

Mitsubishi Tanabe Pharma Corporation

FY2014 Business Results

(April, 2014 – March, 2015)

May 11, 2015

Masayuki Mitsuka

**President & Representative
Director, CEO**



Mitsubishi Tanabe Pharma

FY2014 Business Results

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

Overview of FY2014 Business Results

New **Value** Creation



Net sales

¥ 415.1 billion +0.6%, year-on-year

Operating income

¥ 67.1 billion +13.6%, year-on-year

Net income

¥ 39.5 billion -13.0%, year-on-year

Topics

- Growth of Gilenya and INVOKANA, ¥60.4b of royalty income in FY2014, +60.7%, y-o-y
- Expansion of sales of Tenelia, ¥6.2b of sales in FY2014, + ¥ 5.4b, y-o-y
- Launch of CANAGLU for type2 diabetes mellitus in Japan (Sep., 2014)
- Filed of additional indications of ALS for Radicut (Oct., 2014)
- Filed of additional indications of Behcet's disease with special lesions for Remicade (Oct., 2014)
- In-Licensed of VMAT2 inhibitor from Neurocrine Biosciences(Mar., 2015)
- Promotion of structural reforms
 - ◆ Transfer of Kashima plant of MTPF to Sawai Pharmaceutical(Apr., 2015)
 - ◆ Conclusion of closing of Kazusa office and consolidation of research function into two bases (Feb., 2015)
- Completion of construction of new head office building in Dosho-machi, Osaka (Feb., 2015)
- Completion of construction of new manufacturing facilities in China and Indonesia (Jan., 2015)

FY2014 Financial Results

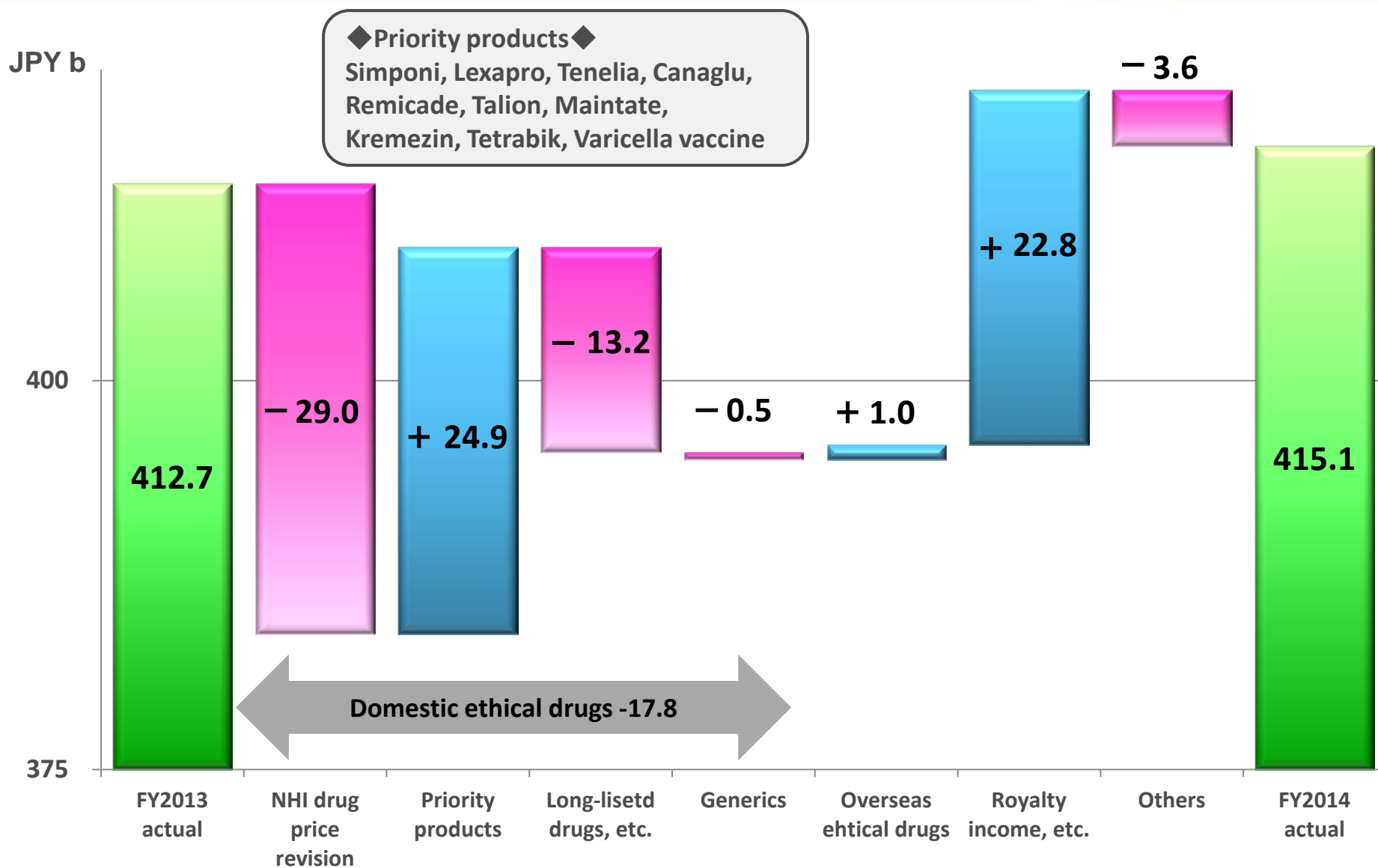
	FY2014	FY2013	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	415.1	412.7	+2.4	+0.6	406.0	102.2
Cost of sales	169.6	169.4	+0.2	+0.1	164.0	103.4
Sales cost ratio	40.9%	41.0%			40.4%	
Gross profit	245.5	243.3	+2.2	+0.9	242.0	101.5
SG&A	178.4	184.2	-5.8	-3.2	182.0	98.0
Operating income	67.1	59.1	+8.0	+13.6	60.0	111.9
Ordinary income	67.7	61.9	+5.8	+9.3	61.5	110.0
Net income	39.5	45.4	-5.9	-13.0	40.5	97.5

*: Revised forecasts announced on October 29, 2014 in the financial results of Q2 FY2014

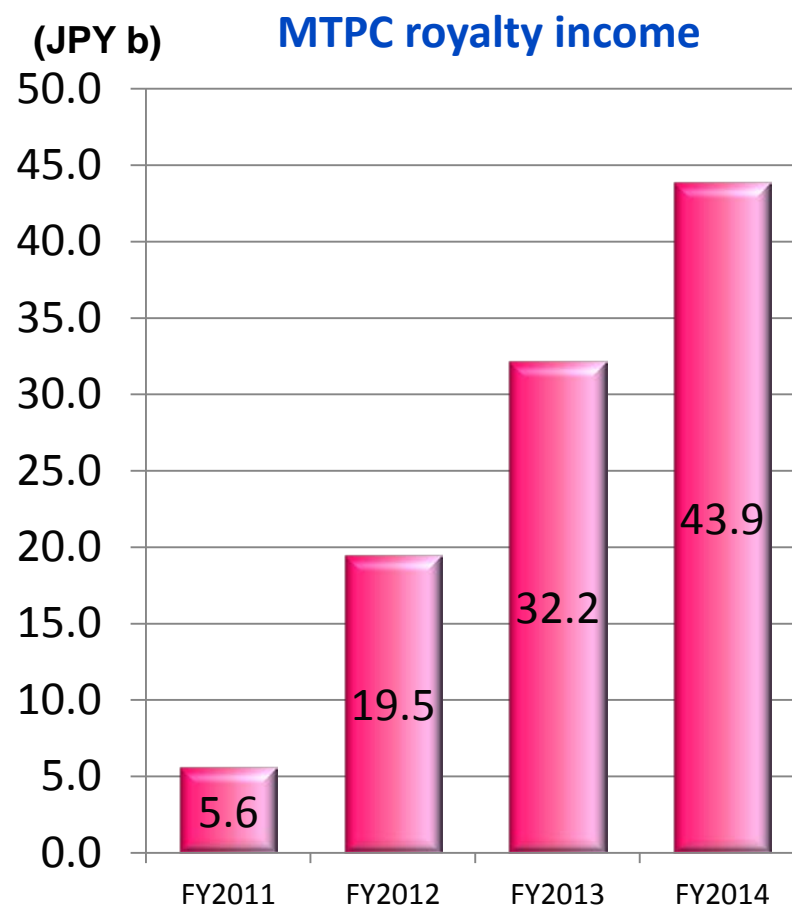
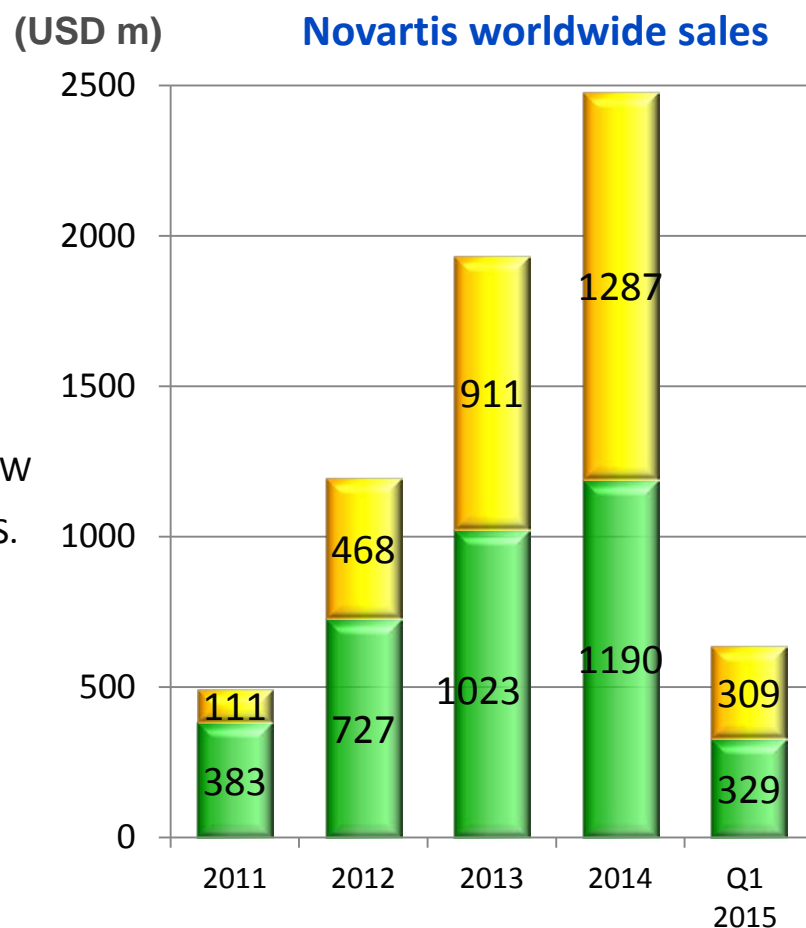
Sales Trends

New **Value** Creation

【FY2014 Business Results】

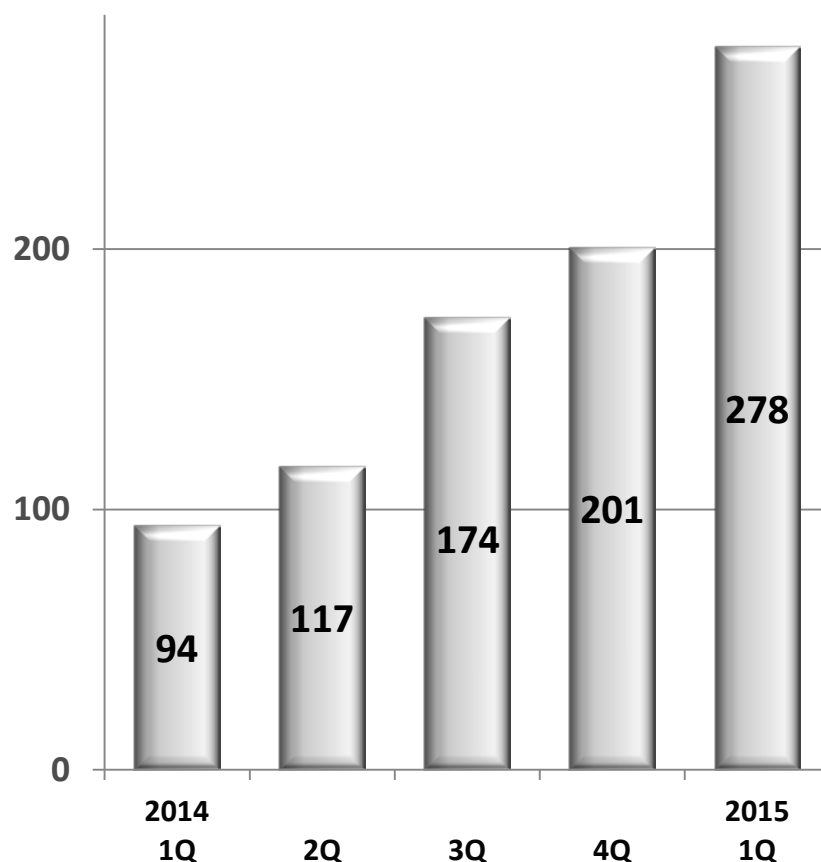


- ◆ Novartis worldwide sales in Jan. to Mar., 2015: \$ 638 m, + 16%, y-o-y
- ◆ MTPC royalty income in FY2014: ¥ 43.9 b, +36.7%, y-o-y

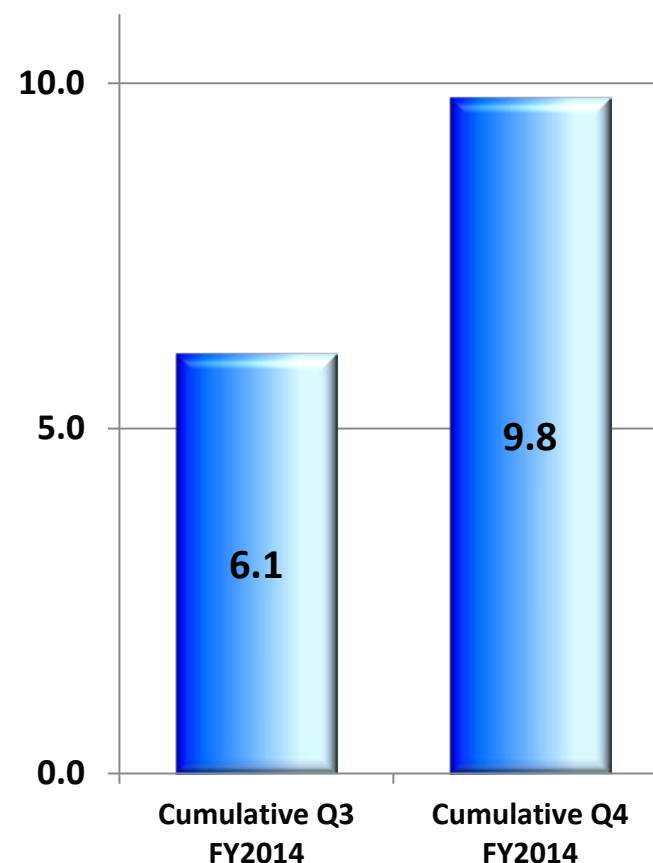


- ◆ Johnson & Johnson sales in Jan.-Mar., 2015: \$ 278m (+ \$ 18.4m, y-o-y)
- ◆ Achieved ~5% in defined U.S. T2DM market and ~12% share with endocrinologists
- ◆ MTPC royalty income in FY2014: ¥ 9.8b

(USD m) **Johnson & Johnson sales**



(JPY b) **MTPC royalty income**



Cost of Sales, SG&A

New **Value** Creation

【FY2014 Business Results】



	FY2014	FY2013	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	415.1	412.7	+2.4	+0.6	406.0	102.2
Cost of Sales	169.6	169.4	+0.2	+0.1	164.0	103.4
Sales cost ratio	40.9%	41.0%			40.4%	
Gross operation profit	245.5	2,43.3	+2.2	+0.9	242.0	101.5
SG&A	178.4	184.2	-5.8	-3.2	182.0	98.0
R&D expenses	69.6	70.4	-0.8	-1.1	72.5	96.0
Labor cost	46.8	48.4	-1.6	-3.3	46.2	101.2
Amortization of goodwill	10.9	10.6	+0.3	+2.6	10.8	101.1
Others	51.1	54.8	-3.7	-6.8	52.5	97.3
Operating income	67.1	59.1	+8.0	+13.6	60.0	111.9

*: Published forecasts announced on October 29, 2014 in the financial results of Q2 FY2014

Non-operating Income and Loss/Extraordinary Income and Loss

New **Value** Creation



【FY2014 Business Results】

	FY2014	FY2013	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Operating income	67.1	59.1	+8.0	+13.6	60.0	111.9
Non-operating income and loss	0.5	2.8	-2.2	-81.1	1.5	34.7
Ordinary income	67.7	61.9	+5.8	+9.3	61.5	110.0
Extraordinary income	13.7	15.3				
Gain on sales of property, plant and equipment	12.0	1.0				
Gain on sale of investment in securities	1.1	2.4				
Gain on sales of shares of subsidiaries and affiliates	0.6	-				
Profit on arbitration award	-	11.0				
Gain on step acquisitions	-	0.9				
Extraordinary loss	18.6	4.8				
Restructuring expenses	12.3	-				
Amortization of goodwill	3.5	-				
Impairment loss	2.6	1.4				
Loss on valuation of investment in securities	0.1	0.6				
Special retirement expenses	-	2.6				
Others	0.1	0.2				
Net income	39.5	45.4	-5.9	-13.0	40.5	97.5

*: Revised forecasts announced on October 29, 2014 in the financial results of Q2 FY2014

Extraordinary Loss

	FY2014	Notes
	Billion yen	
Restructuring expenses	12.3	
Conclusion of closing of Kazusa office	4.5	Base reorganization
Transfer of Kashima plant	3.1	
Relocation and consolidation of head office functions	2.3	
Withdrawal of business of Mitsubishi Tanabe Pharma (Guangzhou)	1.4	Business restructuring
Termination of a part of overseas business	1.0	
Amortization of goodwill	3.5	One-time amortization of goodwill of Bipha
Impairment loss	2.6	
Long-term prepaid expense	1.6	
Dormitories and company housing	1.0	Toda dormitory, Osadano dormitory and company housing

Forecasts for FY2015



Forecasts for FY2015

	FY2015 forecasts	FY2014 actual	Increase/ decrease		Objective of mid. term management plan*
	Billion yen	Billion yen	Billion yen	%	Billion yen
Sales	396.0	415.1	-19.1	-4.6	410.0
Gross profit	249.0	245.5	+3.5	+1.4	
Operating income	67.5	67.1	+0.4	+0.5	65.0
Net income	40.5	39.5	+1.0	+2.5	

(Reference)

Operating income (prior to deduction of R&D expenses)	141.5	136.7	+4.8	+3.5	
R&D expenses	74.0	69.6	+4.4	+6.3	

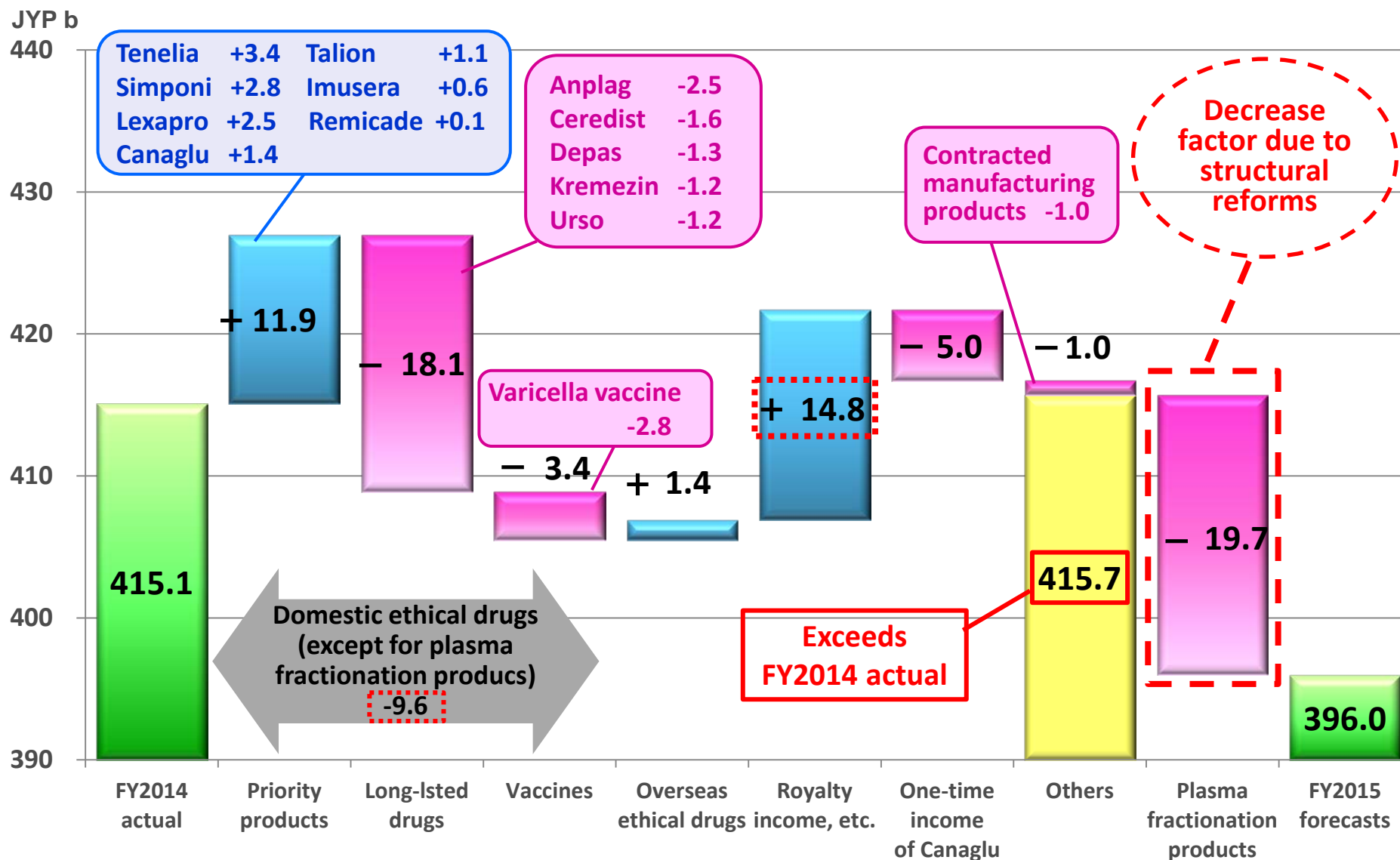
*: Announced on May 8, 2014 in the financial results of FY2013

Sales trends

New *Value* Creation



【Forecasts for FY2015】



Royalty Income, etc.

Gilenya sales

\$ 2.5b in 2014

+28%, y-o-y

\$ 0.6 b in Q1, 2015

+ 16%, y-o-y

INVOKANA/INVOKAMET sales

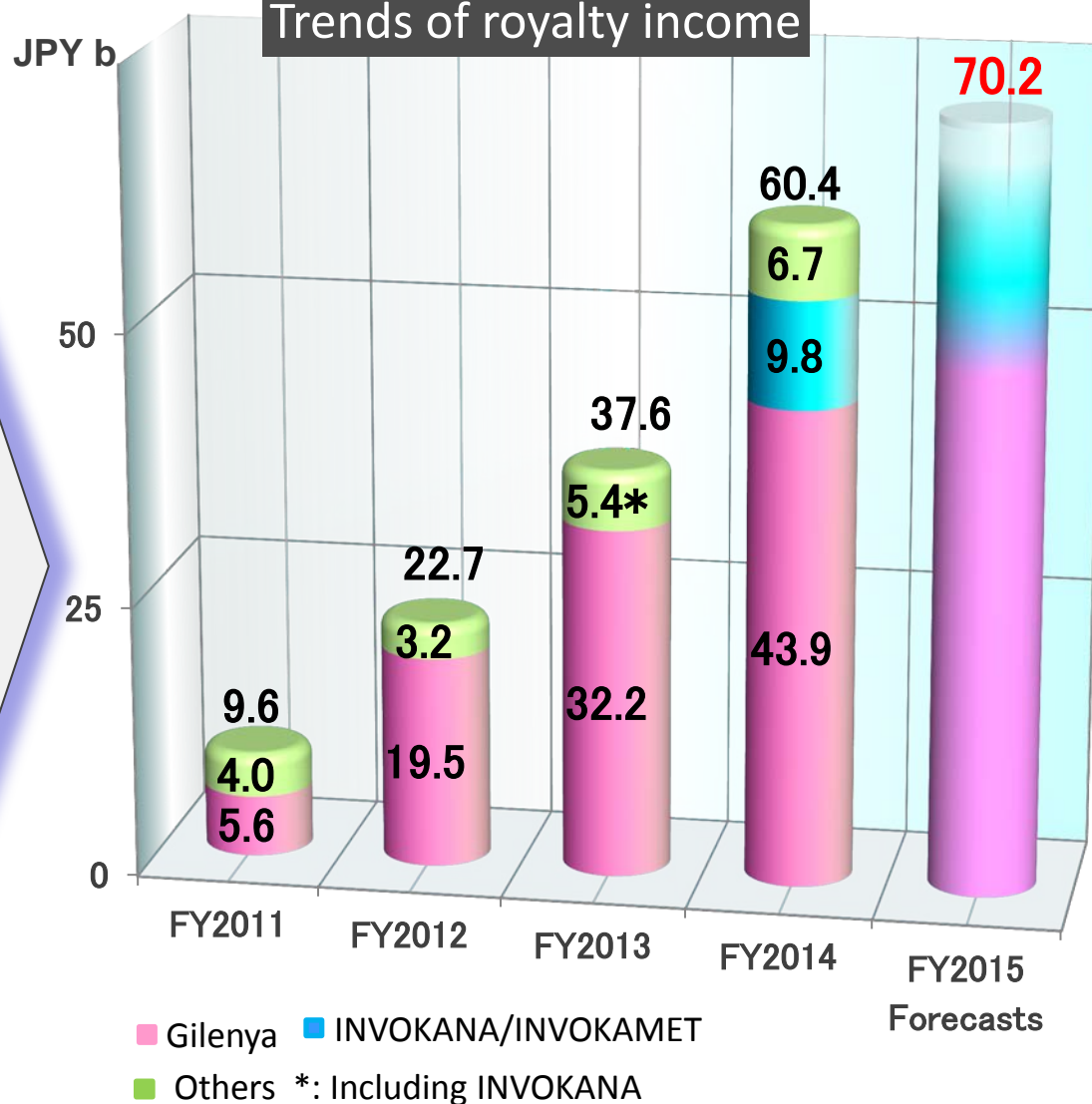
\$ 0.6b in 2014

The second year after the launch

\$ 0.3b in Q1, 2015

The same period last year: \$ 0.1b

Trends of royalty income



Forecasts for FY2015

	FY2015 forecasts	FY2014 actual	Increase/ decrease	
	Billion yen	Billion yen	Billion yen	%
Sales	396.0	415.1	-19.1	-4.6
Cost of sales	147.0	169.6	-22.6	-13.3
Sales cost ratio	37.1%	40.9%		
Gross profit	249.0	245.5	+3.5	+1.4
SG&A expenses	181.5	178.4	+3.1	+1.7
R&D expenses	74.0	69.6	+4.4	+6.3
Labor cost	46.0	46.8	-0.8	-1.6
Amortization of goodwill	10.5	10.9	-0.4	-3.8
Others	51.0	51.1	-0.1	-0.2
Operating income	67.5	67.1	+0.4	+0.5
Non-operating income & loss	-0.5	0.5	-1.0	
Ordinary income	67.0	67.7	-0.7	-1.0
Extraordinarily income & loss	-7.5	-5.0	-2.5	
Net income	40.5	39.5	+1.0	+2.5

Improvement of sales cost ratio

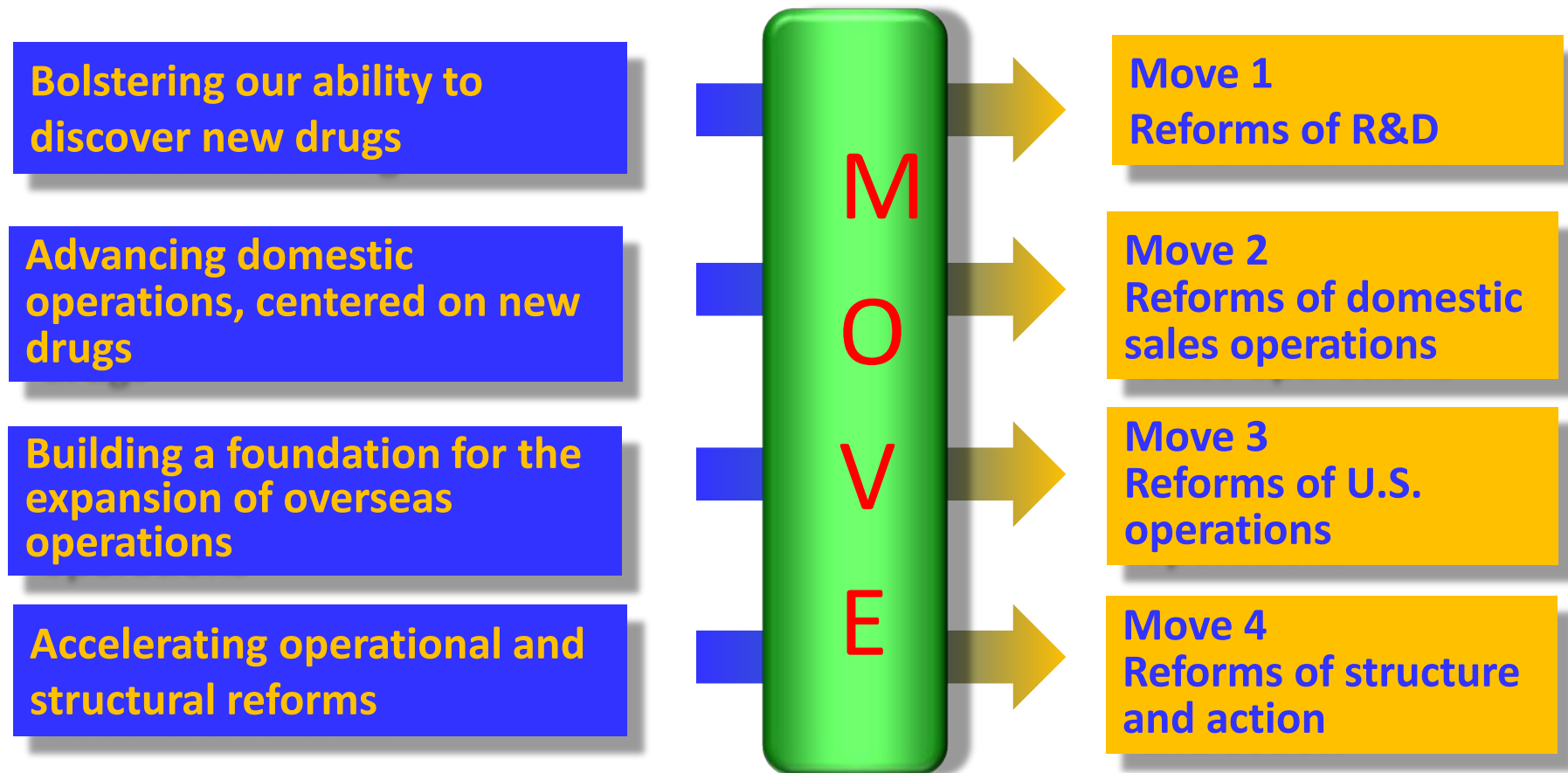
- ◆ Disposal of overstocks
- ◆ Increase of royalty income
- ◆ Transfer of plasma fractionation products

Increase in investment and increase in profit

Promotion of structural reforms

Challenges in FY2015



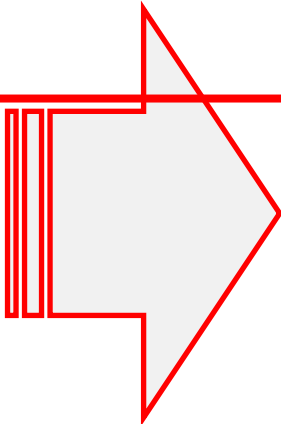


Move forward, working together to plot a course through uncharted territory

Move 1: Reforms of R&D “First to deliver unique value”
Development pipeline (1)

Filed and approved

Product name (indication)	Present stage (region)	Move Forward
Talion (Pediatric usage)	Passed the committee in Apr., 2015 (Japan)	Approval, expected in May-Jun., 2015
Radicut (ALS)	Filed (Japan)	Approval, expected in 1H of FY2015
Remicade (BD with special lesions)	Filed (Japan)	Approval, expected in 1H of FY2015
Remicade (Refractory Kawasaki disease)	P3 (Japan)	Filing, planned in Q1 FY2015



Orphan drug designated, “First to deliver unique value”

Move 1: Reforms of R&D “First to deliver unique value”

Development pipeline (2)

New **Value** Creation

【Challenges in FY2015】



Under clinical studies

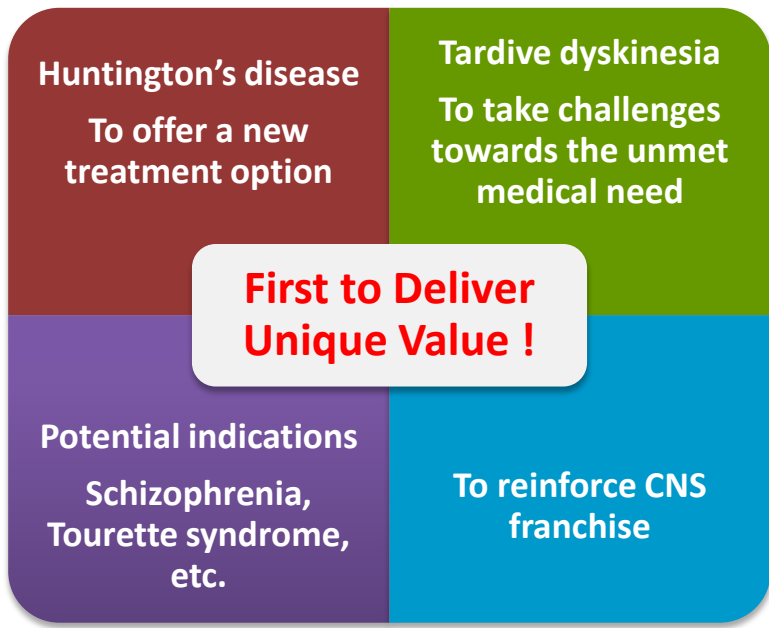
Development code/ (indication)	Present stage (region)		Move Forward
MT-4666 (AD)	P3 (Global clinical trial)		Promotion of global clinical P3
MP-214 (Schizophrenia)	P2b/3 (Japan, Asia)		Completion of enrollment in FY2015
MT-2412 (Type 2 diabetes mellitus)	P3 (Japan)		Completion of enrollment in FY2015
MT-3995 (Diabetic nephropathy)	P2 (Japan, Europe)		Acquisition of POC at an early data
MT-1303 (MS)	P2 (Europe)		Positive POC date, the next step under consideration
MT-1303 (Inflammatory disease, autoimmune disease)	P1 (Japan, Europe, U.S.)		P2 in preparation (Crohn's disease)
Seasonal influenza vaccine	P2 (U.S., Canada)		Start of P2b in FY2015

MT-5199 VMAT2 inhibitor

Inhibition of VMAT2 leads to the reduction of uptake of dopamine and other neurotransmitters into presynaptic vesicles, and normalizing the function of dopaminergic neurons associated with occurrence of involuntary movement.

Indication: Diseases with involuntary movement

- ◆ Tardive dyskinesia
- ◆ Huntington’s chorea



MTPC and Neurocrine Biosciences Inc. concluded a license agreement on NBI-98854 as of March 31, 2015. Through this agreement, the MTPC has acquired exclusive development and commercialization rights for NBI-98854 in Japan and Asian countries.

P1 in preparation, Japan

Disease area	P1	P2	P3	Filed
CNS	MT-5199	MP-214 (Schizophrenia)	MT-4666 (AD)	Radicut (ALS)

Move 1: Reforms of R&D “First to deliver unique value”

Acceleration of R&D speed

New **Value** Creation



【Challenges in FY2015】

R&D Transformation Dept.

Established on Oct., 1, 2014

1 Strengthening collaboration

Academia

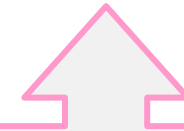
Kyoto University and
Osaka University, etc.

Corporations

AstraZeneca and Covagen, etc.

Reorganization of business
development function
centered on U.S.

2 Acceleration of R&D speed



3 Clarification of clinical value (strengthening of medical science)

Medical science

Open innovation/
shared business

Patients

Medical profession

Insurance payer

Incorporation of various
perspectives

Change of organization to “unit” centered on project on July 1, 2015

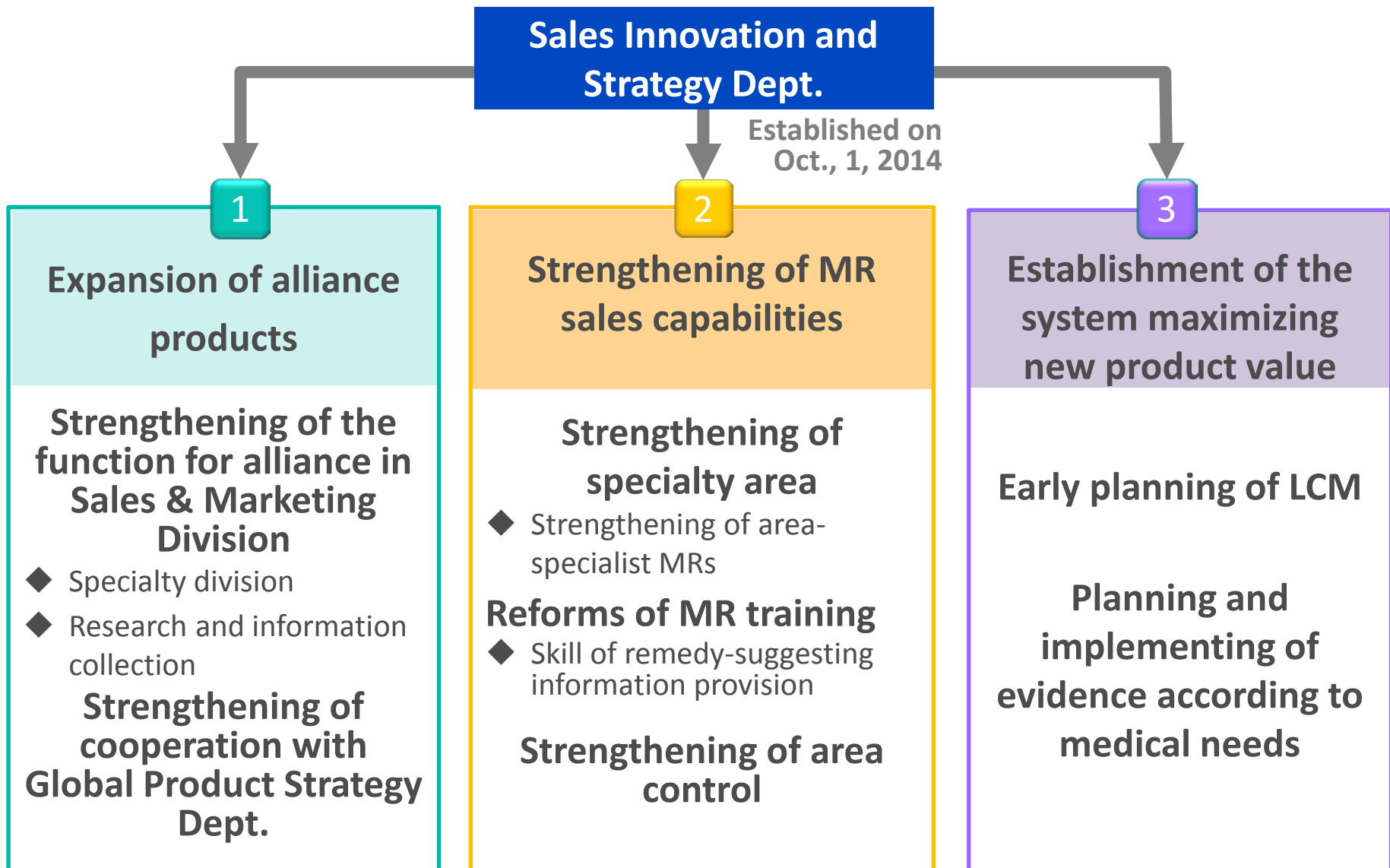
◆ **Discovery excellent compounds under the close cooperation of chemists and pharmacologists**

Move 2: Reforms of domestic sales operations

Sales Innovation and Strategy Department

【Challenges in FY2015】

New **Value** Creation

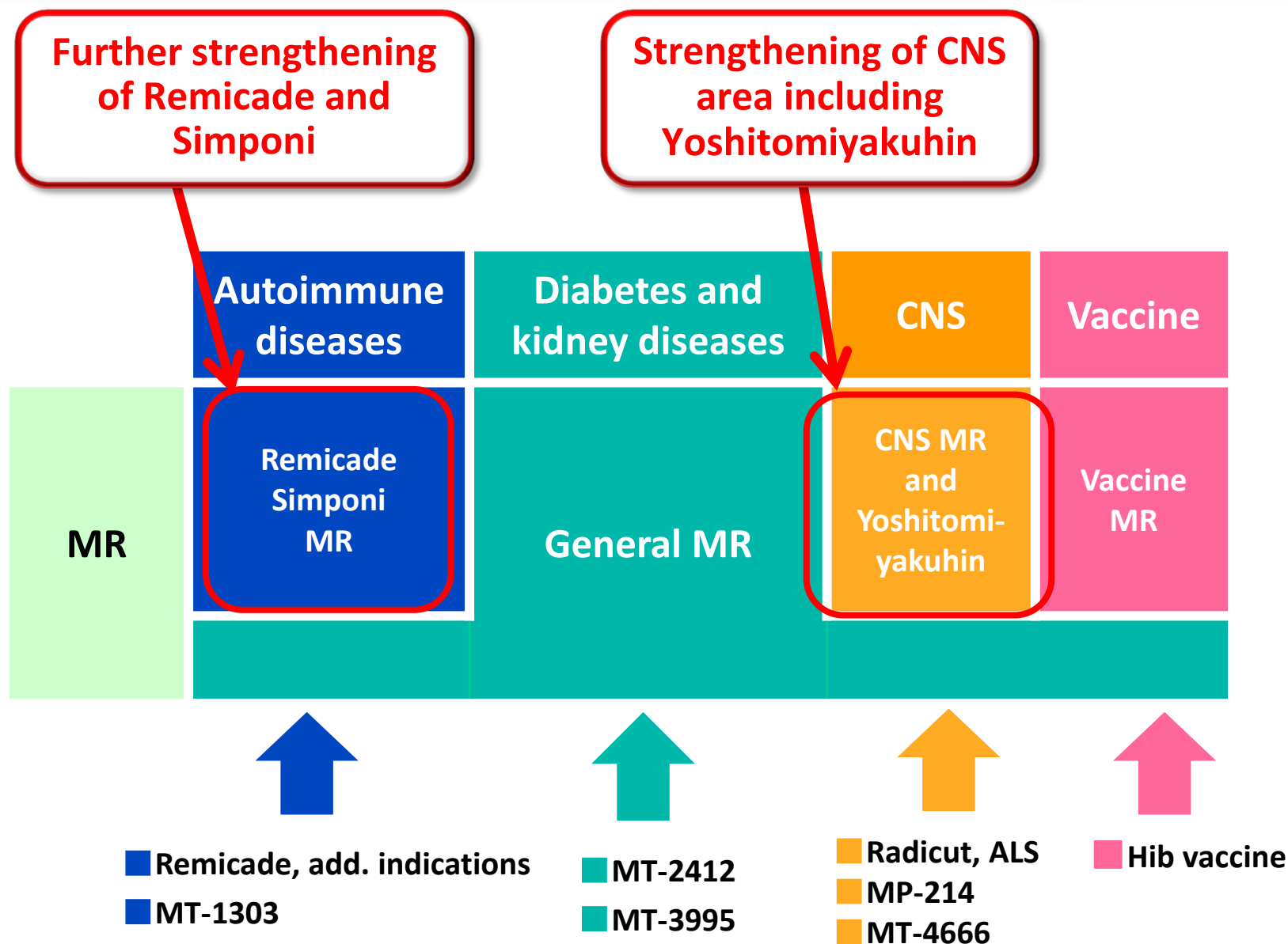


Move 2: Reforms of domestic sales operations Sales & Marketing System

New **Value** Creation









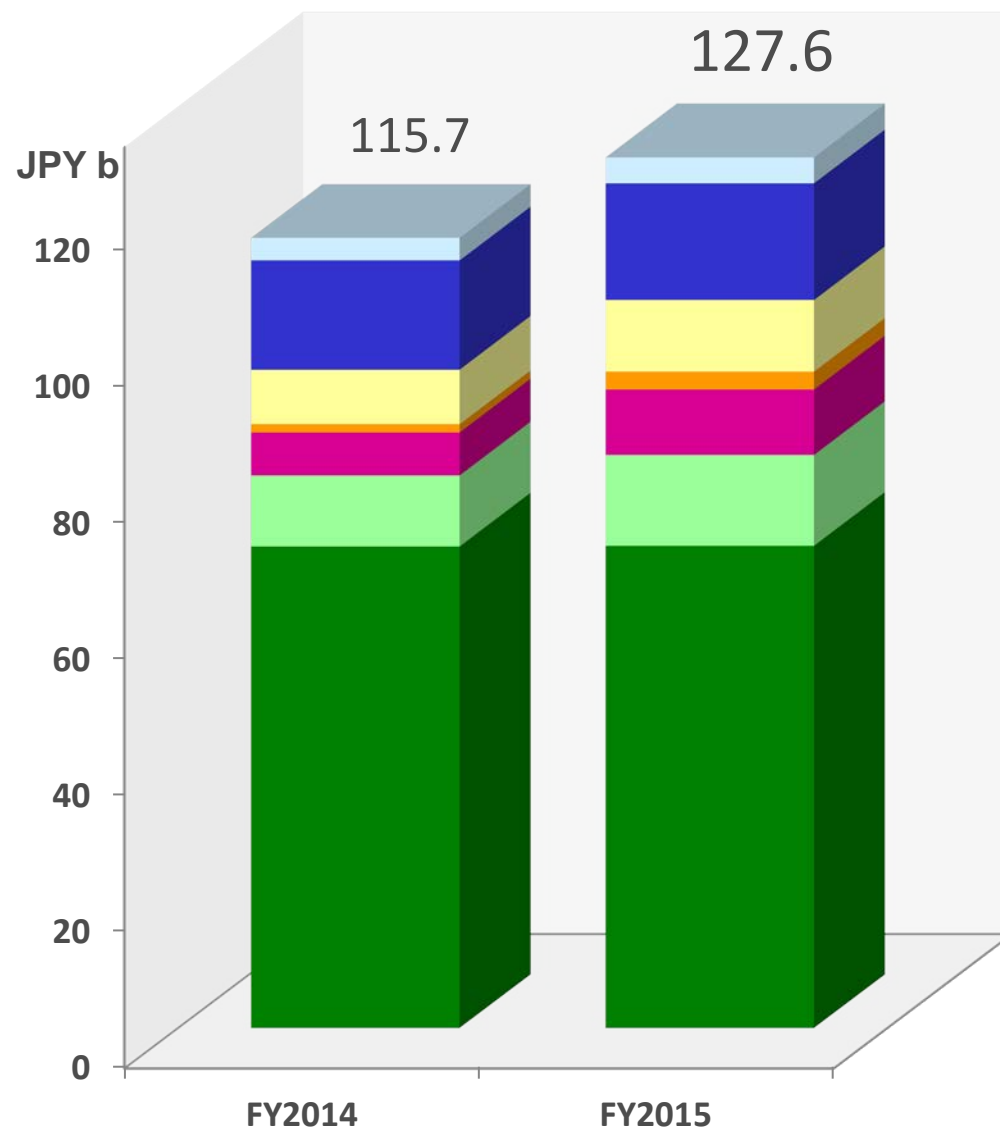
【Challenges in FY2015】






Nurturing of Priority Products

【Challenges in FY2015】

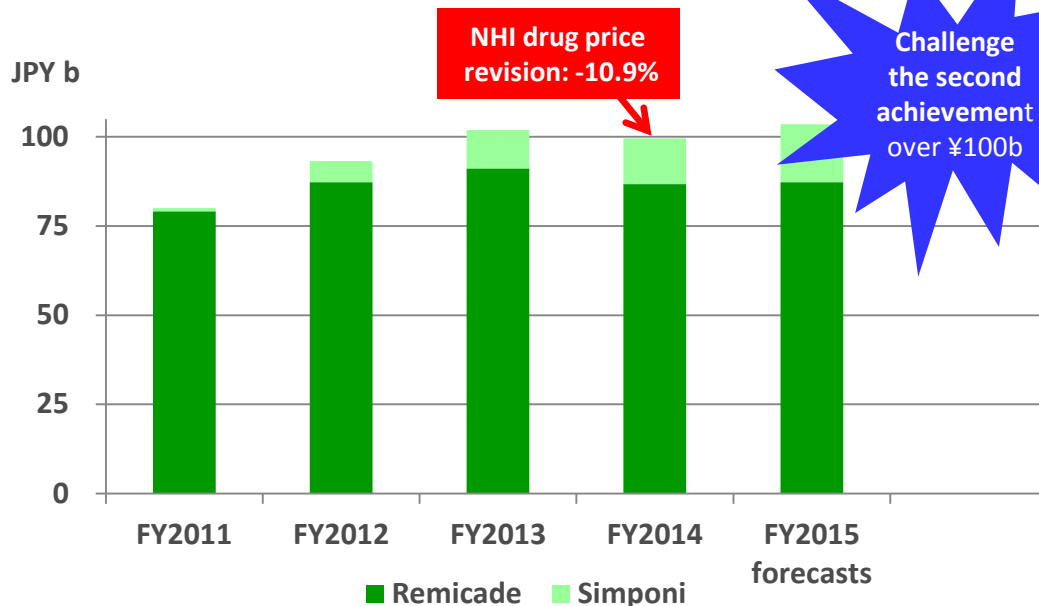
	Products	FY14	FY15	Difference
	Remicade	70.6	70.7	+0.1
	Simponi	10.5	13.3	+2.8
	Tenelia	6.2	9.6	+3.4
	Canaglu	1.2	2.6	+1.4
	Lexapro	8.0	10.5	+2.5
	Talion	16.0	17.1	+1.1
	Imusera	3.2	3.8	+0.6
	Total	115.7	127.6	+11.9



Marketing policy in FY2015

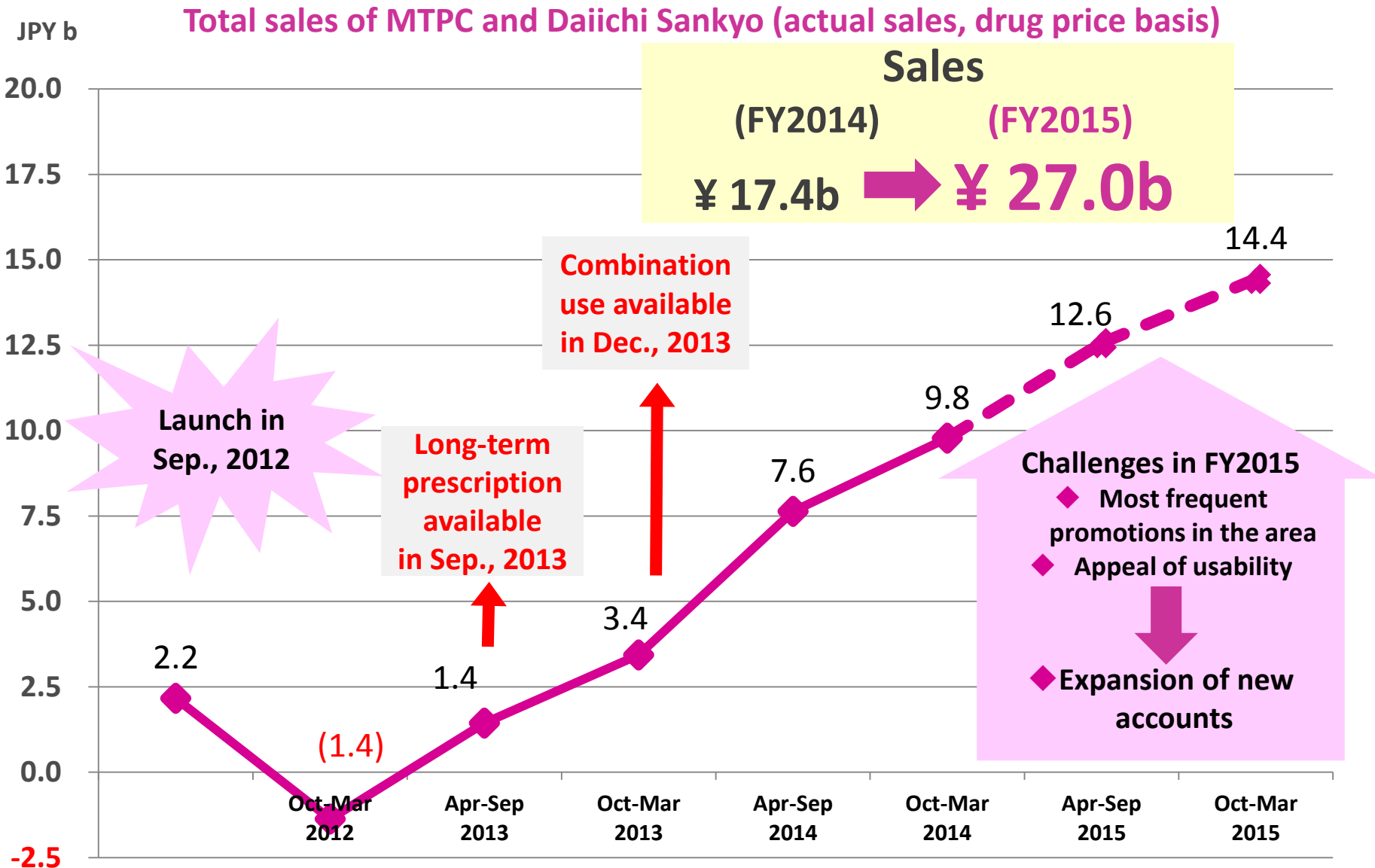
Simponi	RA		Growth driver
Remicade			First-line drug
	IBD		New prescription

Remicade & Simponi actual sales (drug price basis)



Additional indications

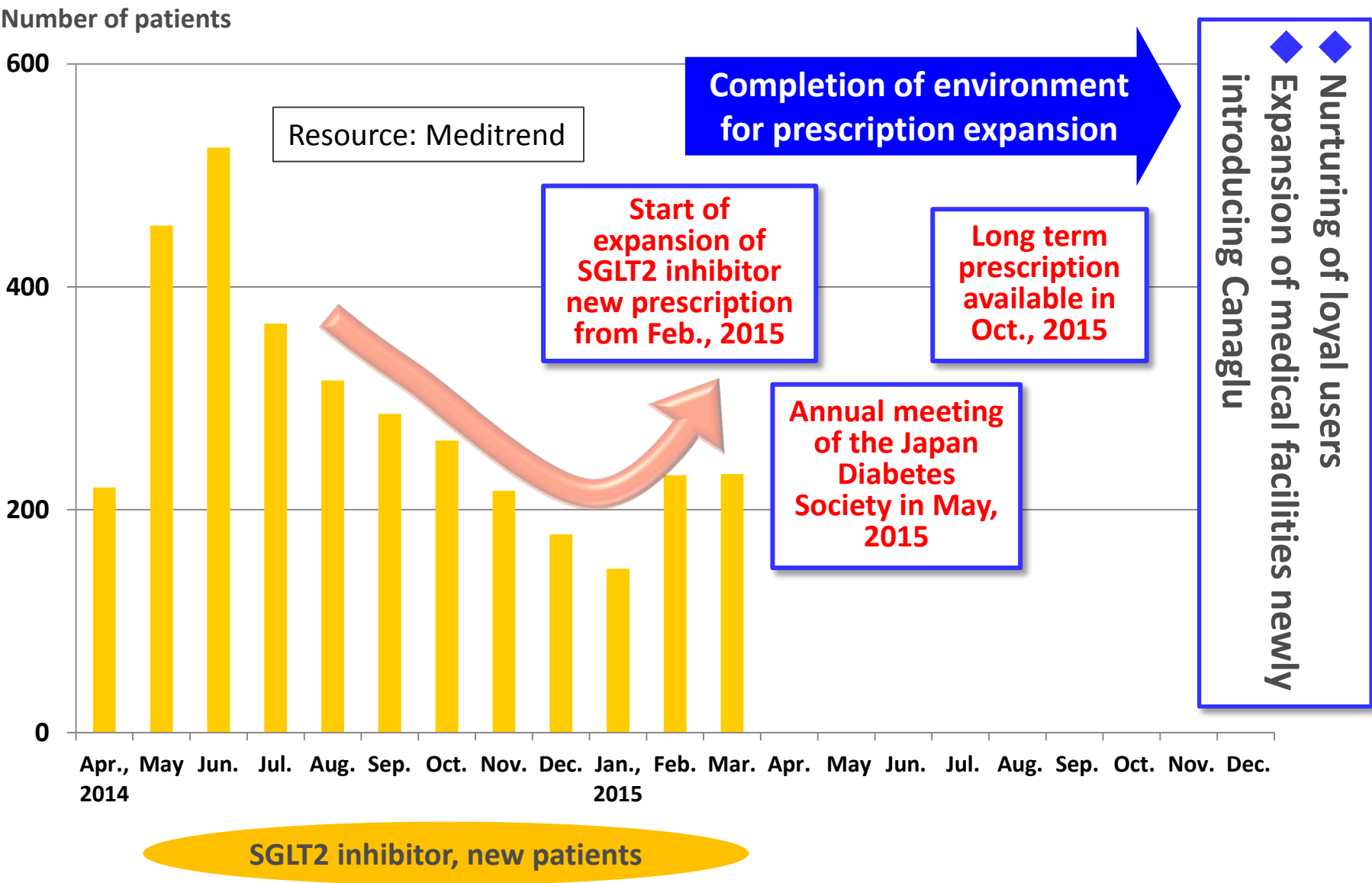
		FY2014	FY2015
Remicade	Behcet's disease with special lesion (Orphan drug)	Filed in Oct., 2014	Approval, expected in 1H FY2015
	Kawasaki disease (Orphan drug)		Filing, planned
	Pediatric Crohn's disease		Filing, planned
	Pediatric ulcerative colitis		Filing, planned
	Psoriasis		Filing, planned
Simponi	Ulcerative colitis	Developed by Janssen Pharmaceutical (P3)	



Move 2: Reforms of domestic sales operations

Canaglu

【Challenges in FY2015】



Move 3: Reforms of U.S. operations

Strengthening of the Function of Global Business Development

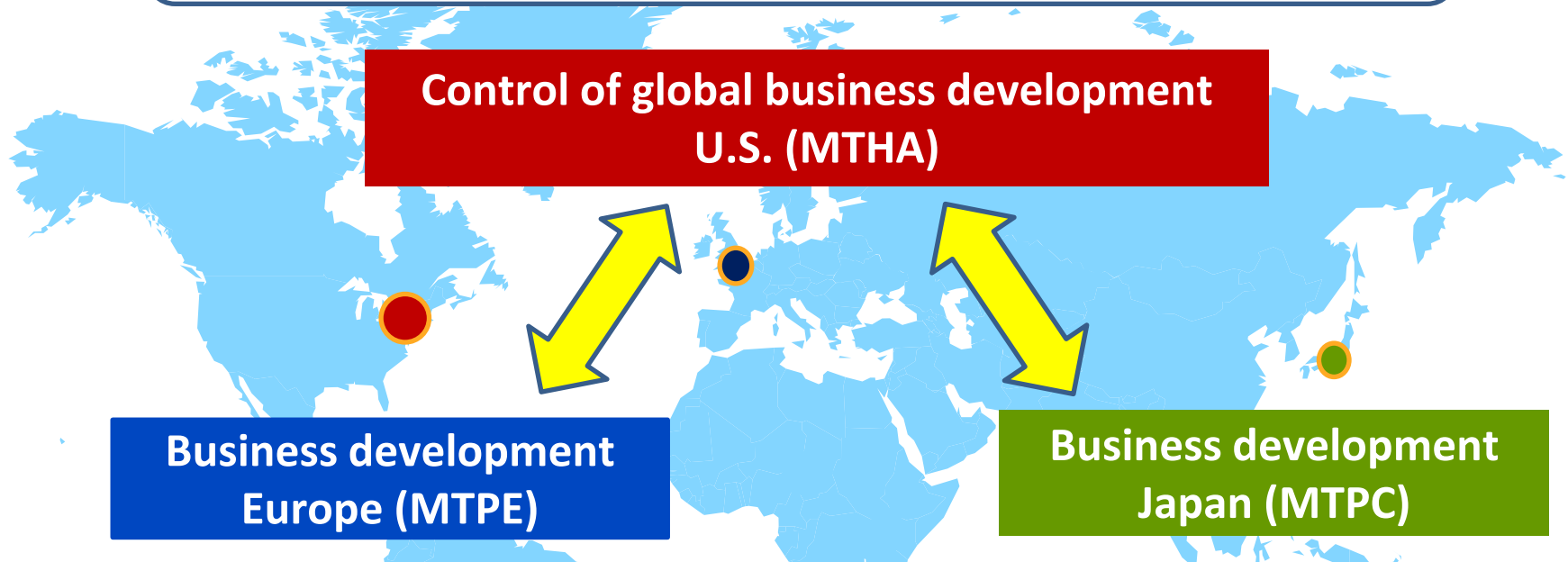
【Challenges in FY2015】

New **Value** Creation



July 1, 2015

- ◆ Set up **the function to control** global business development in **MTHA, U.S.**
- ◆ Allocate business development divisions in Japan, U.S., and Europe



- ◆ Strengthening the mobility of alliance activity
- ◆ Building the network with academia and venture companies
- ◆ Acquisition of products, pipeline, and technology
- ◆ Building of MTPC's own sales structure in U.S.

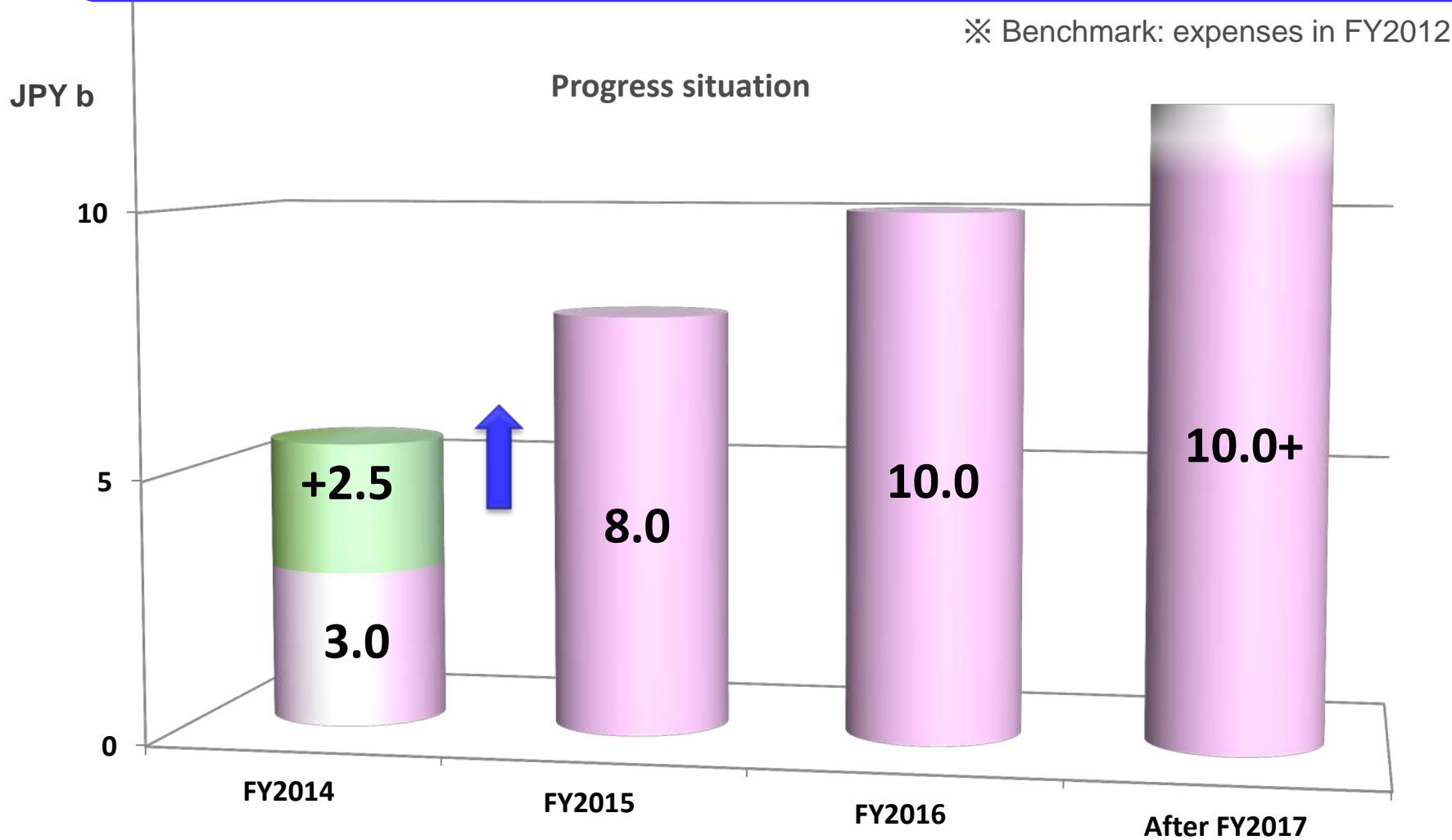
MTPC: Mitsubishi Tanabe Pharma Corporation MTHA : Mitsubishi Tanabe Pharma Holdings America, Inc.
MTPE: Mitsubishi Tanabe Pharma Europe Ltd.

Move 4: Reforms of structure and action

Cost Cut by Structural Reforms

【Challenges in FY2015】

Cost cut in FY2014 by structural reforms including base reorganization: ¥ 5.5b
(Planned at the beginning: ¥3.0b)

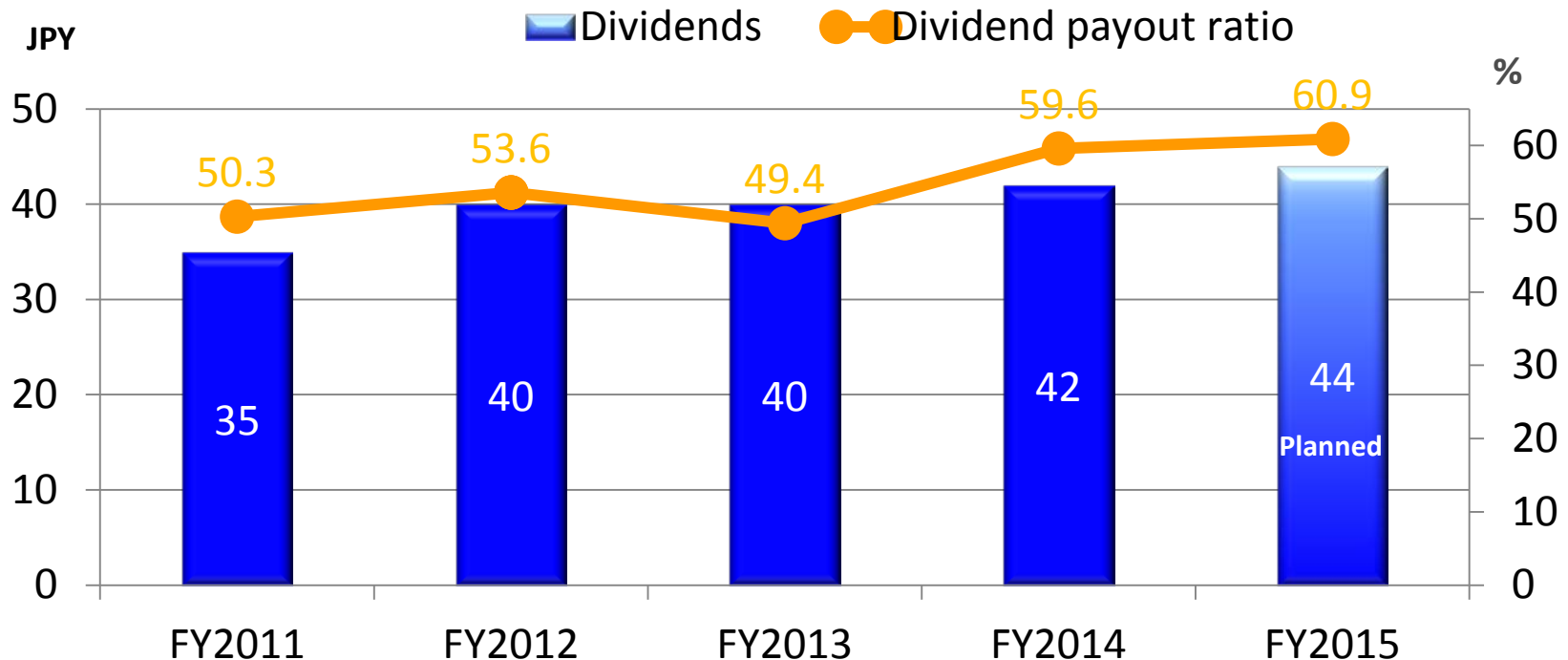


Shareholders Return

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

■ 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”

Appendix



Sales by Business Segment

New **Value** Creation

【FY2014 Business Results, appendix】



	FY2014	FY2013	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	415.1	412.7	+2.4	+0.6	406.0	102.2
(Overseas)	(77.9)	(59.4)	(+18.6)	(+31.3)	(70.3)	(110.9)
Pharmaceuticals	414.7	411.6	+3.1	+0.7	405.6	102.2
Domestic ethical drugs	323.9	341.7	-17.8	-5.2	322.5	100.4
Royalty income, etc.	60.4	37.6	+22.8	+60.7	53.6	112.7
Overseas ethical drugs	23.0	22.0	+1.0	+4.6	22.0	104.9
OTC products	4.0	4.5	-0.5	-10.5	4.3	106.7
Contracted manufacturing products	3.4	5.8	-2.5	-42.2	3.3	101.6
Others	0.4	1.0	-0.6	-58.0	0.4	109.5

*: Published forecasts announced on October 29, 2014 in the financial results of Q2 FY2014

Ethical Drugs Domestic Sales: Priority Products *New Value Creation*

【FY2014 Business Results, appendix】



	FY2014	FY2013	Increase/decrease		Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Simponi	10.5	9.4	+1.1	+11.6	11.5	90.6
Lexapro	8.0	6.5	+1.5	+23.4	8.0	99.6
Tenelia	6.2	0.8	+5.4	+684.1	6.5	96.3
Imusera	3.2	2.3	+1.0	+42.7	3.5	92.9
Canaglu	1.2	-	+1.2	-	-	-
Total of new products(1)	29.0	18.9	+10.2	+53.8	29.5*2	94.6*2
Remicade	70.6	76.3	-5.7	-7.5	70.3	100.4
Talion	16.0	13.7	+2.3	+16.7	16.4	97.6
Maintate	14.1	15.5	-1.3	-8.5	14.5	97.9
Kremezin	10.5	12.5	-2.0	-16.1	10.5	100.1
Total of existing products(2)	111.3	118.0	-6.7	-5.7	111.7	99.6
Tetrabik	7.5	6.7	+0.8	+11.9	7.1	106.5
Varicella vaccine	7.2	3.6	+3.6	+99.6	5.2	136.9
Total of vaccines(3)	14.7	10.3	+4.4	+42.4	12.3	119.4
Total of priority products(1)+(2)+(3)	155.0	147.2	+7.8	+5.3	153.5*2	100.3*2

*1: Published forecasts announced on October 29, 2014 in the financial results of Q2 FY2014 *2:Except for Canaglu






Progress of Development Pipeline

New **Value** Creation

【FY2014 Business Results, appendix】



(Progress after February 2, 2015)

	Development code/product name	Mode of action (indication)	Region	P1	P2	P3	Filed	Approved
In-house	Tribik	Vaccine(Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)	Japan					
	TA-650	Anti-human TNFα monoclonal antibody (CD, UC, pediatric CD, pediatric UC)	Taiwan					
	TA-7284	SGLT2 inhibitor (Type 2 diabetes mellitus)	Taiwan					
	MP-513	DPP-4 inhibitor (Type 2 diabetes mellitus)	Indonesia					
Out-licensed	MP-513 (Licensed to Handok)	DPP-4 inhibitor (Type 2 diabetes mellitus/ fixed dose combination with Met, XR)	Korea					

Pipeline Status

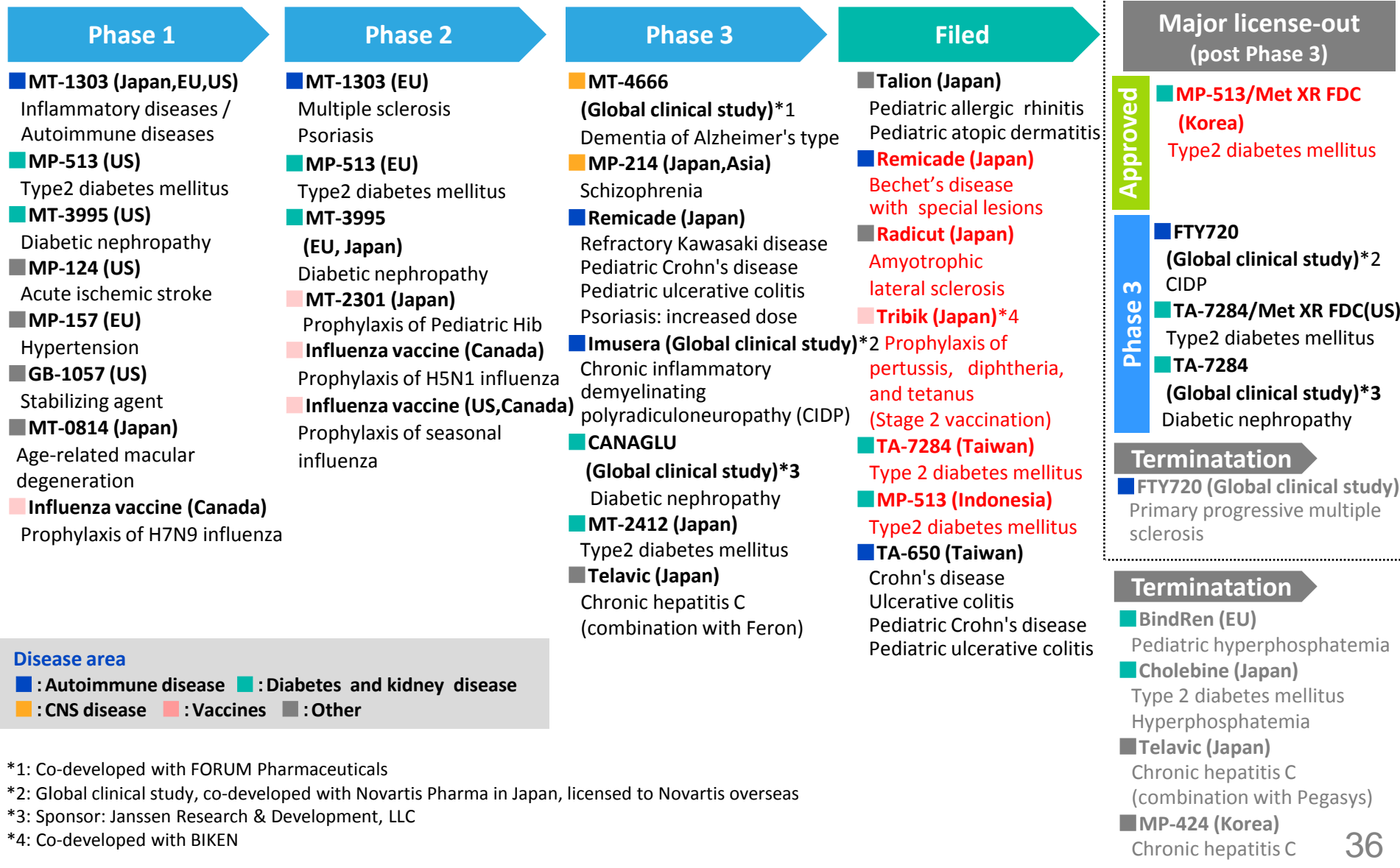
【FY2014 Business Results, appendix】

New Value Creation



Red: progress after October 29, 2014, the financial results for Q2 of 2014

As of May 8, 2015



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.