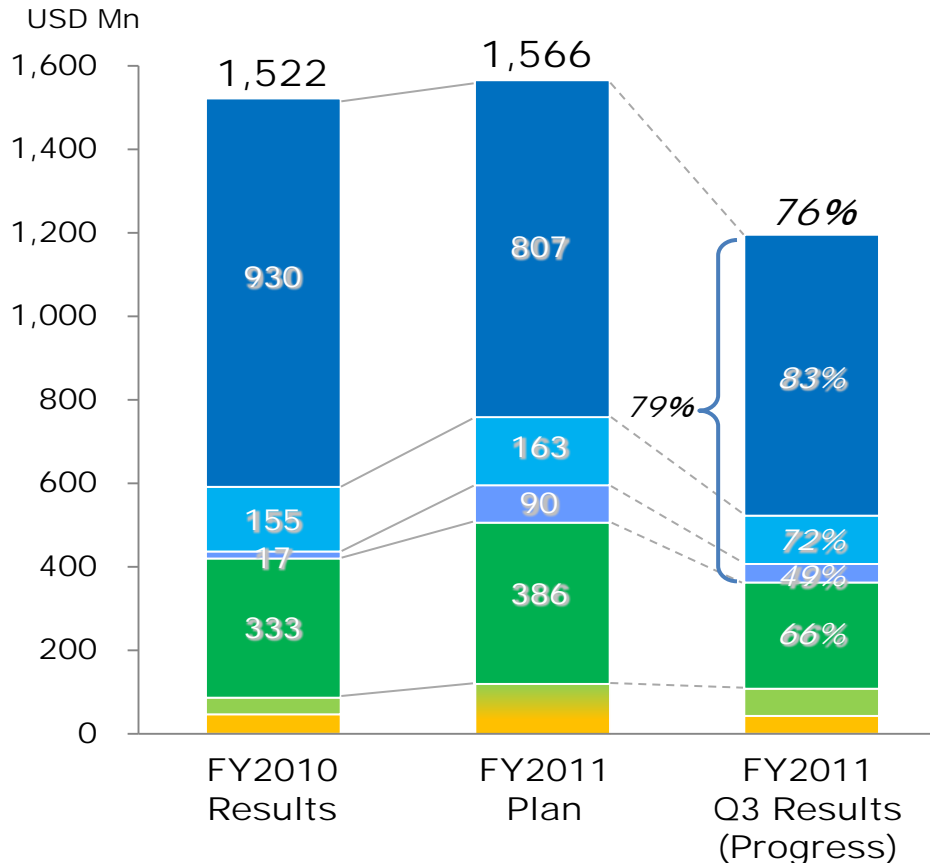


## Status of FY2011 Q3 results

Q3 YTD progress was just 72% of the annual plan. Increasing competition in the ARB market and shortfalls in sales of influenza vaccine have offset the sales from new products launches and growth from certain existing products including Loxonin and ActHIB.

- **Olmetec:**  
Despite Olmetec's solid performance in the mono ARB market, Q3YTD sales was down 1.9% YoY. Q3YTD progress stood at 68% to the annual plan, which was aggressively designed with a target of +13% YoY.
- **Rezaltas:**  
While Rezaltas marked a substantial growth YoY, it is still behind the growth of the ARB+CCB combo market.
- **Loxonin:**  
Led by the strong growth of its Tape formulation, Q3YTD sales of Loxonin brand grew by 14% YoY. Q3YTD progress is already 82% to the annual plan, which aims for a 7.1% growth YoY.

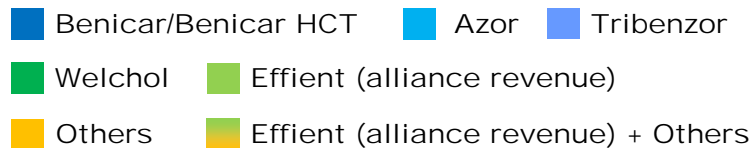
## Daiichi Sankyo, Inc. (US)



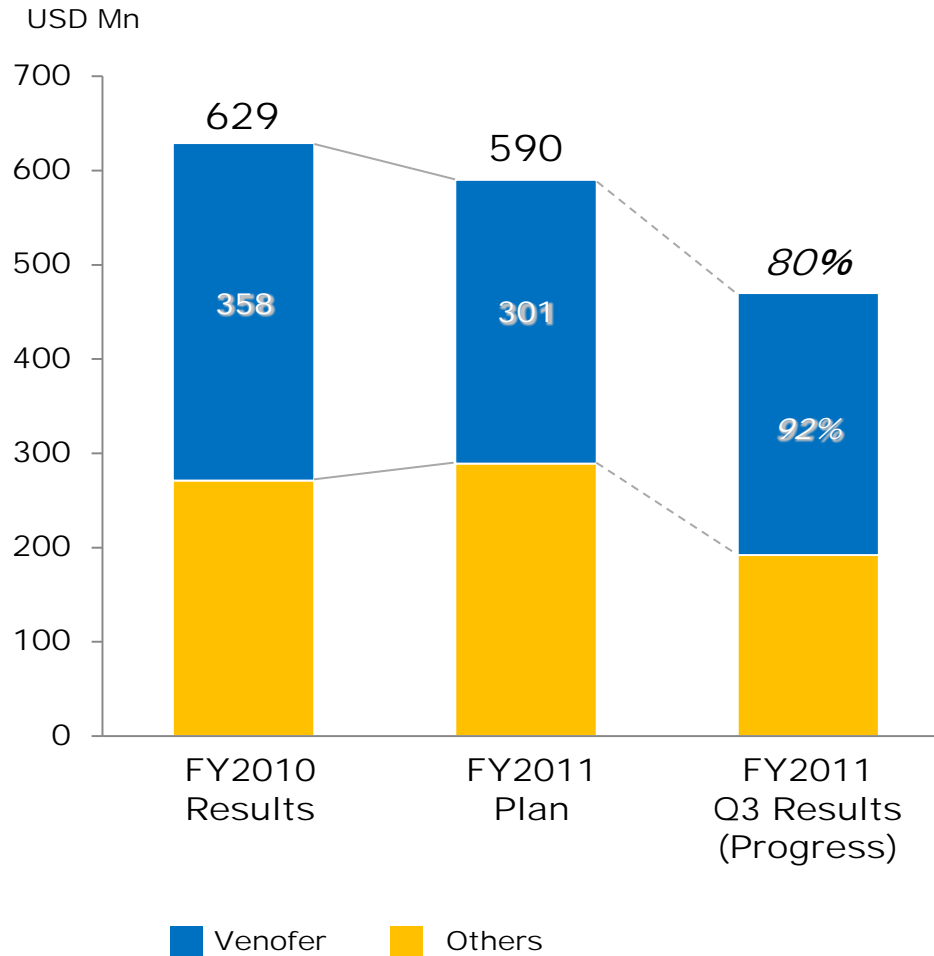
### Status of FY2011 Q3 results

Aided by the continuous growth of Effient, Q3YTD progress overall was 76% to the annual plan (+2.9% YoY).

- **Olmesartan:**  
While facing the negative impact from generic ARB entries since last fiscal year, sales decrease in Q3YTD for the franchise was limited to 3% YoY. Q3YTD progress was 79% to the annual plan.
- **Welchol:**  
While Q3YTD sales were just 66% to the annual plan, which was aggressively designed with a target of +15.9% YoY, Welchol maintained steady sales YoY.



## Luitpold Pharmaceuticals, Inc. (US)

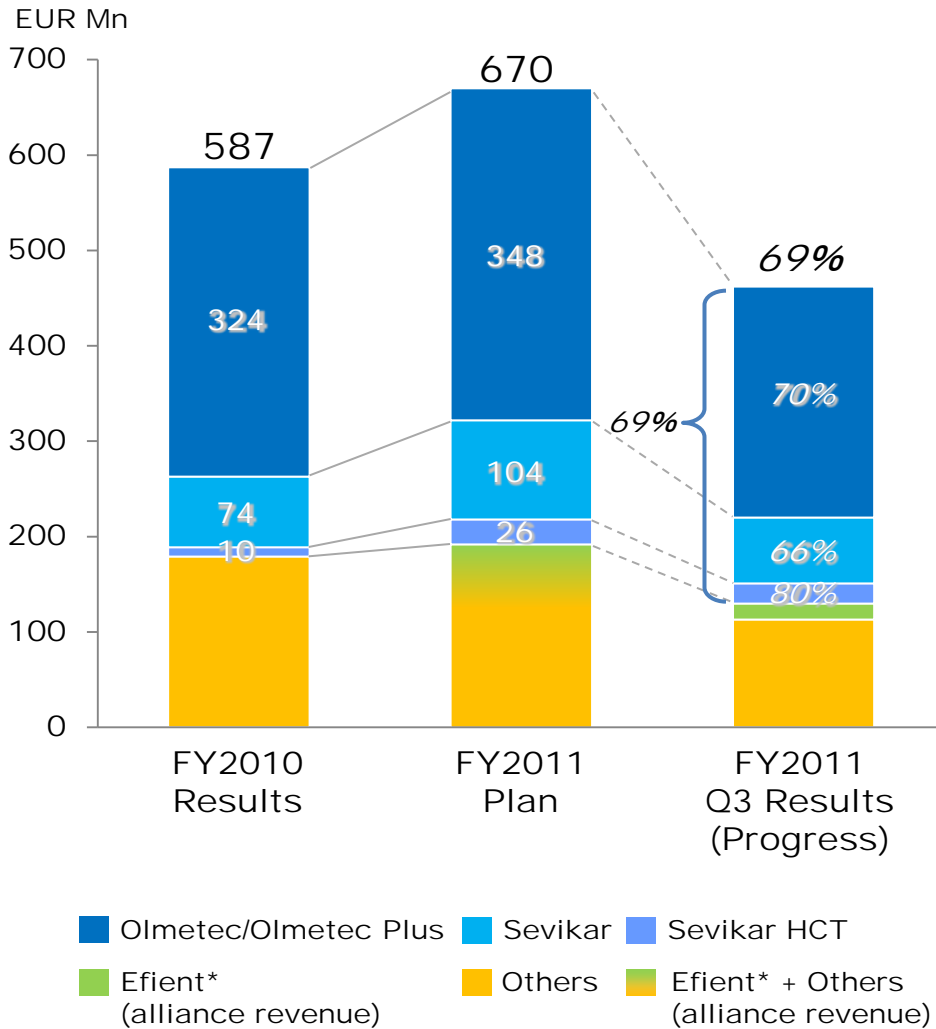


### Status of FY2011 Q3 results

Q3 YTD progress reached 80% of the annual plan, due to advance shipment of Venofer.

- **Venofer:**  
Despite a competitive climate, Q3YTD progress reached 92% of the annual plan, reflecting advance shipments from Q4.
- **Manufacturing status at Shirley facility**  
Following the FDA inspection, Luitpold had temporarily suspended its manufacturing and distribution at Shirley facility in Q1, which was then resumed. Operating rate has been on the rise.

## Daichi Sankyo Europe GmbH



### Status of FY2011 Q3 results

**Q3YTD progress was just 69% of the annual target, which aims for a 14.1% growth YoY driven by olmesartan.**

- Olmesartan:** Q3YTD sales grew 8.4% YoY, led by the expansion of Sevikar and Sevikar HCT. Q3YTD progress stood at 69%, due to delay in the launch of Sevikar in certain country, and partial carry over of sales to partners.

\* Alliance revenue is incorporated into DSE sales since FY2011

## Net Sales

	JPY Bn
Previous Forecasts (Dec 21)	930.0
Change	940.0

Net sales upwardly revised by ¥10.0 billion to ¥940.0 billion

- ✓ Sales decrease in Japan, due to further intensification of competition and cooling market ahead of the NHI price revision in April
- ✓ Contribution from Ranbaxy's U.S. atorvastatin launch

## Operating Income

	JPY Bn
Previous Forecast (Dec 21)	100.0
Change	100.0

No change in operating income

- ✓ Sales contribution from atorvastatin offset by sales decline in Japan

## Ordinary Income

	JPY Bn
Previous Forecasts (Dec 21)	90.0
Change	77.0

Ordinary income downwardly revised by ¥13.0 billion to ¥77.0 billion

- ✓ Forex loss and loss on valuation of derivatives expected in Q4 due to the depreciation of the Indian rupee against the U.S. dollar

## Net Income

	JPY Bn
Previous Forecasts (Dec 21)	26.0
Change	15.0

Net income downwardly revised by ¥11.0 billion to ¥15.0 billion

- ✓ Decrease in ordinary income
- ✓ Increase in accounting tax costs due to the reversal of previously recorded deferred tax assets, triggered by the government's decision to cut the corporate tax rate in Japan

No change in the year-end dividend forecast of ¥30 per share

Therapeutic Area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	<ul style="list-style-type: none"> <li>■ CS-3150 (Antihypertensive)</li> <li>■ DS-7309 (Anti-diabetes)</li> <li>■ DS-7250 (Anti-diabetes)</li> </ul>		<ul style="list-style-type: none"> <li>■ DU-176b (US/EU/JP/Asia) (Edoxaban / AF / oral factor Xa inhibitor)</li> <li>■ DU-176b (US/EU/JP/Asia) (Edoxaban / VTE / oral factor Xa inhibitor)</li> <li>■ CS-747 (US/EU/Asia) (Prasugrel / ACS-MM / anti-platelet agent)</li> <li>■ CS-747 (JP) (Prasugrel / PCI / anti-platelet agent)</li> <li>■ CS-747 (JP) (Prasugrel / ischemic stroke / anti-platelet agent)</li> </ul>	
Oncology	<ul style="list-style-type: none"> <li>■ CS-7017(JP/Asia) (Efatutazone / PPAR<math>\gamma</math> agonist)</li> <li>■ U3-1565 (US/JP) (Anti-HB-EGF antibody)</li> <li>■ U3-1287(JP) (Anti-HER3 antibody)</li> <li>■ DS-2248(US) (Hsp90 inhibitor)</li> <li>■ DS-7423(US) (PI3K/mTOR inhibitor)</li> <li>■ ARQ 092(US) (AKT inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ U3-1287 (US/EU) (Anti-HER3 antibody)</li> <li>■ CS-1008 (US/EU/JP/Asia) (Tigatuzumab / anti-DR5 antibody)</li> <li>■ CS-7017 (US/EU) (Efatutazone / PPAR<math>\gamma</math> agonist)</li> <li>■ DE-766 (JP) (Nimotuzumab / anti-EGFR antibody)</li> <li>■ PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor)</li> <li>■ AMG 162 (JP) (Denosumab / Giant cell tumor of bone / anti-RANKL antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ ARQ 197 (US/EU) (Tivantinib / NSCLC / c-Met inhibitor)</li> <li>■ AMG 162 (JP) (Denosumab / breast cancer adjuvant / anti-RANKL antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ PLX4032 (EU) (Vemurafenib / Melanoma / BRAF inhibitor)</li> <li>■ AMG 162 (JP) (Denosumab / bone metastases of cancer / anti-RANKL antibody)</li> </ul>
Infectious diseases	<ul style="list-style-type: none"> <li>■ CS-8958(US/EU) (Laninamivir / anti-influenza / Outlicensing with Biota)</li> <li>■ CS-4771 (Anti-Sepsis)</li> <li>■ DS-8587 (Broad spectrum antibacterial agent)</li> </ul>		<ul style="list-style-type: none"> <li>■ CS-8958 (JP) (Laninamivir / anti-influenza, prophylactic / Neuraminidase inhibitor)</li> </ul>	
Bone/Joint diseases	<ul style="list-style-type: none"> <li>■ PLX5622 (Rheumatoid arthritis)</li> </ul>	<ul style="list-style-type: none"> <li>■ AMG 162 (JP) (Denosumab / rheumatoid arthritis / anti-RANKL antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ AMG 162 (JP) (Denosumab / osteoporosis / anti-RANKL antibody)</li> </ul>	
Immunological allergic diseases	<ul style="list-style-type: none"> <li>■ CS-0777 (Immunomodulator)</li> </ul>	<ul style="list-style-type: none"> <li>■ SUN13834 (US) (Atopic Dermatitis / Chymase inhibitor)</li> </ul>		
Others	<ul style="list-style-type: none"> <li>■ SUN13837 (Spinal cord injury)</li> </ul>	<ul style="list-style-type: none"> <li>■ DS-5565 (Chronic pain / <math>\alpha 2\delta</math> ligand)</li> </ul>	<ul style="list-style-type: none"> <li>■ SUN11031 (JP) (Human ghrelin / anorexia nervosa)</li> <li>■ DD-723-B (JP) (Perflubutane / Contrast enhanced ultrasonography for prostate cancer / ultrasound contrast agent)</li> </ul>	<ul style="list-style-type: none"> <li>■ DD-723-B (JP) (Perflubutane / Contrast enhanced ultrasonography for breast tumor/ ultrasound contrast agent)</li> </ul>

◆ Change from the announcement in October 2011

□New

□Change of Stage

AMG 162(Giant cell tumor of bone/anti-RANKL antibody/JP), DS-7250(Anti-diabetes), ARQ 092(AKT inhibitor/US)  
 AMG 162(Bone metastases of cancer / anti-RANKL antibody / JP / Approved), DD-723-B(Contrast ultrasonography for breast tumor/  
 ultrasound contrast agent /JP/ Application) , DS-5565(Chronic pain /  $\alpha 2\delta$  ligand / US/JP / P2)

## Edoxaban

Study

ENGAGE AF-TIMI 48 (21,000+ patients, Global Ph3)

Indication

Atrial Fibrillation (prevention of stroke and systemic embolic events in patients with AF)

Schedule

Study to be completed by end of FY2012

Study

HOKUSAI VTE (7,500 patients, Global Ph3)

Indication

Venous Thromboembolism (treatment and prevention of recurrent VTE)

Schedule

Enrollment to be completed by end of FY2012

## Prasugrel

Study

TRILOGY ACS (10,000 patients, Global Ph3)

Indication

ACS-MM (medically managed patients with acute coronary syndrome)

Schedule

Study to be completed this spring, results expected in H2 CY2012

Other Indication

Japan domestic Ph3 trials underway on;

- Elective percutaneous coronary intervention (PCI) patients
- ACS patients who have undergone PCI
- Patients with ischemic cerebrovascular disease

## Denosumab

Indication

Osteoporosis

Status

Pivotal evaluation period of Ph3 completed  
Japanese NDA under preparation

Other Indication

- Adjuvant treatment for women with early-stage breast cancer (Global Ph3)
- Rheumatoid arthritis (Ph2 ongoing in Japan)
- Giant cell tumor of bone (Ph2 ongoing in Japan)







## Contact address regarding this material

Daiichi Sankyo Co., Ltd.  
Corporate Communications Department

TEL: +81-3-6225-1126

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