**Mitsubishi Tanabe Pharma Corporation** 



# FY2017 Business Results (April, 2017 - March, 2018)

## May 10, 2018 Masayuki Mitsuka

**President and Representative Director** 

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# **FY2017 Business Results**



#### **FY2017 Financial Results**





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- •Revenue increased due to increasing sales of high-priority products in domestic ethical drugs and the launch of Radicava in the U.S., etc.
- •Core operating profit decreased due to increasing in SG&A expenses of Radicava and R&D expenses.

	FY2017	FY2016	Increase/decrease		Full year forecasts*
	Billion yen	Billion yen	Billion yen	%	Billion yen
Revenues	433.8	423.9	+9.8	+2.3	433.0
(Domestic sales revenue)	320.8	320.3	+0.5	+0.2	324.6
(Overseas sales revenue)	112.9	103.6	+9.3	+9.0	108.3
Overseas sales ratio	26.0%	24.4%		+1.6	25.0%
Cost of sales	169.7	164.3	+5.3	+3.3	169.5
Sales cost ratio	39.1%	38.8%		+0.3	39.1%
Gross profit	264.1	259.5	+4.5	+1.7	263.5
Core operating profit	78.5	94.5	-15.9	-16.9	80.0
Operating profit	77.2	94.0	-16.7	-17.9	81.0
Net profit attributable to owners of the Company	57.9	71.2	-13.3	-18.7	63.5
Average exchange rate(USD)	¥110.70	¥108.72			¥110.00

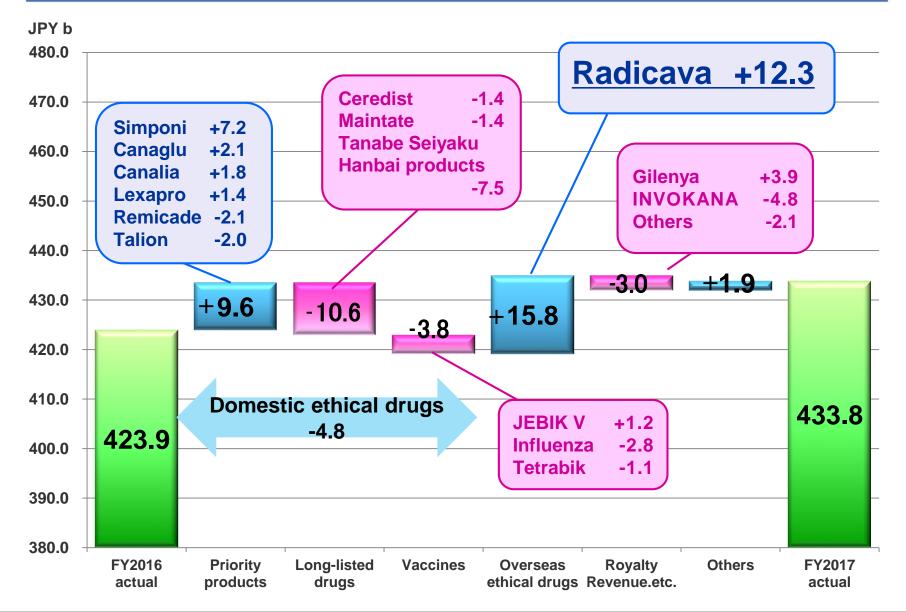
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#### **Revenue Trends**





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

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- SG&A expenses increased due to the launch of Radicava in the U.S.
- R&D expenses increased by the stage up to the late stage of development and NeuroDerm acquisition

	FY2017	FY2016	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	433.8	423.9	+9.8	+2.3
Cost of sales	169.7	164.3	+5.3	+3.3
Sales cost ratio	39.1%	38.8%		+0.3
Gross profit	264.1	259.5	+4.5	+1.7
SG&A expense	104.0	98.3	+5.7	+5.9
R&D expense	79.0	64.7	+14.3	+22.1
Amortization of intangible assets associated with products	2.4	1.5	+0.9	+60.4
Other income and expense*	0.0	-0.4	+0.4	-
Core operating profit	78.5	94.5	-15.9	-16.9

\* Negative signs indicate expense and loss

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#### Non-recurring items, Net Profit





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In Non-recurring items, impairment and restructuring costs were more than the revenue of ٠ business capital gains and gain on sales of fixed assets

	FY2017	FY2016	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Core operating profit	78.5	94.5	-15.9	-16.9
Non-recurring items*	-1.2	-0.4	-0.8	-
Operating profit	77.2	94.0	-16.7	-17.9
Financial income	1.8	2.2	-0.3	-15.0
Financial expense	0.4	0.2	+0.1	+70.3
Net profit attributable to owners of the Company	57.9	71.2	-13.3	-18.7

\* Negative signs indicate expense and loss

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# Medium-Term Management Plan 16-20 Achievements in FY2017 and Plans for FY2018

#### Four Strategic Priorities to Open Up the Future



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#### Fiscal 2020 Objectives Revenue ¥500 billion Core operating profit ¥100 billion **Maximizing Pipeline Value Principal results and progress** 5 candidates progressing to late stage development trials Late-stage drug 10 candidates ✓ MT-2271 (seasonal influenza VLP) Phase3 candidate objective MT-6548 (renal anemia) Phase3 (including in-licensed MT-5547 (osteoarthritis) Phase<sub>2/3</sub> candidates) MT-5199 (tardive dyskinesia) Phase<sub>2/3</sub> ND0612 (Parkinson's) Phase3(Preparations under way) **R&D** investment $\pm 400$ billion Enhancing our pipeline in the field of autoimmune diseases (During the period of Acquisition of STNM01 (Stelic Institute & Co.) the medium-term management plan) Strengthening IKUYAKU and **Principal results and progress** Marketing Domestic ethical sales(FY2017) :¥309.3b New drugs and priority products sales ratio(FY2017) :63% **Domestic revenue** ¥300 billion **Priority diseases areas:** objective (fiscal 2020) Growth of Simponi, Tenelia, Canaglu $\checkmark$ New drug and priority Approval / launch of Canalia 75% Launched Rupafin product revenue ratio • Others: **Priority disease areas** Started operations of vaccine manufacturing joint venture, BIKEN $\checkmark$ Autoimmune | Diabetes and kidney | Central co., Ltd. nervous system | Vaccines

## Four Strategic Priorities to Open Up the Future

#### **Accelerating U.S. Business Principal results and progress** Development Launch of Radicava Solid start $\checkmark$ **U.S. revenue objective** ¥80 billion Sales revenue ¥12.3b(FY2017) (Fiscal Year 2020) Cumulative number of patients who have used Radicava: 2,300 (as of the end of March, 2018) **U.S. strategic** More than Acquisition of NeuroDerm investment ¥200 billion Enhancing the pipeline in neurology in the U.S. $\checkmark$ (During the period of Acquisition procedures completed in October, became wholly $\checkmark$ the medium-term owned subsidiary (total cost approximately ¥120.0 billion) management plan) **Reforming Operational Productivity Principal results and progress** Cost of sales / SG&A Vs. fiscal 2015 Estimate of ¥14.0 billion expense reduction ✓ ¥4.5 billion in cost of sales and ¥9.5 billion in SG&A expenses ¥20 billion objective (Fiscal Year (vs. Fiscal Year 2015) 2020) Number of employees Number of employees **Consolidated domestic** Consolidated domestic workforce: (Fiscal Year 2020) workforce 6,089 (as the end of March, 2016) 5,000 employees 5,158 (as the end of March, 2018) (-931)

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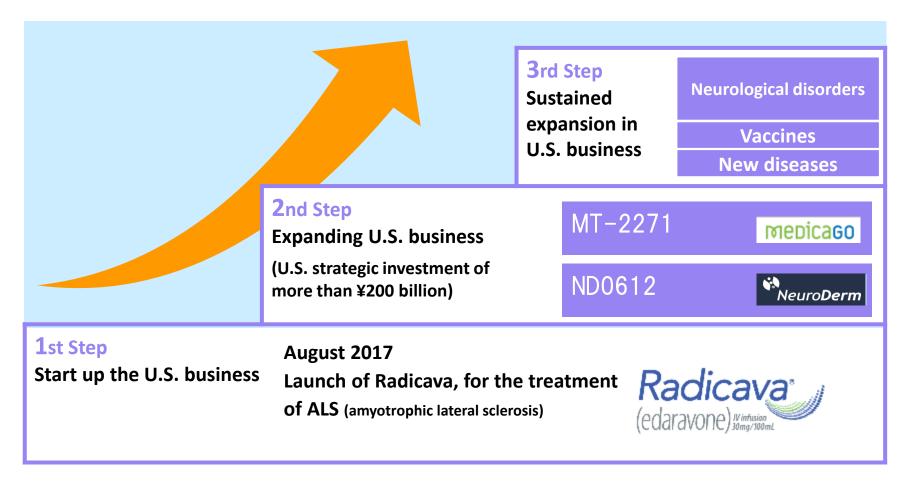
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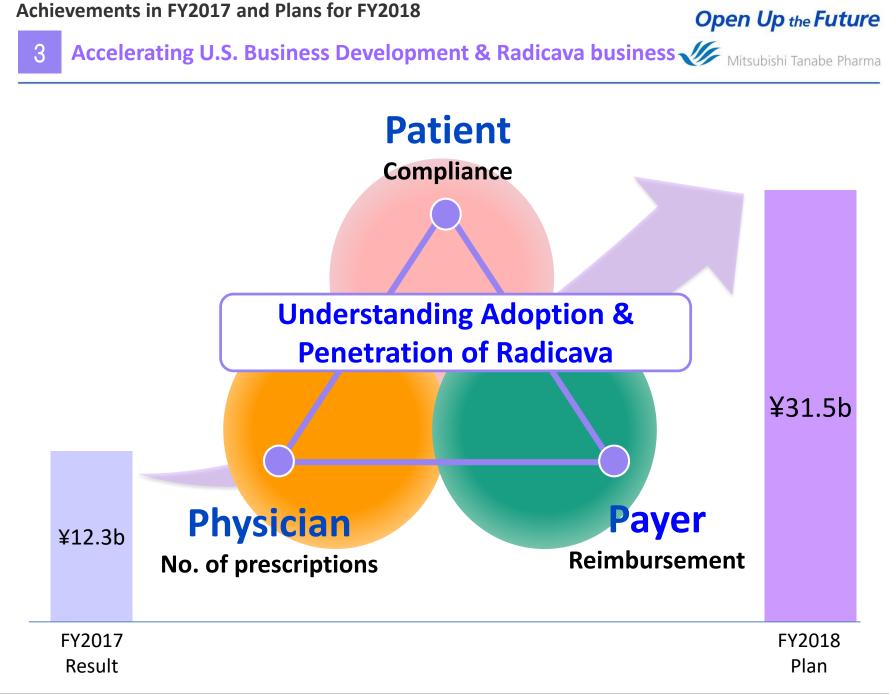
Achievements in FY2017 and Plans for FY2018

#### **3** Roadmap for Accelerating U.S. Business Development

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Make U.S. Business MTPC's second business pillar (following the domestic market) by achieving revenue of ¥80 billion in Fiscal Year 2020 with sustained growth





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#### Open Up the Future



3P	Achievements in FY2017	Plans for FY2018
Physician	<ul> <li>Implemented MR activities         ⇒         Provided information to physicians         ALS specialists(1<sup>st</sup> target 270): 100%         Neurologists         2<sup>nd</sup> target (1,300):More than 90%         3<sup>rd</sup> target (1,400):More than 60%     </li> </ul>	<ul> <li>Understanding adoption and penetration of physicians and providing medical information ⇒</li> <li>Expand the reach to target Physicians         1<sup>st</sup> target 370         2<sup>nd</sup> target 1,000         3<sup>rd</sup> target 1,000</li> </ul>
Patient	<ul> <li>Supported the therapeutic environment to help patients</li> <li>⇒Treated number of patients (total) is 2,300</li> <li>⇒ Treatment facility 40%</li> <li>Infusion center 10%</li> <li>Home Care 50%</li> </ul>	<ul> <li>Shortening the lead-time to the start of patient treatment</li> <li>Enhancing Support and Nursing care</li> </ul>
Payer	<ul> <li>Supported creation of an environment to the enable a smooth start of treatment</li> <li>Promoted understanding of Radicava product value by showing clinical data</li> <li>⇒Medicare approximately 47%; Private insurance approximately 48%; Others 5%</li> </ul>	<ul> <li>Promote understanding and knowledge of Radicava product value by post-analysis of the clinical data</li> </ul>

Sales	¥12.3b	¥31.5b
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#### Achievements in FY2017 and Plans for FY2018

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**Accelerating U.S. Business Development** 

#### Maximize the Value of Radicava





Maximize t	he Value of Radicava	FY2017	Plans for FY2018
Business regions (indication: ALS)	Switzerland	Application accepted	Approval expected
	Canada	—	Application accepted in April Approval expected
	Europe	In discussion with regulatory authorities for filing	Preparation for filing
	ASEAN, others	Under consideration	Under consideration
LCM (Life Cycle Management)	Application for 60 mg intravenous infusion bag formulation (Increased convenience with change from 2 bags per administration to 1 bag per administration)		Approval expected Plan to launch in FY2019
	Developing MT-1186 (New administration route)	_	Plan to initiate Phase1

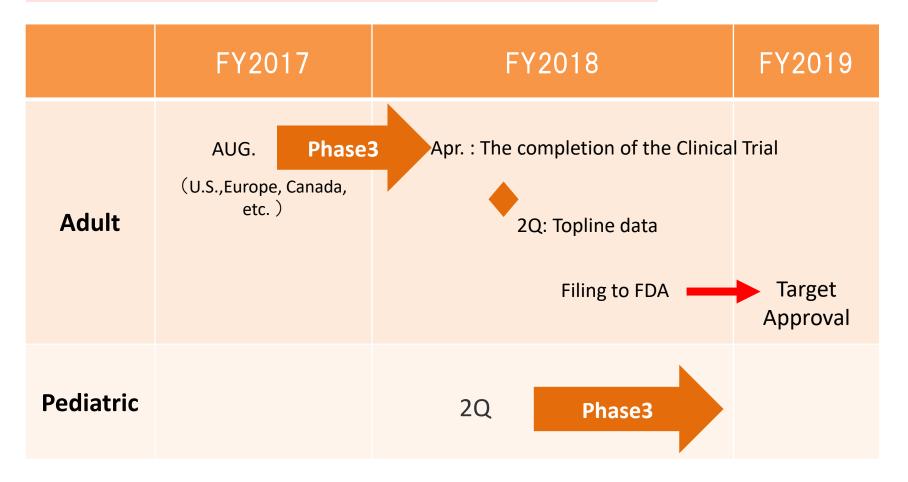


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Accelerating U.S. Business Development MT-2271 (Medicago) J

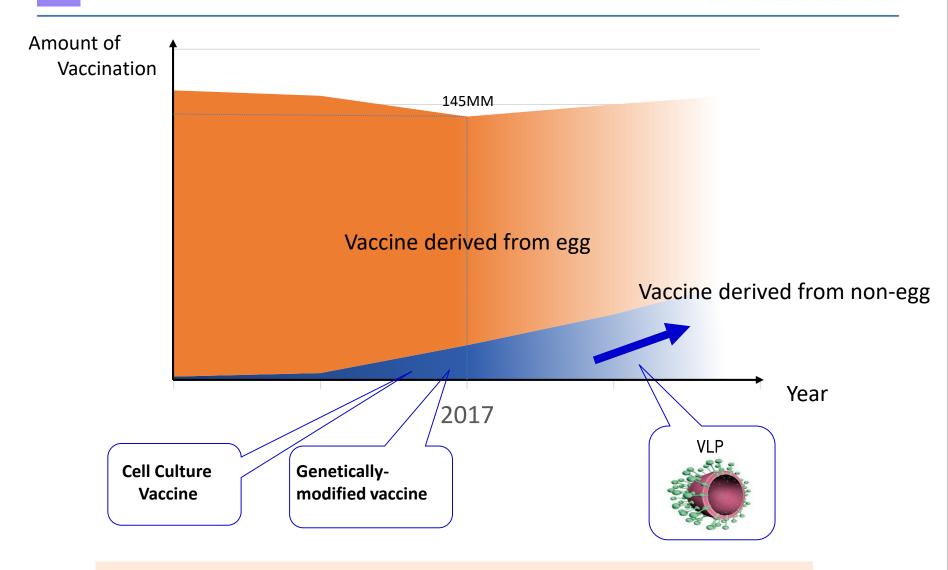
#### **MT-2271:** Plant-based Seasonal Influenza VLP Vaccine



#### Achievements in FY2017 and Plans for FY2018

#### **Open Up** the **Future**

3 Accelerating U.S. Business Development MT-2271 (Medicago) Mitsubishi Tanabe Pharma



U.S. Market size of Seasonal influenza vaccine : approximately ¥240b







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#### Autoimmune Diseases Area

Product	Achievements in FY2017	Plans for FY2018
MT-1303 (amiselimod/S1P receptor functional antagonist)	Reevaluated the development plan for in-house development	Promoting activity for the co- operation with other companies
MT-5547 (fasinumab/ anti- NGF antibody)	Phase 2/3 initiated (Japan, Osteoarthritis)	Promotion of Phase 2/3
MT-7117 (Dermatologicals, etc.)	Phase 1 completed	Phase 2 initiated (Oversea, POC achieved)
MT-2990	Phase 1 initiated	Phase 2 initiated (Oversea, POC achieved)

Achievements in FY2017 and Plans for FY2018







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Diabetes and kidney diseases Area

Product	Achievements in FY2017	Plans for FY2018
MT-6548 (vadadustat/ HIF-PH inhibitor)	Phase 3 initiated (Japan, Renal anemia)	Promotion of Phase3 Target approval in FY2020
TA-7284 (SGLT2 inhibitor)	Promotion of CREDENCE study (Japan, U.S., Europe, etc., Diabetic nephropathy)	Target end of Clinical trial at June, 2019 Under consideration for approval the acquisition of diabetic nephropathy
MT-3995 (Selective mineralocorticoid receptor antagonist)	Promotion of Phase2 (Japan, focused on Non-alcoholic steatohepatitis)	Promoting activity for the co-operation with other companies

Achievements in FY2017 and Plans for FY2018

## **Maximizing Pipeline Value**





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CNS Diseases Area		
Product	Achievements in FY2017	Plans for FY2018
MT-5199 (valbenazine/ VMAT2 inhibitor)	Phase 2/3 initiated (Japan, Tardive dyskinesia)	Promotion of Phase 2/3 Target approval in FY2021
MT-8554 (Nervous system, etc.)	Phase 2 initiated (EU: Painful diabetic peripheral neuropathy) (US: Vasomotor symptoms associated with menopause)	Target POC achieved in Q3, FY2018
ND0612 (Levodopa (LD) / Carbidopa (CD))	NeuroDerm Acquisition procedures completed in October, became wholly owned subsidiary(Oct.2017) Promoted the long-term safety study	Phase 3 initiated (U.S., Europe)
MT-1186 (Amyotrophic lateral sclerosis/New administration route)	Considering new administration route	Phase 1 initiated

Achievements in FY2017 and Plans for FY2018



### **Maximizing Pipeline Value**





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## Vaccines

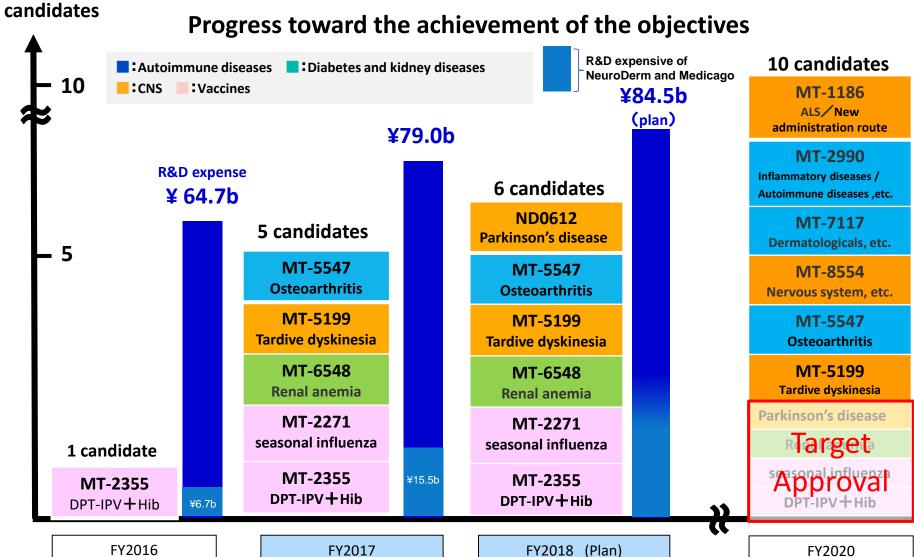
Product	Achievements in FY2017	Plans for FY2018
MT-2355 (DPT-IPV <b>十</b> Hib)	Promoted Phase 3 (Japan)	Promotion of Phase 3
MT-2271 (Seasonal influenza VLP)	Phase 3(adult) initiated (US, EU, Canada, etc.)	Filing in North America in FY2018 Target approval in FY2019

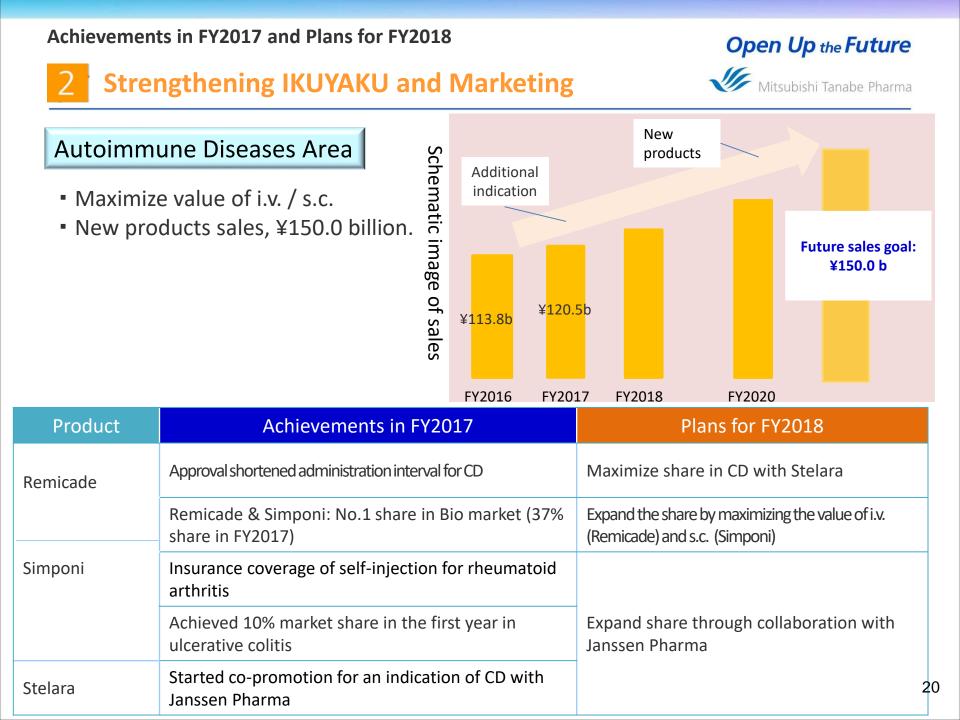
Achievements in FY2017 and Plans for FY2018











#### **Future sales goal** ¥100.0 bil. ¥41.4b ¥33.5b FY2020 FY2016 FY2017 FY2018 Product Achievements in FY2017 Plans for FY2018 Expanded share by penetration among the Expand share based on good collaboration Tenelia patient with weak kidney and the elderly with Daiichi Sankyo Expanded prescription for the heart Expand share by showing the evidence problem and renal complication of disease Canaglu about the safety and efficacy for the case by showing the results of CANVAS cardiovascular system and kidneys trials No.1 position in combination drug including Canalia Launched Sep. 2017 both DPP-4 and SGLT2 inhibitor

#### Achievements in FY2017 and Plans for FY2018

## **Strengthening IKUYAKU and Marketing**

#### Diabetes and kidney diseases area

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

CREDENCE Schematic image of sales CANVAS Canalia launched





New products,

LCM



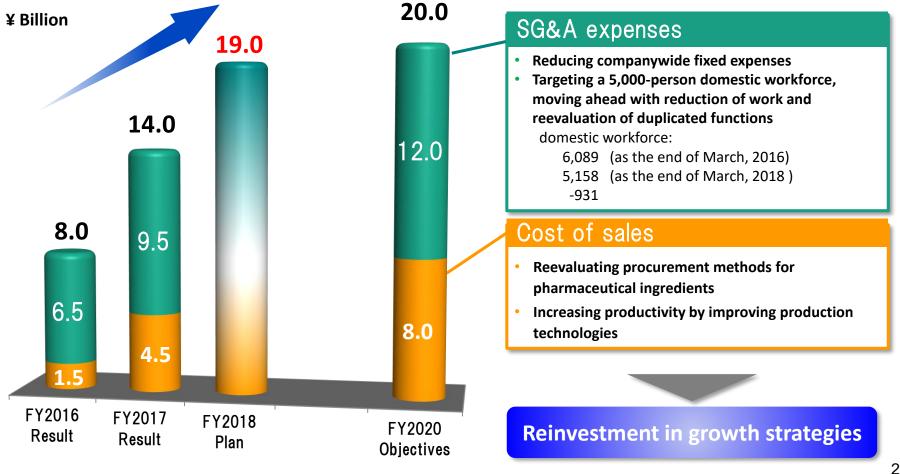
#### Achievements in FY2017 and Plans for FY2018

## **4** Reforming Operational Productivity





- **FY2017 Result** : Reduced ¥14.0b companywide fixed expenses because of cost reduction, restructuring, and natural decrease of personnel, etc. (Target ¥10.0b)
- **FY2018 Plan :** Targeting to reduce ¥19.0b further promoted cost and SG&A expenses reductions, in addition to the period difference



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# **Forecasts of FY2018**

#### **Forecasts of FY2018**

- Extending Radicava sales in the U.S will cover the decrease in revenue in domestic ethical drugs and royalty income.
- Sales cost ratio will increase by the impact of NHI drug price revision and the change of the product mix.

	FY2018 Forecasts	FY2017 Actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	435.0	433.8	+1.1	+0.3
(Domestic sales revenue)	304.7	320.8	-16.1	-5.0
(Overseas sales revenue)	130.2	112.9	+17.2	+15.3
Overseas sales ratio	29.9%	26.0%		
Cost of sales	176.0	169.7	+6.2	+3.7
Sales cost ratio	40.5%	39.1%		
Gross operation profit	259.0	264.1	-5.1	-1.9
Core operating profit	70.0	78.5	-8.5	-10.9
Net profit attributable to owners of the Company	47.0	57.9	-10.9	-18.9
Average exchange rate (USD)	¥105.00	¥110.70	I	I

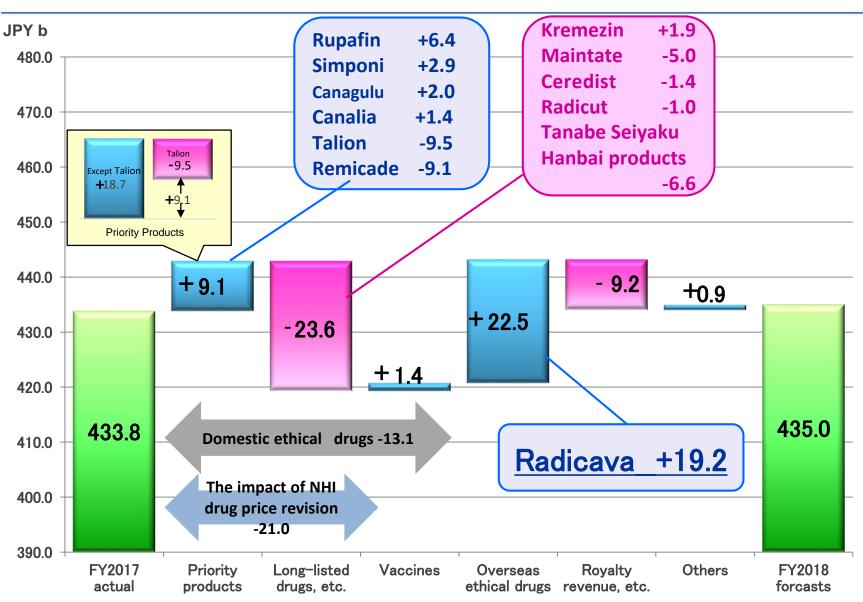
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**Revenue Trends** 

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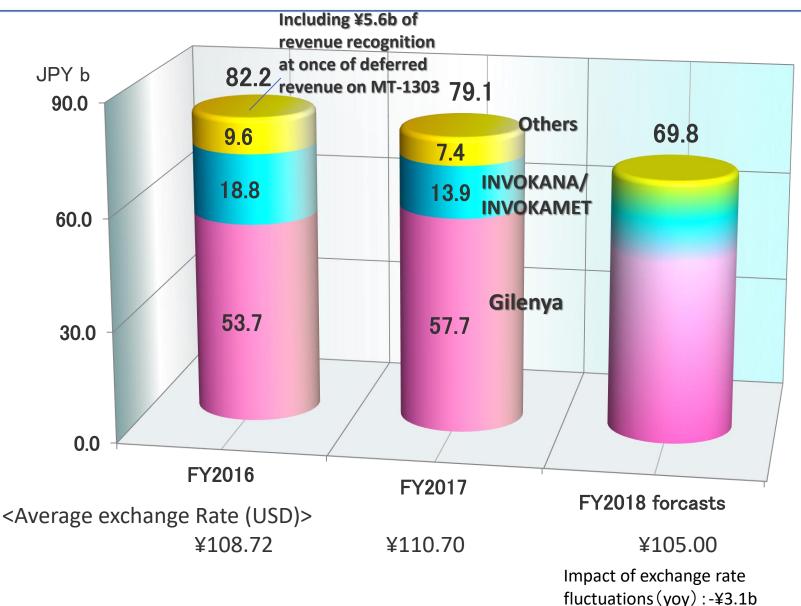


Royalty revenue, etc.

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**Forecasts of FY2018** 

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Core operating profit will decrease due to an increase R&D expenses in the late-stage ٠ drug development

	FY2018 forecasts	FY2017 actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	435.0	433.8	+1.1	+0.3
Cost of sales	176.0	169.7	+6.2	+3.7
Sales cost ratio	40.5%	39.1%		
Gross operating profit	259.0	264.1	-5.1	-1.9
SG&A expenses	101.0	104.0	-3.0	-2.9
R&D expenses	84.5	79.0	+5.4	+6.8
Amortization of intangible assets associated with products	3.0	2.4	+0.5	+22.4
Other income and expense*	-0.5	0.0	-0.5	-
Core operating profit	70.0	78.5	-8.5	-10.9

\* Negative signs indicate expense and loss

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#### Restructuring cost in liquidating assets incurred in non recurring costs ٠

	FY2018 forecasts	FY2017 actual	Increase/decrease	
	Billion yen	Billion yen	Billion yen	%
Core operating profit	70.0	78.5	-8.5	-10.9
Non-recurring items*	-3.0	-1.2	-1.7	-
Operating profit	67.0	77.2	-10.2	-13.3
Net profit attributable to owners of the Company	47.0	57.9	-10.9	-18.9

\* Negative signs indicate expense and loss

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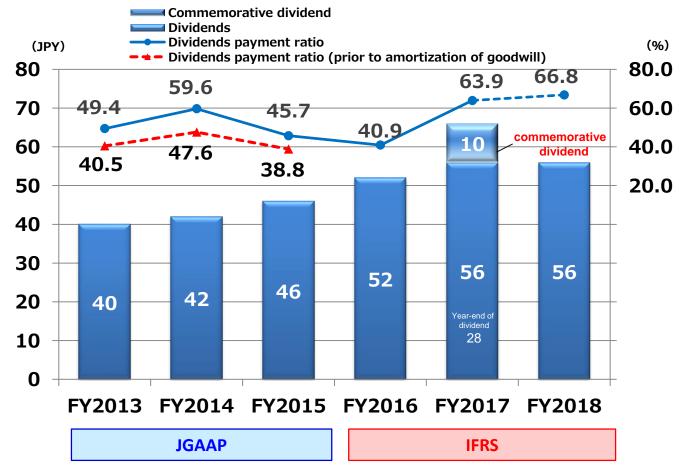
## **Shareholders Return**

#### **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).
- A-year-end dividend for FY2017 is ¥28 per share as expected.



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# Main IR Event of FY2018

#### Main IR Event of FY2018



- The end of July 2018
- The end of Oct. 2018
- November 20, 2018

Announcement of Financial results 1Q

Announcement of Financial results 2Q

Business briefing session for investors

in Tokyo

• The beginning of Feb. 2019

Announcement of Financial results 3Q





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# **Open Up** the **Future**

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



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**Details of Revenue** 

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	FY2017	FY2016	Increase/decrease		*Forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	433.8	423.9	+9.8	+2.3	433.0	100.2
(Overseas revenue)	112.9	103.6	+9.3	+9.0	108.3	104.3
Domestic ethical drugs	309.3	314.2	-4.8	-1.5	315.4	98.1
Overseas ethical drugs	38.5	22.6	+15.8	+70.0	32.4	118.7
Royalty revenue, etc.	79.1	82.2	-3.0	-3.8	80.2	98.6
отс	3.7	3.4	+0.3	+9.3	4.1	89.0
Others	3.0	1.4	+1.6	+113.9	0.9	306.3

\*: Forecasts of FY2017 announced on Oct. 24, 2017.

### **Domestic Ethical Drugs**

#### **Revenue of Priority Products and Vaccines**





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	-	-								
	FY2017	FY2016	Increase/decrease		Increase/decrease		Increase/decrease		*Forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%				
Remicade	64.6	66.8	-2.1	-3.2	64.7	100.0				
Simponi	32.1	24.9	+7.2	+29.0	30.3	105.9				
Tenelia	17.5	16.5	+0.9	+5.8	19.1	91.7				
Talion	16.9	18.9	-2.0	-10.7	20.8	81.4				
Lexapro	12.7	11.2	+1.4	+13.2	12.9	98.8				
Canaglu	5.6	3.4	+2.1	+60.8	6.9	80.8				
Imusera	4.7	4.9	-0.1	-3.5	5.1	92.7				
Total of priority products	154.4	146.9	+7.4	+5.1	159.9	96.5				
(New Product) Canalia	1.8	—	+1.8	—	N/A					
Rupafin	0.4		+0.4		N/A					
Influenza vaccine	9.9	12.7	-2.8	-22.2	10.0	99.1				
Tetrabik	8.7	9.9	-1.1	-12.0	9.2	95.1				
Varicella vaccine	5.2	5.4	-0.1	-3.2	5.7	91.8				
JEBIK V	5.2	3.9	+1.2	+30.4	4.9	104.8				
Mearubik	5.0	5.9	-0.8	-15.0	5.2	95.1				
Total of vaccines	35.0	38.9	-3.8	-10.0	36.1	97.2				
Total	189.4	185.9	+3.5	+1.9	196.0	96.6				

\*: Forecasts of FY2017 announced on Oct. 24, 2017.

**Domestic Ethical Drugs** 

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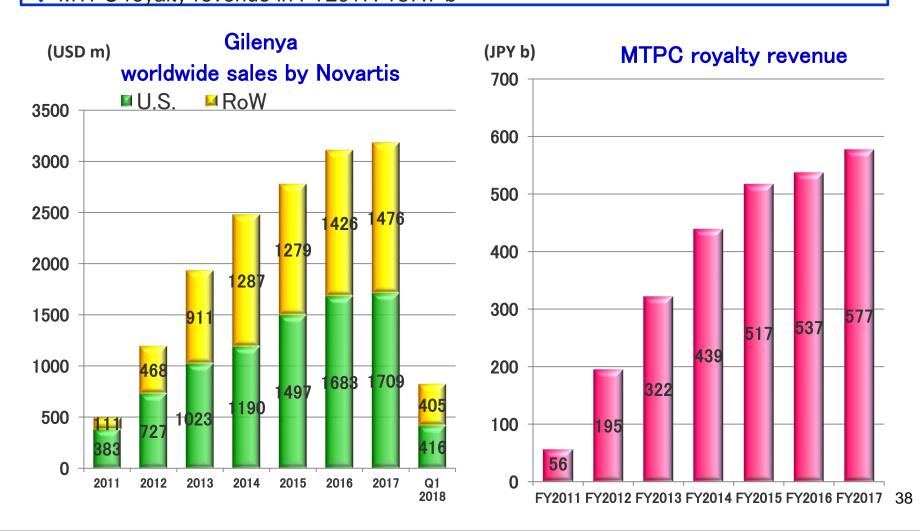
	FY2018 forecasts	FY2017	Increase/c	lecrease
	Billion yen	Billion yen	Billion yen	%
Remicade	55.5	64.6	-9.1	-14.1
Simponi	35.0	32.1	+2.9	+9.2
Tenelia	17.0	17.5	-0.4	-2.8
Lexapro	13.1	12.7	+0.3	+3.1
Canaglu	7.6	5.6	+2.0	+36.5
Talion	7.3	16.9	-9.5	-56.6
Rupafin	6.8	0.4	+6.4	+1,464.8
Imusera	4.9	4.7	+0.2	+5.4
Canalia	3.2	1.8	+1.4	+79.6
Total of priority products	150.9	156.6	-5.6	-3.6
Influenza vaccine	11.2	9.9	+1.2	+12.8
Tetrabik	9.1	8.7	+0.3	+4.2
Varicella vaccine	5.5	5.2	+0.2	+4.2
Mearubik	5.5	5.0	+0.5	+11.1
JEBIK V	4.3	5.2	-0.8	-17.1
Total of vaccines	36.5	5 35.0 +1.4		+4.2
Total	187.5	191.7	-4.2 -2	

### Gilenya





Gilenya worldwide sales by Novartis in Q1 FY2018 (January to March, 2018) : \$821 m (\$722m, the same period of previous year)
 MTPC royalty revenue in FY2017: ¥57.7 b



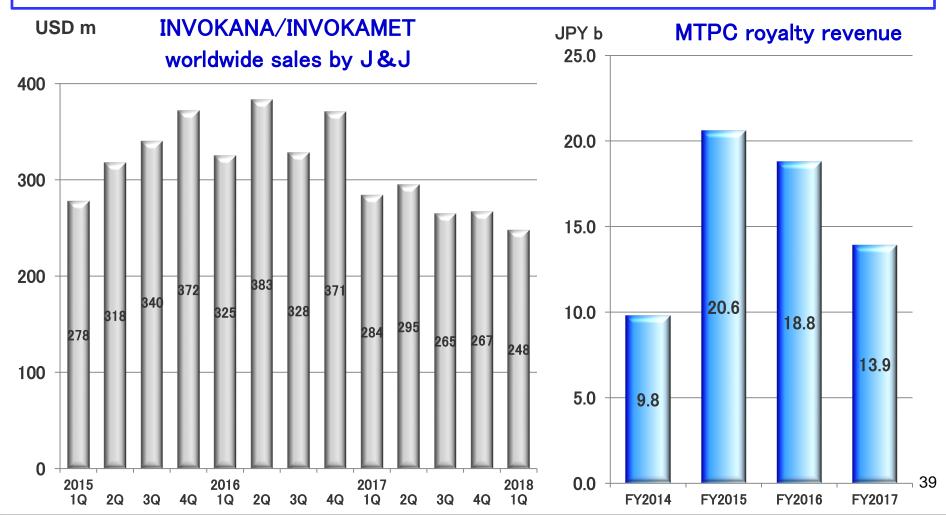
## **INVOKANA/INVOKAMET**





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- INVOKANA/INVOKAMET worldwide sales by Johnson & Johnson in Q1 FY2018 (January to March, 2018) : \$248m (the same period of previous year : \$284m)
- INVOKANA/INVOKAMET TRx share 6.0% in defined U.S. T2D market
- MTPC royalty revenue in FY2017 : ¥13.9b



# **Pipeline Status**

#### **Disease area**

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

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#### Red: Progress after Feb. 5, 2018, the financial results for Q3 FY2017

#### As of Apr. 30, 2018

Phase 1	Phase 2	Phase 3	Filed	Approved
MT-7529	MT-1303 (EU)	Canaglu (Global clinical study)*1	MP-513 (Indonesia)	Novastan (China)
Prophylaxis of H7N9 influenza	Multiple sclerosis, Psoriasis	Diabetic nephropathy	Type2 diabetes mellitus	Acute cerebral thrombosis
GB-1057	MT-1303 (JP, EU)	<b>MP-513 (China)</b>	TA-7284 (Indonesia)	
Blood and blood forming	Crohn's disease	Type2 diabetes mellitus	Type2 diabetes mellitus	
organs	MP-513 (EU)	MT-2355 (JP) *2	<mark>–</mark> MP-214 (Korea, Taiwan)	
<mark>—</mark> MP-124	Type2 diabetes mellitus	5 combined vaccine	Schizophrenia	
Nervous system	MT-3995 (JP, EU)	(4 combined + Hib)	MCI-186 (Switzerland)	
MT-0814	Diabetic nephropathy	MT-2271 (US, EU, Canada, etc.)	Amyotrophic lateral scleros	is
Ophthalmologicals	MT-8972 (Canada)	Prophylaxis of seasonal influenza	🗖 Valixa (Japan)	
MT-7117	Prophylaxis of H5N1 influen	za <mark>MT-5199 (JP)</mark>	Prevention of cytomegalovi	rus
Dermatologicals, etc.	MT-3995 (JP)	Tardive dyskinesia	disease in pediatric organ	
MT-4129	NASH	MT-6548 (JP)	transplant patients	
Cardiovascular system, etc.	<mark>–</mark> MT-8554 (EU)	Renal anemia	MCI-186 (Canada)	
MT-2990	Painful diabetic peripheral	MT-5547 (JP)	Amyotrophic lateral scleros	IS
Inflammatory diseases /	neuropathy	Osteoarthritis		
Autoimmune diseases , etc.	<mark>–</mark> ND0612 (US, EU)	*1: Sponsor: Janssen Research	& Development LLC	
MT-2765	Parkinson's disease		arch Foundation for Microbial Dis	eases of Osaka University (JP)
Cardiovascular system, etc.	ND0801 (Israel)	······		······
ND0701	CNS Disease	Major license-out produc	ts 😨 MT-4580 (JP)	
Parkinson's disease	Cognition disorders	(post Phase 3)	Secondary hype	erparathyroidism in disease patients
MT-1186	MT-8554 (US)	(poer i hadd d)	on maintenanc	
Amyotrophic lateral sclerosis	Vasomotor symptoms associated with	TA-7284 (Global clinical study		e alarysis
(New administration route)		Diabetic nephropathy		
	menopause	MT-4580 (JP)	TA-7284 (US, I	
			• •	of death in Type 2 diabetes
		Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism	with establishe	d, or risk for, cardiovascular
		Primary Hyperparathyroidism	with established disease (CANVA	
		MT-210 (US, EU)	<b>FTY720 (US, E</b>	
		Schizophrenia	Pediatric multip	

### **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.