

Passion for Innovation.  
Compassion for Patients.™



# Top Management Presentation

## Financial Results of Fiscal Year 2013

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# Overview of FY2013 Results

## IFRS

JPY Bn

	FY2012 Results	FY2013 Results	YoY
Revenue	994.7	1118.2	+12.4% +123.6
Cost of Sales	338.5	402.3	+63.8
R&D Expenses	184.4	191.2	+6.8
SG&A Expenses	373.0	413.2	+40.2
Operating Income	98.7	111.6	+13.0% +12.8
Income before income taxes	95.9	99.8	+3.9
Net income (Owners of the company)	64.0	60.9	-4.8% -3.1

Dividend per share	60 yen	60 yen
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Currency Rate	USD/JPY (average)	83.11	100.24
	EUR/JPY (average)	107.15	134.38
	INR/JPY (Average)	1.50	1.68

## Reference\* : J-GAAP

JPY Bn

	FY2012 Results	FY2013 Results
Net Sales	997.9	1,118.8
Cost of Sales	313.7	375.5
SG&A Expenses	583.7	627.3
R&D Expenses	183.0	189.7
Other Expenses	400.6	437.6
Operating Income	100.5	115.9
Ordinary Income	99.1	105.0
Income before income taxes	92.1	109.3
Net Income	66.6	65.7

\*Non audit for FY2013 results on J-GAAP

# FY2013 Results

-Reference\*: GAAP variance-

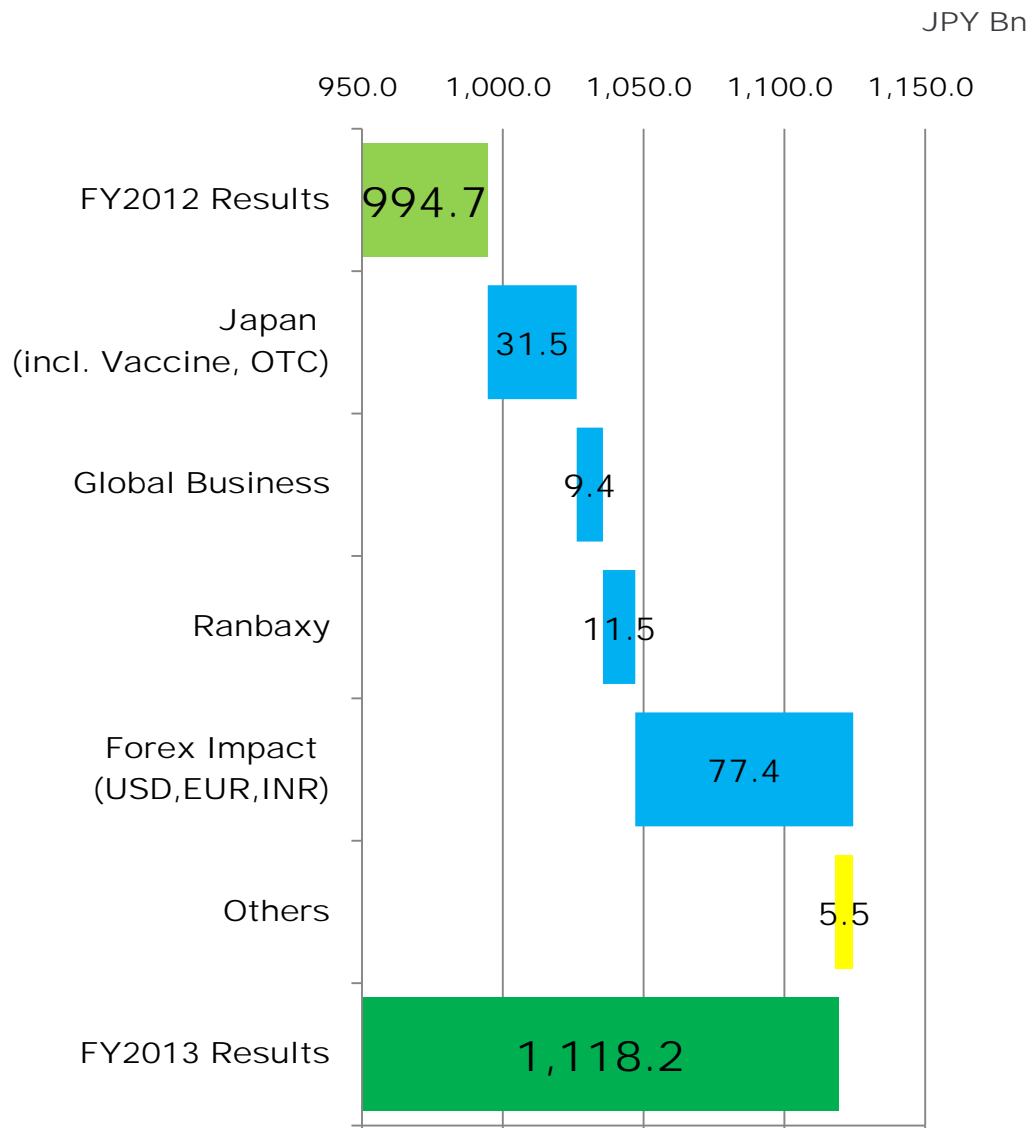


JPY Bn

	IFRS	J-GAAP	variance	Main Reasons
Revenue	1,118.2	1,118.8	-0.5	Provision for sales returns -0.5
Cost of Sales	402.3	375.5	+26.8	Transfer from SG&A expenses +16.3 (Amortization for Non-current assets+8.0, Transfer of Royalty+8.3) Transfer from Non-operating income/expenses, Extraordinary income/losses +7.8
R&D Expenses	191.2	189.7	+1.5	Transfer to Cost of sales -16.3
SG&A Expenses	413.2	437.6	-24.4	Transfer from Non-operating income/expenses, Extraordinary income/losses +4.6 Non-amortization of goodwill -7.6
Operating Income	111.6	115.9	-4.4	Transfer from Non-operating income/expenses, Extraordinary income/losses -12.6 Non-amortization of goodwill +7.6
Income before income taxes	99.8	109.3	-9.5	Transfer sale of investment securities gains to comprehensive income -16.4 Non-amortization of goodwill +7.6
Net income (Owners of the company)	60.9	65.7	-4.7	

\*Non audit for FY2013 results on J-GAAP

# FY2013 Revenue



Positive Factors

Negative Factors

## Japan

- + : Nexium +32.7 , Memary +9.5, Ranmark +3.6  
Olmotec/Rezaltas +2.3
- : Mevalotin -4.3, Cravit -2.4, Calblock -2.0

## Global business

- Daiichi Sankyo Inc. (DSI) ± 0
  - Luitpold Pharmaceuticals, Inc. (LPI) -5.8
  - Daiichi Sankyo Europe GmbH (DSE) +2.5
  - Asia, South and Central America (ASCA) +12.6\*
- \*including currency impact

## Ranbaxy (RLL)

15month financial period (An additional Qtr.) +415

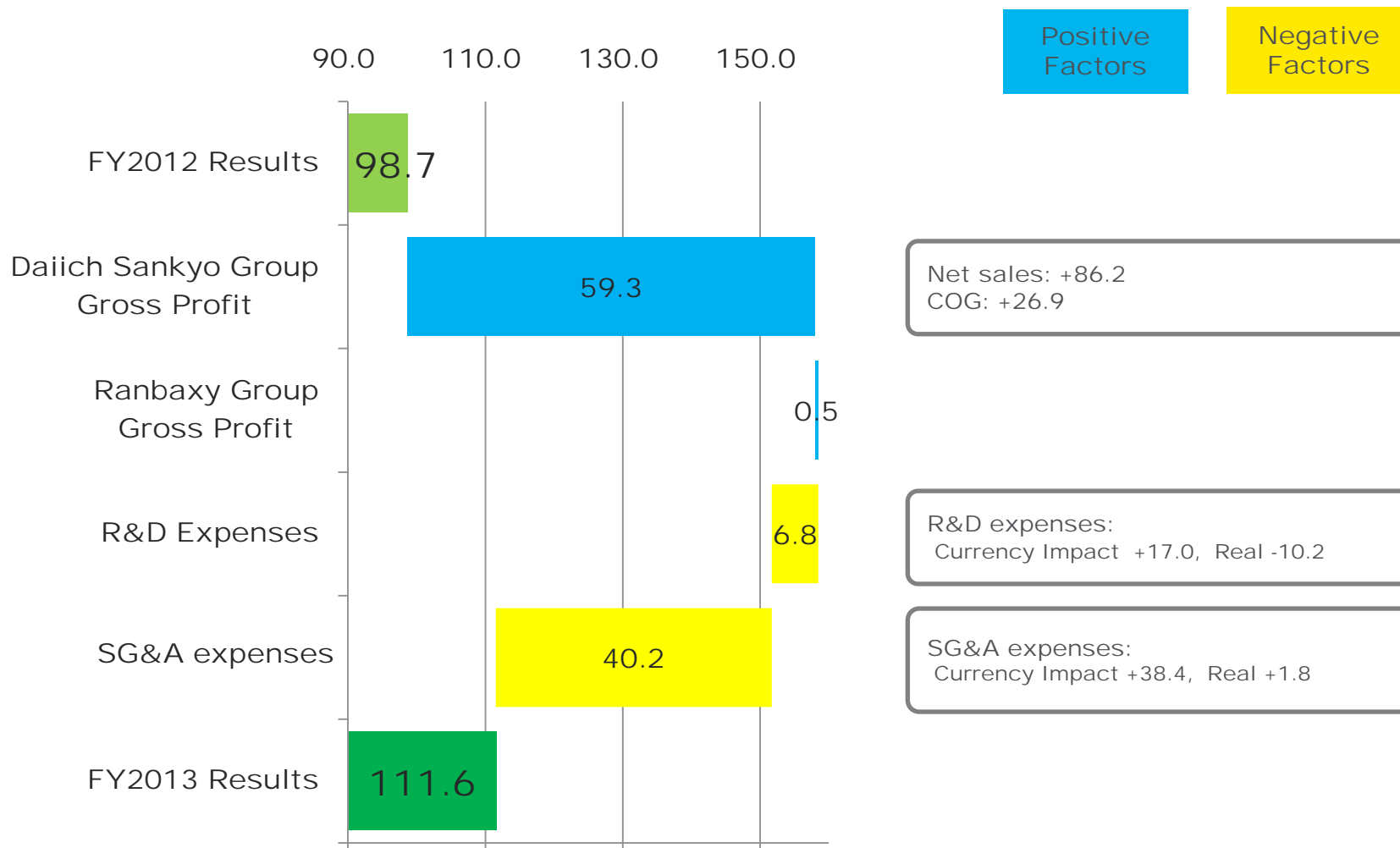
## Currency Impact

USD: +37.6 EUR: +16.1 INR: +23.6

Currency Rate	FY2012 Results	FY2013 Results
	USD/JPY	83.11
EUR/JPY	107.15	134.38
INR/JPY	1.50	1.68

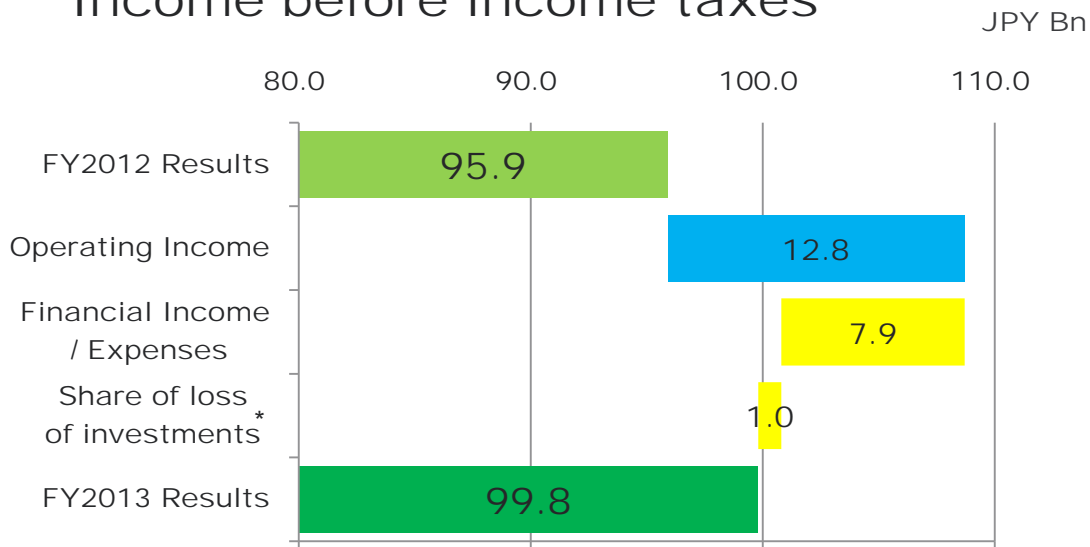
# FY2013 Operating Income

JPY Bn



# FY2013 Income / Net Income

## Income before income taxes



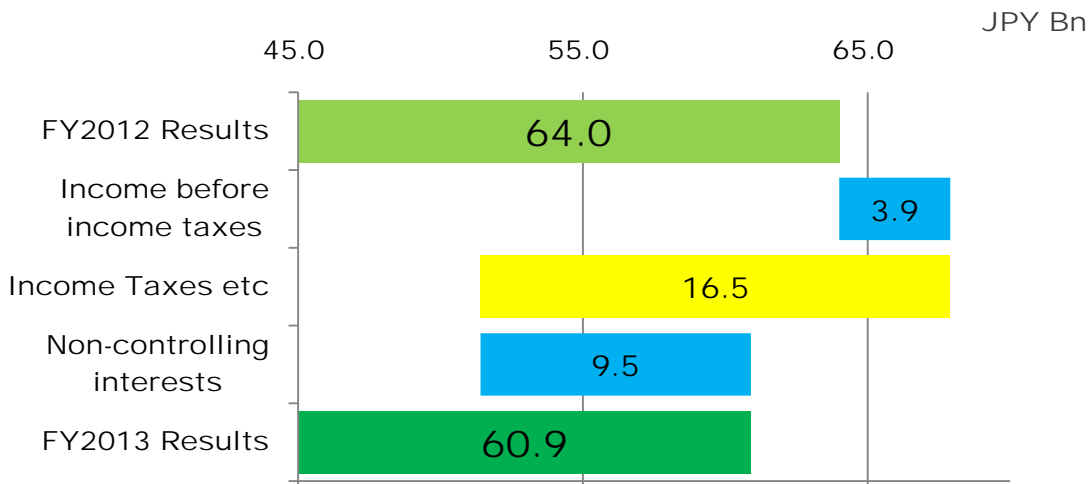
Positive Factors

Negative Factors

RLL: derivatives losses and higher finance cost etc.

\*Share of loss of investments accounted for using the equity method

## Net Income (Owners of the company)



### Income Taxes:

- Effective tax rate: 31.2% → 46.5%
- Non-application of R&D tax credit following the tax loss carried forward after the tax write-off of edoxaban clinical study expenses
- DTA reversal due to expiration of the special corporation tax

# Forecast of FY2014

- Daiichi Sankyo Group only -

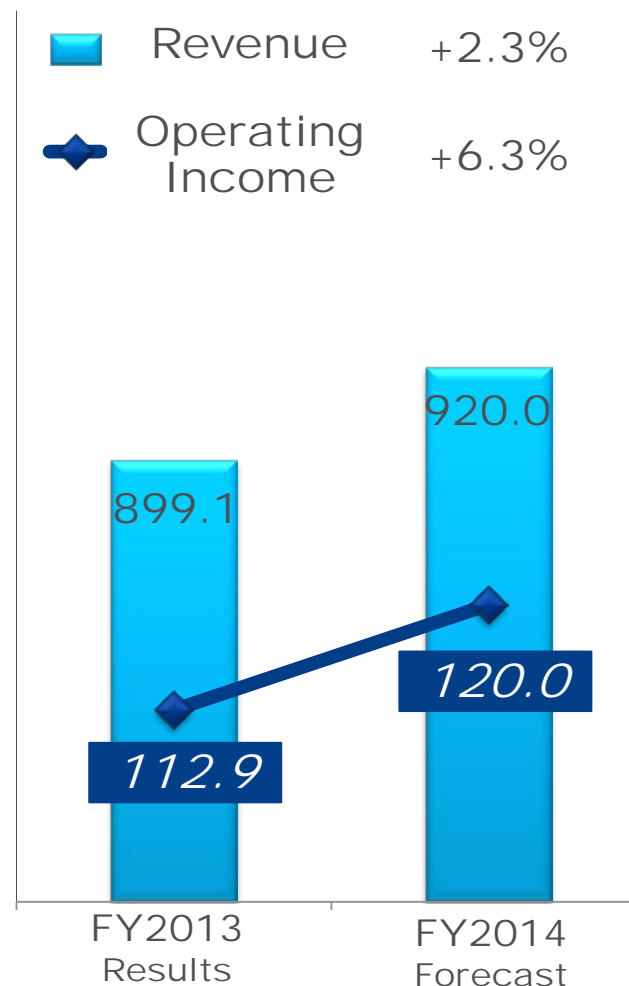


JPY Bn

	FY2013 Results	FY2014 Forecast	YoY
Revenue	899.1	920.0	+20.9 +2.3%
Cost of Sales	282.9	285.0	+2.1
R&D Expenses	180.7	182.0	+1.3
Other Expenses	322.7	333.0	+10.3
Operating Income	112.9	120.0	+7.1 +6.3%
Income before income tax	112.9	120.0	+7.1
Net income (attributable to owners)	68.8	78.0	+9.2 +13.3%

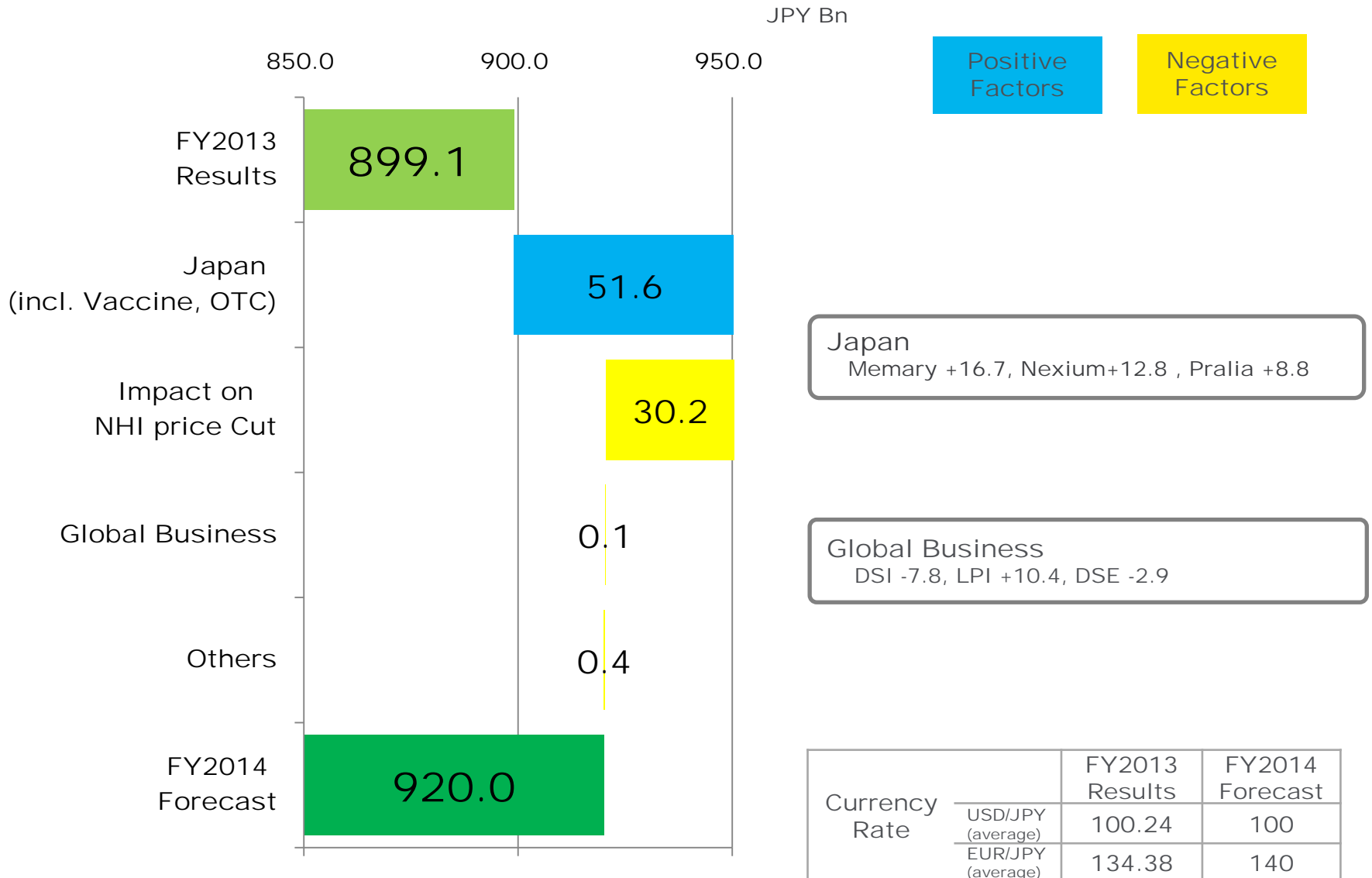
Dividend per share	60 yen	60 yen
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Currency Rate	USD/JPY (average)	100.24	100
	EUR/JPY (average)	134.38	140



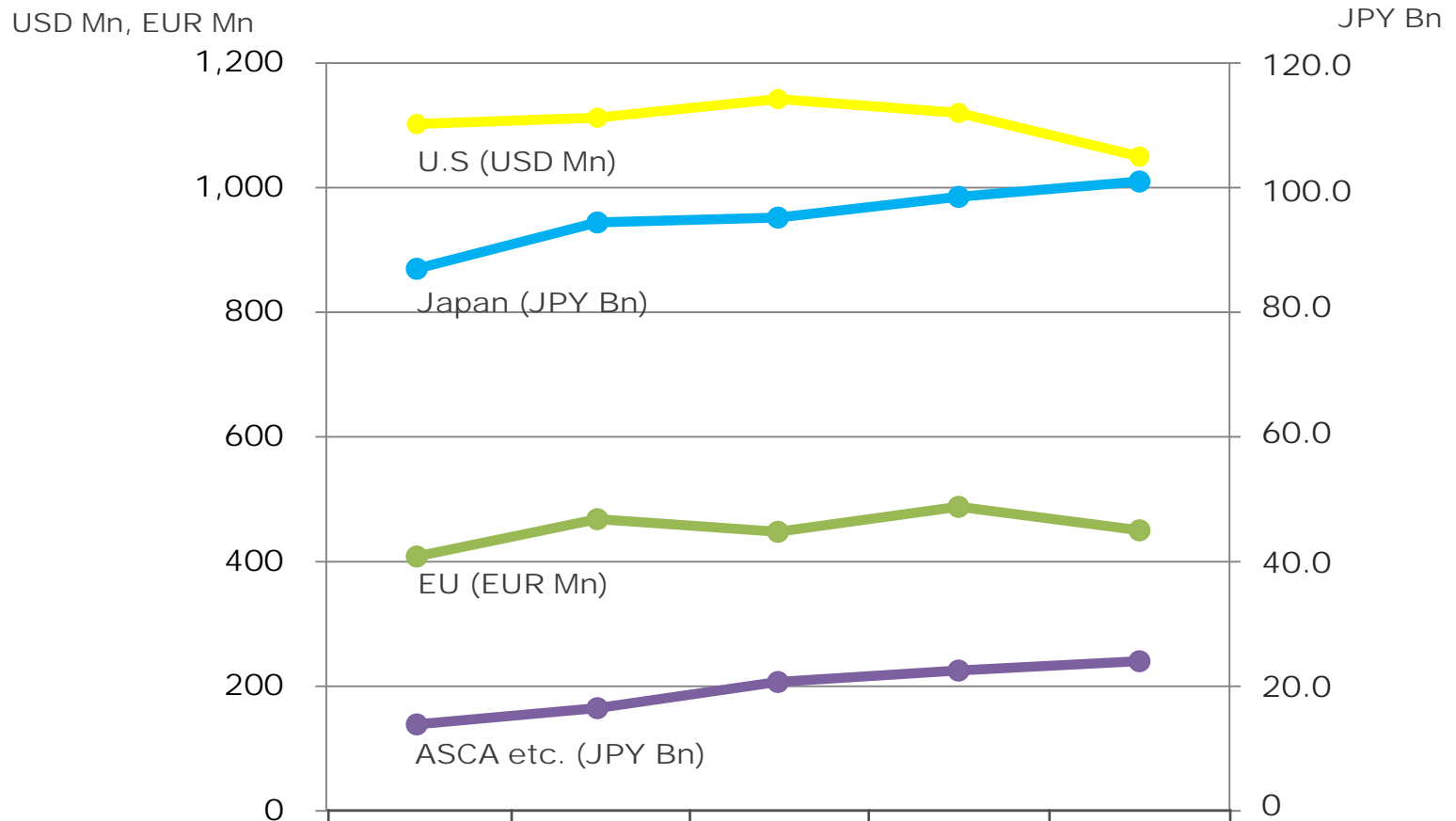
Figures do not include Ranbaxy, which will not be consolidated, post its merger with Sun Pharma.

# FY2014 Revenue Forecast





# Sales of Olmesartan (Local Currency Basis)



	FY2010 Results	FY2011 Results	FY2012 Results	FY2013 Results	FY2014 Plan
Japan (JPY Bn)	87.0	94.4	95.2	97.6	101.0
U.S. (USD Mn)	110.2	111.2	114.2	112.0	105.0
EU (EUR Mn)	40.8	46.8	44.8	48.8	45.0
ASCA etc.(JPY Bn)	13.9	16.5	20.7	24.7	24.0

Breakdown for Olmesartan

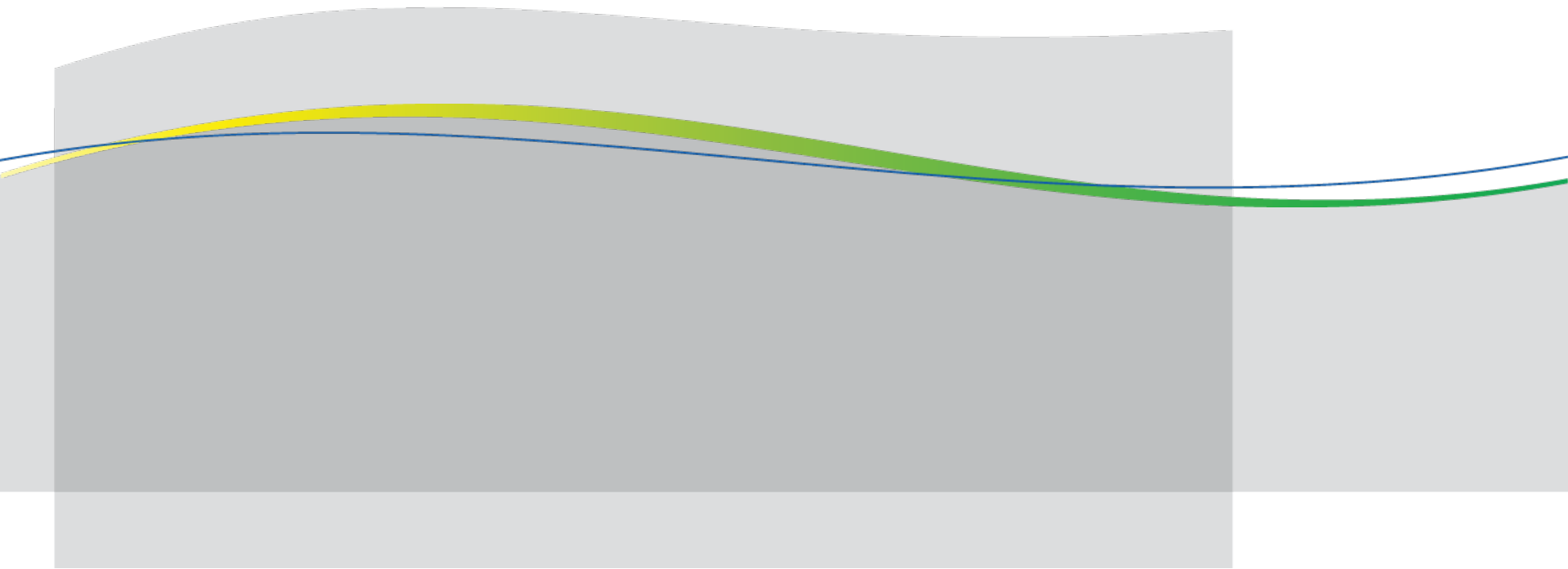
Japan: Olmetec, Rezaltas

U.S.: Benicar, Benicar HCT, Azor, Tribenzor

Europe: Olmetec, Olmetec Plus, Sevikar, Sevikar HCT

- ◆ Target Revenue growth and higher profits
  - Revenue : JPY 920 Bn (*YoY + 2.3%*)
  - Op. Income : JPY 120 Bn (*YoY + 6.3%*)
  
- ◆ Maximize full potential of global products
  - Olmesartan: Maintain sales at JPY 300 Bn level
  - Prasugrel : Japan launch and expansion in existing markets
  - Edoxaban : Secure NDA approval and launch
  
- ◆ Focused regional strategy
  - Japan: Expanded market share through new products
  - LPI: Injectafer to bring back sales growth
  
- ◆ Ramp up efforts on improving profitability
  - Drive structural reform to optimize business operation

# Target at Japan business



- ◆ Aim to become the standard antiplatelet therapy in Japan
  - Prevent MACE\* earlier after treatment
  - Similar safety profile with Clopidogrel
  - More stable reduction of platelet aggregation activities

\* Major Adverse Cardiovascular Events

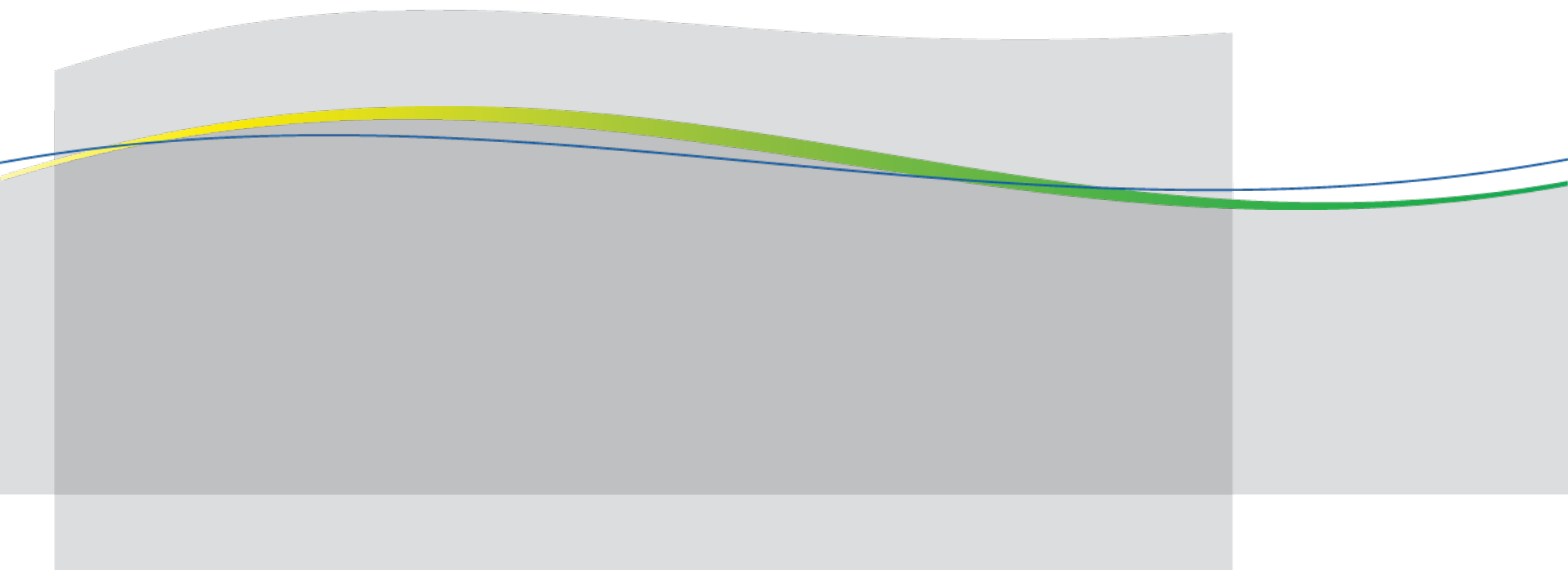
- ◆ Japanese Anti-platelet market
  - Over JPY 180 billion scale (*NHI price basis*)
  - Expanded over 30% in last five years
  - Clopidogrel, market leader with over 60% market share

# Major Products in Japan

JPY Bn

		FY2012 Results	FY2013 Results	FY2014 Plan
Olmetec	anti-hypertension	78.3	79.1	79.0
Rezaltas	anti-hypertension	16.9	18.5	22.0
Loxonin	analgesic and anti-inflammatory	59.6	59.3	52.0
Cravit	antibacterial	35.9	33.5	29.0
Nexium	anti-ulcer (Proton Pump Inhibitor)	21.6	54.2	67.0
Memary	treatment for Alzheimer	23.8	33.3	50.0
Artist	anti-hypertension	25.8	21.5	17.0
Mevalotin	anti-hyperlipidemia	22.4	22.4	21.0
Omnipaque	contrast medium	20.2	19.7	15.0
Urief	treatment for dysuria	11.1	11.4	10.0
Inavir	anti-influenza	11.1	13.4	10.0
Ranmark	treatment for bone metastasis	4.4	8.1	10.0
Pralia	osteoporosis	-	3.2	12.0

# Target at US / EU affiliates



## FY 2013 (Results)

- Olmesartan maintained its market share in ARB segment
- Effient and Welchol grew

## FY 2014 (Target)

- Protect Olmesartan and Effient sales
- Welchol loss of Exclusivity
- Successful Edoxaban launch and smooth market dissemination
- Look for in-organic growth opportunities

## FY 2013 (Results)

- Olmesartan sales grew
- Increasing competition impacted Efient growth
- Optimized sales force to tune with changing environment

## FY 2014 (Target)

- Protect Olmesartan and Efient sales
- Successful Edoxaban launch and smooth market dissemination
- Secure the new marketing model, "Access model"



## FY 2013 (Results)

- Successful Injectafer launch and smooth market dissemination
- Optimized manufacturing at Shirley, while undergoing GMP remediation process

## FY 2014 (Target)

- Injectafer rapid growth
- Maintain Venofer solid position
- Back to full scale manufacturing at Shirley and start manufacturing at New Ohio facility\*

\* Subject to successful USFDA inspection

# Injectafer

- New treatment option -

## ◆ Market leading potential

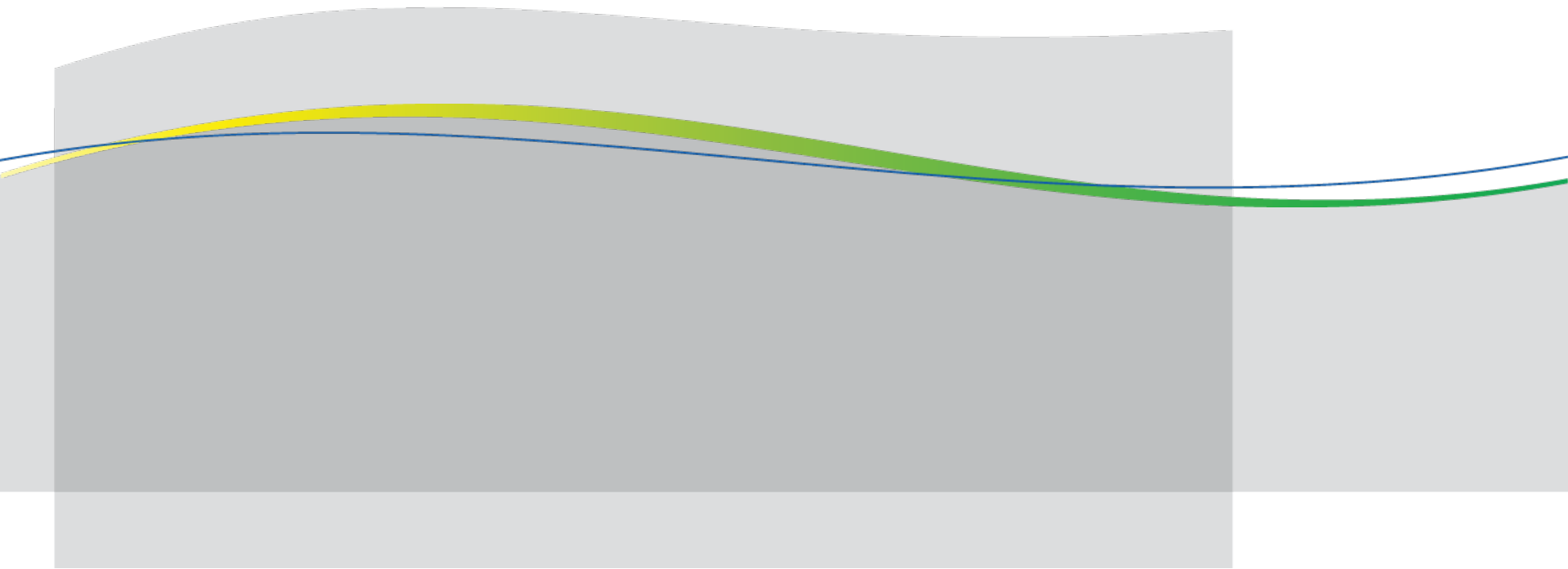
- Broader Indication
- Superior anemia improvement compare to oral iron
- Highest FDA approved IV iron dose
- Fast infusion time(minimum 15 minutes)



## ◆ Iron IV Market for IDA

- Dialysis market: Mature
- Non-dialysis market: Expected huge potential
  - Unmet needs
  - Expecting double digit annual growth by expanding into GI, Hem/Onc, and Women's health area

# Edoxaban Marketing Strategy



## ◆ Market characteristics

- NOAC sales growing rapidly
- Warfarin volume still significant
- Current market leader: Rivaroxaban
- Mature markets, such as Japan, US and Europe, driving the NOAC market growth

## ◆ Required capabilities

- “Quality” over “Quantity”
- Multiple stakeholder interactions
- Consistent brand strategies and quick decision making

# Edoxaban: Competitive advantage

- ◆ Unique combination of both once-daily convenience and superior safety
- ◆ Patient specific dosing based on patients' condition
- ◆ Results from the largest single comparative studies in SPAF and VTE with very high quality
  - ENGAGE AF-TIMI 48 (n=21,105, 2.8 year follow up)
  - Hokusai-VTE (n=8,292, 12 month follow up)
  - Non-inferior in efficacy and superior in safety compared to well-managed warfarin
- ◆ Accumulated safety data from more than 150,000 DVT-OS patients post launch of Lixiana in Japan

- ◆ Strong presence in cardiovascular and thrombosis areas through Olmesartan and Prasugrel
- ◆ High-quality commercial capabilities in Japan, US and Europe
  - ✓ Japan: Top class commercial capabilities
  - ✓ US and EU: Shift of business model to the "Access Model"

## □ Japan, US and Europe



- No global partnering
- Maintain consistent brand strategies and quick decision making

## □ Other regions and countries

- Optimize business model through adequate partnering in each country or region

# Edoxaban

## Global NDA / Launch Schedule

Target Indications	FY2014		FY2015 ~	
	Apr-Sep	Oct-Mar		
Prevention of stroke and systemic embolic events in patients with atrial fibrillation 	NDA filing <u>JPN</u> Dec/2013	Authority's Review →	Approval Launch JP,US,EU	Launch EU, Asia, Latin America & others
Acute treatment and long-term prevention of thromboembolic event in patient with DVT*/PE** 	<u>US/EU</u> Jan/2014	Authority's Review →	Approval Launch JP,US,EU	Launch EU, Asia, Latin America & others

\*DVT : Deep Vein Thrombosis  
 \*\*PE : Pulmonary Embolism



- ◆ Growth in Sales and Operating Income
  - Sales Target: JPY 920 Bn (*YoY + 2.3%*)
  - Operating Income Target: JPY 120 Bn (*YoY + 6.3%*)
- ◆ Edoxaban successful launch and smooth market dissemination
- ◆ Market share expansion in Japan
- ◆ Injectafer rapid expanding

# Major R&D Pipeline

As of May 2014



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	<ul style="list-style-type: none"> <li>■ DS-7309 (Diabetes / Glucokinase activator)</li> <li>■ DS-8500 (Diabetes / GPR119 agonist)</li> <li>■ DS-1442 (Dyslipidemia / CETP inhibitor)</li> <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> </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>■ <b>Prasugrel (JP)</b> (CS-747 / PCI / anti-platelet agent)</li> <li>■ Edoxaban (US/EU /JP) (DU-176b / AF / oral factor Xa inhibitor)</li> <li>■ Edoxaban (US/EU /JP) (DU-176b / VTE / oral factor Xa inhibitor)</li> </ul>
Oncology	<ul style="list-style-type: none"> <li>■ U3-1565 (US/JP) (Anti-HB-EGF antibody)</li> <li>■ DS-2248 (US) (HSP90 inhibitor)</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> </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> </ul>	<ul style="list-style-type: none"> <li>■ Denosumab (JP) (AMG 162 / Giant Cell tumor / anti-RANKL antibody)</li> </ul>
Others	<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 obstipation/GPR 38 agonist)</li> <li>■ DS-1971 (Chronic pain)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Mirogabalin (Global)</b> (DS-5565 / <b>Chronic pain</b> / <b>α2δ ligand</b>)</li> <li>■ SUN13837 (US/EU) (Spinal cord injury / Modulator of bFGF signaling system)</li> <li>■ Laninamivir (US/EU) (CS-8958 / anti-influenza / Outlicensing with Biota)</li> <li>■ Ioforninol (JP) (GE-145/X-ray contrast media/Angiography)</li> </ul>	<ul style="list-style-type: none"> <li>■ Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone)</li> <li>■ Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body)</li> <li>■ Hydromorphone (DS-7113 / Narcotic analgesic / opioid mu-receptor regulator)</li> </ul>	

- Prasugrel : Approved in Mar 2013 and to be launched in May in Japan
- Mirogabalin :Plan to be presented its P2 results at ADA in Jun 2014 (DS-5565) Plan to be started P3 study in FY2014

## Contact address regarding this material

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