Mitsubishi Tanabe Pharma Corporation

FY2016 Business Results
(April, 2016 - March, 2017)

May 11, 2017

Masayuki Mitsuka
President and Representative Director

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FY2016 Business Results

The Company has adopted IFRS, effective from Q1 FY2016.
Amounts less than ¥100 million are rounded down.

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Overview of FY2016 Business Results

Revenue	¥ 423.9 billion	- 0.4%, year-on-year
Core operating profit	¥94.5 billion	- 11.7%, year-on-year
Operating profit	¥94.0 billion	+ 15.0%, year-on-year
Net profit attributable to owners of the Company	¥71.2 billion	+ 20.2%, year-on-year

Topics

- Revenue decreased by 0.4%, year-on-year. In total sales of domestic ethical drugs, sales of high-priority products as SIMPONI remained firm, but NHI drug price revision and decrease of long-listed drug were negatively impacted, and in royalty revenue, etc., lump-sum revenue related to the license agreement decreased.
- Core operating profit decreased, year-on-year, due to the decrease of revenue and increase of start up costs in the U.S. market.
- Operating profit was up, year-on-year. Strctual reform costs incurred in the previous year and non recurring costs improved drastically in FY2016.
- Net profit attributable to owners of the Company hit record high, year-on-year.
- FDA Approval of RADICAVA ™ , a treatment for ALS.

FY2016 Financial Results

	FY2016	FY2015	Increase/decrease		Full year forcasts*
	Billion yen	Billion yen	Billion yen	%	*Billion yen*
Revenues	423.9	425.7	-1.7	-0.4	*425.0*
(Overseas sales revenue)	103.6	110.3	-6.7	-6.1	*103.0*
Overseas sales ratio	24.4%	25.9%		-1.5	*24.2%*
Cost of sales	164.3	155.8	+8.5	+5.5	*163.0*
Sales cost ratio	38.8%	36.6%		+2.2	*38.3%*
Gross profit	259.5	269.9	-10.3	-3.8	*262.0*
Core operating profit	94.5	106.9	-12.4	-11.7	*97.0*
Operating profit	94.0	81.8	+12.2	+15.0	*96.0*
Net profit attributable to owners of the Company	71.2	59.3	+11.9	+20.2	*72.0*
Average exchange rate(USD)	¥108.72	¥120.16			*¥110.00*

*: Announced on Feburuary 6, 2017 in the financial results of Q3 FY2016

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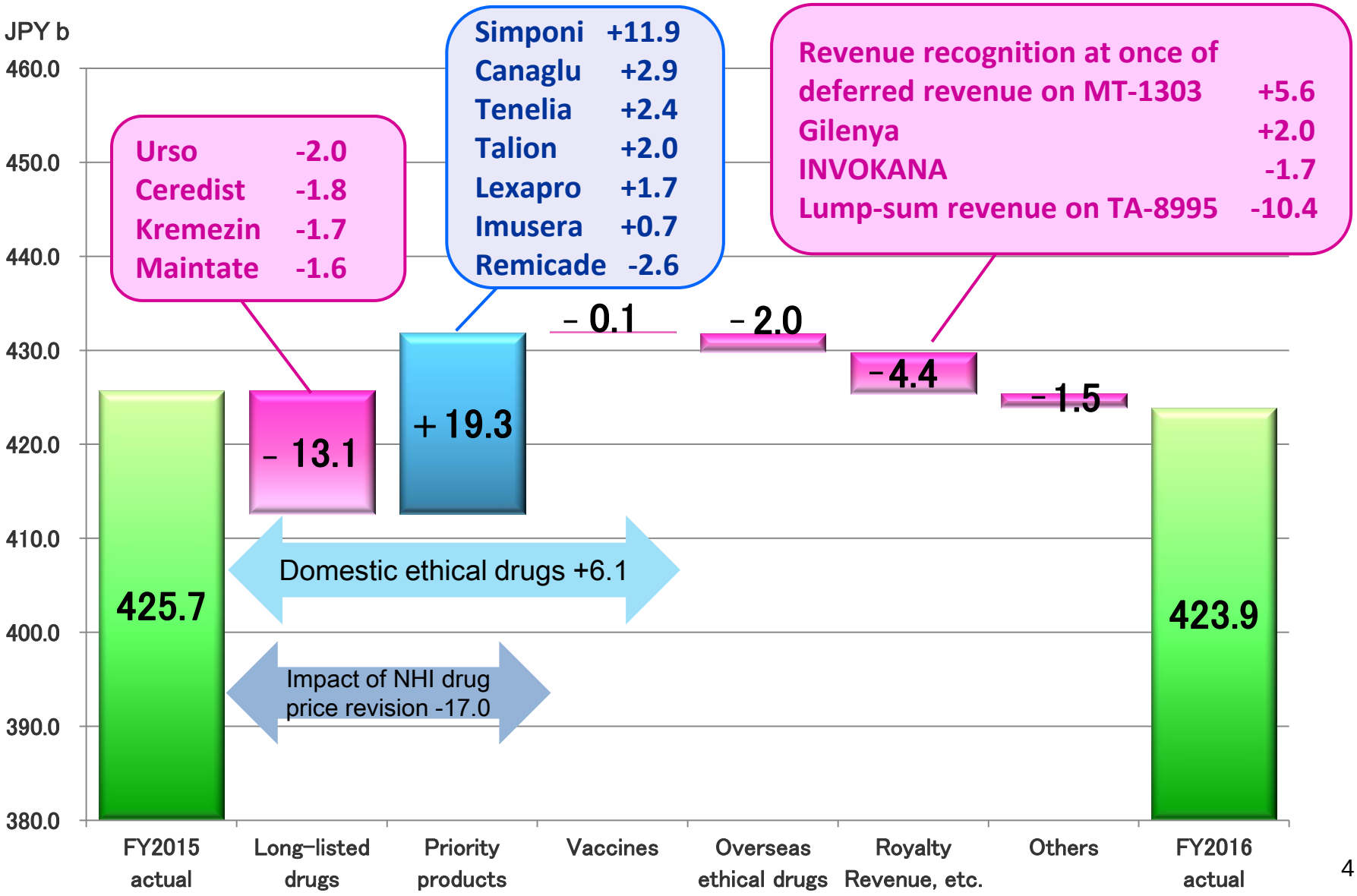
Revenue Trends



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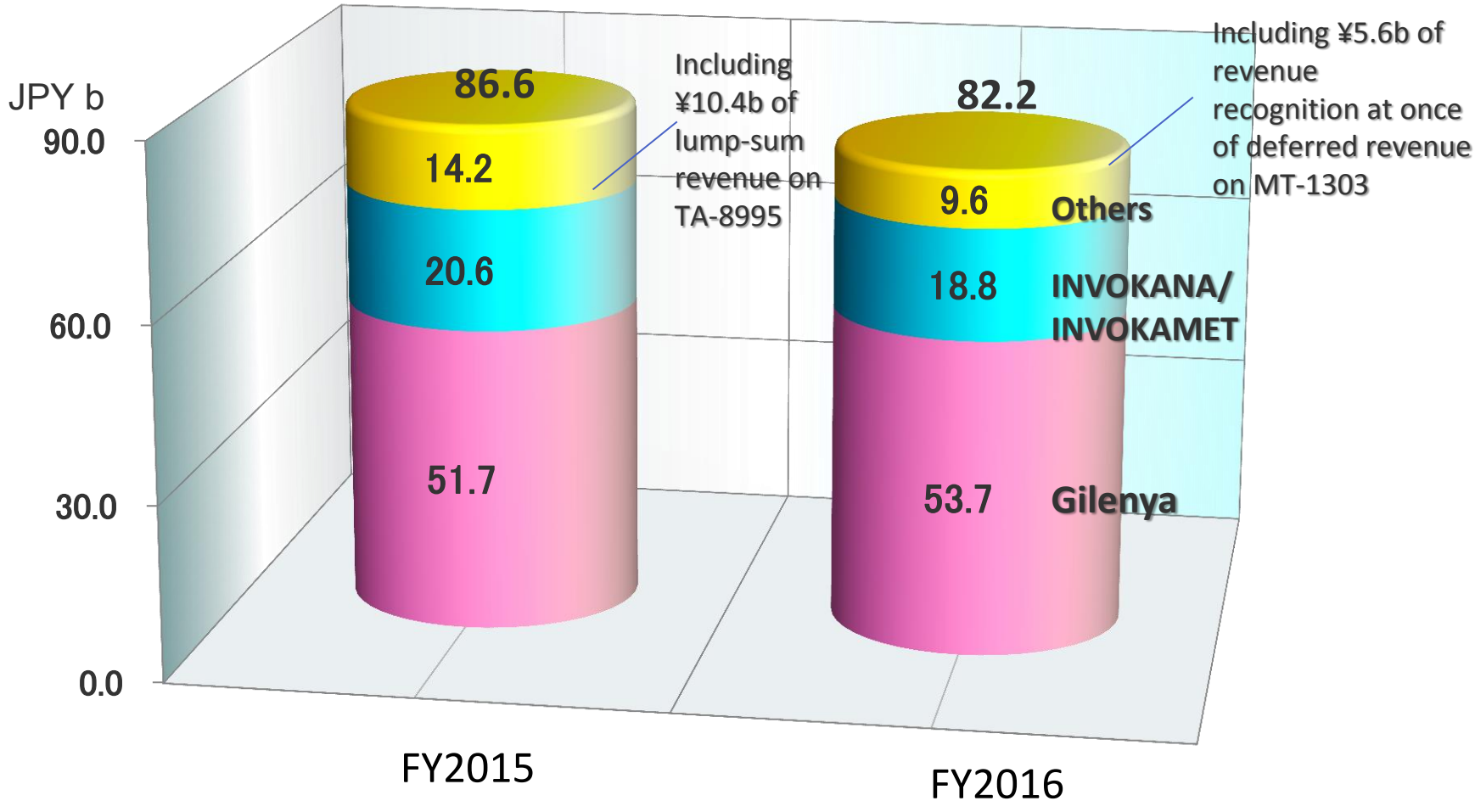
Royality revenue, etc.



<Average exchange Rate (USD)>

¥120.16 ¥108.72

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Cost of Sales, SG&A Expense, Core Operating Profit

	FY2016	FY2015	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	423.9	425.7	-1.7	-0.4
Cost of sales	164.3	155.8	+8.5	+5.5
Sales cost ratio	38.8%	36.6%		+2.2
Gross profit	259.5	269.9	-10.3	-3.8
SG&A expense	98.3	96.3	+1.9	+2.0
R&D expense	64.7	64.6	+0.1	+0.3
Amortization of intangible assets associated with products	1.5	1.4	0.0	+3.7
Other income and expense*	-0.4	-0.5	0.0	-
Core operating profit	94.5	106.9	-12.4	-11.7
Total labor cost	72.7	80.7	-8.0	-9.9

* Negative signs indicate expense and loss

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Non-recurring items, Net Profit

	FY2016	FY2015	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Core operating profit	94.5	106.9	-12.4	-11.7
Non-recurring items*	-0.4	-25.1	+24.7	-
Operating profit	94.0	81.8	+12.2	+15.0
Financial income	2.2	2.9	-0.7	-26.1
Financial expense	0.2	1.5	-1.3	-84.7
Net profit attributable to owners of the Company	71.2	59.3	+11.9	+20.2

* Negative signs indicate expense and loss

Medium-Term Management Plan 16-20
Achievements in FY2016 and Plans in FY2017

Four Strategic Priorities to Open Up the Future

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1 Maximizing Pipeline Value

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

2 Strengthening IKUYAKU and Marketing

- Domestic sales objective
  ¥300.0 billion (FY2020)
  New drugs and priority products sales ratio: 75%
- Priority diseases areas: Autoimmune, diabetes & kidney diseases, CNS, vaccines

Investment → Profit

3 Accelerating U.S. Business Development

- US sales objective
  ¥80.0 billion (FY 2020)
- US strategic investment
  More than ¥200.0 billion

4 Reforming Operational Productivity

- Cost of sales / SG&A expenses reduction objective:**¥20.0 billion** (FY2020 compared to FY2015)
- Number of employees
  Consolidated domestic workforce: 5,000 employees*
  *As of the end of Sep 2015: 6,176 employees

FY2020 objective　Revenues ¥ 500.0b　Core operating profit ¥100.0b

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1 Maximizing Pipeline Value - 10 late-stage drug candidates -

Late-stage drug candidates		Phase1	Phase2 / POC study	Late-stage study
Achievements in FY2016		3 products	2 products	1 product
Plans in FY2017		1 product	2 products	5 products
Auto immune diseases	MT-1303	Japan: Inflammatory diseases, autoimmune diseases	Europe: MS, PS, CD Japan: CD	→
	MT-5547			→
	MT-7117	Europe: Dermatologicals, etc.	→	
	New project in house	→		
Diabetes and kidney diseases	MT-6548		Japan: Renal anemia	→
	MT-3995		Japan: NASH Japan, Europe: Diabetic nephropathy	
CNS diseases	MT-5199	Japan: Tardive dyskinesia		→
	MT-8554	Europe: Nervous system, etc.	→	
Vaccine Others	MT-2355			Japan: DPT-IPV+Hib
	Plant-based VLP vacccine		US, Canada: Seasonal influenza	→
	MT-4129	Europe: Cardiovascular system, etc.		

FY2016 Achievements → FY2017 Plans

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1 Maximizing Pipeline Value

Autoimmune Diseases Area

Product	Achievements in FY2016	Plans in FY2017
MT-1303 (amiselimod/S1Preceptor functional antagonist)	Terminated the license agreement with Biogen. Topline data in Phase2 (Japan and Europe) for Crohn's disease obtained	Oversea late-stage study scheduled to start Target launch in US in FY2020 or later
MT-5547 (fasinumab/ anti-NGF antibody)	Phase1 in Japanese patients completed	Domestic late-stage study scheduled to start
MT-7117 (Dermatologicals, etc.)	Phase1 initiated	Overseas POC study scheduled to start
Invossa (Cell Therapy)	Concluded the license agreement with Kolon Life Science	Schedule to start clinical study in Japan is under consideration

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1 Maximizing Pipeline Value

Diabetes and kidney diseases Area

Product	Achievements in FY2016	Plans in FY2017
MT-6548 (vadadustat/ HIF-PH inhibitor)	Phase2 (Japan, Renal anemia)	late-stage study in Japan scheduled to start Target launch by FY2020
MT-3995 (Selective mineralocorticoid receptor antagonist)	POC achieved in diabetic neuropathy Phase2 study initiated (Japan, Non-alcoholic steatohepatitis)	Maximize product value including out-license

1 Maximizing Pipeline Value

CNS Diseases Area

Product	Achievements in FY2016	Plans in FY2017
MP-214 (Cariprazine/ dopamine D3/D2 receptor partial agonist)	Not achieved primary endpoint in Phase2b/3 in Schizophrenia (Japan/Korea/Taiwan)	Future development strategy to be decided by Q1 FY2017
MT-5199 (valbenazine/ VMAT2 inhibitor)	Phase1 initiated (Japan)	Domestic late-stage study in Tardive dyskinesia scheduled to start
MT-8554 (Nervous system, etc.)	Phase1	POC study scheduled to start

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1 Maximizing Pipeline Value

Vaccines

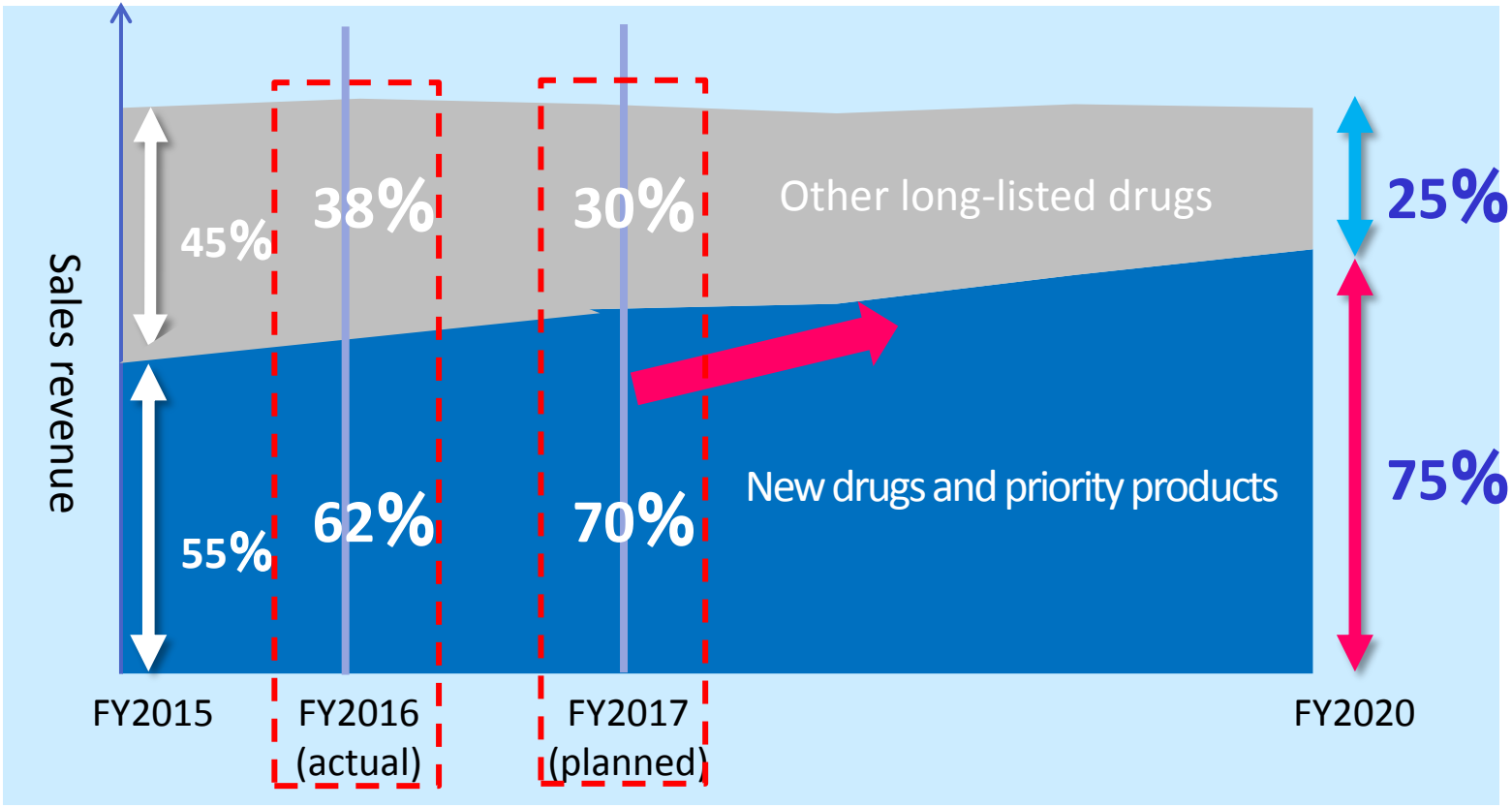
Product	Achievements in FY2016	Plans in FY2017
MT-2355 (DPT-IPV＋Hib)	Phase3 initiated (Japan)	→
Plant-based VLP vaccine (Seasonal influenza)	Phase2 initiated (US/Canada) Data obtained	Scheduled to start overseas late-stage study Target launch in FY2020 (US)

Others

Product	Achievements in FY2016	Plans in FY2017
MT-4129 (Cardiovascular system etc.)	Phase1 initiated	→

2 Strengthening IKUYAKU and Marketing

Toward ¥300.0 billion, domestic sales objective, achieve 75%, new drugs and priority products sales ratio in product mix.



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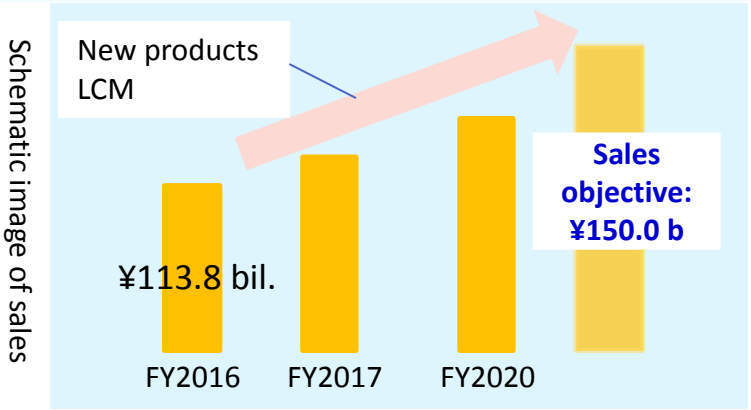
2 Strengthening IKUYAKU and Marketing

Autoimmune diseases area

- Maximize value of i.v. / s.c.
- New products sales, ¥150.0 billion.



Product	Achievements in FY2016	Plans in FY2017
Remicade	Filed shortened administration interval for CD	Approval Maximize share in CD with Stelara
Simponi	Remicade & Simponi: No.1 share in Bio market (39% share in FY2016)	Expand the share by maximizing the value of i.v. (Remicade) and s.c. (Simponi)
	Changes of sales scheme in RA	Expand share through collaboration with Janssen Pharma
	Approval in additional indication (UC)	
Stelara	Co-promotion agreement for an indication of CD	

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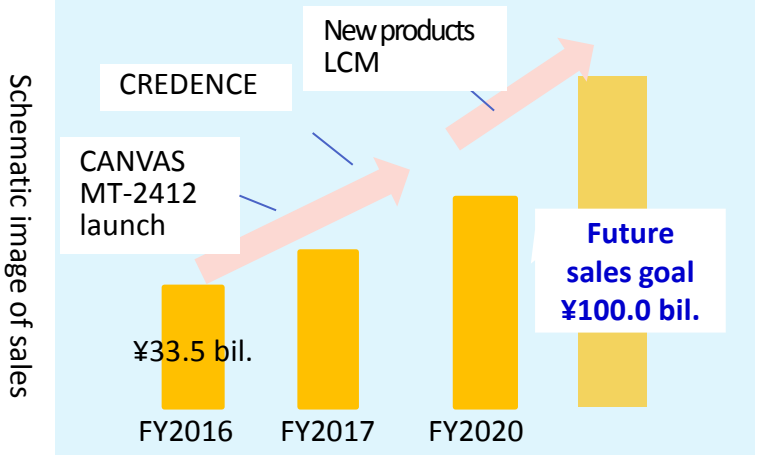
2 Strengthening IKUYAKU and Marketing

Diabetes and kidney diseases area

- Strengthen a product line-up in the diabetes and kidney diseases area
- Sales objective of ¥100.0 billion, No. 1 presence in the diseases area



Product	Achievements in FY2016	Plans in FY2017
Tenelia	Expanded share by penetration among the patient with weak kidney and the elderly	Expand share based on good collaboration with Daiichi Sankyo
Canaglu	Increased prescription through a recommendation revise of proper use and accumulation of safety information, etc.	Announcement of CANVAS/CANVAS-R study
MT-2412 (Tenelia+Canaglu)	Application filed Agreement concluded to expand a strategic alliance in the diabetes field with Daiichi Sankyo	Approval A new treatment in 1st in class

2 Strengthening IKUYAKU and Marketing

CNS diseases area

Product	Achievements in FY2016	Plans in FY2017
Lexapro	No.1 share in SSRI (39% share in FY2016)	Expand share in anti-depression market

Others

Product	Achievements in FY2016	Plans in FY2017
Rupatadine (Anti-allergy agent)	Concluded basic agreement for Sales with Teikoku Seiyaku	Target launch in FY2017 No.1 share in anti-allergy market with Talion

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2 Strengthening IKUYAKU and Marketing

Area marketing

Achievement plan continuously and No.1 share in the area by execution area marketing strategy for heterogeneity and uniqueness in the areas

Achievements in FY2016	Plans in FY2017
▪ AMPs* in all sales offices ▪ Established area marketing platform	Strengthen area marketing strategy

* AMPs = Area marketing planners

Digital marketing

Construct the industry-leading digital marketing system

Achievements in FY2016	Plans in FY2017
Significant increase in the number of new members on the website 「Medical View Point」for medical staffs	▪ Utilize digital marketing ▪ Education for MR as a multi-channel coordinator

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3 Accelerating U.S. Business Development

MCI-186 (RADICAVA ™)

Achievements in FY2016	Plans in FY2017
Jun. 2016 NDA submitted to FDA	May 5, 2017 FDA granted approval
Aug. 2016 NDA accepted	Target of launch in mid-Aug., 2017
Sales/ support organization under establishment (Allocation of sales reps and target sites, Reimbursement support, Patient support), Preparation of manufacture and logistics	

R&D pipeline in US

Achievements in FY2016	Plans in FY2017
Establishment of product line-up mainly in neurological diseases and autoimmune diseases area - Neurological diseases area: Acquire products/late-stage products - Autoimmune diseases area: Establishment of R&D pipeline in-house (MT-1303 etc.)	

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3 U.S. Business Development RADICAVA ™

RADICAVA ™

◆Contents of Approval

【Labeling】

Indications and Usage：Treatment of amyotrophic lateral sclerosis (ALS)

Dosage and Administration：

An intravenous infusion of 60 mg administered over a 60-minute period according to the following schedule

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

【Postmarketing commitments subject 】

Conduct a study of safety and efficacy in multiple and high dosage of RADICAVA ™ (Consulting with FDA)

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3 U.S. Business Development RADICAVA ™

RADICAVA ™

◆ Launch

Target of Launch :

Mid-Aug., 2017

(About 3 months after FDA approval)

Drug costs :

About $145,000 / year ($543 / bag)

◆ Support for patients

Searchlight Support：

Financial support (medical reimbursement system)

Personal case management

Introduction of hospital (infusion center)

4 Reforming Operational Productivity

Others

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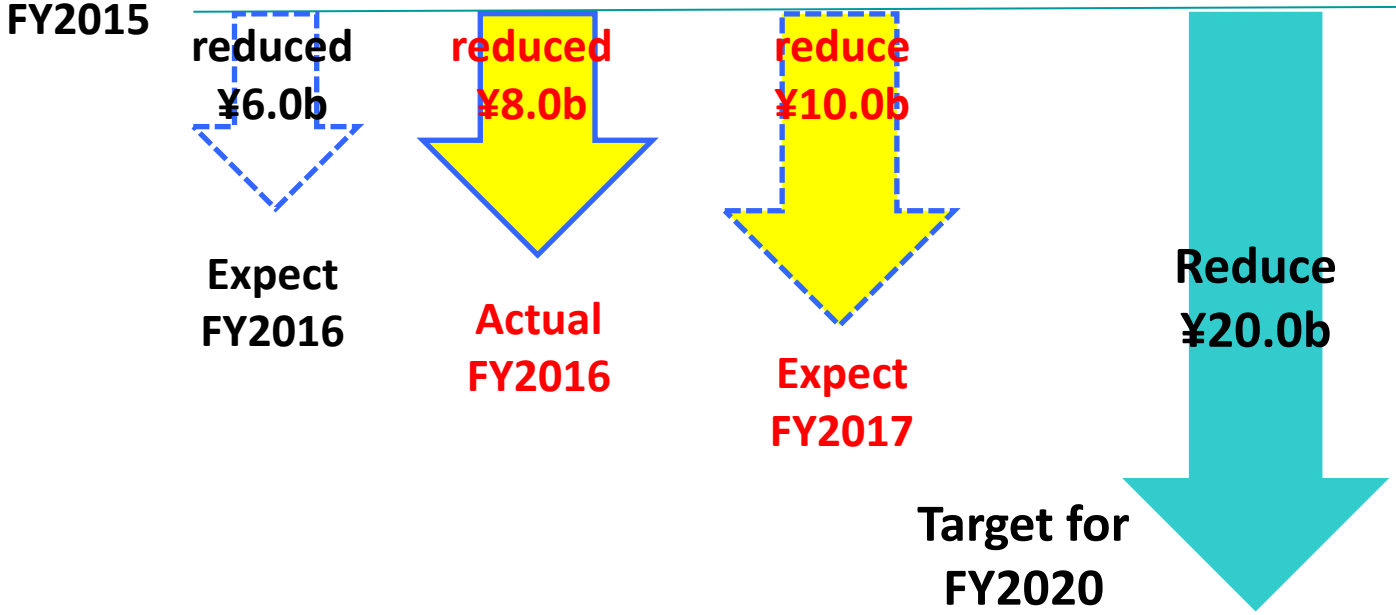
4



Others

1. Joint venture “BIKEN Corporation” with BIKEN Foundation
   - Contribution to more steady supply of vaccines
2. Transfer the business of generic drugs and a part of long-listed drugs to Nipro
   - Focus on providing new drugs

Forecasts of FY2017

Forecasts of FY2017

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	FY2017 Forecasts	FY2016 Actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	441.0	423.9	+17.0	+4.0
(Overseas sales revenue)	115.5	103.6	+11.8	+11.5
Overseas sales ratio	26.2%	24.4%		+1.8
Cost of sales	169.5	164.3	+5.1	+3.1
Sales cost ratio	38.4%	38.8%		-0.4%
Gross operation profit	271.5	259.5	+11.9	+4.6
Core operating profit	90.0	94.5	-4.5	-4.8
Net profit attributable to owners of the Company	71.5	71.2	+0.2	+0.3
Average exchange rate (USD)	¥110	¥108.72		

Revenue Trends

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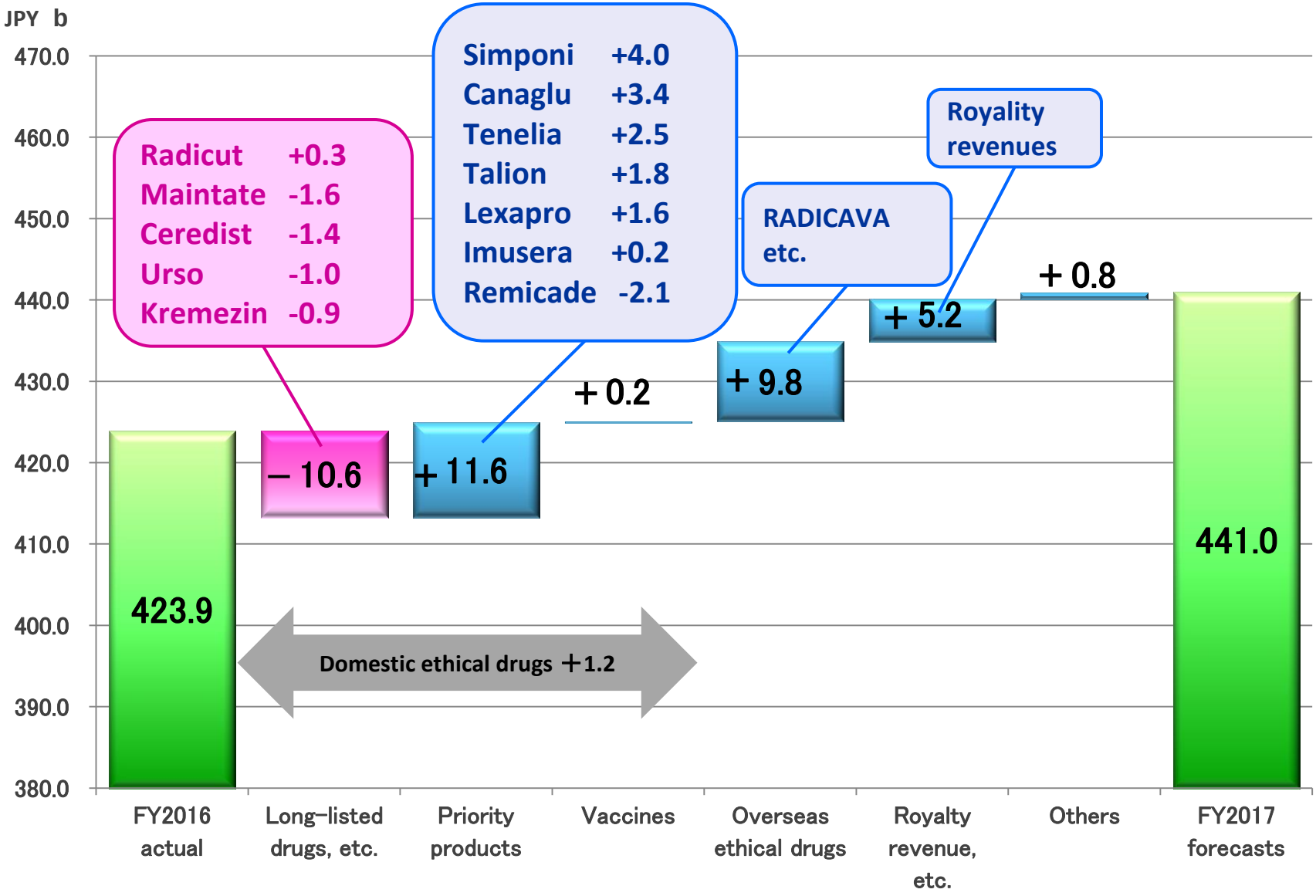

Forecasts of FY2017

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	FY2017 forecasts	FY2016 actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	441.0	423.9	+17.0	+4.0
Cost of sales	169.5	164.3	+5.1	+3.1
Sales cost ratio	38.4%	38.8%		
Gross operating profit	271.5	259.5	+11.9	+4.6
SG&A expenses	105.0	98.3	+6.6	+6.8
R&D expenses	73.5	64.7	+8.7	+13.5
Amortization of intangible assets associated with products	2.5	1.5	0.9	+63.6
Other income and expense*	-0.5	-0.4	-0.0	-
Core operating profit	90.0	94.5	-4.5	-4.8
Total labor costs	72.8	72.7	0.0	+0.1

* Negative signs indicate expense and loss

Forecasts of FY2017

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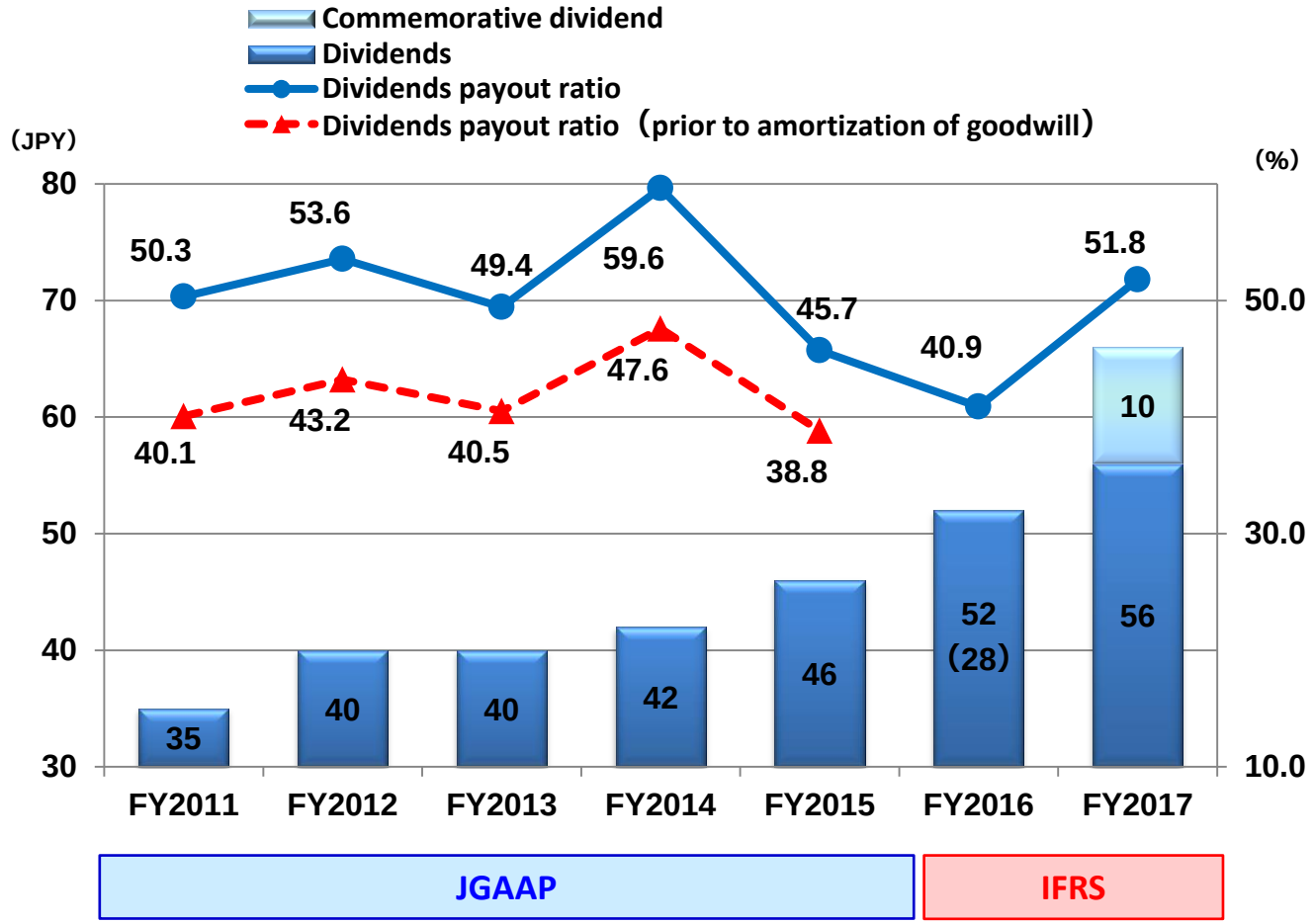
	FY2017 forecasts	FY2016 actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Core operating profit	90.0	94.5	-4.5	-4.8
Non-recurring items*	-	-0.4	+0.4	-
Operating profit	90.0	94.0	-4.0	-4.3
Net profit attributable to owners of the Company	71.5	71.2	+0.2	+0.3

* Negative signs indicate expense and loss

Shareholders Return

Dividends Trends

- 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.
- 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).



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

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Appendix

Appendix

Details of Revenue

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	FY2016	FY2015	Increase/decrease		*Forecasts	Achived
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	423.9	425.7	−1.7	−0.4	*425.0*	99.8
(Overseas ratio)	103.6	110.3	−6.7	−6.1	*103.0*	100.6
Domestic ethical drugs	314.2	308.0	+6.1	+2.0	*314.5*	99.9
Overseas ethical drugs	22.6	24.7	−2.0	−8.2	*21.2*	106.9
Royalty revenue, etc.	82.2	86.6	−4.4	−5.1	*83.3*	98.6
OTC	3.4	3.7	−0.3	−9.3	*4.3*	79.6
Others	1.4	2.5	−1.1	−44.8	*1.4*	94.4

*: Forecasts of FY2016 announced on Feb. 6, 2017.

Appendix

Domestic Ethical Drugs
Revenue of Priority Products and Vaccines

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	FY2016	FY2015	Increase/decrease		*Forecasts	Achived
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	66.8	69.4	-2.6	-3.7	*66.4*	100.7
Simponi	24.9	12.9	+11.9	+92.9	*25.4*	97.8
Talion	18.9	16.8	+2.0	+12.3	*19.1*	99.1
Tenelia	16.5	14.1	+2.4	+17.1	*17.4*	95.0
Lexapro	11.2	9.5	+1.7	+18.6	*12.5*	89.9
Imusera	4.9	4.1	+0.7	+19.3	*4.8*	101.4
Canaglu	3.4	0.5	+2.9	+515.8	*3.2*	106.4
Total of priority products	146.9	127.5	+19.3	+15.2	*149.1*	98.5
Influenza vaccine	12.7	13.7	-0.9	-7.1	*12.0*	106.6
Tetrabik	9.9	9.5	+0.4	+4.5	*9.7*	101.9
Mearubik	5.9	4.9	+0.9	+18.8	*5.7*	103.1
Varicella vaccine	5.4	6.3	-0.8	-14.0	*5.5*	99.2
JEBIK V	3.9	3.6	+0.3	+9.2	*3.8*	104.0
Total of vaccines	38.9	39.0	-0.1	-0.3	*37.6*	103.5
Total	185.9	166.6	+19.2	+11.6	*186.8*	99.5

*: Forecasts of FY2016 announced on Feb. 6, 2017.

Domestic Ethical Drugs
Forecasts of Revenue of Priority Products and Vaccines

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	FY2017 forecasts	FY2016	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Remicade	64.7	66.8	- 2.1	- 3.2
Simponi	29.0	24.9	+4.0	+16.5
Talion	20.8	18.9	+1.8	+9.7
Tenelia	19.1	16.5	+2.5	+15.4
Lexapro	12.9	11.2	+1.6	+14.6
Canaglu	6.9	3.4	+3.4	+99.0
Imusera	5.1	4.9	+0.2	+4.1
Total of priority products	158.6	146.9	+11.6	+7.9
Influenza vaccine	14.1	12.7	+1.3	+10.4
Tetrabik	9.2	9.9	- 0.7	- 7.4
Varicella vaccine	5.7	5.4	+0.3	+5.5
Mearubik	5.2	5.9	- 0.6	- 10.6
JEBIK V	3.9	3.9	- 0.0	- 1.0
Total of vaccines	39.1	38.9	+0.2	+0.5
Total	197.8	185.9	+11.8	+6.4

Gilenya

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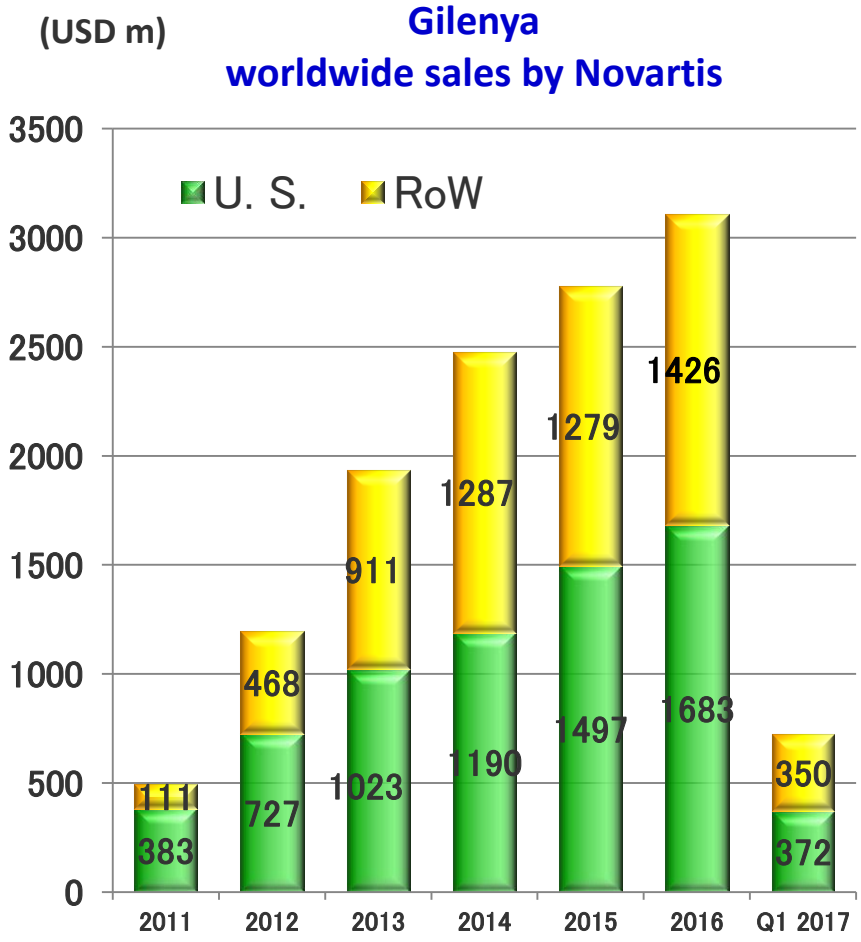
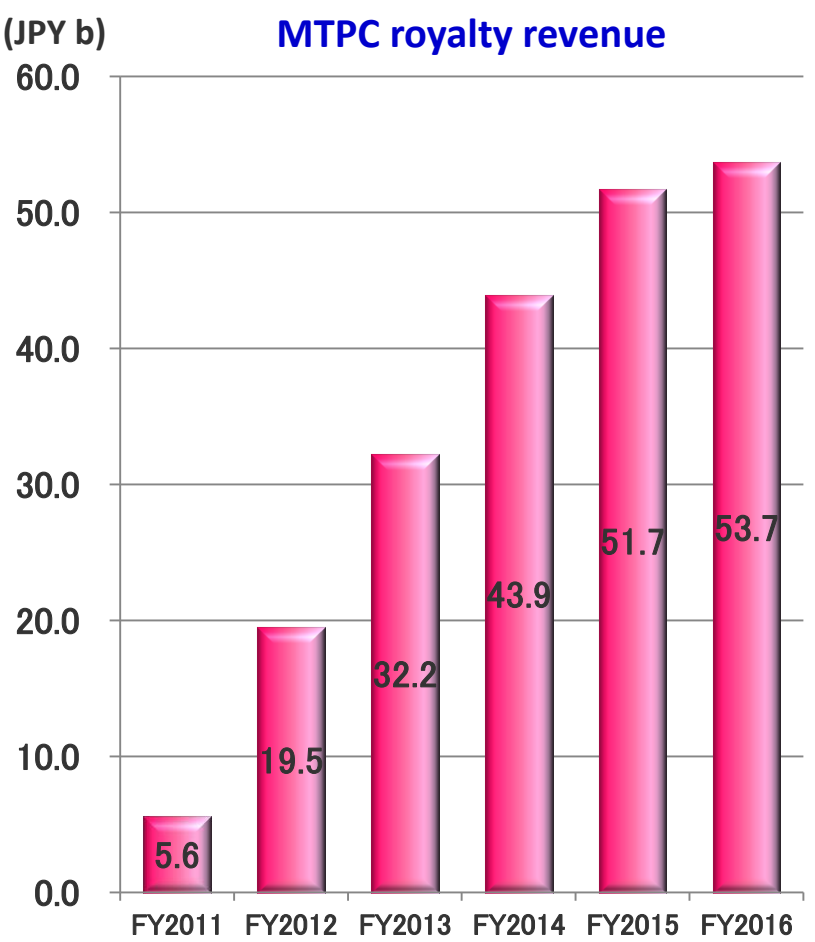
- Gilenya worldwide sales by Novartis in Q1 FY2017 (January to March, 2017) : $722 m ($698m, the same period of previous year)
- MTPC royalty revenue in FY2016: ¥53.7 b





INVOKANA/INVOKAMET

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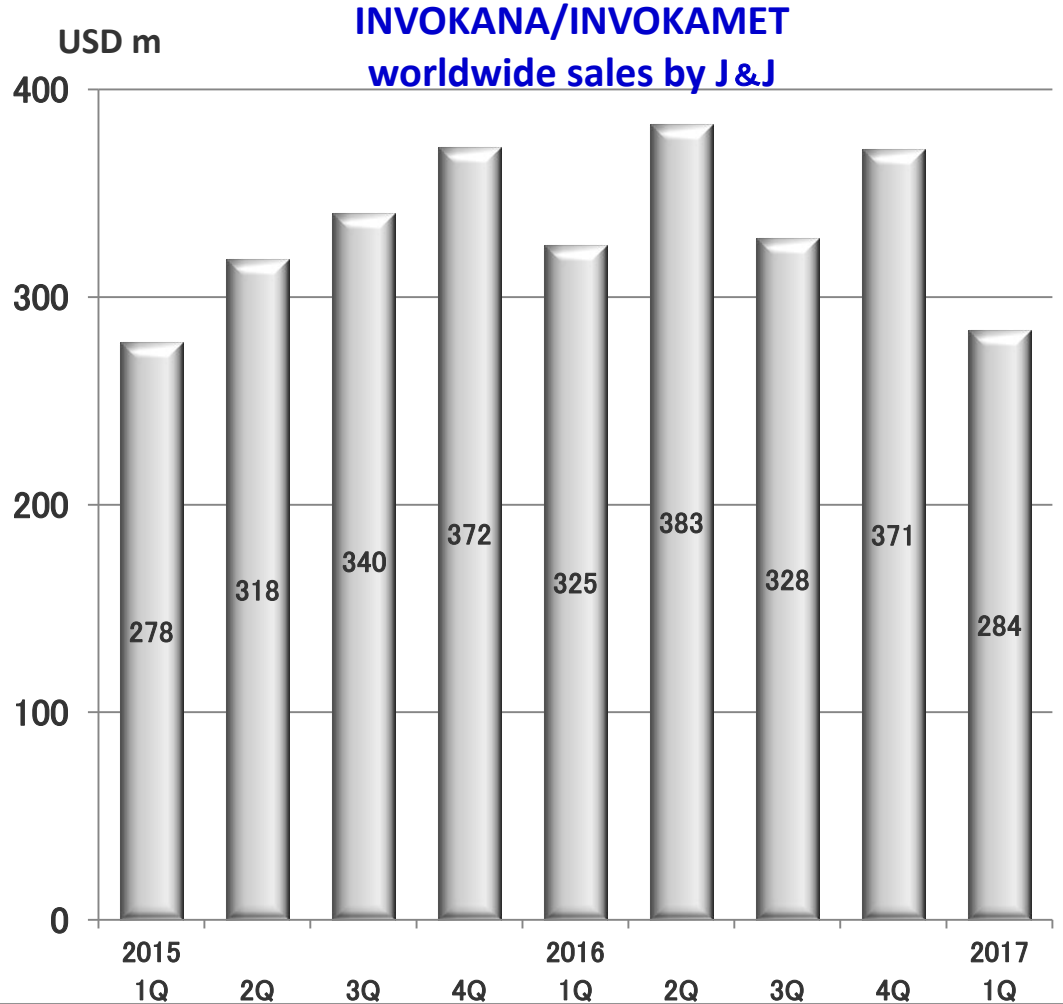
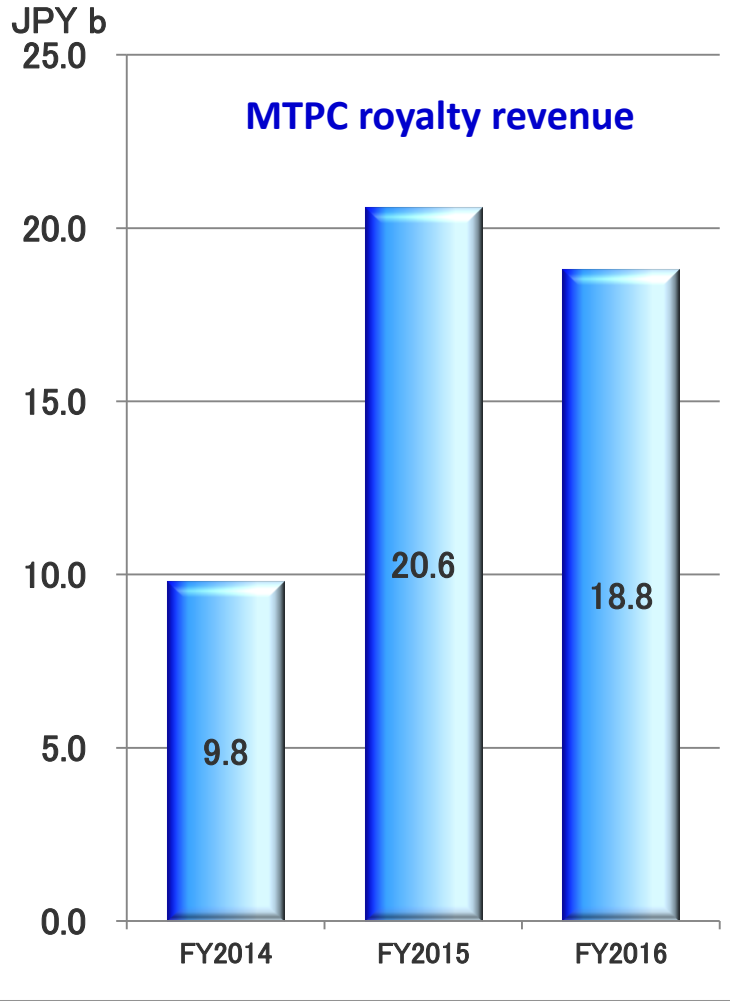
- INVOKANA/INVOKAMET worldwide sales by Johnson & Johnson in Q1 FY2017 (January to March, 2017) : $284m (the same period of previous year : $325m)
- INVOKANA/INVOKAMET TRx share 6.0% in defined U.S. T2D market
- MTPC royalty revenue in FY2016 : ¥18.8b





Appendix

Pipeline Status

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Red: progress after November 1, 2016, the financial results for Q2 FY2016

As of May 10, 2017

Phase 1

- **MT-1303 (JP,EU,US)**
  Inflammatory diseases / Autoimmune diseases
- **MP-513 (US)**
  Type2 diabetes mellitus
- **MT-3995 (US)**
  Diabetic nephropathy
- **Influenza vaccine (Canada)**
  Prophylaxis of H7N9 influenza
- **GB-1057 (US)**
  Blood and blood forming organs
- **MP-124 (US)**
  Nervous system
- **MP-157 (EU)**
  Cardiovascular system
- **MT-0814 (JP)**
  Ophthalmologicals
- **MT-8554 (EU)**
  Nervous system, etc.
- **MT-5199 (JP)**
  Tardive dyskinesia
- **MT-7117 (EU)**
  Dermatologicals,etc.
- **MT-4129 (EU)**
  Cardiovascular system, etc.

Phase 2

- **MT-1303 (EU)**
  Multiple sclerosis
  Psoriasis
- **MT-1303 (EU,JP)**
  Crohn's disease
- **MP-513 (EU)**
  Type2 diabetes mellitus
- **MT-3995 (EU, JP)**
  Diabetic nephropathy
- **Influenza vaccine (Canada)**
  Prophylaxis of H5N1 influenza
- **Influenza vaccine (US,Canada)**
  Prophylaxis of seasonal influenza
- **MT-3995 (JP)**
  NASH
- **MT-6548 (JP)**
  Renal anemia

Phase 3

- **Imusera (Global clinical study)** *1
  Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)
- **CANAGLU (Global clinical study)** *2
  Diabetic nephropathy
- **MP-214 (JP,Asia)**
  Schizophrenia
- **MP-513 (China)**
  Type2 diabetes mellitus
- **MT-2355 (JP)** *3
  5 combined vaccine (4 combined + Hib)

Filed

- **MP-513 (Indonesia)**
  Type2 diabetes mellitus
- **MT-2412 (JP)**
  Type2 diabetes mellitus
- **Remicade (JP)**
  CD: shortened administration interval
- **Novastan (China)**
  Acute cerebral infarction

Approved

- **TAU-284 (China)**
  Pediatric allergic rhinitis, Pediatric atopic dermatitis
- **Simponi (JP)** *4
  Ulcerative colitis
- **TA-7284 (Taiwan)**
  Type 2 diabetes mellitus
- **MCI-186 (US)**
  ALS

Disease area

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

Major license-out products (post Phase 3)

Filed

- **MT-4580(JP)**
  Secondary hyperparathyroidism in chronic kidney disease patients on maintenance

Phase 3

- **FTY720 (Global clinical study)***1
  CIDP
- **TA-7284 (Global clinical study)***2
  Diabetic nephropathy

*1: Global clinical study, co-developed with Novartis Pharma in Japan, licensed to Novartis overseas
*2: Sponsor: Janssen Research & Development, LLC
*3: Co-developed with The Research Foundation for Microbial Diseases of Osaka University (JP)
*4: Co-developed with Janssen Pharmaceutical K. K. (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.