



FY2015 Business Results

(April, 2015-March, 2016)

May 12, 2016

Masayuki Mitsuka

President and Representative Director

FY2015 Business Results

Overview of FY2015 Business Results

Net sales	¥ 431.7 billion	+4.0%, year-on-year
Operating income	¥ 94.9 billion	+41.4%, year-on-year
Net income attributable to shareholders of the Company	¥ 56.4 billion	+42.9%, year-on-year

Topics

- Hit new record highs in net sales and profits at all levels
- Growth of royalty income from Gilenya and INVOKANA; ¥72.4b in FY2015(+35%, y-o-y)
- Receipt of ¥ 17.6 b as lump-sum payments from MT-1303 and TA-8995
- Approval of Radicut for ALS in Japan in Jun., 2015 and in Korea in Dec., 2015
- Approval of REMICADE for an additional indication for entero-, neuro-, and vasculo-Behcet's diseases in Aug., and for Kawasaki diseases in Dec., 2015.
- Announcement of conclusion of collaboration agreement for fasinumab with Regeneron in Sep., 2015.
- Conclusion of the development and commercialization agreement for vadadustat with Akebia in Dec., 2015.
- Promotion of structural reforms, recruiting of early retirement in Oct., 2015 and consolidation of research bases in Mar., 2016.
- Establishment of a sales company in US in Feb., 2016. toward approval and marketing of MCI-186
- Announcement of change of sales scheme for Simponi in Japan in Mar., 2016
- Announcement of “Mid-term management plan 16-20” in Nov., 2015

FY2015 Financial Results

	FY2015	FY2014	Increase/decrease		Forecasts*
	Billion yen	Billion yen	Billion yen	%	Billion yen
Sales	431.7	415.1	+16.6	+4.0	429.0
Overseas sales ratio	27.1%	18.8%			
Cost of sales	155.8	169.6	-13.8	-8.1	155.0
Sales cost ratio	36.1%	40.9%			36.1%
Gross profit	275.9	245.5	+30.4	+12.4	274.0
SG&A	181.0	178.4	+2.6	+1.5	182.0
Operating income	94.9	67.1	+27.8	+41.4	92.0
Ordinary income	94.8	67.7	+27.1	+40.1	91.0
Net income attributable to shareholders of the Company	56.4	39.5	+16.9	+42.9	53.0

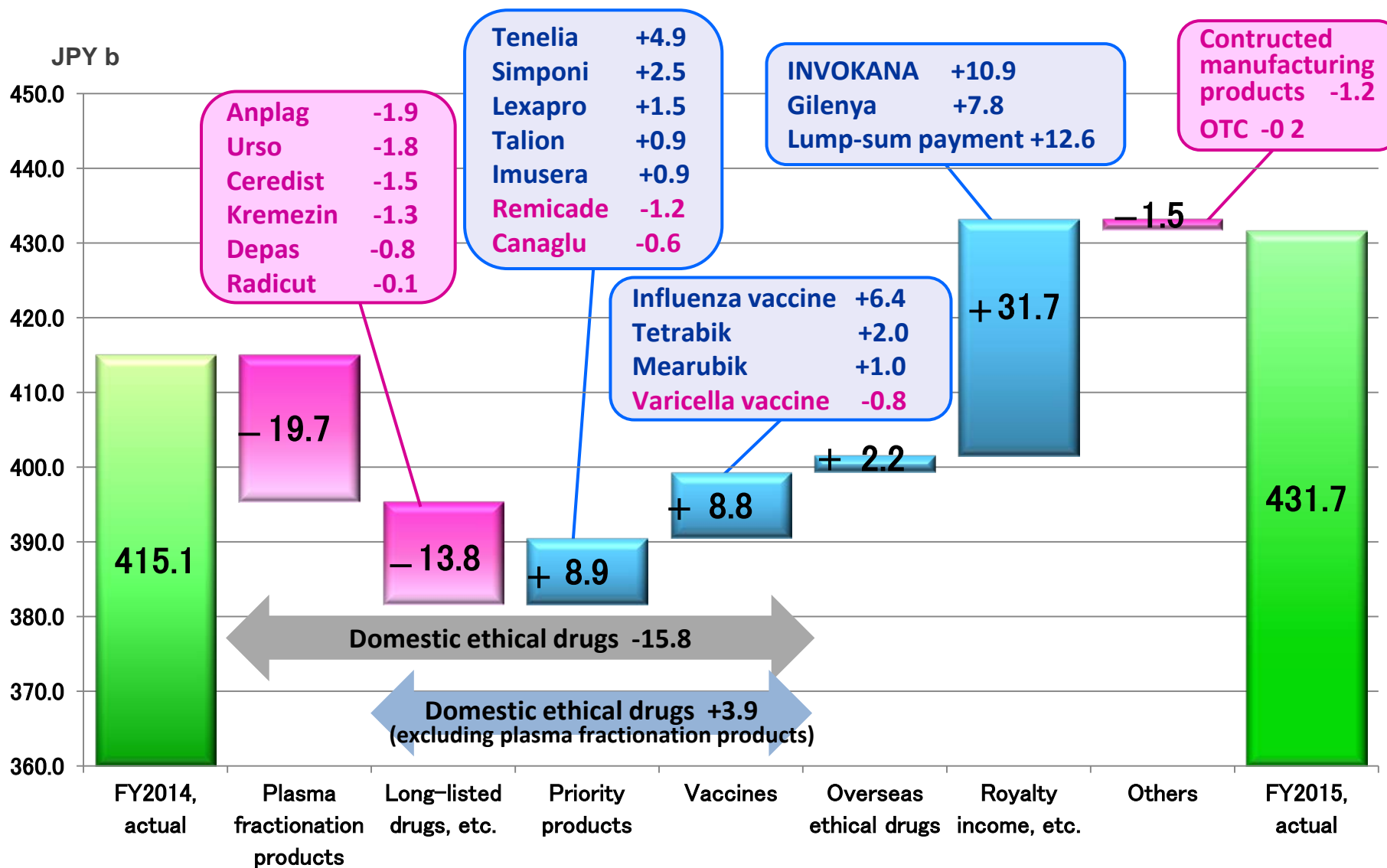
<Average exchange rate>

	FY2015	FY2014	FY2015, planned
US \$	¥120.16	¥110.62	¥120

*: Announced on February 3, 2016 in the financial results of Q3 FY2015

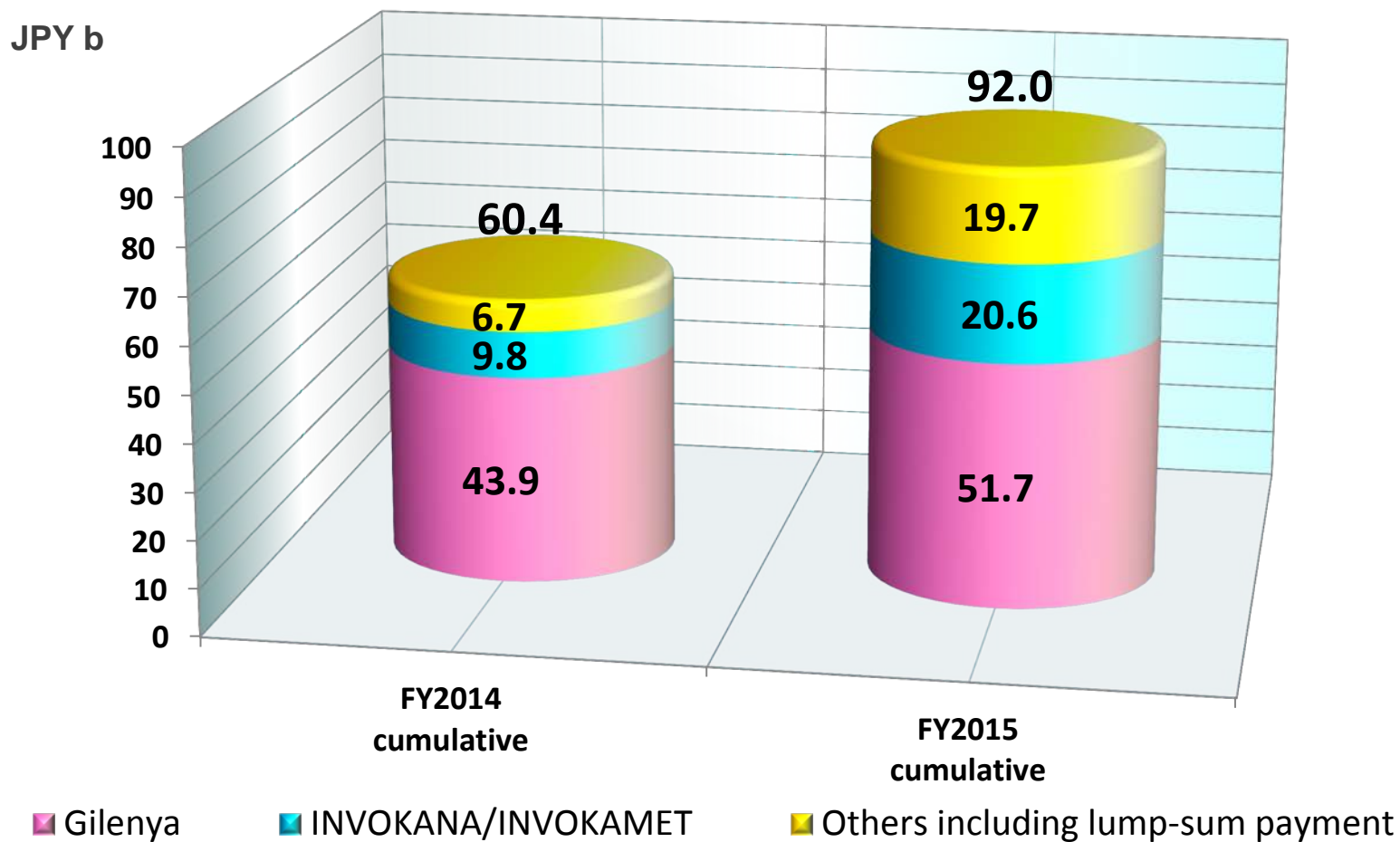


Sales Trends





Royalty income, etc.



<Average exchange rate>

	FY2014	FY2015
US\$	¥110.62	¥120.16

FY2015 Business Results

Cost of Sales, SG&A

	FY2015	FY2014	Increase/decrease		Forecasts*
	Billion yen	Billion yen	Billion yen	%	Billion yen
Sales	431.7	415.1	+16.6	+4.0	429.0
Cost of Sales	155.8	169.6	-13.8	-8.1	155.0
Sales cost ratio	36.1%	40.9%			36.1%
Gross profit	275.9	245.5	+30.4	+12.4	274.0
SG&A	181.0	178.4	+2.6	+1.5	182.0
R&D expenses	75.3	69.6	+5.7	+8.2	74.0
Labor cost	46.6	46.8	-0.2	-0.4	47.0
Amortization of goodwill	10.5	10.9	-0.4	-3.8	10.5
Others	48.6	51.1	-2.5	-4.8	50.5
Operating income	94.9	67.1	+27.8	+41.4	92.0

*: Announced on February 3, 2016 in the financial results of Q3 FY2015

Non-operating Income and Loss/ Extraordinary Income and Loss

	FY2015	FY2014	Increase/decrease		Forecasts*
	Billion yen	Billion yen	Billion yen	%	Billion yen
Operating income	94.9	67.1	+27.8	+41.4	92.0
Non-operating income and loss	-0.1	0.5	-0.7		-1.0
Ordinary income	94.8	67.7	+27.1	+40.1	91.0
Extraordinary income	14.1	13.7	+0.5		
Gain on sales of property, plant and equipment	0.7	12.0	-11.3		
Gain on sales of investment in securities	13.4	1.1	+12.4		
Gain on sales of shares of subsidiaries and affiliates	-	0.6	-0.6		
Extraordinary loss	24.6	18.6	+6.0		
Restructuring expenses	16.3	12.3	+4.0		
Impairment loss	4.5	2.6	+1.9		
Provision for reserve for HCV litigation	3.5	-	+3.5		
Amortization of goodwill	-	3.5	-3.5		
Other	0.3	0.3	0.0		
Net income attributable to shareholders of the Company	56.4	39.5	+16.9	+42.9	53.0

*: Announced on February 3, 2016 in the financial results of Q3 FY2015

Extraordinary Loss

	FY2015	Notes
	Billion yen	
Restructuring expenses	16.3	
Extra retirement payments accompanied with early retirement program	15.3	
Losses according to close of Kazusa office	0.9	Reorganization of business location
Impairment loss	4.5	
Impairment of fixed assets of Bipha	3.6	
Unused research building at Kashima	0.8	

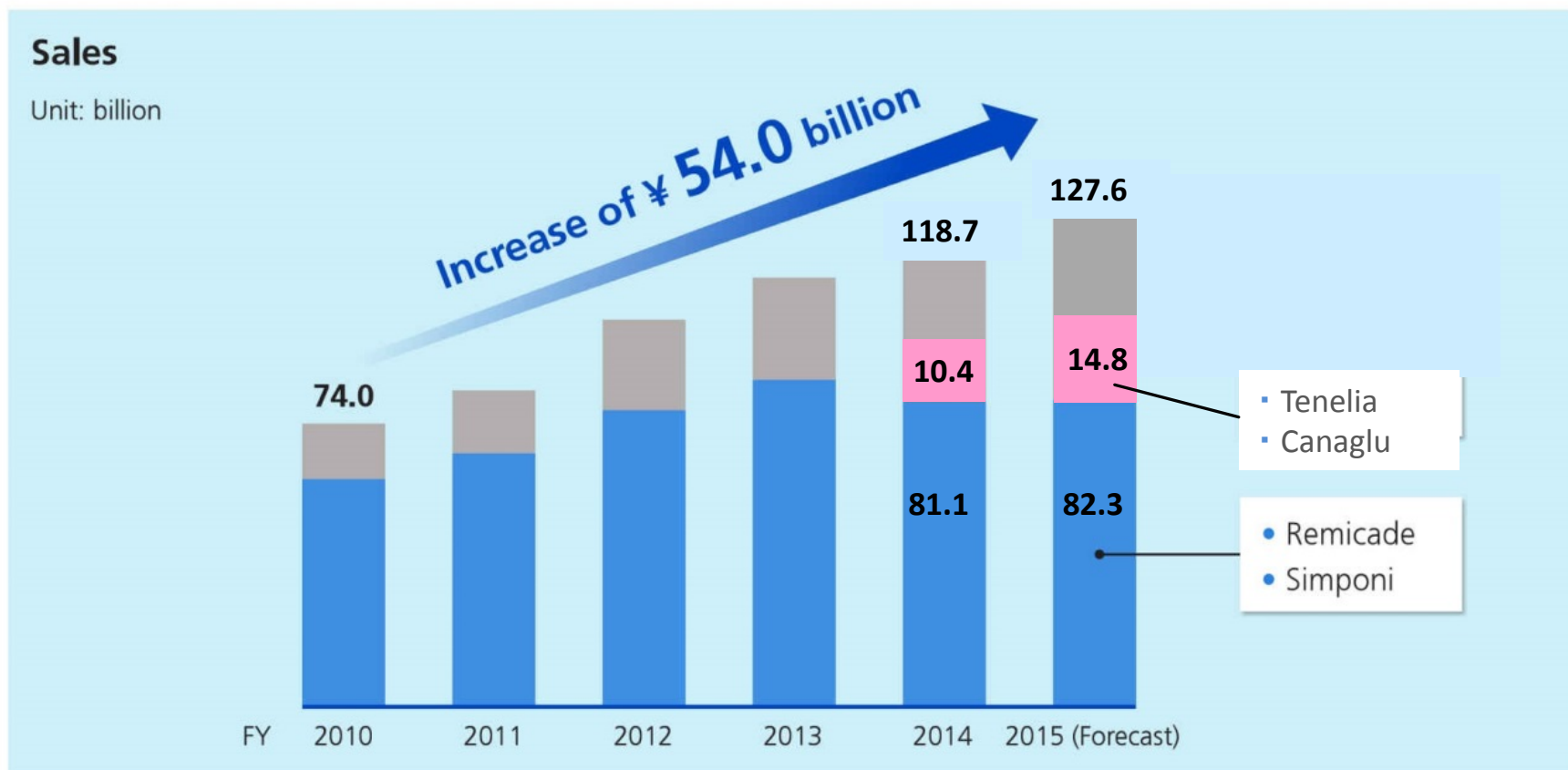
Achievements in FY2015



Growth of priority products in Japan

Steady growth of seven priority products in Japan

- Growth of sales of Remicade and Simponi, main products in autoimmune disease area
Growth of sales in diabetes and kidney disease area by appeal for usability and efficacy of Tenelia





Progress of Major Pipeline

	Code/product name	Indications	Progress in FY2015
In-house development	MT-4666	Dementia of Alzheimer's type	Discontinuation caused by termination of global Ph3 trial in Japan
	MP-214	Schizophrenia	Ph2b/3 trial in Japan, Korea and Taiwan did not meet the primary endpoint. Future plans will be finalized based on further ad-hoc analyses and PMDA consultation.
	MT-1303	MS, psoriasis, CD, etc.	Start pf P2 for CD in Europe and Japan License agreement with Biogen
	MT-8554	Nervous system, etc	Start of P1 in Europe
	Radicut	ALS	Approval in Japan and Korea
	Talion	Pediatric allergic rhinitis, atopic dermatitis	Approval in Japan
	Remicade	Kawasaki disease	File and approval in Japan
		Entero-, neuro-, and vasculo-Behcet's diseases	Approval in Japan
		Psoriasis: increased dose	File in Japan
Licensing-out	TA-7284 (Janssen)	T2DM/ FDC with metformin, XR, etc.	File in US
	TA-8995 (Dezima)	Dyslipidemia	Transfer of the rights excluding Japan and Asia to Amgen
	MT-4580 (Kyowa Hakko Kirin)	Secondary hyperparathyroidism in hemodialysis patients	Start of P3 in Japan
	Y-803 (Merck)	Cancer	Start of P2 in Europe and Canada



Acquisition of new pipeline

Area	Development code/generic name(MOA)	Indications	Development stage overseas	Licensor
Auto immune	MT-5547 fasinumab (anti-NGF antibody)	Osteoarthritis(OA) Low back pain(LB)	OA, P2/3 (US) LB, P2/3(US)	Regeneron (US)
Diabetes, kidney	MT-6548 vadadustat (HIF-PH inhibitor)	Chronic anemia	Chronic anemia P3(US, Europe)	Akebia (US)
CNS	MT-5199 valbenazine (VMAT2 inhibitor)	Tardive dyskinesia (TD) Huntington's disease(HD)	TD, P3(US) Tourette's syndrome, P2 (US)	Neurocrine Biosciences(US)

Acquisition of development and commercialization rights in Japan and certain other countries in Asia



MT-5199: start of P1 in April, 2016

MT-5547, MT-6548: aim for prompt launch

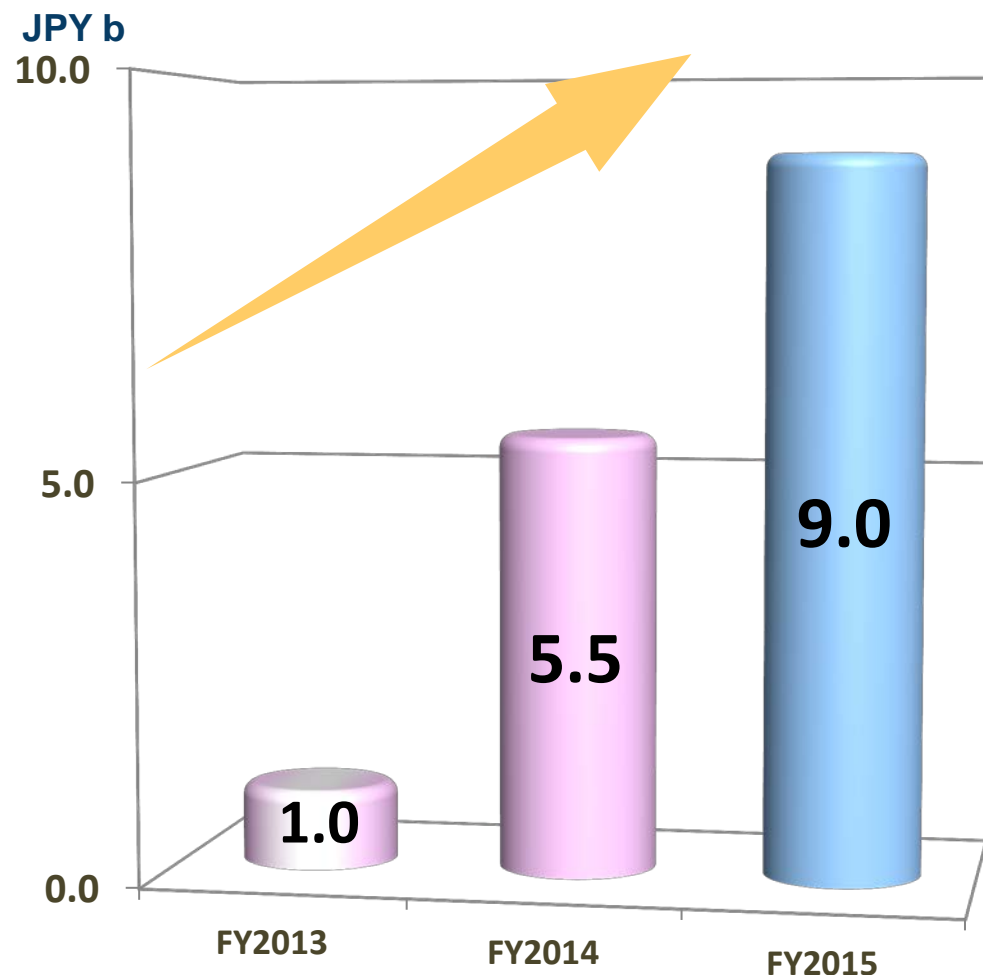
Licensing-out

Development code/generic name(MOA)	Indications	Licensee	Progress in FY2015
MT-1303 amiselimod (S1P receptor functional antagonist)	Ulcerative colitis, Crohn's disease, etc.	Biogen (US)	<ul style="list-style-type: none"> ▪ Transfer of the rights excluding Japan and Asia ▪ Receipt of lump-sum payment of \$60m
TA-8995 (CETP inhibitor)	Dyslipidemia	Amgen(US), Licensed to Dezima in 2012	<ul style="list-style-type: none"> ▪ Transfer of the rights excluding Japan and Asia ▪ Receipt of a portion of amount paid for acquisition (Dezima was acquired by Amgen for \$300m)

Cost Cuts by Structural Reforms

¥10b cost cut per year, target of FY2016, will be achieved by measures carried out until FY2015

※ Benchmark: expenses in FY2012



Main measures

- Revision and streamlining of SG&A expenses
- Revision of purchasing system and contracts
- Transfer of intravenous solution operation in China
- Consolidation of business bases (manufacture, research, and headquarters function)

Forecasts of FY2016

Definition of Core Operating Profit

“Profit to represent recurring profitability” excluding nonrecurring factors
→ Important indicator for business management and external explanation

PL including core operating profit	
Revenues	
Cost of sales	
Gross operation profit	
SG&A expenses	
Amortization of intangible assets with products	
R&D expenses	
Investment profit and loss on equity method	
Other operating revenue and expenses (deduction of non-recurring items)	
Core operating profit	
Non-recurring items	
Operating income	
Financial income, financial expenses	
Income tax, other	
Income and loss attributable to non-controlling interests	
Profit before income taxes	

【Temporary items】

Restructuring expenses

- Sale/termination of business
- Reorganization of business location
- Extra retirement payments

Impairment of intangible assets with products

- Termination of development/sales

Disposition of idle assets

Loss on disaster

Legal expenses

FY2015 Financial Result, Impacts of IFRS adoption (1)

JGAAP		IFRS (pro forma)		Notes
	Billion yen		Billion yen	
Sales	431.7	Revenues	425.8	Lump-sum payment at out-licensing of MT-1303 is deferred. (- ¥7.2b)
Cost of sales	155.8	Cost of sales	156.0	
Sales cost ratio	36.1%	Sales cost ratio	36.6%	
Gross operation profit	275.9	Gross operation profit	269.8	
SG&A expenses (excluding R&D expenses)	105.7	SG&A expenses	95.9	Goodwill is not depreciated. (- ¥10.5b)
		Amortization of intangible assets with products	1.5	
R&D expenses	75.3	R&D expenses	64.7	In-licensing budget is recognized as intangible assets. (- ¥11.4b)
—		Other gains and losses	-0.5	
—		Core operating profit	107.2	
—		Non-recurring items	-25.2	Reclassified from extraordinary income and loss, excluding gain on sale of investment in securities. (- ¥ 23.2b)
Operating income	94.9	Operating income	82.1	

*: "IFRS (pro forma)" is non-audited.

FY2015 Financial Result, Impacts of IFRS adoption (2)

JGAAP		IFRS (pro forma)		Notes
	Billion yen		Billion yen	
Operating income	94.9	Operating income	82.1	
Non-operating income and loss	-0.1	–		
–		Financial income, financial expense	1.5	
Extraordinary income and loss	-10.5	–		Reclassified to non-recurring items: +¥23.2b Gain on sale of investment in securities is reclassified to other comprehensive income, exempted from profit and loss: -¥13.4b
Net income attributable to shareholders of the Company	56.4	Net profit attributable to owners of the Company	59.5	

*: “IFRS (pro forma)” is non-audited.

Forecasts of FY2016, IFRS

	FY2016 forecasts	FY2015 actual, pro forma*	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenues	406.5	425.8	-19.3	-4.5
Cost of sales	159.0	156.0	+3.0	+1.9
Sales cost ratio	39.1%	36.6%		
Gross operating profit	247.5	269.8	-22.3	-8.3
SG&A expenses	98.5	95.9	+2.6	+2.7
Amortization of intangible assets with products	1.5	1.5	-	-
R&D expenses	70.0	64.7	+5.3	+8.2
Other profit and loss	-0.5	-0.5	-	-
Core operating profit	77.0	107.2	-30.2	-28.2
Non-recurring items	-1.5	-25.2	+23.7	-
Operating income	75.5	82.1	-6.6	-8.0
Financial income, financial expense	1.5	1.5	-	-
Profit before income taxes	77.0	83.5	-6.5	-7.8
Net profit attributable to owners of the Company	57.0	59.5	-2.5	-4.2

<Average exchange rate>

*: FY2015 actual is non-audited (pro forma).

US\$

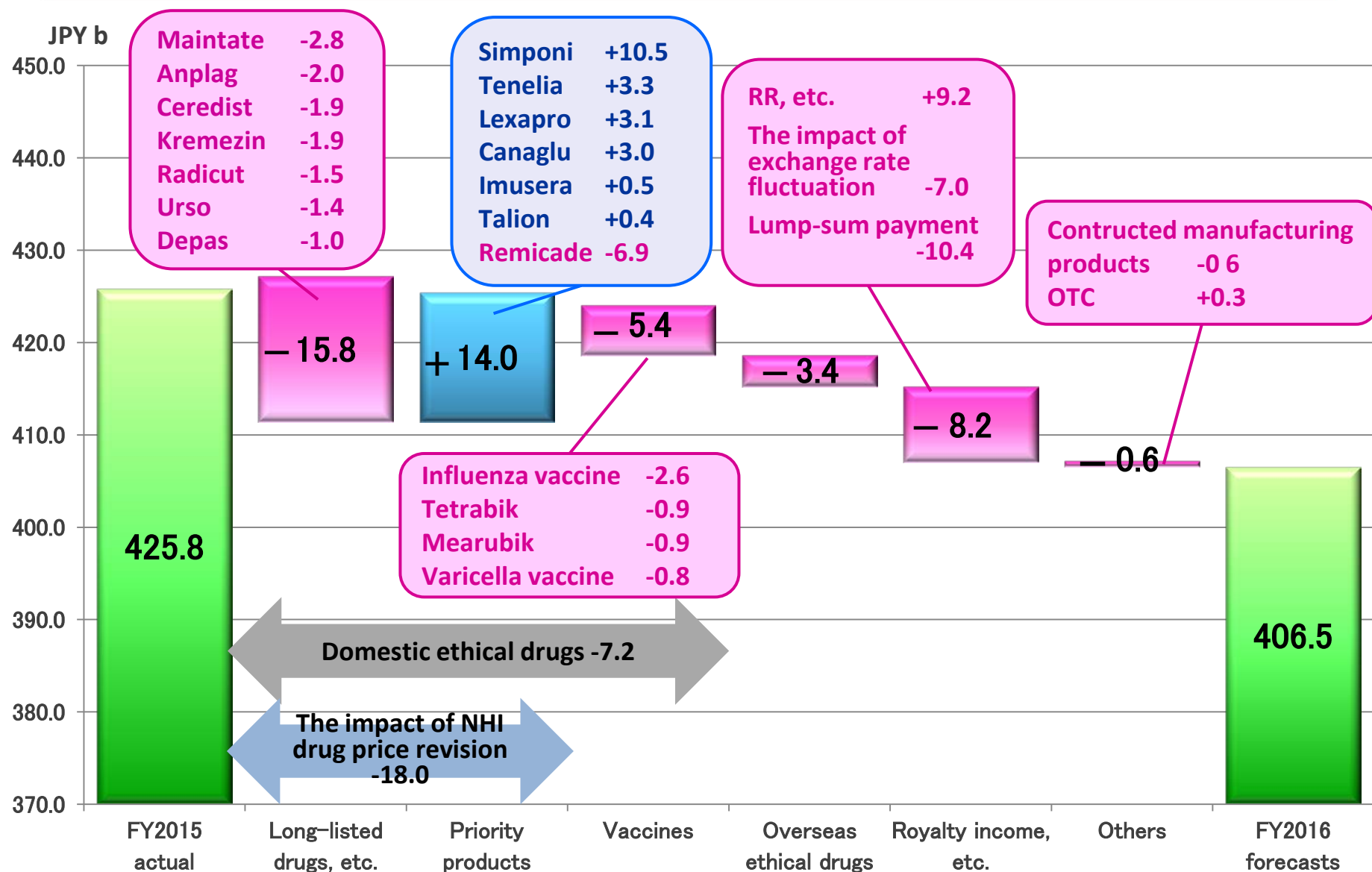
FY2015 actual

¥ 120.16

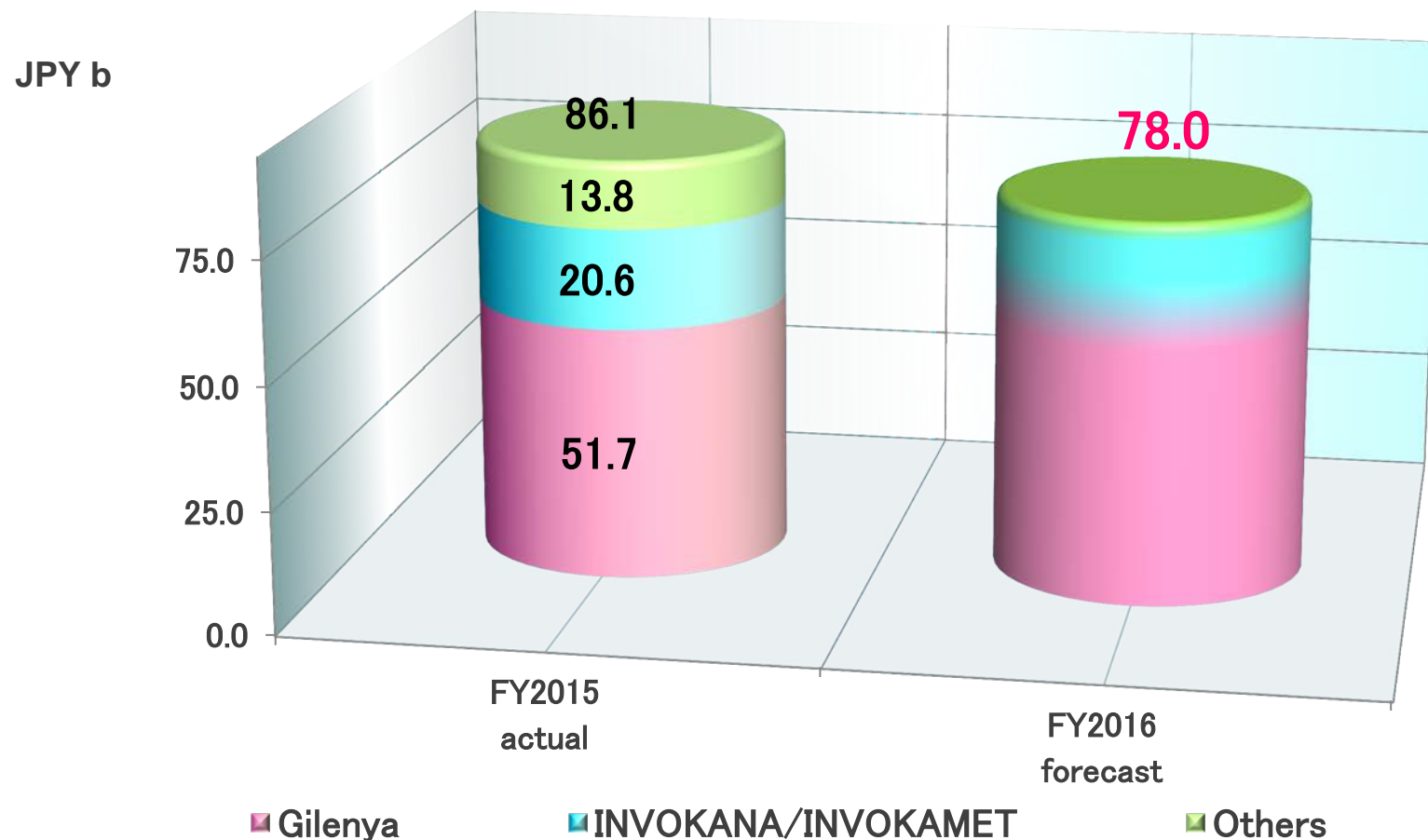
FY2016, planned

¥ 110

Sales Revenue Trend



Royalty income, etc. (IFRS)



<Average exchange rate>

	FY2015	FY2016, planned
US \$	¥120.16	¥110

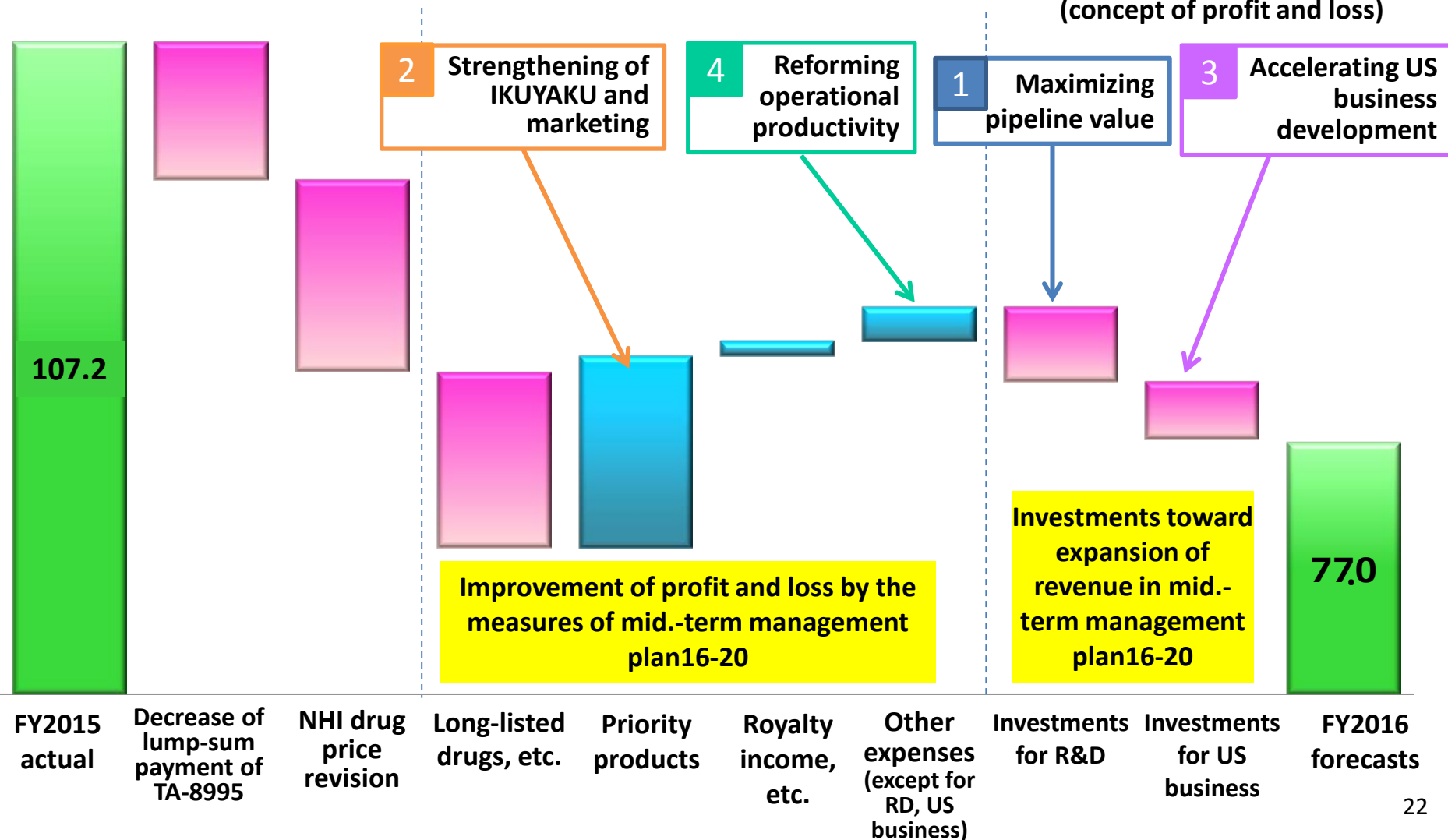


Trends of Core Operating Profit

Trends of core operating profit(FY2015 actual → FY2016 forecasts)

[JPY b]

(concept of profit and loss)



Efforts in FY2016 toward Achievement of Med.-term Management Plan 16-20



Four Strategic Priorities to Open Up the Future

1

Maximizing Pipeline Value

- Late-stage drug candidate objectives
10 candidates (including in-licensed candidates)
- Investment in R&D
More than ¥400.0 billion

Investment

3

Accelerating U.S. Business Development

- U.S. sales objective
¥80.0 billion (FY 2020)
- U.S. strategic investment
More than ¥200.0 billion

2

Strengthening IKUYAKU and Marketing

- Domestic sales objective
¥300.0 billion (FY 2020)
New drugs and priority products sales ratio: 75%
- Priority disease areas
Autoimmune diseases, diabetes and kidney,
central nervous system, vaccines

Earnings

4

Reforming Operational Productivity

- Cost of sales / SG&A expenses reduction
objective ¥20.0 billion
(FY 2020, in comparison with FY 2015)
 - Number of employees
Consolidated domestic workforce: 5,000 employees*
- *As of the end of September 2015: 6,176 employees



1. Maximizing Pipeline Value

Pipeline Status and Progress in FY2016

Area	P1	P2	P3	File	Approval
Auto immune	MT-1303 (JP:autoimmune) MT-7117 → MT-5547 →	MT-1303 (EU:MS, PS, CD JP:CD)	Remicade (JP: Pediatric CD/UC) Imusera (JP:CIDP)	Remicade (JP:PS,increased dose) →	
Diabetes, kidney	MT-3995 (US:diabetic nephropathy)	MT-3995 (JP, EU: diabetic nephropathy) MT-6548 →	Canaglu (JP: diabetic nephropathy) MT-2412 (JP: Tenelia+Canaglu) → MP-513 (China: T2DM) →		
CNS	MT-8554 → MT-5199 MP-214 (China) →	MT-4666 (JP:AD)	MP-214 (JP, Korea, Taiwan: Schizophrenia)	MCI-186 (US: ALS) →	
Vaccine	Plant based VLP vaccine (Canada: H7N9)	MT-2301 (JP: Hib vaccine) MT-2355 (JP: DPT-IPV+Hib) → Plant based VLP vaccine (US, Canada: seasonal) Plant based VLP vaccine (Canada: H5N1)		Current pipeline Stage up, planned →	

Red box: Late-stage drug candidates
(objectives in Med.-term management plan: 10 candidates)

Efforts in FY2016

Strengthening of IKUYAKU and Marketing

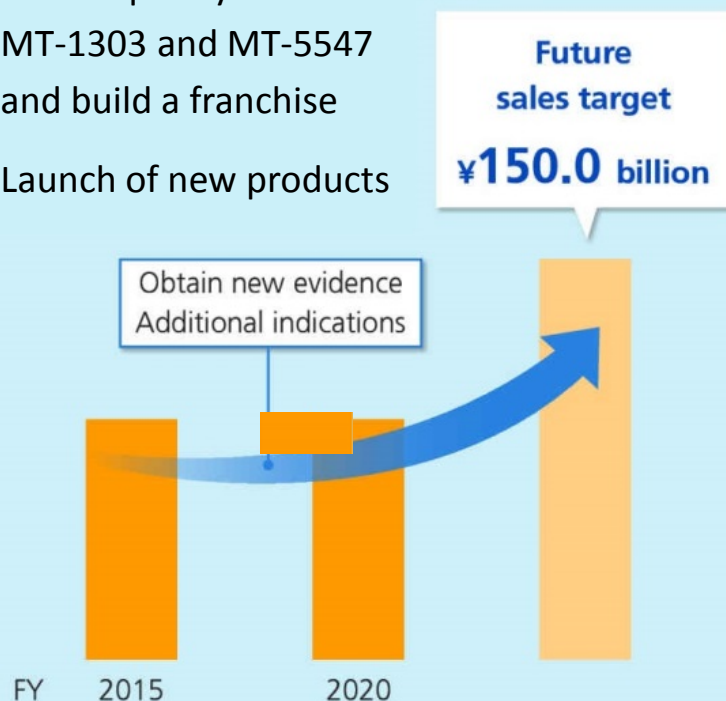
Autoimmune Disease Area

Mid.-term management plan 16-20

Autoimmune Diseases

Priority products: Remicade, Simponi, Imusera

- Maintain No. 1 share
- Aim to quickly launch MT-1303 and MT-5547 and build a franchise
- Launch of new products



*: Conducted by Janssen Pharma

Efforts in FY2016

Remicade/Simpomi

Maximizing the value of i.v./s.c

Nurturing policy

- RA:
Remicade: fast acting and available of increase dose, establishment of positioning in high active RA and early stage RA
Simponi: expansion of 100mg administration for MTX unavailable patients
- UC
Remicade: penetration of biologics and differentiation from other drugs

Change of sales scheme of Simponi

- Aim for No.1 share in s.c. drugs by synergy of both of MTPC and Janssen Pharma

Additional indication, usage and dosage, additional form

- Remicade: increased dose for psoriasis
- Simponi: additional indication of UC*, additional form of 100mg syringe*

Promotion of development

- MT-5547, MT-1303

Efforts in FY2016

Strengthening of IKUYAKU and Marketing

Diabetes and Kidney Disease Area

Mid.-term management plan 16-20

Diabetes and Kidney Diseases

Priority products: Tenelia, Canaglu

- No. 1 presence through new drug growth
- Rapid realization of additional indications
- Launch of new products

FY2017

Canaglu
CANVAS/CANVAS-R
10,000 cases

Combination drug of
Tenelia and Canaglu

Future
sales target
¥100.0 billion

Additional indications

Obtain new evidence

FY 2015

2020

Efforts in FY2016

Tenelia: more growth and share expansion

Nurturing policy

- Unnecessary of dose adjustment depend on kidney function, usability in the elderly, strong efficacy→establishment of the positioning in the elderly and the patient with weak kidney
- Expansion of prescription in cardiovascular and nephrology by strength of both of MTPC and Daiichi Sankyo

Canaglu: establishment of the base in the market

Nuturing policy

- Pursuing of appropriate use
- Global evidence, HbA1c lowering effect with one dose

Filed of combination drug

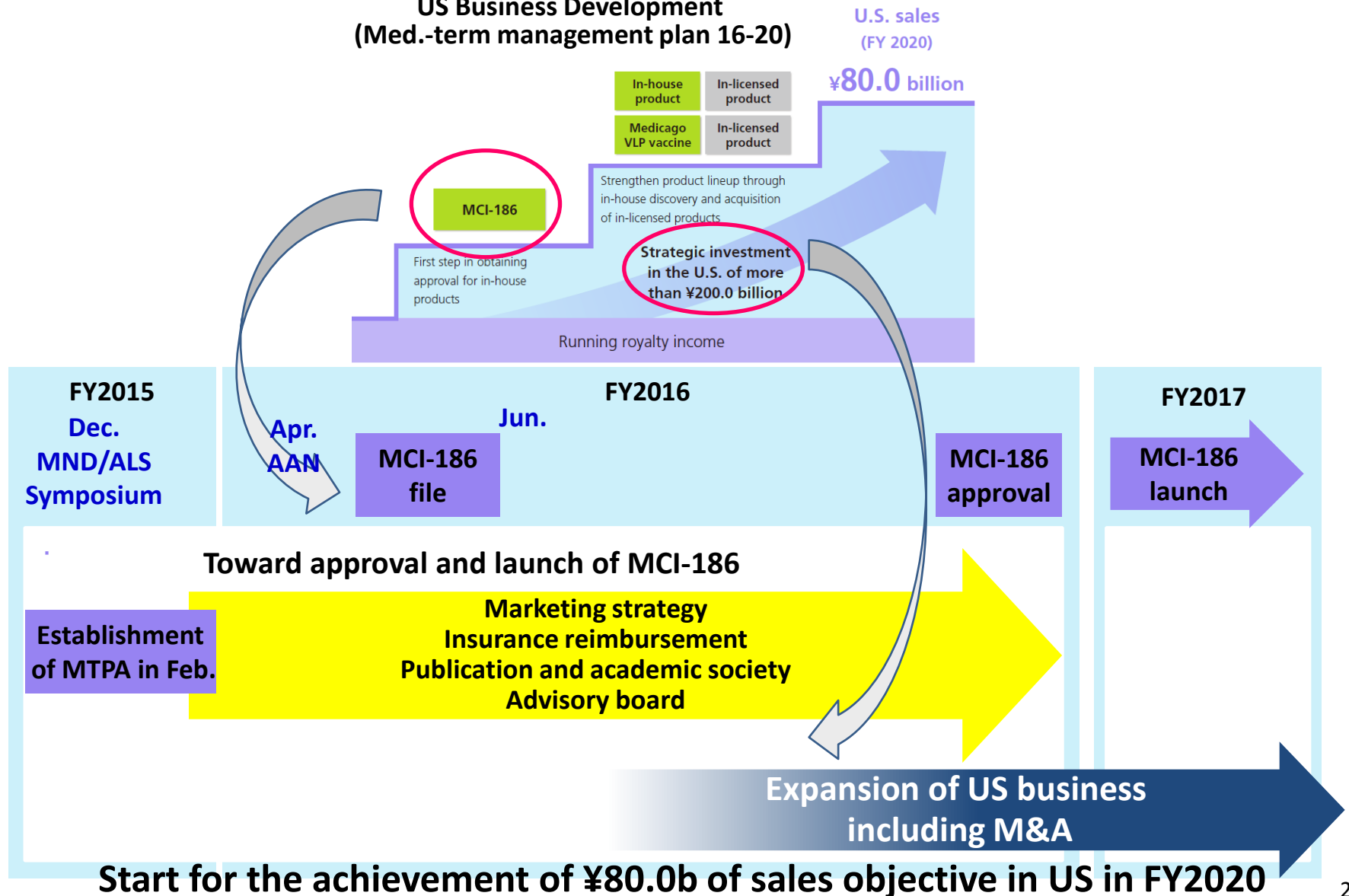
- Filed of MT-2412(Canaglu+Tenelia), launch in FY2017

Promotion of development

- MT-3995, MT-6548

3. Accelerating US Business Development Establishment of Business Base

US Business Development (Med.-term management plan 16-20)



4. Reforming operating productivity

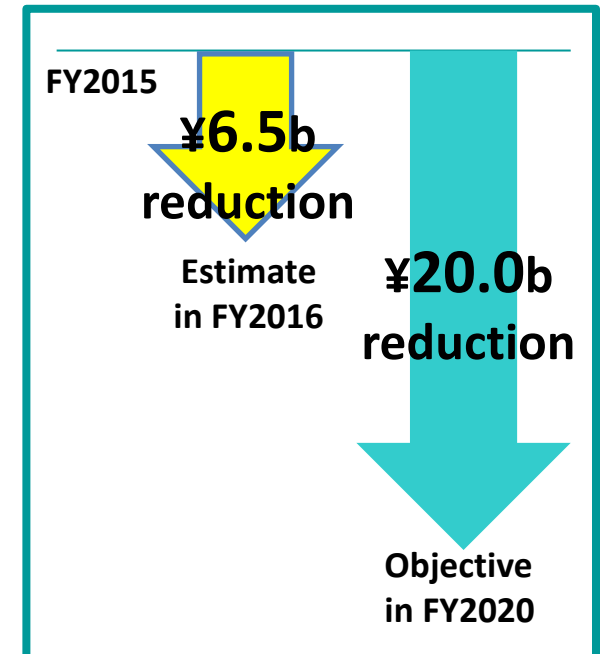
Cost reduction

**Objective: total ¥20.0b of cost reduction
(in comparison with FY2015)**

- **Cost of sales :**
 - Reforms of manufacturing and supply chain
- **SG&A expenses**
 - Reduction of fixed cost, effective expenses

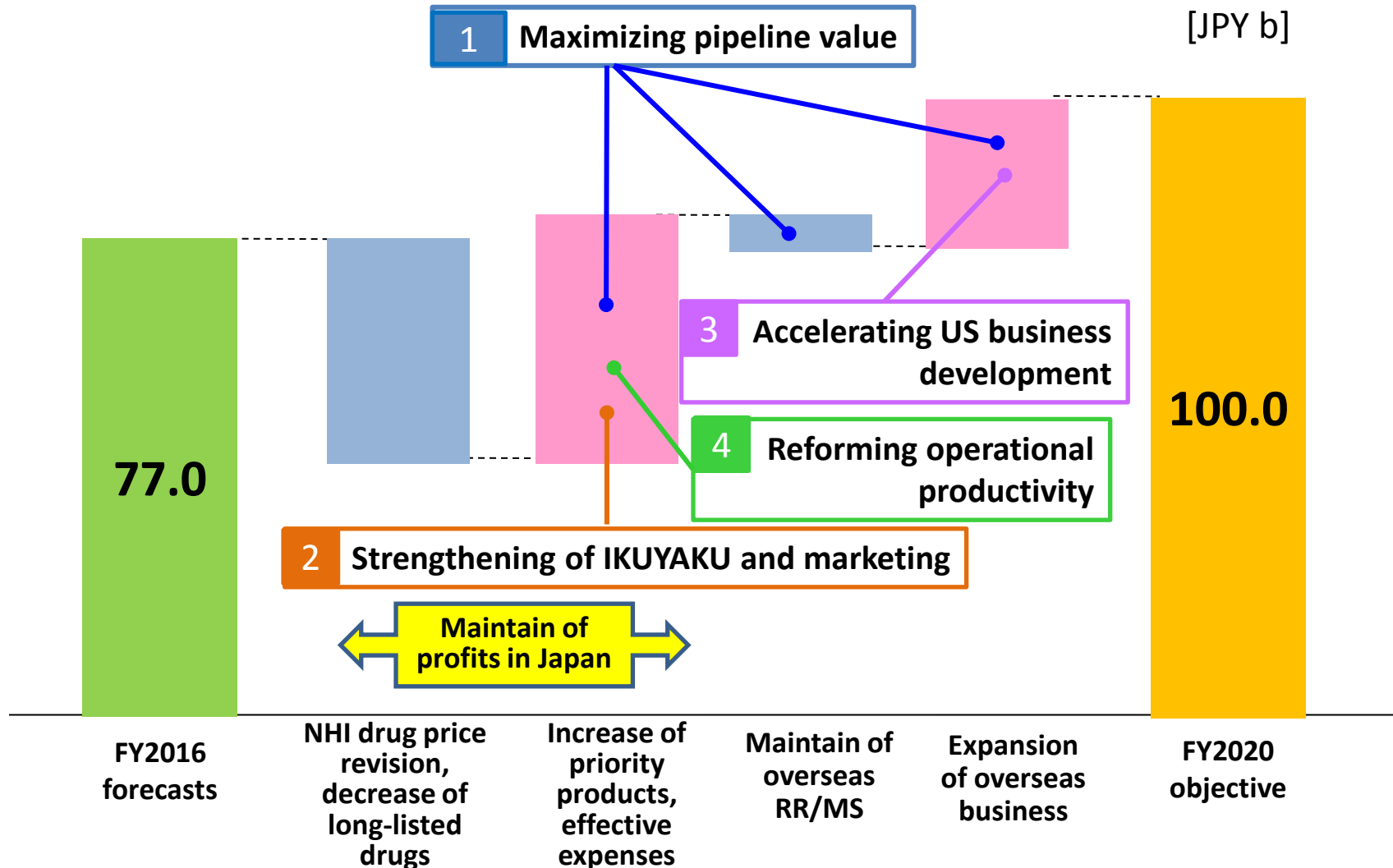
Actively utilizing human resources

- **Japan: Downsized organization through reduction of operations and revision of redundant function → 5,000 employees in FY2020(objective)**
- **Overseas: Allocation of human resources centered in US**



Efforts in FY2016
**Toward the Objectives of Mid.-term Management
Plan 16-20**

Accomplishment of “the four strategic priorities” and achievement of ¥100b of core operating profit in FY2020



Shareholders Return

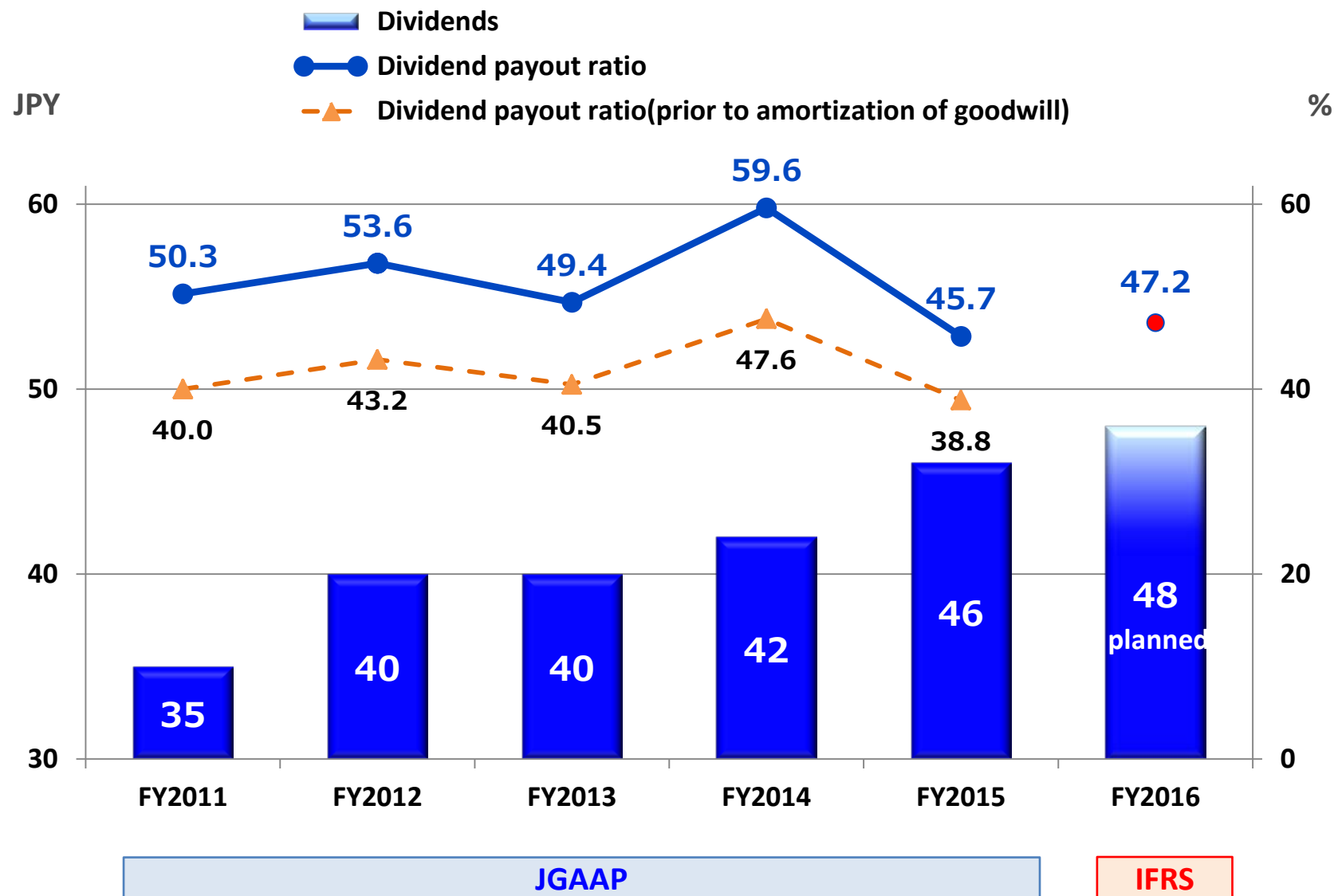
Shareholders Return

FY2015

- Dividend policy of the consolidated payout ratio in mid.-term management plan 11-15: 50% (JGAAP)
- Hit new record highs in sales and profits because of overseas royalty revenues, lump-sum payments, increased sales of priority products and vaccine and promotion of structural reforms
- Year-end dividend: ¥24 increased by ¥2 in comparison with interim dividend
Annual dividend: ¥46 increased by ¥4, including the interim dividend of ¥22

FY2016

- In mid.-term management plan 16-20, implementation of dividends based on mid., long-term profit growth and the dividend policy of **the consolidated dividend payout ratio to 50% (IFRS)**. Equivalent to an increase of 10% in real terms because under the current dividend policy the consolidated dividend payout ratio of 50% is equivalent to 40% prior to amortization of goodwill.
- Prospect of ROE: the second half of 7% by the achievement of ¥70.0b of the net income in FY2020
- Estimate of annual dividend for FY2016: **¥48 increased by ¥2** in comparison with the previous fiscal year



Open Up the Future

Becoming a company that works with a sense
of speed and is the first to deliver differentiated value



Mitsubishi Tanabe Pharma

Appendix



Sales by Business Segment

	FY2015	FY2014	Increase/decrease		Full year forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	431.7	415.1	+16.6	+4.0	<i>429.0</i>	100.6
(Overseas)	(116.9)	(77.9)	(+39.0)	(+50.0)	(114.6)	(102.0)
Pharmaceuticals	431.3	414.7	+16.6	+4.0	417.6	103.3
Domestic ethical drugs	308.1	323.9	-15.8	-4.9	296.6	103.9
Overseas ethical drugs	25.2	23.0	+2.2	+9.6	25.2	100.0
Contracted manufacturing products	2.2	3.4	-1.2	-35.2	2.1	106.2
Royalty income, etc.	92.0	60.4	+31.7	+52.5	89.6	102.7
OTC products	3.8	4.0	-0.2	-5.8	4.1	91.7
Others	0.4	0.4	-0.1	-13.5	0.4	95.7

*: Announced on February 3, 2016 in the financial results of Q3 FY2015. The forecasts except sales indicated in italics were announced on October 30 in the financial results of Q2 FY2015

Ethical Drugs Domestic Sales (Priority Products and Vaccines)

	FY2015	FY2014	Increase/decrease		Full year forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	69.4	70.6	-1.2	-1.7	67.7	102.6
Talion	16.9	16.0	+0.9	+5.6	16.9	100.2
Simponi	12.9	10.5	+2.5	+23.5	12.6	102.7
Lexapro	9.5	8.0	+1.5	+19.2	10.4	91.1
Tenelia	14.2	9.2	+4.9	+53.6	13.6	104.3
Imusera	4.1	3.2	+0.9	+27.0	4.1	100.2
Canaglu	0.6	1.2	-0.6	-50.9	2.5	22.9
Total of priority products	127.6	118.7	+8.9	+7.5	127.7	99.9
Influenza vaccine	13.8	7.4	+6.4	+86.5	11.2	122.8
Tetrabik	9.5	7.5	+2.0	+26.5	7.4	128.5
Varicella vaccine	6.4	7.2	-0.8	-11.2	6.1	103.7
Total of vaccines	29.6	22.1	+7.6	+34.4	24.8	119.8
Total of priority products and vaccines	157.2	140.7	+16.5	+11.7	152.5	103.1

*: Announced on October 30, 2015 in the financial results of Q2 FY2015

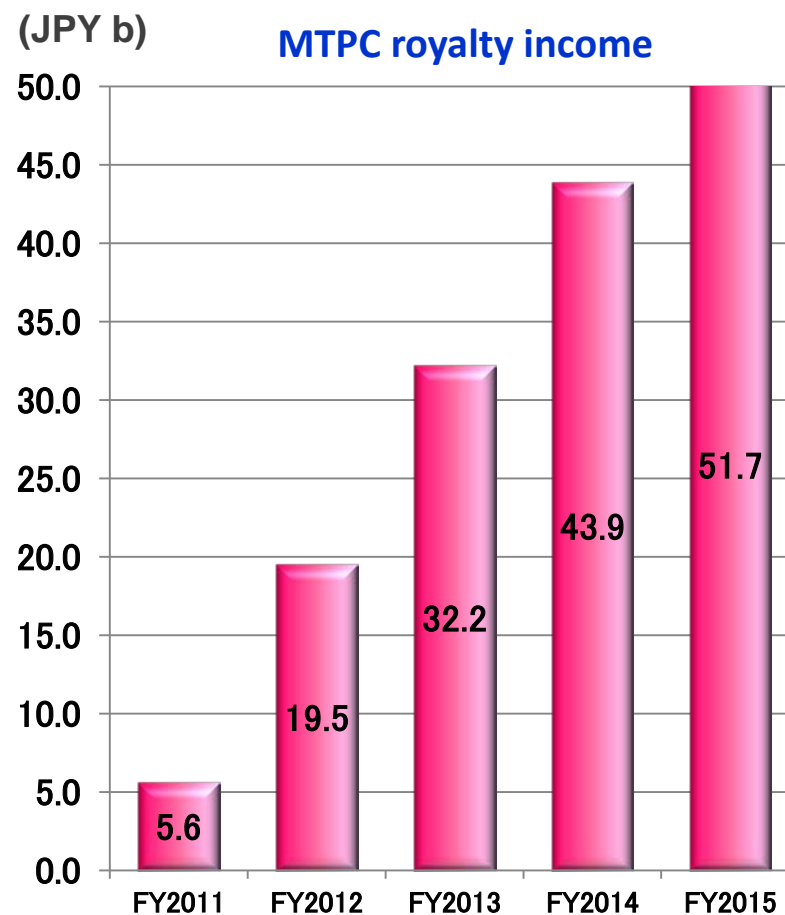
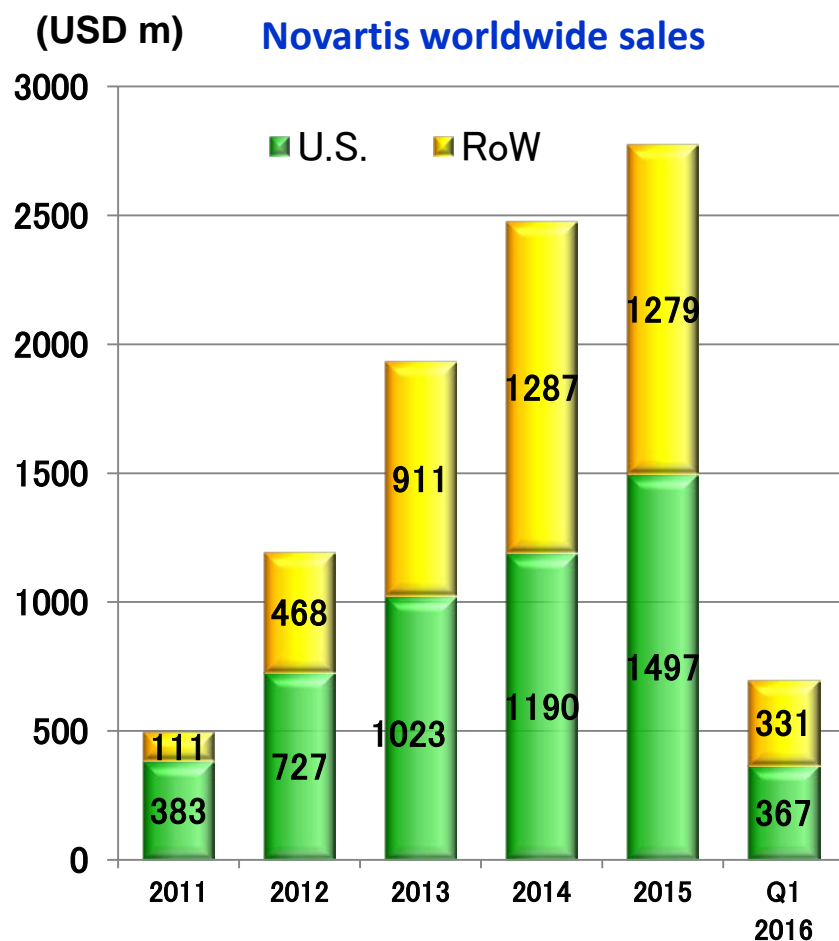
Forecasts of Sales by Business Segment (IFRS)

	FY2016 forecasts	FY2015 actual (pro forma)	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenues	406.5	425.8	-19.3	-4.5
(Overseas)	(98.7)	(110.4)	(-11.7)	(-10.6)
Pharmaceuticals	406.3	425.4	-19.1	-4.5
Domestic ethical drugs	300.9	308.1	-7.2	-2.3
Overseas ethical drugs	21.8	25.2	-3.4	-13.7
Contracted manufacturing products	1.6	2.2	-0.6	-29.1
Royalty income, etc.	78.0	86.1	-8.2	-9.5
OTC products	4.1	3.8	+0.3	+8.9
Others	0.2	0.4	-0.2	-43.3

Forecasts of Ethical Drugs Domestic Sales (Priority Products and Vaccines)

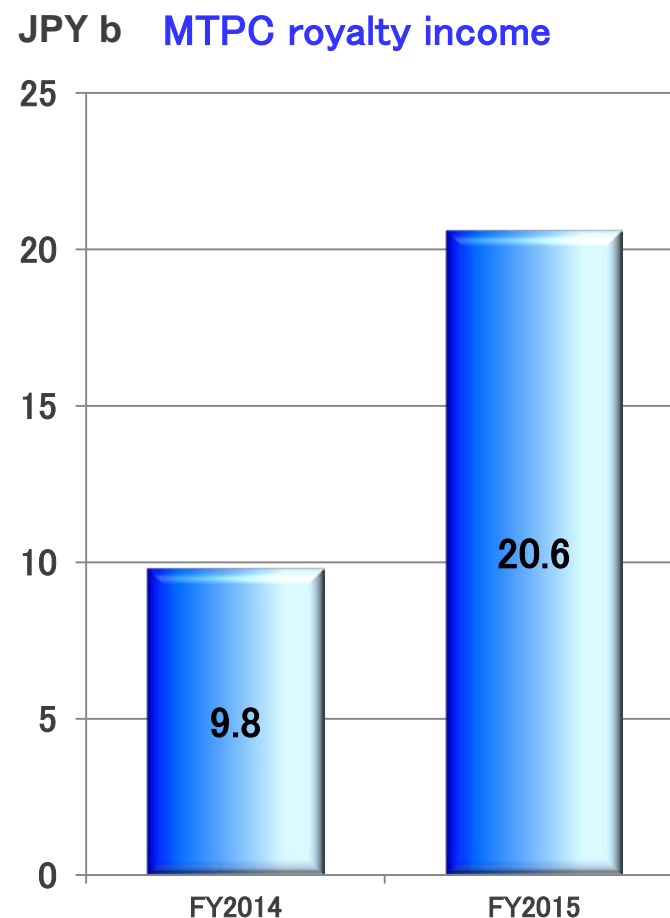
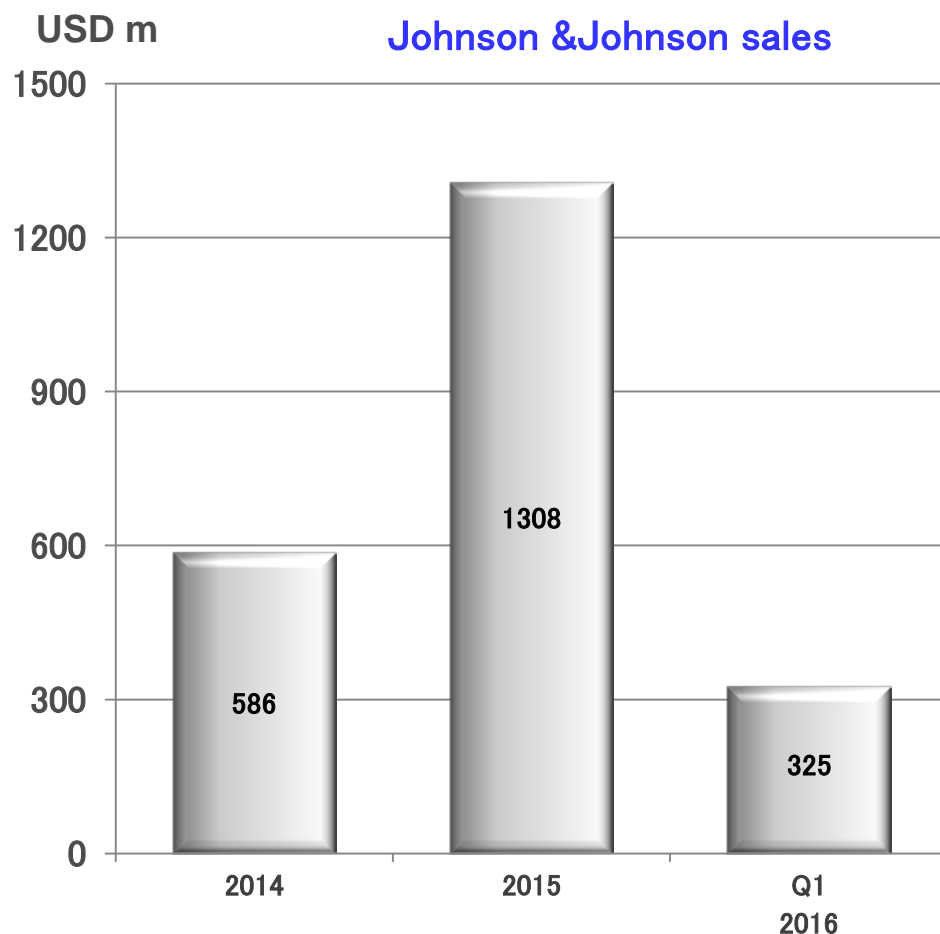
	FY2016	FY2015	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Remicade	62.5	69.4	-6.9	-9.9
Simponi	23.4	12.9	+10.5	+81.0
Canaglu	3.6	0.6	+3.0	+536.3
Tenelia	17.5	14.2	+3.3	+23.6
Lexapro	12.6	9.5	+3.1	+32.9
Talion	17.3	16.9	+0.4	+2.7
Imusera	4.6	4.1	+0.5	+12.8
Total of priority products	141.6	127.6	+14.0	+11.0
Influenza vaccine	11.1	13.8	-2.6	-19.2
Tetrabik	8.6	9.5	-0.9	-9.9
Varicella vaccine	5.5	6.4	-0.8	-12.8
Mearubik	4.1	5.0	-0.9	-18.0
JEBIK V	3.6	3.7	0.0	-1.1
Total of vaccines	29.3	34.6	-5.3	-15.3
Total of priority products and vaccines	171.0	162.2	+8.7	+5.4

- ◆ Novartis worldwide sales in Jan. to Mar., 2016: \$698m, +12%, y-o-y
- ◆ MTPC royalty income in FY2015: ¥51.7b



INVOKANA/INVOKAMET

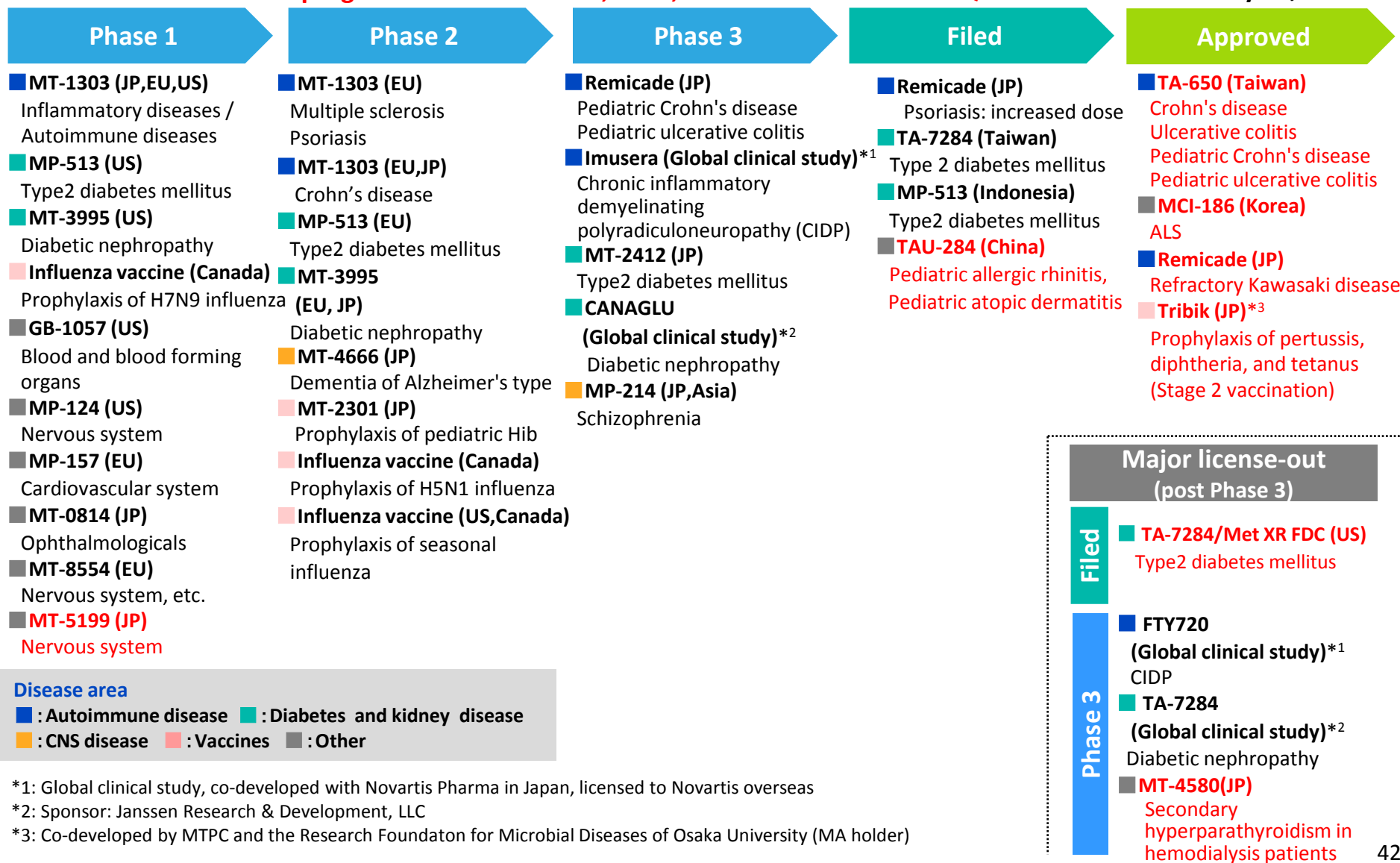
- ◆ Johnson & Johnson sales in Jan. to Mar., 2016: \$325m (the same period the previous year: \$278m)
- ◆ INVOKANA/INVOKAMET TRx share 6.1% in defined U.S. T2D market and ~12% TRx share with endocrinologists
- ◆ MTPC royalty income in FY2015: ¥20.6b



Pipeline Status

Red: progress after October 30, 2015, the financial results for Q2 FY2015

As of May 11, 2016



*1: Global clinical study, co-developed with Novartis Pharma in Japan, licensed to Novartis overseas

*2: Sponsor: Janssen Research & Development, LLC

*3: Co-developed by MTPC and the Research Foundation for Microbial Diseases of Osaka University (MA holder)

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.