

Mitsubishi Tanabe Pharma Corporation

# 2<sup>nd</sup> Quarter of FY2013

## Business Results

(April – September, 2013)

November 1, 2013

Michihiro Tsuchiya

President and CEO



Mitsubishi Tanabe Pharma

# Q2 FY2013 Business Results Outline

A decorative horizontal bar with a blue-to-teal gradient, starting as a solid blue bar on the left and fading into a light teal gradient on the right.

# Overview of Q2 FY2013 Business Results

New **Value** Creation



## Net sales

¥ 202.8 billion -0.5%, year-on-year

## Operating income

¥ 30.5 billion -5.5%, year-on-year

## Net income

¥ 28.5 billion +46.4%, year-on-year

- Decreased sales and operating income
- Significantly increased net income

## Topics

- ✓ **Growth of Remicade and Simponi:** Total ¥43.4 billion, 12% up, y-o-y
- ✓ **Royalty income of Gilenya:** 14.1 billion yen in 1<sup>st</sup> half of FY2013, 134% up, y-o-y
- ✓ **INVOKANA:** Prescriptions in US are steadily growing, favorable penetration
- ✓ **Acquisition of Medicago in September:** Strengthens vaccine business globally
- ✓ **Reduction of purchase price for Remicade:** 11.0 billion yen of extraordinary income, reimbursed as a overpayment attributable to previous years
- ✓ **Consolidates domestic production bases:** five plants now, two plants by the end of FY2017
- ✓ **Started construction of new production facilities in China and Indonesia**

# Q2 FY2013 Financial Results

New Value Creation

【April to September, 2013】



	FY2013	FY2012	Increase/decrease		Forecasts for 1st half*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Net sales	202.8	203.8	-1.0	-0.5	200.0	101.4
Cost of sales	82.4	79.3	+3.2	+4.0	78.0	105.7
Sales cost ratio	40.6%	38.9%			39.0%	
Gross operation profit	120.4	124.6	-4.1	-3.3	122.0	98.7
SG&A	90.0	92.3	-2.4	-2.6	92.0	97.8
Operating income	30.5	32.2	-1.8	-5.5	30.0	101.5
Ordinary income	32.2	33.1	-0.9	-2.8	31.0	103.9
Net income	28.5	19.5	+9.1	+46.4	26.0	109.8

\*: Published forecasts announced on May 8, 2013 in the financial results for FY2012.

Net income was revised on Sep. 25; 19.0 billion yen → 26.0 billion yen

# Ethical Drugs Domestic Sales of Main Products

**[Q2 FY2013 Financial Results]**

New Value Creation



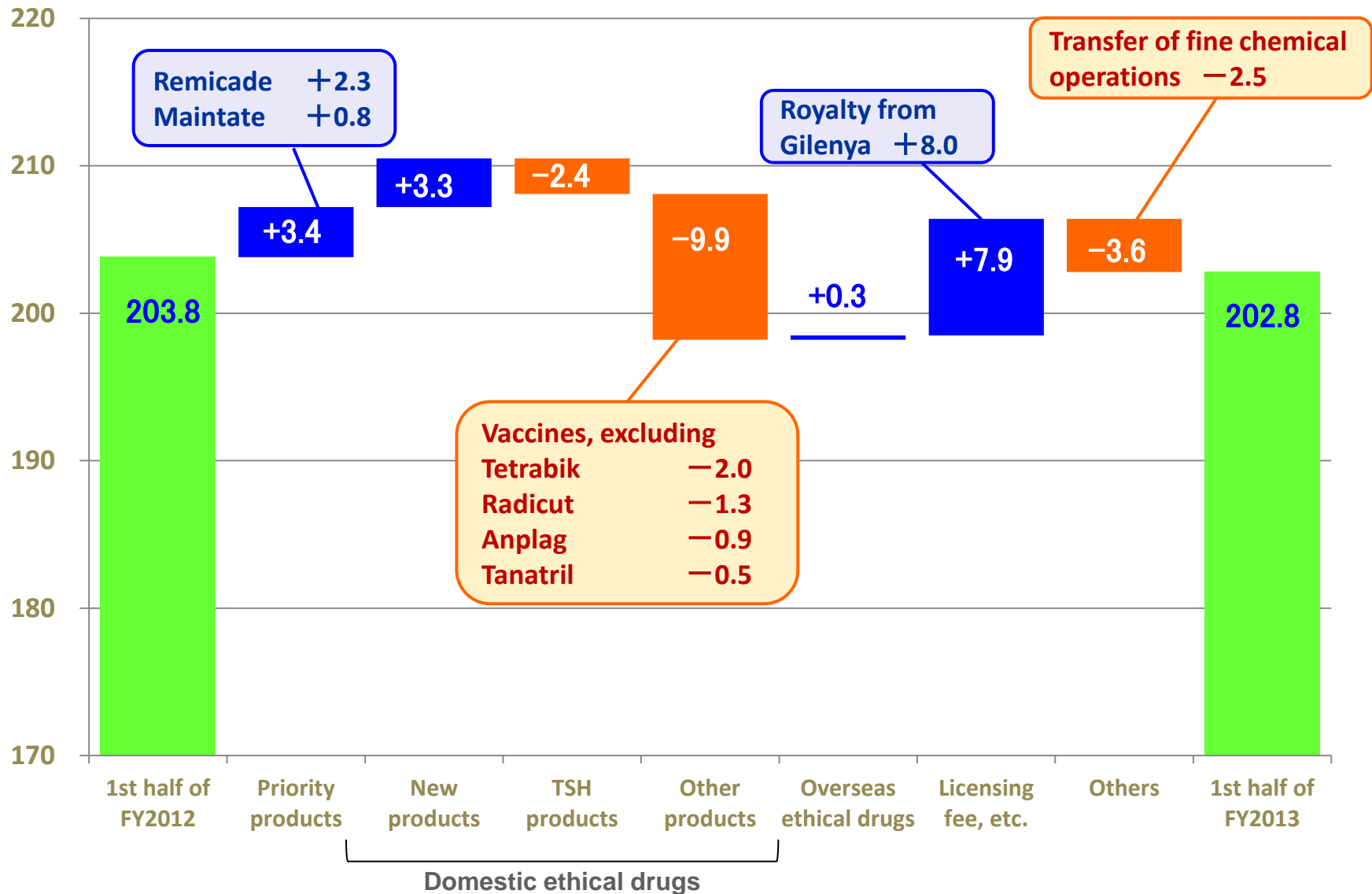
		FY2013	FY2012	Increase/decrease		Forecasts for 1 <sup>st</sup> half	Achieved
		Billion yen	Billion yen	Billion yen	%		%
Ethical drugs domestic sales		171.0	176.6	-5.6	-3.2	169.7	100.8
Priority products	Remicade	39.0	36.7	+2.3	+6.3	38.6	101.2
	Maintate	7.7	7.0	+0.8	+10.9	7.5	103.0
	Kremezin	6.4	6.0	+0.4	+6.7	6.3	101.7
	Talion	5.1	5.3	-0.1	-2.8	5.4	94.9
New products	Simponi	4.4	2.2	+2.2	+98.7	4.1	107.9
	Lexapro	2.4	1.7	+0.8	+46.5	3.3	73.8
	Telavic	1.1	3.5	-2.4	-68.3	1.9	57.8
	Imusera	1.0	0.5	+0.5	+118.4	1.3	75.9
Vaccines		14.0	12.6	+1.4	+10.8	12.7	110.1
[Tetrabik]		(3.4)	(-)	(+3.4)	(-)	(4.3)	(79.1)
Generics*		6.7	9.1	-2.4	-26.4	6.7	99.7
Licensing fee, etc		15.3	7.4	+7.9	+107.3	13.0	117.6
[Royalty income from Gilenya]		(14.1)	(6.0)	(+8.0)	(+133.7)	(-)	(-)

\*: Generics and the long-listed drugs which were transferred from MTPC

# Changes in Sales

## 【Q2 FY2013 Financial Results】

JPY b



# Cost of Sales/SG&A Expenses

New Value Creation



## 【Q2 FY2013 Financial Results】

	FY2013	FY2012	Increase/decrease		Forecasts for 1 <sup>st</sup> half	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Net sales	202.8	203.8	-1.0	-0.5	200.0	101.4
Cost of sales	82.4	79.3	+3.2	+4.0	78.0	105.7
Sales cost ratio	40.6%	38.9%			39.0%	
Gross operation profit	120.4	124.6	-4.1	-3.3	122.0	98.7
SG&A	90.0	92.3	-2.4	-2.6	92.0	97.8
R&D expenses	34.3	34.2	+0.1	+0.1	35.4	96.9
Labor cost	23.9	26.0	-2.1	-8.1	23.8	100.2
Amortization of goodwill	5.3	5.1	+0.2	+4.0	5.2	101.2
Others	26.6	27.1	-0.5	-1.8	27.6	96.2
Operating income	30.5	32.2	-1.8	-5.5	30.0	101.5

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

【Q2 FY2013 Financial Results】

New Value Creation



	FY2013	FY2012	Increase/decrease		Forecasts for 1 <sup>st</sup> half	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Operating income	30.5	32.2	-1.8	-5.5	30.0	101.5
Non-operating income & loss	1.7	0.9	+0.9			
Ordinary income	32.2	33.1	-0.9	-2.8	31.0	103.9
Extraordinary income	11.9	1.2	+10.7			
Profit on arbitration award	11.0	-	+11.0			
Gain on step acquisitions	0.9	-	+0.9			
Others	-	1.2	-1.2			
Extraordinary loss	0.9	3.6	-2.8			
Impairment loss	0.8	0.3	+0.5			
Loss on business integration	-	2.2	-2.2			
Loss on valuation investments in securities	-	0.7	-0.7			
Others	0.1	0.4	-0.3			
Net income	28.5	19.5	+9.1	+46.4	26.0	109.8



# Forecast for FY2013 (Ending March 31, 2014)



# Revised Forecasts for FY2013 (year-on-year)

	FY2013 (Estimate)	FY2012 (Achieved)	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Net sales	419.0	419.2	-0.2	0.0
Cost of sales	170.0	166.4	+3.6	+2.2
Sales cost ratio	40.6%	39.7%		
Gross operation profit	249.0	252.8	-3.8	-1.5
SG&A	186.0	183.8	+2.2	+1.2
R&D expenses	71.0	66.5	+4.5	+6.7
Labor cost	48.3	51.9	-3.6	-6.9
Amortization of goodwill	10.4	10.3	+0.1	+1.0
Others	56.3	55.1	+1.2	+2.2
Operating income	63.0	69.0	-6.0	-8.7
Non-operating profit and loss	2.5	0.4	+2.1	-
Ordinary income	65.5	69.4	-3.9	-5.6
Extraordinary income or loss	4.0	-1.7	+5.7	-
Net income	45.0	41.9	+3.1	+7.4

# Ethical Drugs Domestic Sales of Main Products

New Value Creation

【Revised Forecasts for FY2013 (year-on-year)】



		FY2013 (Estimate)	FY2012 (Achieved)	Increase/decrease	
		Billion yen	Billion yen	Billion yen	%
Ethical drugs domestic sales		354.4	356.6	-2.1	-0.6
Priority products	Remicade	79.0	73.5	+5.5	+7.5
	Maintate	16.2	14.1	+2.1	+15.0
	Talion	15.6	14.3	+1.3	+9.1
	Kremezin	12.9	12.2	+0.7	+5.9
New products	Simponi	10.1	5.3	+4.8	+91.9
	Lexapro	7.5	4.6	+3.0	+65.6
	Telavic	2.2	5.1	-2.9	-57.3
	Tenelia	3.2	1.2	+2.0	+166.6
	Imusera	2.4	1.3	+1.1	+90.8
Vaccines		30.7	28.8	+1.9	+6.6
	[Tetrabik]	(8.4)	(4.5)	(+3.9)	(+85.4)
	[Influenza]	(8.2)	(7.7)	(+0.5)	(+7.1)
Generics*		14.0	19.0	-4.9	-26.0
Licensing fee, etc		33.2	22.7	+10.6	+46.7

\*: Generics, and the long-listed drugs which were transferred from MTPC

# Revised Forecasts for FY2013 (compared with previous forecast)

	Revised forecast	Previous forecast	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Net sales	419.0	417.0	+2.0	+0.5
Cost of sales	170.0	163.0	+7.0	+4.3
Sales cost ratio	40.6%	39.1%		
Gross operation profit	249.0	254.0	-5.0	-2.0
SG&A	186.0	184.0	+2.0	+1.1
R&D expenses	71.0	70.5	+0.5	+0.7
Labor cost	48.3	47.9	+0.4	+0.8
Amortization of goodwill	10.4	10.4	-	-
Others	56.3	55.2	+1.1	+2.0
Operating income	63.0	70.0	-7.0	-10.0
Non-operating profit and loss	2.5	1.5	+1.0	-
Ordinary income	65.5	71.5	-6.0	-8.4
Extraordinary income or loss	4.0	-2.5	+6.5	-
Net income	45.0	44.0	+1.0	+2.3

# Topics in Q2 FY2013

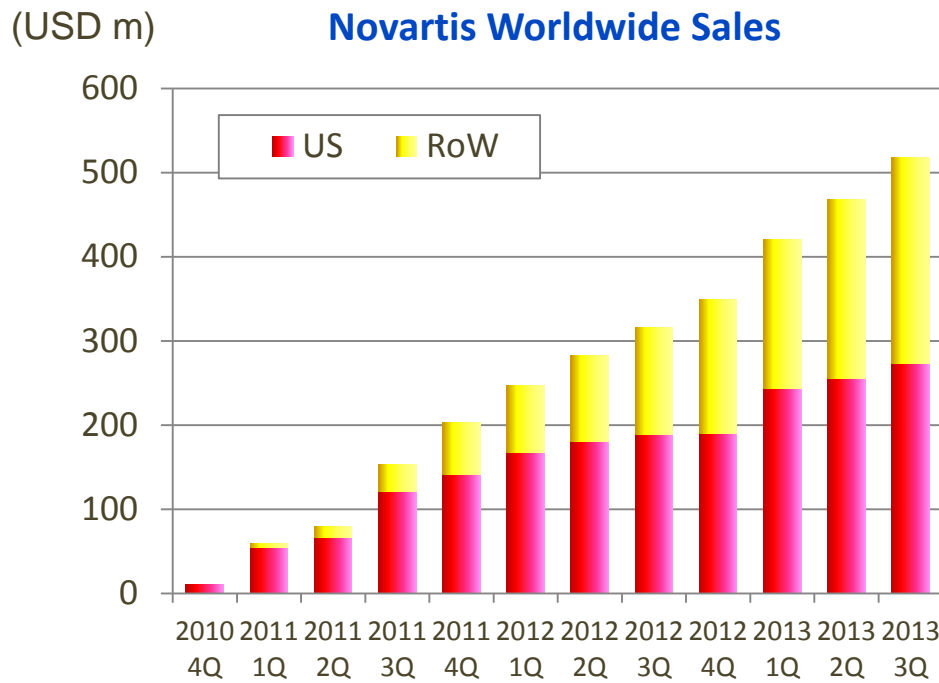


# Growth of Gilenya

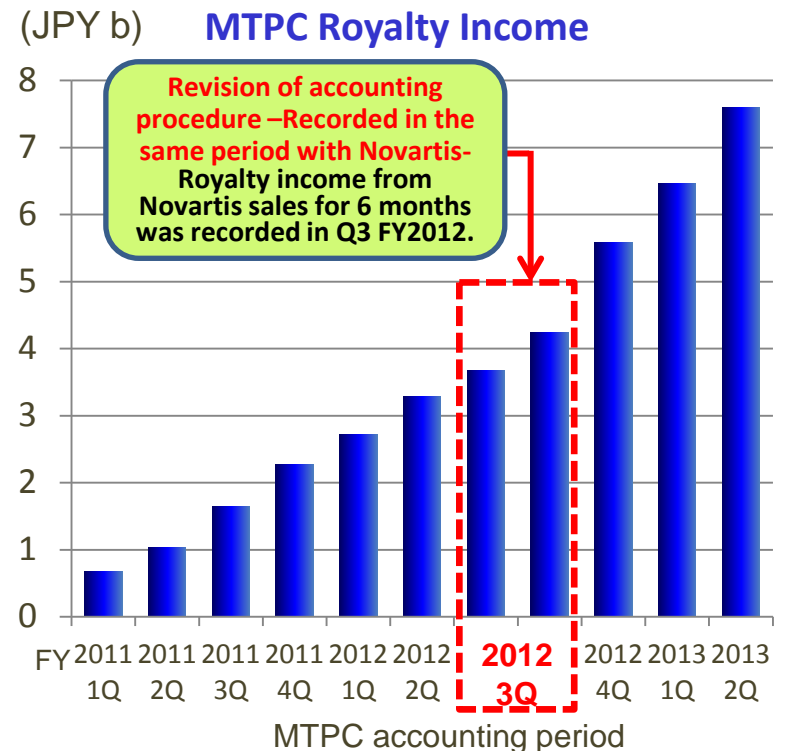
## 【Q2 FY2013 Financial Results】



- ◆ Discovered by MTPC and licensed to Novartis for overseas market
- ◆ Approved in more than 75 countries
- ◆ Used to treat more than 78,500 patients in clinical trials and the post-marketing setting
- ◆ Novartis 2012 worldwide sales: about \$1.2 billion
- ◆ Novartis Q1-3 2013 (Jan - Sep, 2013) worldwide sales: \$1.4 billion



Source: Novartis financial results



## **SGLT2 inhibitor discovered by MTPC and licensed to Janssen Pharmaceuticals for overseas market**

### ● US

- Approved in March 2013
- First SGLT2 inhibitor in US
- Trade name: INVOKANA™
- No.1 branded therapy prescribed by US endocrinologists when adding or switching non-insulin type 2 diabetes medications

### ● EU

- Positive opinion by CHMP in September 2013

### ● Japan

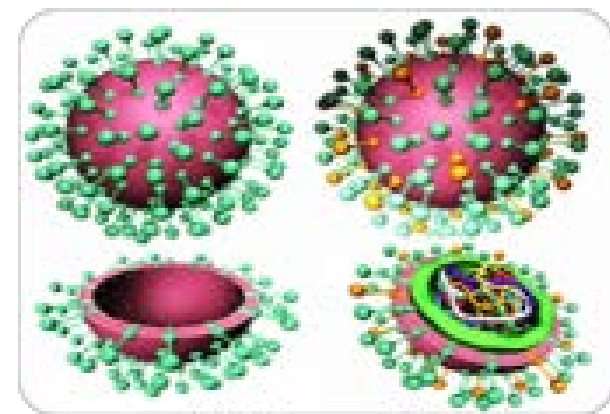
- Filed in May 2013

## Acquisition of Medicago

- Platform technology of plant-derived VLP vaccine production
- Expansion of pipeline
  - Quadrivalent seasonal influenza vaccine
  - Pandemic influenza vaccine
  - New vaccine candidates such as rotavirus, etc.



Commercial scale facility (RTP, North Carolina, USA)



VLP

Flu virus



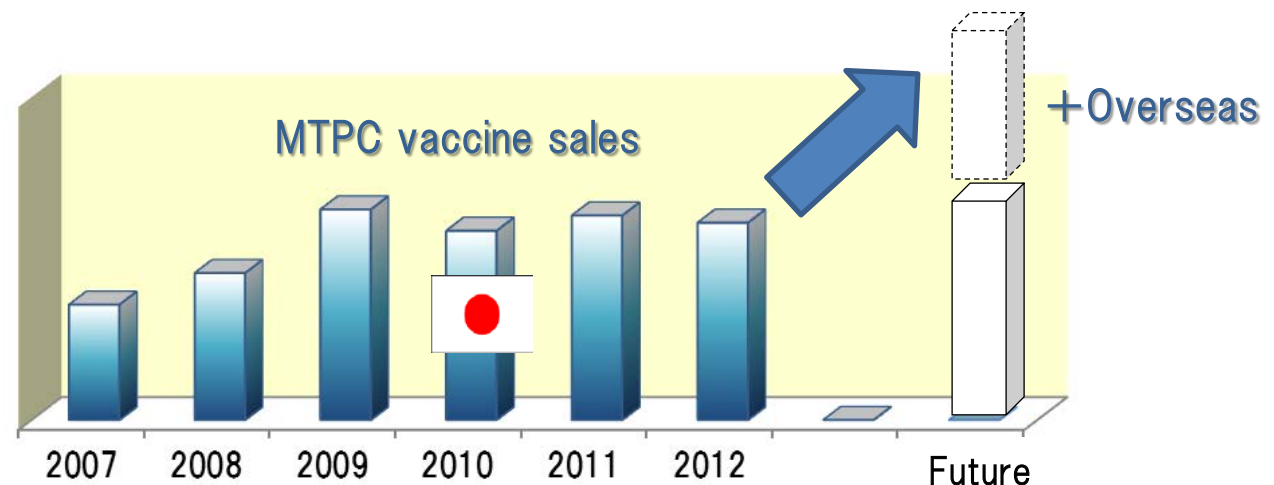
# Strengthening of Vaccine Business (2)

## Strengthening of the collaboration with BIKEN

- Promotion and co-development of BIKEN products (Japan)

## Setting Up Vaccine Business Development Department

- Planning and promotion of the strategy and partnership regarding vaccine business
- Management of Medicago




# Organizational Reform

## The progress of existing projects, Medium-Term Management Plan 11-15

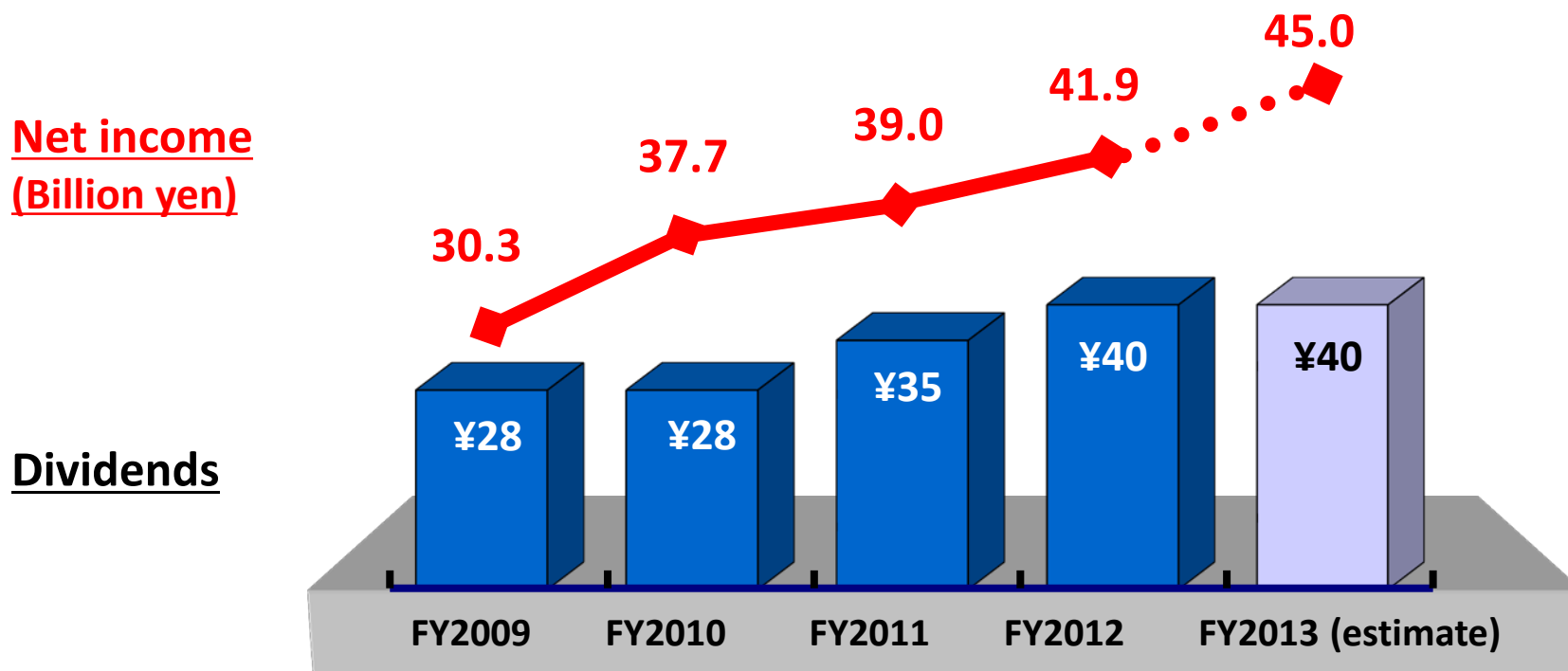
Base reorganization (at the merger)	Domestic production(eight bases)		Transfer Ashikaga plant in 2014	Consolidate MTPF into two plants(Yoshitomi and Onoda) by the end of FY2017
	Overseas production		Complete a new production facility at Tanabe Indonesia in Sep., 2014	Complete a new production facility at Tianjin Tanabe in May, 2015
	Research facilities	Reorganized to three bases by 2012		
	Head office(seven buildings), other	Head office (two buildings)/consolidated Tokyo buildings by 2012		Reorganize head office functions in Osaka and Kashima by 2015
Operational reorganization	Plasma fractionation operations	Transferred the operations in 2012		
	Other	Transferred fine chemical operations in 2012-2013		

New project	2013	2014	After 2015
<b>Organization reform project</b> <ul style="list-style-type: none"> <li>• Reduce purchase cost</li> <li>• Streamline cost</li> <li>• Restructure organization and human resources, other</li> </ul>	Formulate action plans	[ Implementate of the plans sequentially ]	Maximize the achievement



## 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.



# *New Value Creation*

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

# Pipeline Status (New Drugs, Additional Indications)

Red: progress after May 8, 2013, the financial results for FY2012

As of October 30, 2013

## Phase 1

- **MP-513 (US)**  
Type2 diabetes mellitus
- **MT-1303 (Japan)**  
Multiple sclerosis
- **MT-1303 (EU)**  
IBD
- **MP-124 (US, Canada)**  
Acute ischemic stroke
- **MP-157 (Europe)**  
Hypertension
- **GB-1057 (US)**  
Stabilizing agent
- **MP-424 (Korea)**  
Chronic hepatitis C
- **Cholebine (Japan)**  
Hyperphosphatemia

## Phase 2

- **MT-1303 (Europe)**  
Multiple sclerosis
- **MT-1303 (Europe)**  
Psoriasis
- **MT-9938 (US, Canada)**  
Refractory pruritus
- **MP-513 (Europe)**  
Type2 diabetes mellitus
- **MT-3995 (Europe, Japan)**  
Diabetic nephropathy
- **MT-4666 (Japan)**  
Dementia of Alzheimer's type
- **Cholebine (Japan)**  
Type 2 diabetes mellitus

## Phase 3

- **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)**  
CIDP\*
- **BindRen (Europe)**  
Pediatric hyperphosphatemia
- **Radicut (Japan)**  
ALS
- **Talion (Japan)**  
Pediatric allergic rhinitis  
Pediatric atopic dermatitis
- **Telavic (Japan)**  
Chronic hepatitis C [genotype2]  
Chronic hepatitis C [combination with Pegasys]  
Chronic hepatitis C [combination with Feron]
- Discontinued ---
- **MP-146 (US, Europe)**  
Chronic kidney disease

## Filed

- **TA-7284 (Japan)**  
Type 2 diabetes mellitus
- **MP-424 (Taiwan)**  
Chronic hepatitis C
- **Tenelia (Japan)**  
Type2 diabetes mellitus,  
additional combination

## Approved, Launch (After May 2013)

- **Maintate (Japan)**  
Tachycardiac atrial fibrillation

## Major license-out (post Phase 3)

Approved,  
Launch

- **TA-1790 (Europe)**  
Erectile dysfunction

Filed

- **TA-7284 (Europe)**  
Type2 diabetes mellitus
- **TA-1790 (Europe)**  
Erectile dysfunction
- **MP-513 (Korea)**  
Type2 diabetes mellitus

### Disease area

- : Autoimmune disease
- : Diabetes and kidney disease
- : CNS disease
- : Other

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

### **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.**