

Mitsubishi Tanabe Pharma Corporation

# FY2013 Business Results

## (April, 2013 – March, 2014)

May 9<sup>th</sup>, 2014

**Michihiro Tsuchiya**  
President and CEO



Mitsubishi Tanabe Pharma

# FY2013 Business Results

# Overview of FY2013 Business Results

**Net sales**

¥ 412.7 billion

-1.6%, year-on-year

**Operating income**

¥ 59.1 billion

-14.3%, year-on-year

**Net income**

¥ 45.4 billion

+8.4%, year-on-year

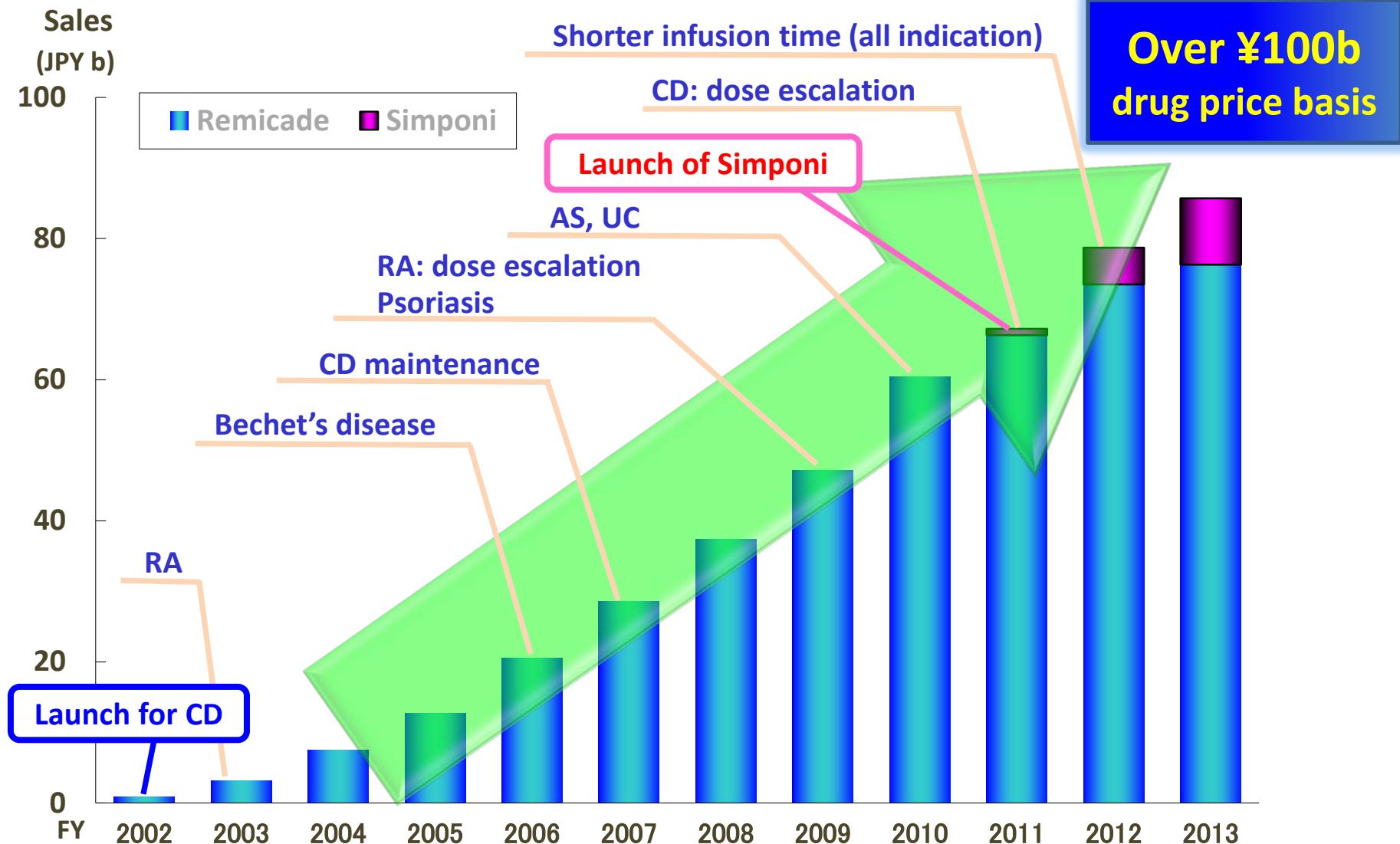
**Topics**

- Achieved a record net income for 6 fiscal years straight since the Company has started
- Sales of Remicade and Simponi: Pass a total of ¥100 b, drug price basis
- Royalty income of Gilenya: ¥32.2 b, 64.8% up, y/y
- INVOKANA: Favorable penetration in US, launched in Europe
- Strengthens vaccine business: Acquisition of Medicago in Sep.
- Reorganizes domestic production bases: Transferred Ashikaga plant to CMIC
- Development pipeline: Filed TA-7284 in Japan(May), participated multinational study of MT-4666 (Feb.)
- Reduction of Remicade purchase price : ¥11.0 b of extraordinary income as a result of arbitration award

# Growth Remicade and Simponi

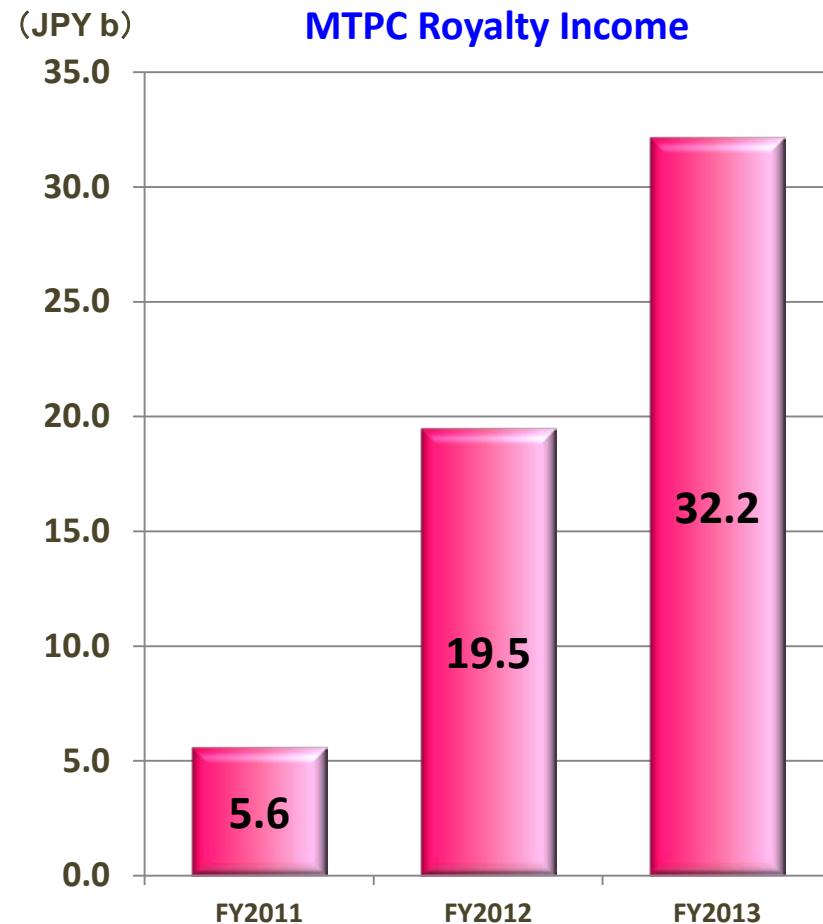
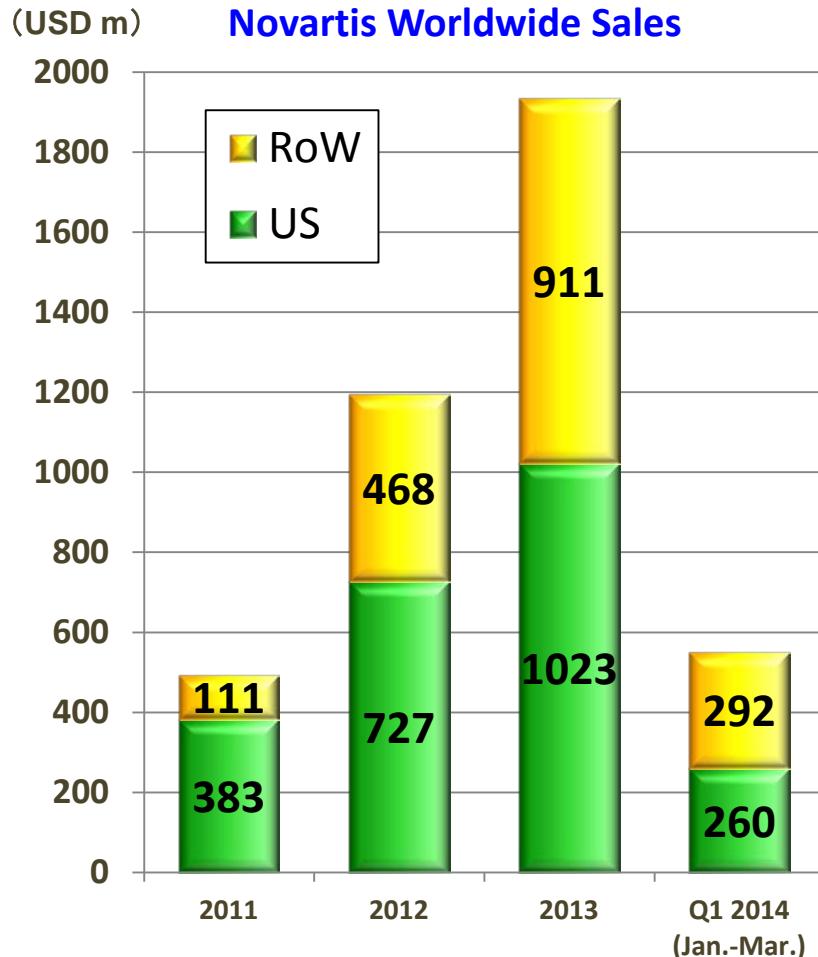
## 【Overview of FY2013 Business Results】

New Value Creation



## 【Overview of FY2013 Business Results】

- Big growth in countries other than US in 2013
- Novartis worldwide sales in Jan.- Mar., 2014: \$552 m (31% up, y/y)
- MTPC royalty income: ¥32.2 b (64.8% up, y/y)



# FY2013 Financial Results

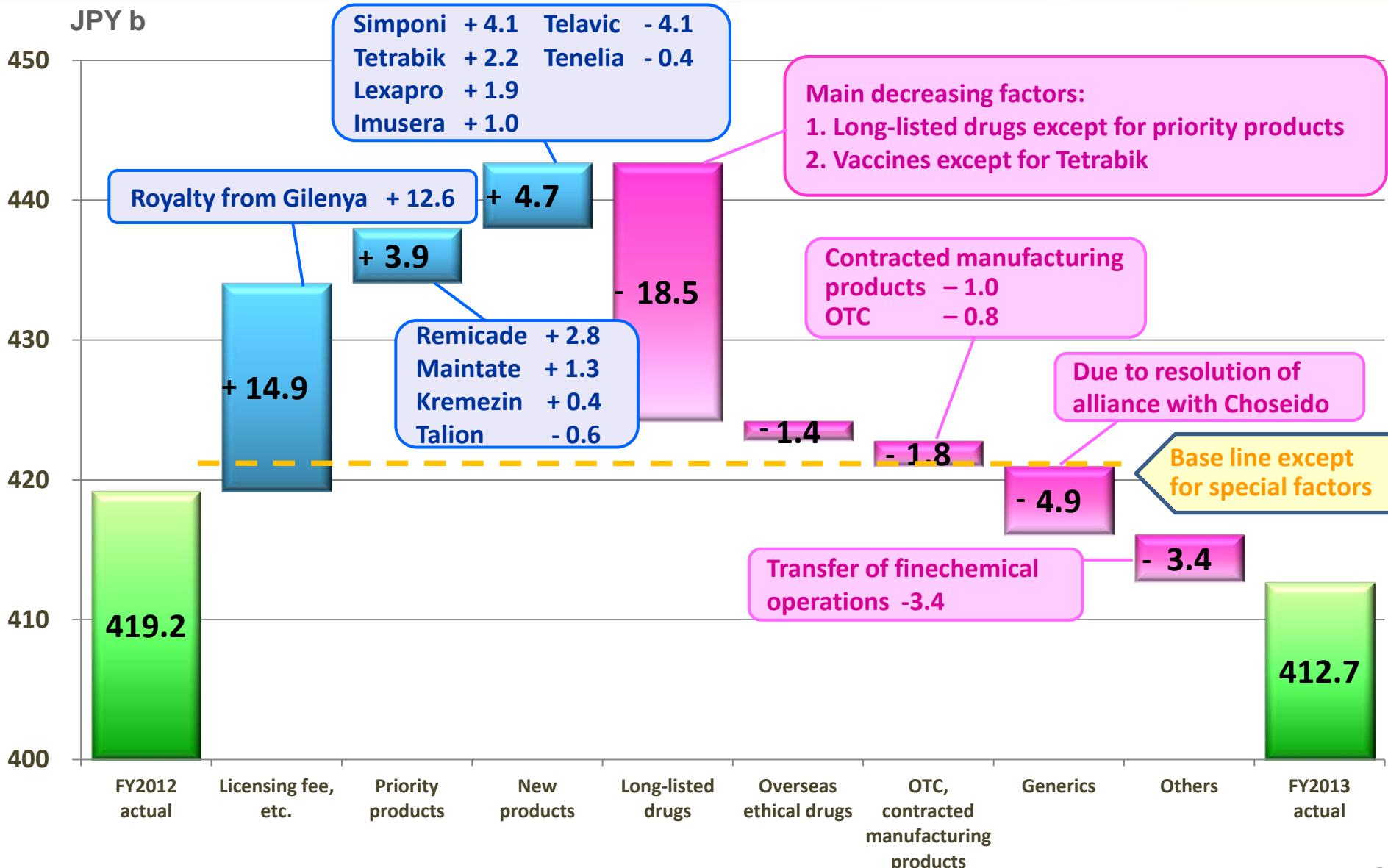
	FY2013	FY2012	Increase/decrease		Full-year forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Net sales	412.7	419.2	-6.5	-1.6	419.0	98.5
Cost of sales	169.4	166.4	+3.0	+1.8	170.0	99.6
Sales cost ratio	41.0%	39.7%			40.6%	
Gross operation profit	243.3	252.8	-9.5	-3.7	249.0	97.7
SG&A	184.2	183.8	+0.4	+0.2	186.0	99.0
Operating income	59.1	69.0	-9.8	-14.3	63.0	93.8
Ordinary income	61.9	69.4	-7.5	-10.8	65.5	94.5
Net income	45.4	41.9	+3.5	+8.4	45.0	100.9

\*: Published forecasts announced on October 30, 2013 in the financial results for Q2 FY2013.

# Sales Trends (year-on-year)

New Value Creation

## FY2013 Financial Results



# Sales Trends (Comparison with forecasts)

[FY2013 Financial Results]

New Value Creation



Mitsubishi Tanabe Pharma

JPY b

425

420

415

410

405

FY2013  
forecasts

Licensing  
fee, etc.

Priority  
products

New  
products

Long-listed  
drugs, etc.

Overseas  
ethical  
drugs

Generics

Others

FY2013  
actual

419.0

+4.3

-5.8

Remicade -2.7  
Talion -1.9  
Maintate -0.8  
Kremezin -0.4

-7.2

Tenelia -2.4  
Tetrabik -1.7  
Lexapro -1.1  
Tetrabik -1.1  
Simponi -0.8  
Imusera -0.1

+0.3

+1.7

+0.0

+0.4

412.7

# Cost of Sales/SG&A Expenses

New Value Creation

【FY2013 Financial Results】



	FY2013	FY2012	Increase/decrease		Full year forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Net sales	412.7	419.2	-6.5	-1.6	419.0	98.5
Cost of sales	169.4	166.4	+3.0	+1.8	170.0	99.6
Sales cost ratio	41.0%	39.7%			40.6%	
Gross operation profit	243.3	252.8	-9.5	-3.7	249.0	97.7
SG&A	184.2	183.8	+0.4	+0.2	186.0	99.0
R&D expenses	70.4	66.5	+3.9	+5.8	71.0	99.2
Labor cost	48.4	51.9	-3.5	-6.8	48.3	100.1
Amortization of goodwill	10.6	10.3	+0.3	+3.3	10.4	102.3
Others	54.8	55.1	-0.3	-0.6	56.3	97.3
Operating income	59.1	69.0	-9.8	-14.3	63.0	93.8

# Non-operating Income and Loss/ Extraordinary Income and Loss

**[FY2013 Financial Results]**

New Value Creation



	FY2013	FY2012	Increase/decrease		Full year forecasts	Achieved
			Billion yen	Billion yen		
Operating income	59.1	69.0	-9.8	-14.3	63.0	93.8
Non-operating income & loss	2.8	0.4	+2.3		65.5	94.5
Ordinary income	61.9	69.4	-7.5	-10.8		
Extraordinary income	15.3	4.2	+11.1			
Profit on arbitration award	11.0	-				
Gain on sales of property, plant and equipment	1.0	3.0				
Others	3.3	1.3				
Extraordinary loss	4.8	5.9	-1.2			
Special retirement expenses	2.6	-				
Impairment loss	1.4	0.8				
Loss on business integration	-	2.3				
Provision of reserve for HCV litigation	-	2.0				
Others	0.7	0.9				
Net income	45.4	41.9	+3.5	+8.4	45.0	100.9

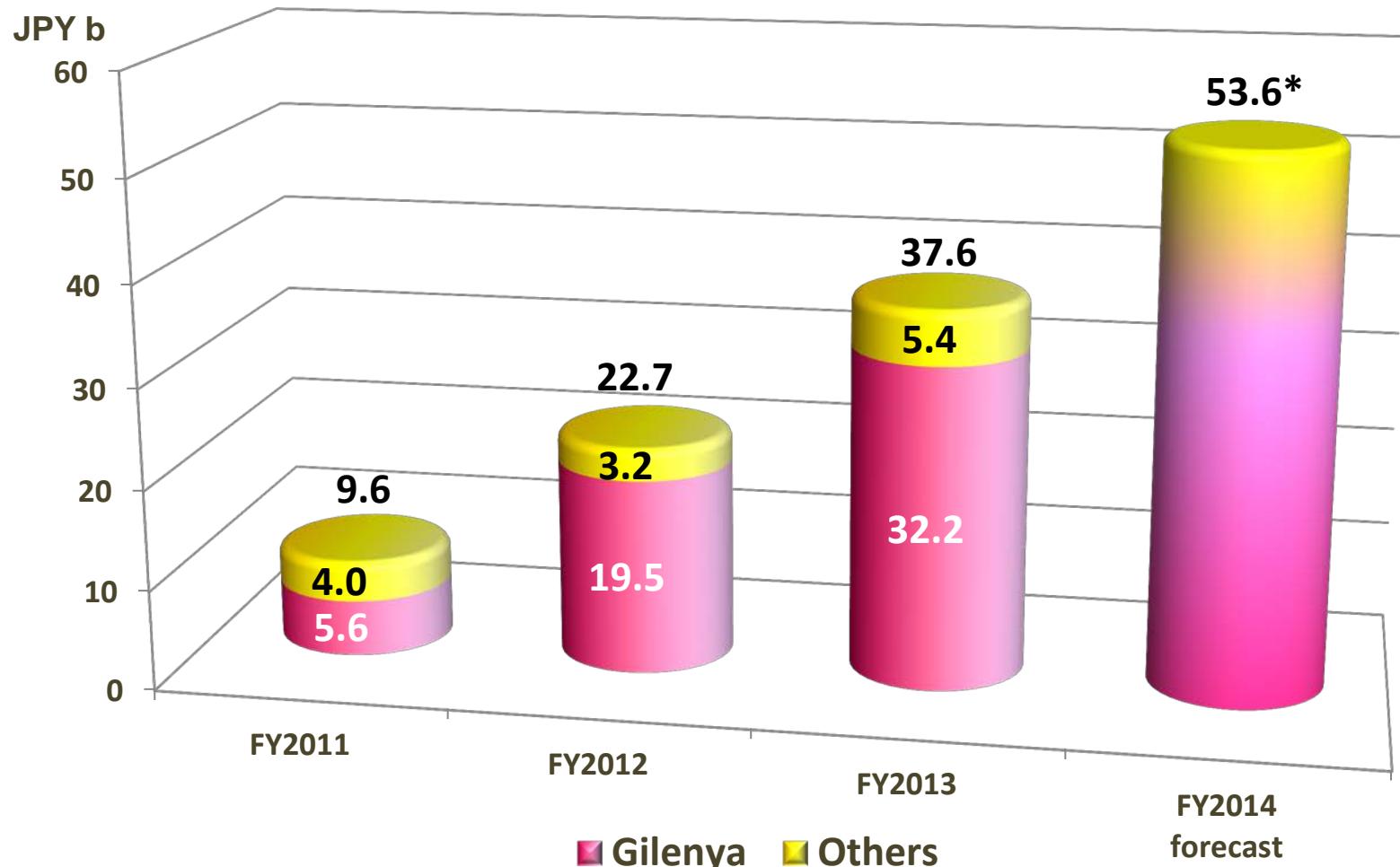
## Forecasts for FY2014 (Ending March 31, 2015)

# Licensing Fee, etc.

[Forecasts for FY2014]



Trends of Licensing Fee, etc.

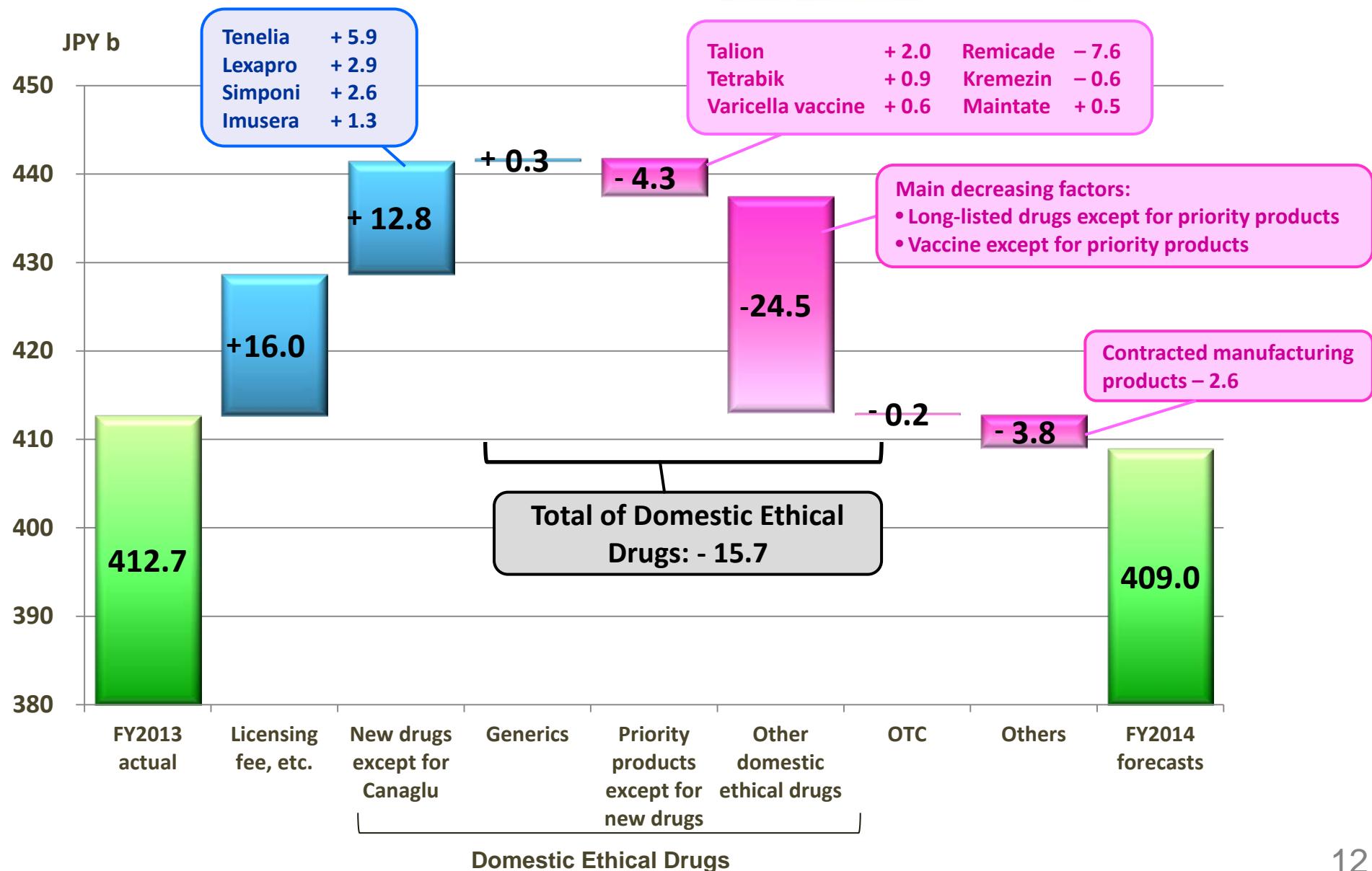


\* FY2014 forecasts: The amount of royalty income from Gilenya is not disclosed.

# Sales Trends

New Value Creation

[Forecasts for FY2014]



# Forecasts for FY2014

	FY2014 Forecast	FY2013 Actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Net sales	409.0	412.7	-3.7	-0.9
Cost of sales	161.5	169.4	-7.9	-4.6
Sales cost ratio	39.5%	41.0%		
Gross operation profit	247.5	243.3	+4.2	+1.7
SG&A	187.5	184.2	+3.3	+1.8
R&D expenses	73.0	70.4	+2.6	+3.7
Labor cost	47.0	48.4	-1.4	-2.8
Amortization of goodwill	10.8	10.6	+0.2	+1.5
Others	56.7	54.8	+1.9	+3.5
Operating income	60.0	59.1	+0.9	+1.5
Non-operating profit and loss	1.5	2.8	-1.3	
Ordinary income	61.5	61.9	-0.4	-0.6
Extraordinary income or loss	0.0	10.6	-10.6	
Net income	40.5	45.4	-4.9	-10.8

# Medium-Term Management Plan 11-15

# Challenges in FY2014

New Value Creation



## 1. Bolstering Our Ability to Discover New Drugs

- Strengthening Priority Disease Areas and Vaccine Business
- Expansion of TA-7284 (INVOKANA/Canaglu)

## 2. Advancing Domestic Operations Centered on New Products

- Strategy of Domestic Ethical Drugs Operations -Essential Features-
- Growth Centered on New Products
- Further Growth of Remicade and Simponi
- Growth Strategy in Diabetes Area
- Sales Strategy of Lexapro and Vaccine (Tetrabik and varicella vaccine)

## 3. Accelerating Operational and Structural Reforms

- Cost Cut by structural reform project (KKP)
- Reorganization of Domestic Production Sites
- Construction of New Pharmaceutical Production Building at Yoshitomi, China, and Indonesia

# Strengthening Priority Disease Areas and Vaccine Business

【Challenges in FY2014】

New Value Creation



**TA-7284 (T2DM)**

**FDC\* (TA-7284+Tenelia)**

**MT-3995 (Diabetic nephropathy)**

\*: Fixed dose combination

Tenelia  
Tanatril  
Kremezin  
BindRen

**Diabetes and  
Kidney Disease**

**MT-1303 (MS, etc.)  
Remicade  
(new indications)**

Remicade  
Simponi  
Imusera

**Autoimmune  
Disease**

**New!**

**Vaccine**

Tetrabik  
Influenza vaccine  
etc.

**Plant-based VLP vaccines  
Hib vaccine(Influenxa)**

**CNS Disease**

Lexapro

**MP-214( Schizophrenia)  
MT-4666(AD)**

# Expansion of TA-7284 (INVOKANA/Canaglu)

【Challenges in FY2014】

New Value Creation



Mitsubishi Tanabe Pharma

## Global Expansion

(Janssen Pharmaceuticals)

Mar. 2013  
Launched  
(US)

Feb. 2014  
Launched  
(EU)

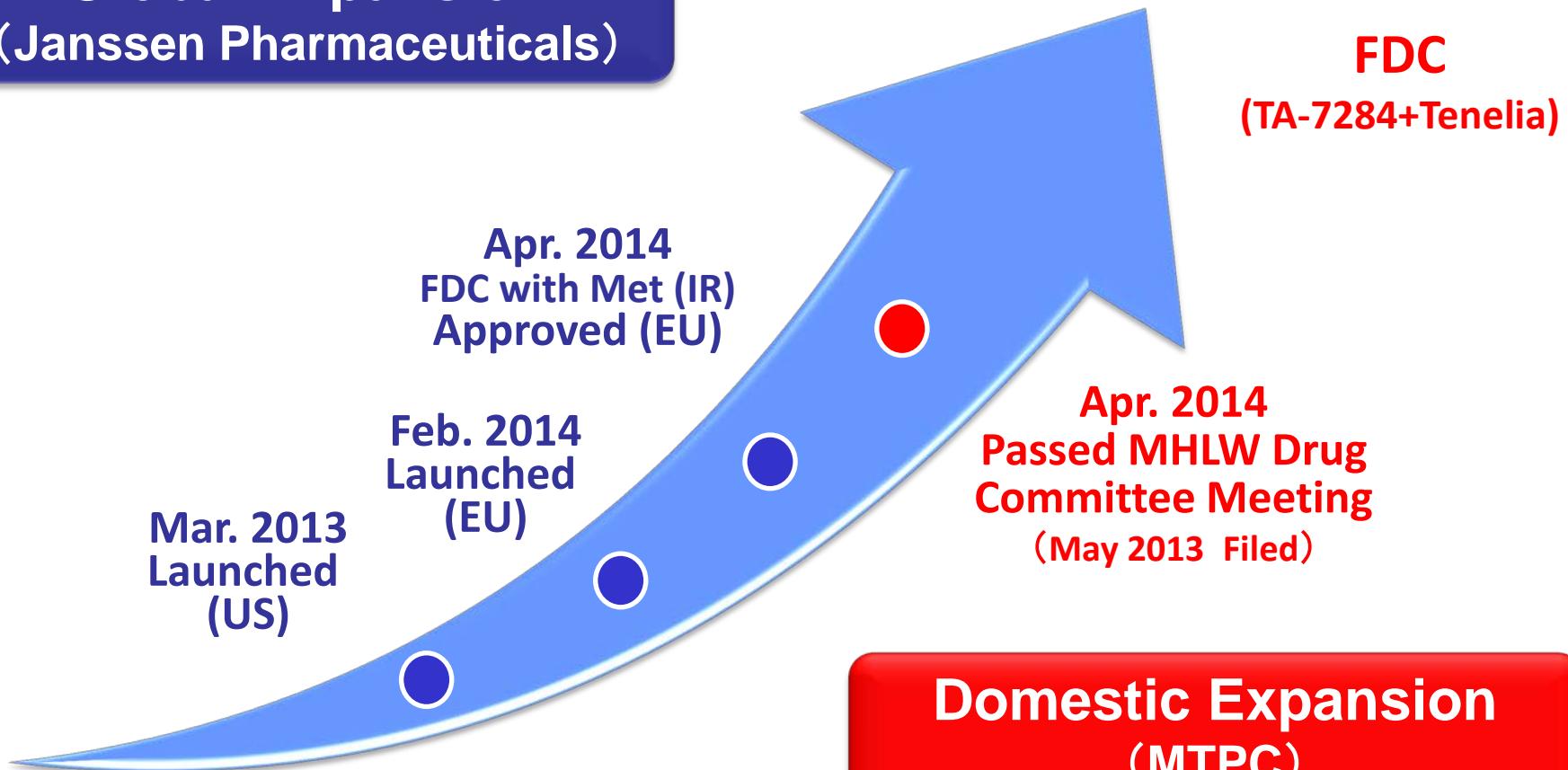
Apr. 2014  
FDC with Met (IR)  
Approved (EU)

Domestic Expansion  
(MTPC)

FDC with Met (XR/IR)  
Diabetic nephropathy

FDC

(TA-7284+Tenelia)



## -Essential Features-

## [Challenges in FY2014]



- Keep and expansion of priority products sales by post-marketing developments
- Strengthening of GE operation and approach to maintain earnings of the products except for priority products

### Priority Products

#### ■ New Products

Simponi, Lexapro, Tenelia, Imusera, Canaglu

#### ■ Vaccines

Tetrabik, varicella vaccine

#### ■ Existing Products

Remicade, Maintate, Talion, Kremezin

### Generics

### Long-listed Drugs

#### ■ Advancing LCM

- Acquisition of evidences
- Additional indication and dosage form

#### ■ Strengthening of sales forces by alliance

#### ■ Strengthening of marketing system

**Input operating resources maximally**

#### ■ Strategic Alliance

#### ■ Promotion without MR, etc.

# Growth centered on New Products

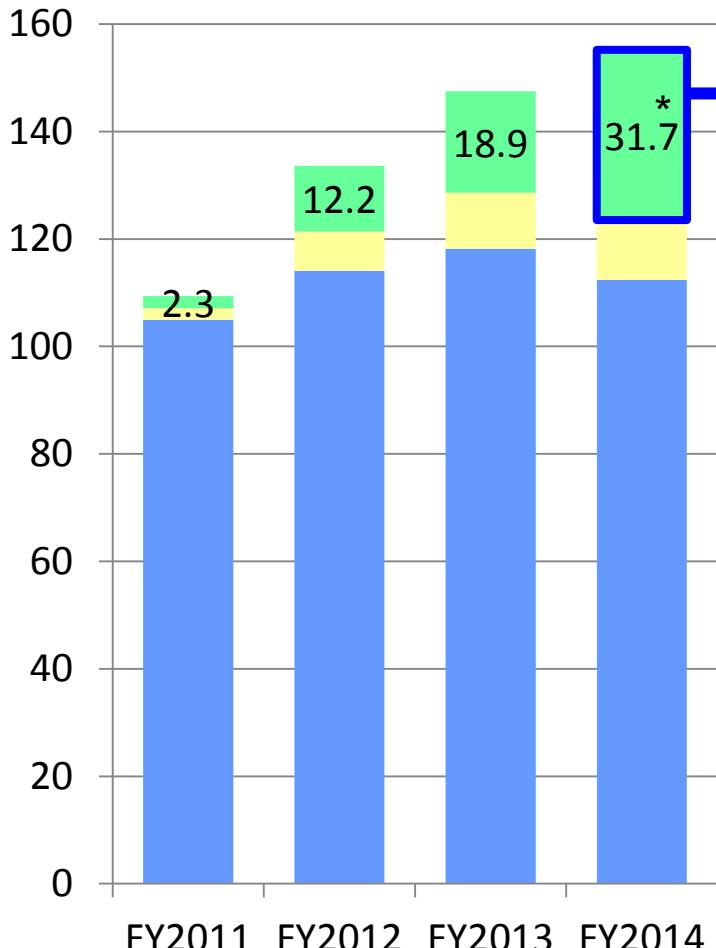
【Challenges in FY2014】

New Value Creation



## Sales Trends of Priority Products

JPY b  
■ Existing products ■ Vaccines  
■ New products



## Growth drivers

### New products

Simponi  
Lexapro  
Tenelia  
Imusera  
Canaglu

- Strengthening of marketing system (concentration of operating resources)

### Alliance

- Strengthening of the alliance with Daiichi Sankyo and Mochida Pharmaceutical

\*: Total sales of new products except for Canaglu

# Further Growth of Remicade and Simponi

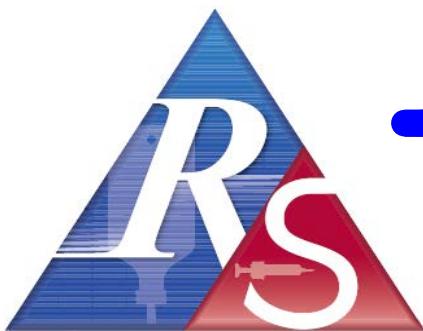
New Value Creation

## 【Challenges in FY2014】



Respond to various life styles of patients

- Adjustment of dosage in response to each symptoms
- Remicade: i.v., Simponi: s.c.



### Remicade

To patients, treatment holiday

To doctors, development of individualized medicine, a partner in RA therapy

Goal: Be in a permanent place as "standard drug in RA therapy"

2013 2014 2015 2016 2017 2018 2019 2020

### Simponi

No.2 position in s.c. biologics

No.1 position in s.c. biologics

Goal: Easy prescription, high effectiveness, standard s.c. biologics

2013 2014 2015 2016 2017 2018 2019 2020

## Turning point for sales expansion of Tenelia

This slide is only projected at the meeting.  
Handout is not available.

# Growth Strategy in Diabetes Area

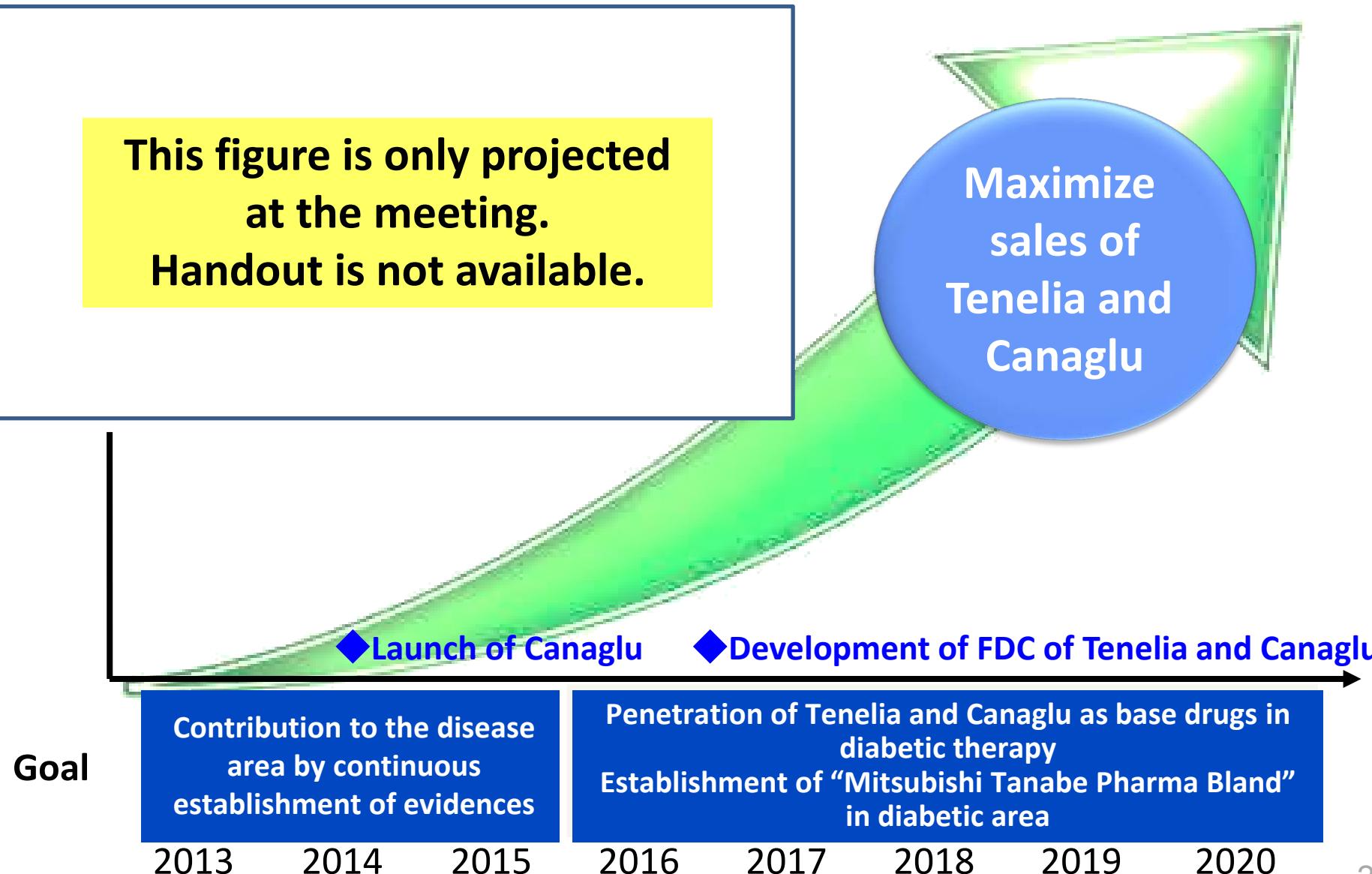
New Value Creation

【Challenges in FY2014】



This figure is only projected  
at the meeting.  
Handout is not available.

Maximize  
sales of  
Tenelia and  
Canaglu



# Sales Strategy of Lexapro

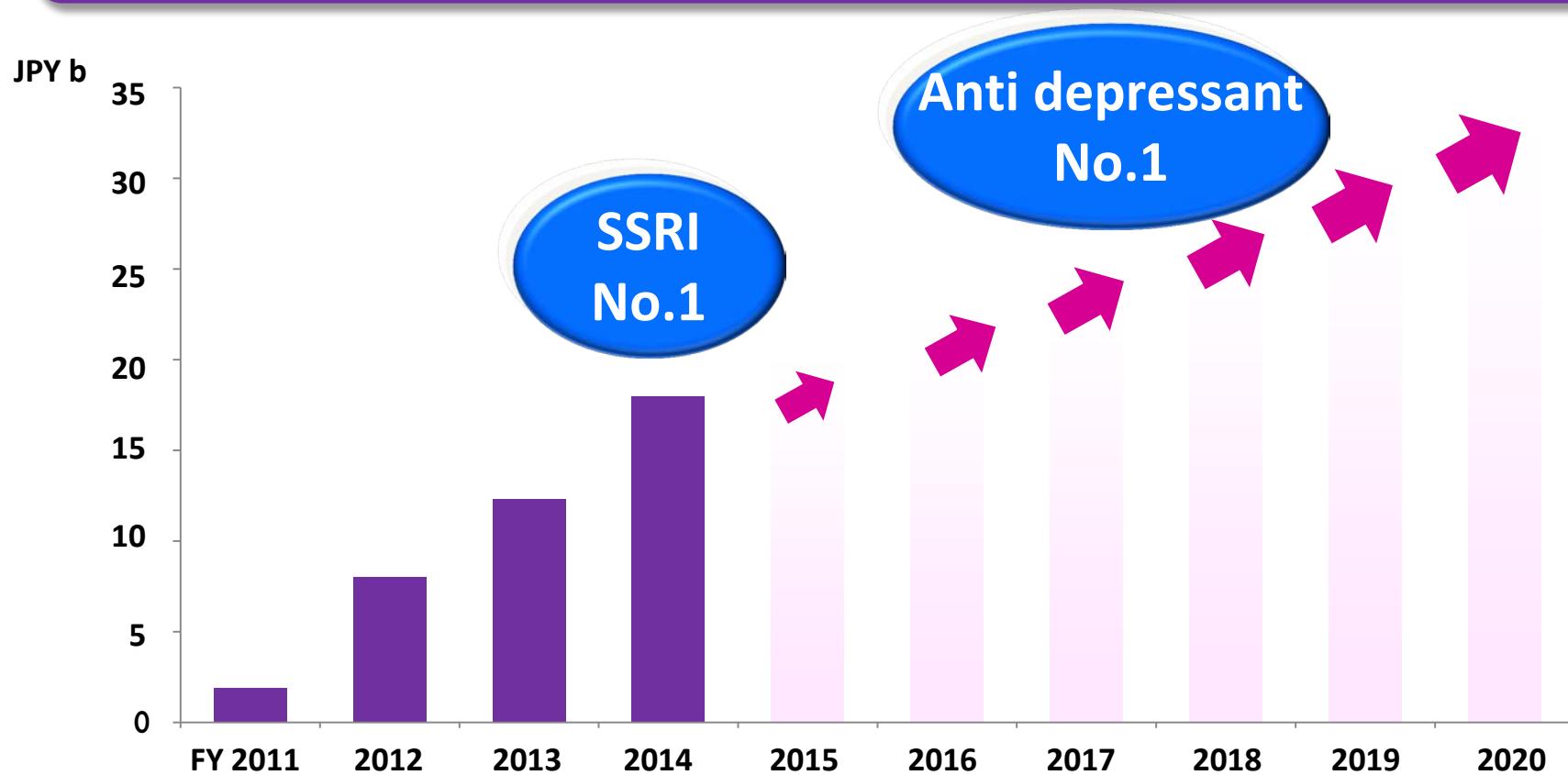
New Value Creation

【Challenges in FY2014】



## ■ To Share 20% of SSRI

- ◆ Fortifying “multi visits” by Mochida Pharmaceutical, Yoshitomiyakuhin and MTPC
- ◆ Diffusion of high remission rate, evidence based medicine

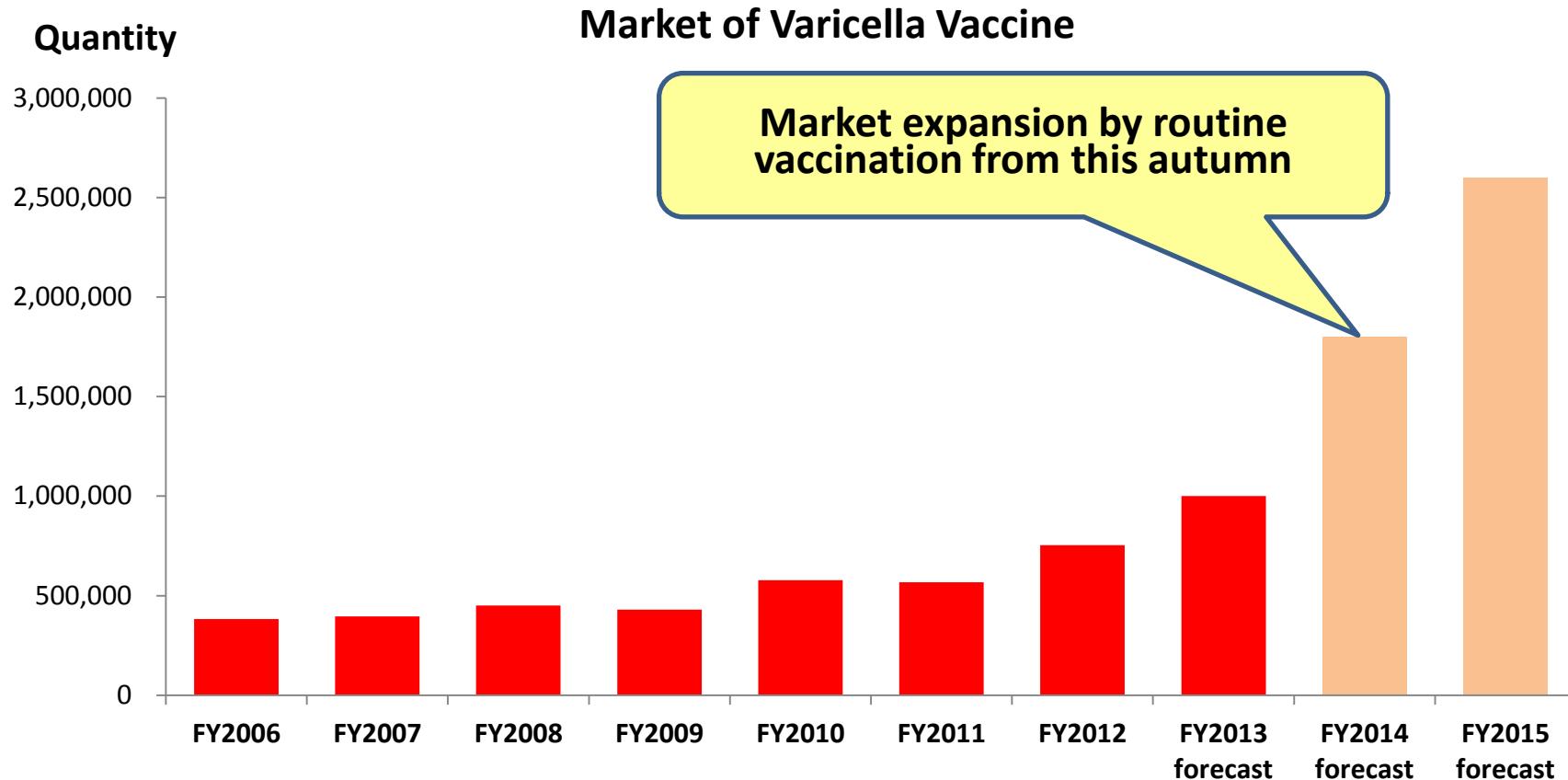


# Sales Strategy of Tetrabik and Varicella Vaccine

## 【Challenges in FY2014】

New Value Creation  
Mitsubishi Tanabe Pharma

- **Strengthening of vaccine operation system**
  - ◆ Input of MR resources and enhancement of vaccine representative
  - ◆ Market expansion of varicella vaccine by routine vaccination

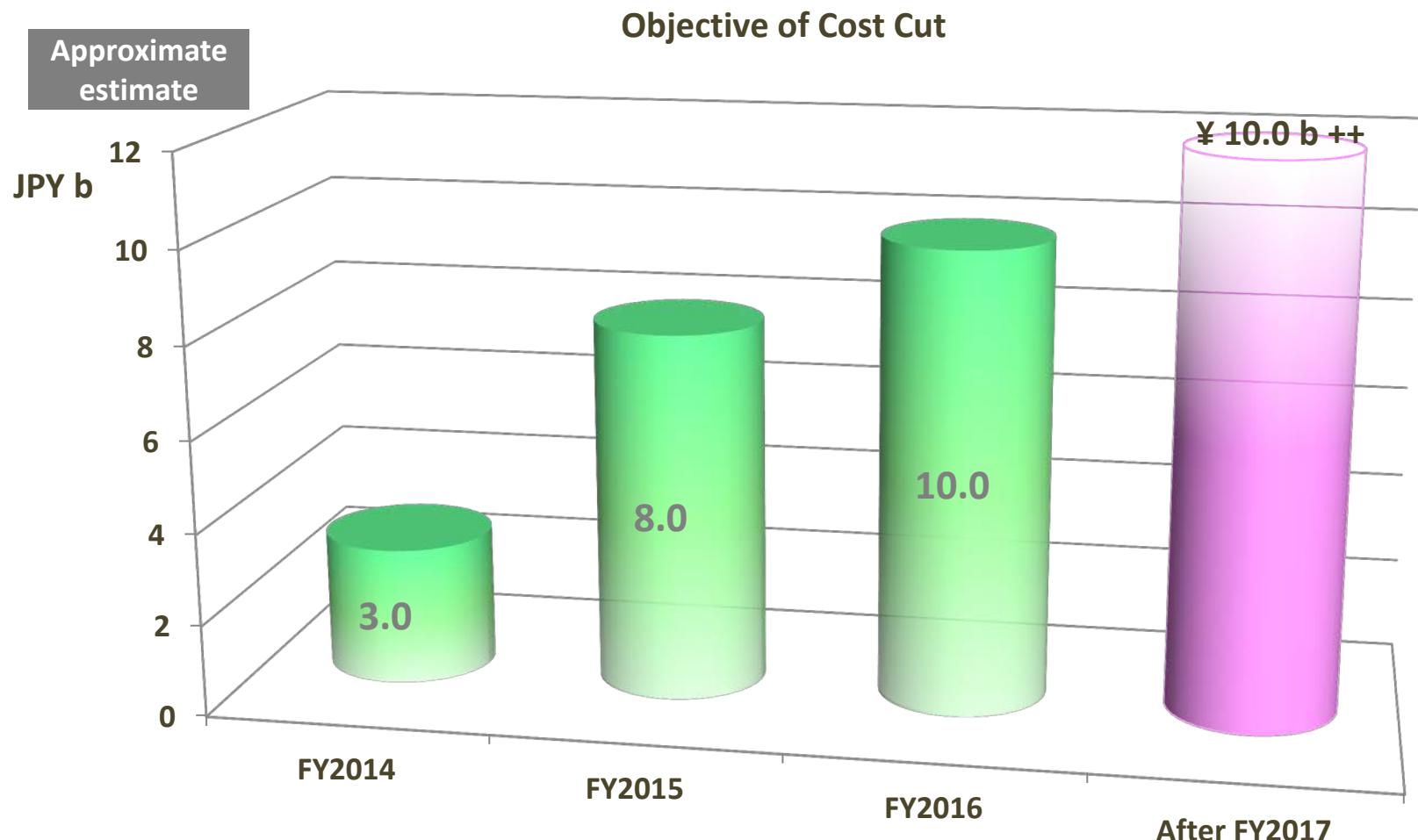


# Implementation of Structural Reforms, Kouzou Kaikaku Project (KKP)【Challenges in FY2014】

New Value Creation



- Cost cut of ¥ 10.0 b level by implementation of structural reforms project (KKP)
- After 2017, extra cost cut by reorganization of production sites, etc. besides KKP



# Medium-Term Management Plan 11-15



## ■ Downward revision of sales and operating income

Previous  
objective

Sales: ¥ 500 b, Operating income: ¥100 b

Positive  
factors

- Increase of royalty income from Gilenya and INVOKANA
- Cost cut by structural reforms, etc.

Negative  
factors

- Long-listed drugs (penetration of GE)
- Telavic (adverse event and launch of competitor)
- Unrealization of expansion of GE and overseas operation
- Transfer of finechemical operations

Revised  
objective

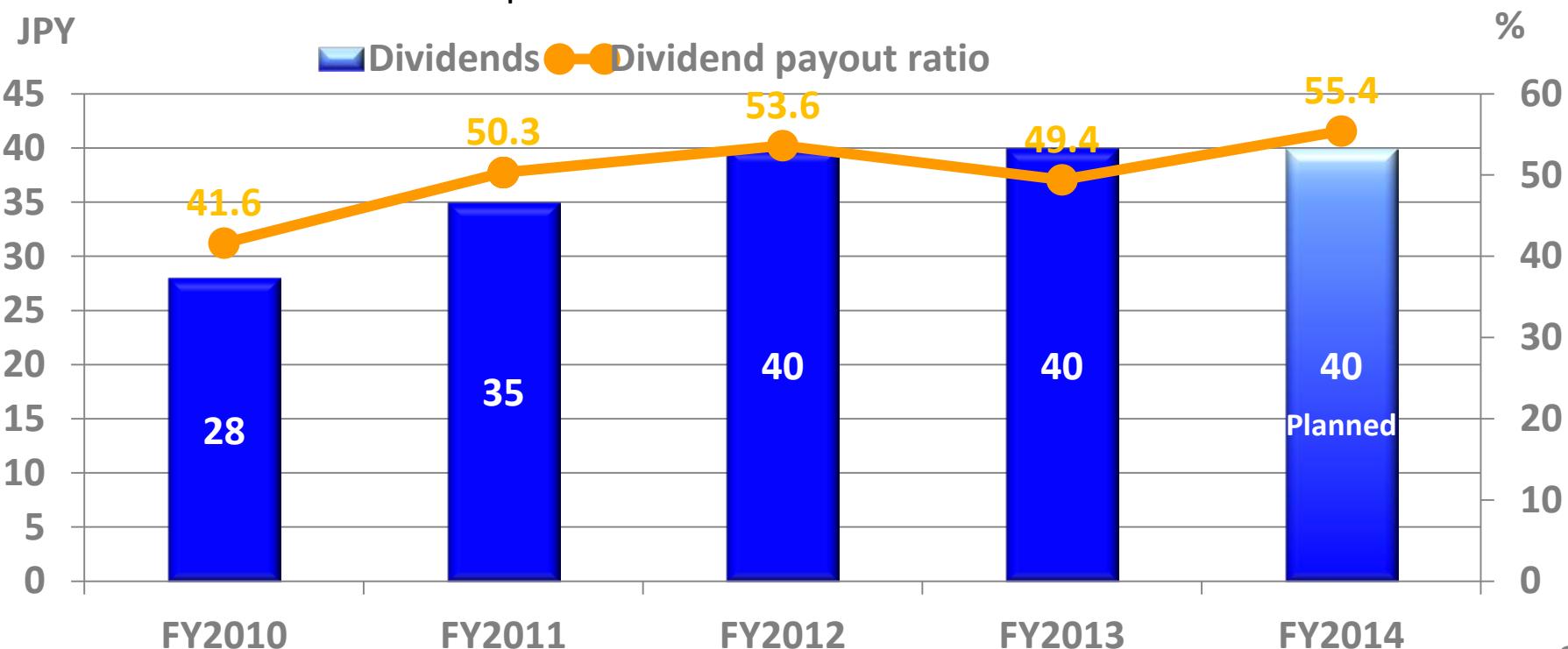
Sales: ¥ 410 b, Operating income: ¥65.0 b

# Shareholders Return

# Shareholders Return

## Policy

- MTPC's basic policy calls for providing a stable and continuous return to shareholders while striving to maximize enterprise value by aggressively investing in future growth.
- Under this medium-term management plan, in addition to profit growth, the basic for the dividend payout ratio is 50% (that prior to amortization of goodwill is 40%), and MTPC will work to provide an enhanced return to shareholders.



## Progress of the Development Pipeline



# In-House Development

Development code/Product name	Mode of Action (Indications)	Region	P1	P2	P3	Filling	Approval
TA-7284	SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan				Passed Drug Committee Meeting on 25 <sup>th</sup> April	
MT-4666	α7nACh receptor antagonist (Dementia of Alzheimer's type)	Multinational Study (co-developed with Forum)					
MT-1303	S1P receptor functional antagonist (Psoriasis)	Europe					
	(Inflammatory disease, Autoimmune disease)	Japan, Europe, US					
MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Japan					
Influenza (H5N1)vaccine	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada					
Seasonal influenza vaccine	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US					
Influenza (H7N9)vaccine	Plant-based VLP vaccine (Prophylaxis of H7N9 influenza)	Canada					
Maintate	Selective β1 blocker (Atrial fibrillation [tachycardic])	Japan					
Tenelia	DPP-4 inhibitor (Type 2 diabetes mellitus, additional combination)	Japan					
Telavic	NS3-4A protease inhibitor (Chronic hepatitis C, [genotype2])	Japan					

# Out-Licensed Products

Development code (Licensee)	Mode of Action (Indications)	Region	P1	P2	P3	Filing	Approval
TA-7284 (Janssen Pharmaceuticals)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Europe					
	(Diabetic nephropathy)	Multinational Study					
	(Type 2 diabetes mellitus / fixed dose combination with metformin, IR)	Europe					
		US					FDA Complete Response
TA-1790 (Vivus)	PDE5 inhibitor (Erectile dysfunction)	US					
		Europe					
MP-513 (Handok)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Korea					

# New **Value** Creation

**Becoming a “Company that Can Continue to Create New Value”**

# Appendix

# Sales by Business Segment

## 【Overview of FY2013 Business Results】

New Value Creation



Mitsubishi Tanabe Pharma

	FY2013	FY2012	Increase/decrease		Full-year forecasts	Achieved
			Billion yen	Billion yen		
Pharmaceuticals	411.6	414.7	-3.1	-0.7	418.0	98.5
Ethical drugs domestic sales	341.7	356.6	-14.8	-4.2	354.4	96.4
Ethical drugs overseas sales	22.0	23.4	-1.4	-5.8	20.3	108.5
OTC	4.5	5.3	-0.8	-15.6	4.6	98.1
Contracted manufacturing products	5.8	6.8	-1.0	-14.1	5.5	106.3
Licensing fee, etc.	37.6	22.7	+14.9	+65.8	33.3	113.0
Others	1.0	4.5	-3.4	-76.8	1.0	106.9
Total sales	412.7	419.2	-6.5	-1.6	419.0	98.5
Overseas	59.4	47.7	+11.6	+24.4	53.5	111.1

# Sales of Ethical Drugs: Main Products

## 【Overview of FY2013 Business Results】

New Value Creation



	FY2013	FY2012	Increase/decrease		Full-year forecasts	Achieved	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%	
Priority products	Ethical drugs domestic sales	341.7	356.6	-14.8	-4.2	354.4	96.4
	Remicade	76.3	73.5	+2.8	+3.9	79.0	96.6
	Maintate	15.5	14.1	+1.3	+9.6	16.2	95.3
	Talion	13.7	14.3	-0.6	-4.4	15.6	87.6
	Kremezin	12.6	12.2	+0.4	+3.0	12.9	97.3
	Simponi	9.4	5.3	+4.1	+77.5	10.1	92.5
	Lexapro	6.5	4.6	+1.9	+42.0	7.5	85.7
	Imusera	2.3	1.3	+1.0	+81.2	2.4	95.0
	Telavic	1.1	5.1	-4.1	-78.8	2.2	49.6
	Tenelia	0.8	1.2	-0.4	-34.5	3.2	24.6
New products	Vaccines	28.4	28.8	-0.4	-1.3	30.7	92.6
	[Influenza]	[7.2]	[7.7]	[-0.4]	[-5.9]	[8.2]	[87.9]
	New products	[Tetrabik]	[6.7]	[4.5]	[+2.2]	[8.4]	[80.0]
	Generics*	14.1	19.0	-4.9	-25.9	14.0	100.2
Licensing fee, etc.	Licensing fee, etc.	37.6	22.7	+14.9	+65.8	33.3	113.0
	[Royalty from Gilenya]	[32.2]	[19.5]	[+12.6]	[+64.8]		

\*: Generics and long listed drugs transferred from MTPC

# Sales of Ethical Drugs: Main Products

New Value Creation

【Forecasts for FY2014】



	FY2014 Forecasts	FY2013 Actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
<b>Remicade</b>	68.7	76.3	-7.6	-10.0
<b>Maintate</b>	16.0	15.5	+0.5	+3.5
<b>Talion</b>	15.7	13.7	+2.0	+14.6
<b>Simponi</b>	12.0	9.4	+2.6	+28.1
<b>Kremezin</b>	12.0	12.6	-0.6	-4.4
<b>Lexapro</b>	9.4	6.5	+2.9	+45.5
<b>Tenelia</b>	6.7	0.8	+5.9	+743.8
<b>Imusera</b>	3.6	2.3	+1.3	+58.8
<b>Tetrabik</b>	7.6	6.7	+0.9	+13.1
<b>Varicella vaccine</b>	4.2	3.6	+0.6	+17.2

# Pipeline Status (New Drugs, Additional Indications)

New Value Creation



Red: progress after October 30, 2013, the financial results for Q2 of 2013

As of May 8, 2014

## Phase 1

## Phase 2

## Phase 3

## Filed

## Approved, Launch (After Oct. 2013)

**MT-1303 (Japan,EU,US)**  
Inflammatory diseases /  
Autoimmune diseases

**MP-513 (US)**  
Type2 diabetes mellitus

**MT-3995 (US)**  
Diabetic nephropathy

**MP-124 (US)**  
Acute ischemic stroke

**MP-157 (EU)**  
Hypertension

**GB-1057 (US)**  
Stabilizing agent

**MP-424 (Korea)**  
Chronic hepatitis C

**Cholebline (Japan)**  
Hyperphosphatemia

**Influenza vaccine (Canada)**  
Prophylaxis of H7N9 influenza

### Disease area

■ : Autoimmune disease

■ : Diabetes and kidney  
disease

■ : CNS disease

■ : Vaccines

■ : Other

**MT-1303 (EU)**  
Multiple sclerosis

**MT-1303 (EU)**  
Psoriasis

**MT-9938 (US)**  
Refractory pruritus

**MP-513 (EU)**  
Type2 diabetes mellitus

**MT-3995  
(EU, Japan)**  
Diabetic nephropathy

**Influenza vaccine (Canada)**  
Prophylaxis of H5N1 influenza

**Influenza vaccine (US)**  
Prophylaxis of seasonal influenza

**Cholebline (Japan)**  
Type 2 diabetes mellitus

**MT-4666  
(Multinational study)\*1**

Dementia of  
Alzheimer's type

**MP-214 (Japan)**  
Schizophrenia

**Remicade (Japan)**  
Refractory Kawasaki disease  
Bechet's disease with special lesions  
Pediatric Crohn's disease  
Pediatric ulcerative colitis  
Psoriasis: increased dose

**Imusera (Multinational study)\*2**  
CIDP

**BindRen (EU)**  
Pediatric hyperphosphatemia

**Radicut (Japan)**  
ALS

**Talion (Japan)**  
Pediatric allergic rhinitis  
Pediatric atopic dermatitis

**Telavic (Japan)**  
Chronic hepatitis C [combination with Pegasys]  
Chronic hepatitis C [combination with Feron]

**Tribik (Japan)\*3**  
Prophylaxis of pertussis, diphtheria,  
and tetanus [The second inoculation]

**TA-7284 (Japan)**  
Type 2 diabetes mellitus

**MP-424 (Taiwan)**  
Chronic hepatitis C

**Telavic (Japan)**  
Chronic hepatitis C  
[genotype2]

**Tenelia (Japan)**  
Type2 diabetes mellitus,  
additional combination

### Major license-out (post Phase 3)

**TA-7284 (EU)**  
Type2 diabetes mellitus

**TA-7284/Met IR FDC  
(EU)**  
Type2 diabetes mellitus

**MP-513 (Korea)**  
Type2 diabetes mellitus

**TA-7284/Met IR FDC  
(US)**  
Type2 diabetes mellitus

**FTY720  
(Multinational study)\*2**  
CIDP

**TA-7284/Met XR FDC  
(US)**  
Type2 diabetes mellitus

**TA-7284  
(Multinational study)**  
Diabetic nephropathy

### Approved, Launch Approved, Launch

### Filed

### Phase 3

\*1: Co-developed with FORUM Pharmaceuticals

\*2: Multinational study, co-developed with Novartis Pharma in Japan, licensed to Novartis overseas

\*3: Co-developed with BIKEN

### **Cautionary Statement**

**The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the company and is subject to significant risks and uncertainties.**