



**Q2 FY2020 Business Results  
(April – September, 2020)**

**November 4, 2020**

	Q2 FY2020	Comparison to previous year		
		Q2 FY2019	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Revenue	187.3	188.1	(0.8)	(0.4)
(Domestic)	155.0	154.6	0.4	0.3
(Overseas)	32.3	33.5	(1.2)	(3.6)
Overseas sales ratio	17.2%	17.8%		
Cost of sales	94.8	88.5	6.3	7.1
Sales cost ratio	50.6%	47.1%		
Gross profit	92.5	99.6	(7.1)	(7.1)
SG&A expense, etc.	77.9	87.9	(10.0)	(11.4)
(R&D expense)	33.9	39.8	(5.9)	(14.8)
Core operating profit*1	14.6	11.7	2.9	24.5
Non-recurring items*2	(76.5)	0.9	(77.3)	-
Gain from sales of Toda office	7.5	-	7.5	-
Loss from impairment*3	(84.5)	-	(84.5)	-
Operating profit*2	(61.9)	12.6	(74.5)	-
Financial income and loss*2	0.3	(0.4)	0.7	-
Net profit attributable to owners of the Company*2	(51.0)	8.3	(59.3)	-

Average exchange rate US\$

¥106.32

¥108.67

\*1: ¥5.5B of impact from COVID-19 included

Decreased expenses by shrinkage in sales promotion and delay in R&amp;D expenses incurred overtake sales decrease

\*2: Brackets indicate expense and loss

\*3: See "Changes in ND0612 Development Plan and Impairment Loss"

	Q2 FY2020	Comparison to previous year		
		Q2 FY2019	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Domestic ethical drugs	150.3	149.2	1.2	0.8
Priority products	89.9	88.7	1.1	1.3
Vaccines	21.1	15.7	5.4	34.3
Long-listed drugs, etc.	39.3	44.7	(5.4)	(12.0)
Overseas ethical drugs	25.1	24.9	0.3	1.0
Radicava	11.1	11.6	(0.6)	(4.9)
Royalty revenue, etc.	7.8	9.2	(1.4)	(15.1)

# Q2 FY2020 Business Results

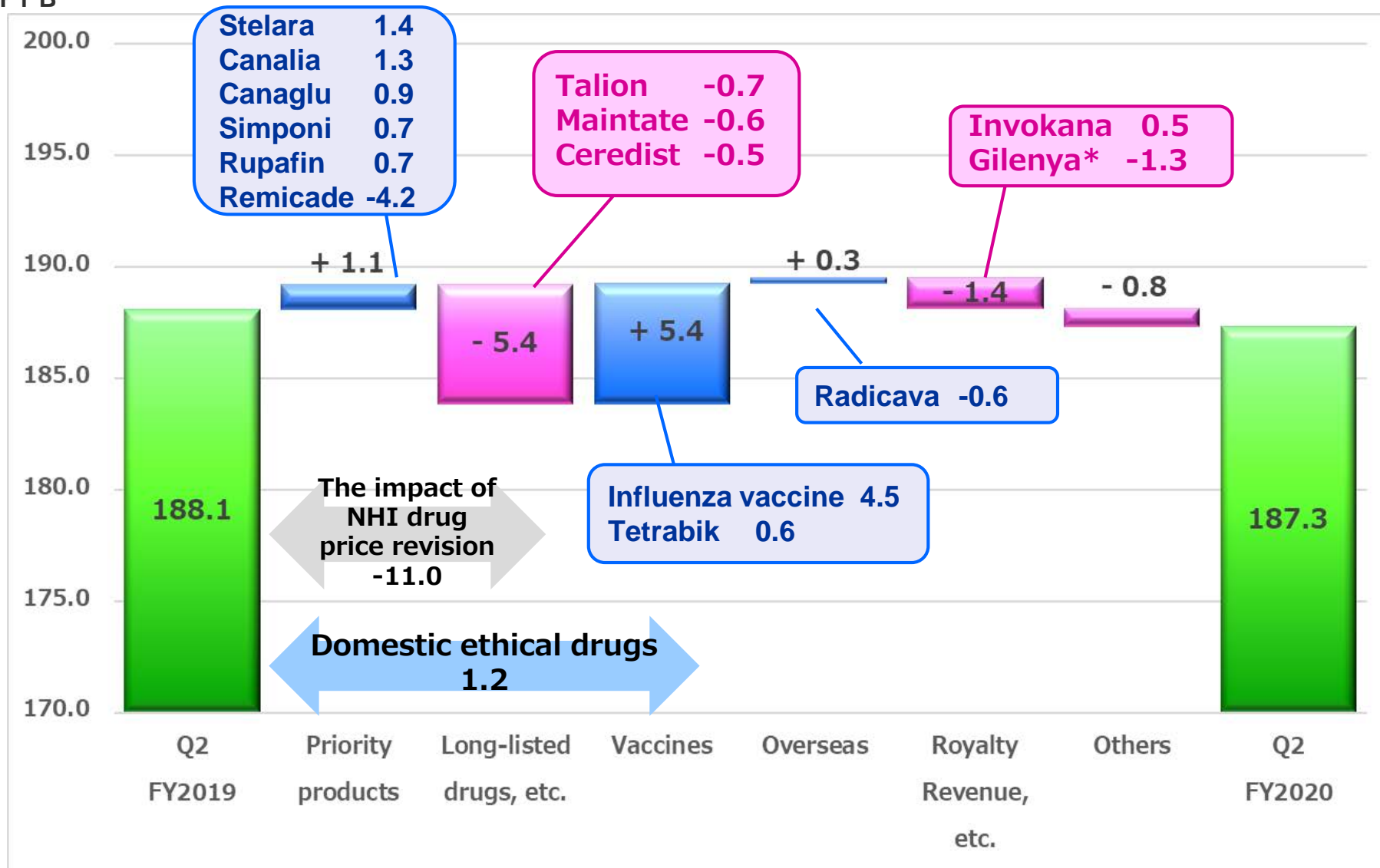
## Domestic Ethical Drugs

### Revenue of Priority Products and Vaccines

	Q2 FY2020	Comparison to previous year		
		Q2 FY2019	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Remicade	23.4	27.6	(4.2)	(15.2)
Simponi	21.2	20.5	0.7	3.6
Stelara	14.0	12.6	1.4	10.9
Tenelia	8.0	8.1	(0.1)	(1.5)
Canaglu	5.0	4.1	0.9	22.8
Canalia	5.0	3.8	1.3	33.6
Vafseo (launched in Aug.)	0.3	-	0.3	-
Lexapro	7.6	7.5	0.2	2.1
Rupafin	3.2	2.5	0.7	29.0
Imusera	2.1	2.2	(0.0)	(2.1)
<b>Total of priority products</b>	<b>89.9</b>	<b>88.7</b>	<b>1.1</b>	<b>1.3</b>
Influenza vaccine	6.3	1.8	4.5	253.2
Tetrabik	5.1	4.6	0.6	12.5
Mearubik	3.7	3.5	0.2	5.3
JEBIK V	2.9	2.9	0.0	1.3
Varicella vaccine	2.5	2.5	(0.0)	(0.6)
<b>Total of vaccines</b>	<b>21.1</b>	<b>15.7</b>	<b>5.4</b>	<b>34.3</b>
<b>Total of priority products and vaccines</b>	<b>111.0</b>	<b>104.5</b>	<b>6.5</b>	<b>6.2</b>

# Revenue Trends

JPY B



\* Including a decline of "GILENYA® Royalty" amounts which will not be recognized as sales revenue during arbitration proceedings

## Revised Forecasts of FY2020

	Revised forecasts	Original forecasts <sup>*1</sup>	Increase / Decrease		FY2019 actual
	Billion yen		Billion yen	%	Billion yen
Revenue	373.0	383.5	(10.5)	(2.7)	379.8
SG&A expense, etc.	168.5	186.0	(17.5)	(9.4)	179.7
R&D expense	72.5	83.5	(11.0)	(13.2)	79.4
Core operating profit*2	17.0	10.0	7.0	70.0	19.1
Operating profit*3	(62.5)	17.0	(79.5)	-	(6.1)
Net profit attributable to owners of the Company*3	(52.5)	8.5	(61.0)	-	0.1

<Reasons of revision>

Revenue : Decrease due to suppression of consultation under COVID-19 spread and royalty revenue etc.

Core operating profit : Expenses decreased by shrinkage in sales promotion and delay in R&D expenses incurrence overtake sales decrease

Operating profit : Decrease due to impairment loss from NeuroDerm's projects

\*1: Original was announced on May 13

\*2: ¥3.5B of impact from COVID-19 included in revised forecasts

\*3: Brackets indicate expense and loss

# Details of Revenue

	Revised forecasts	Original forecasts*	Increase / Decrease		FY2019 actual
	Billion yen	Billion yen	Billion yen	%	Billion yen
Domestic ethical drugs	302.3	303.6	(1.3)	(0.4)	304.4
Priority products	183.0	182.4	0.6	0.3	177.1
Vaccines	40.8	41.0	(0.2)	(0.5)	39.0
Long-listed drugs, etc.	78.5	80.2	(1.7)	(2.1)	88.3
Overseas ethical drugs	47.0	50.9	(3.9)	(7.7)	49.7
Radicava	20.1	22.4	(2.3)	(10.3)	23.1
Royalty revenue, etc.	15.2	19.9	(4.7)	(23.6)	17.4

\* Original was announced on May 13



	Revised forecasts	Original forecasts*	Increase / Decrease		FY2019 actual
	Billion yen	Billion yen	Billion yen	%	Billion yen
Remicade	45.0	44.8	0.2	0.4	53.4
Simponi	42.7	42.3	0.4	0.9	41.0
Stelara	31.9	32.8	(0.9)	(2.7)	26.0
Tenelia	14.9	14.9	-	-	15.2
Canaglu	9.8	9.2	0.6	6.5	8.8
Canalia	9.3	9.3	-	-	6.7
Vafseo (launched in Aug.)	0.5	0.2	0.3	150.0	-
Lexapro	14.8	14.6	0.2	1.4	15.0
Rupafin	10.0	10.2	(0.2)	(2.0)	6.8
Imusera	4.1	4.1	-	-	4.2
Total of priority products	183.0	182.4	0.6	0.3	177.1
Influenza vaccine	13.2	12.2	1.0	8.2	12.6
Tetrabik	11.1	11.3	(0.2)	(1.8)	9.5
Mearubik	6.4	6.4	-	-	6.0
JEBIK V	5.3	5.3	-	-	5.2
Varicella vaccine	4.8	4.8	-	-	4.9
Total of vaccines	40.8	41.0	(0.2)	(0.5)	39.0
Total of priority products and vaccines	223.8	223.4	0.4	0.2	216.1

\* Original was announced on May 13



# Status of research and development etc.



# FY 2020 Q2 Overview

## Major Development Pipeline

Code	Indications	Stage	Topics
<b>MT-1186</b>	Amyotrophic lateral sclerosis: ALS	P3	<ul style="list-style-type: none"> <li>Global P3 study (long-term safety study) is ongoing. Enrollment completed in October.</li> </ul>
<b>ND0612</b>	Parkinson's disease	P3	<ul style="list-style-type: none"> <li>The overlap between the expansion of COVID-19 and the start-up period of the P3 study affected the study plan.</li> <li>NDA / MAA are to be filed in FY2023</li> </ul>
<b>MT-7117</b>	Erythropoietic protoporphyria: EPP X-linked protoporphyria: XLP	P3	<ul style="list-style-type: none"> <li>Global P3 study started in June is ongoing.</li> </ul>
<b>MT-2766</b>	Prophylaxis of COVID-19 (Plant-based VLP* vaccine)	P1	<ul style="list-style-type: none"> <li>The P1 study started in July is scheduled to be completed soon. Phase 2/3 study is planned to be started in the future.</li> <li>In October, reached the agreements with government of Canada to receive development funding and to supply VLP vaccine.</li> </ul>

\*VLP : Virus-like particle

## Topics in Japan

Launch of VAFSEO for the treatment of renal anemia in August.

## ■ Changes in ND0612 development plan

Due to the overlap between the expansion of COVID-19 and the important start-up period of phase 3 study; opening clinical trial sites and patient enrollment, it was found that the study plan would be affected. Therefore, we decided to extend the development period for about 1.5 years.

## ■ Impairment loss (non-recurring item)

Based on the above changes in the development plan, profitability is expected to decline due to delayed clinical study and the competitors' development status. As a result of reviewing the business plan based on the results of recent market research, we recorded an impairment loss of 84.5 billion Japanese yen for intangible assets related to NeuroDerm projects.

## ■ Future plans

Under the revised ND0612 development plan, NDA / MAA are to be filed in the U.S. and Europe simultaneously in FY2023 after the completion of the ongoing phase 3 clinical study. We aim at launch in FY2024 after the approval obtained.

# HIF-PH inhibitor -treatment of renal anemia- **VAFSEO** launched

## For reducing burden on patients with renal anemia



- Launched on Aug. 26, 2020, (peak sales: ¥14.1B)
- Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor **can be taken by patients prior to dialysis**
- Co-marketing with Fuso Pharmaceutical Industries Ltd. which has strength in the dialysis field.
- Current standard drugs are injectable agents and **oral agents** including VAFSEO are expected a new treatment, that would ease burden of visiting clinics, administration pains and infection risks from patients.

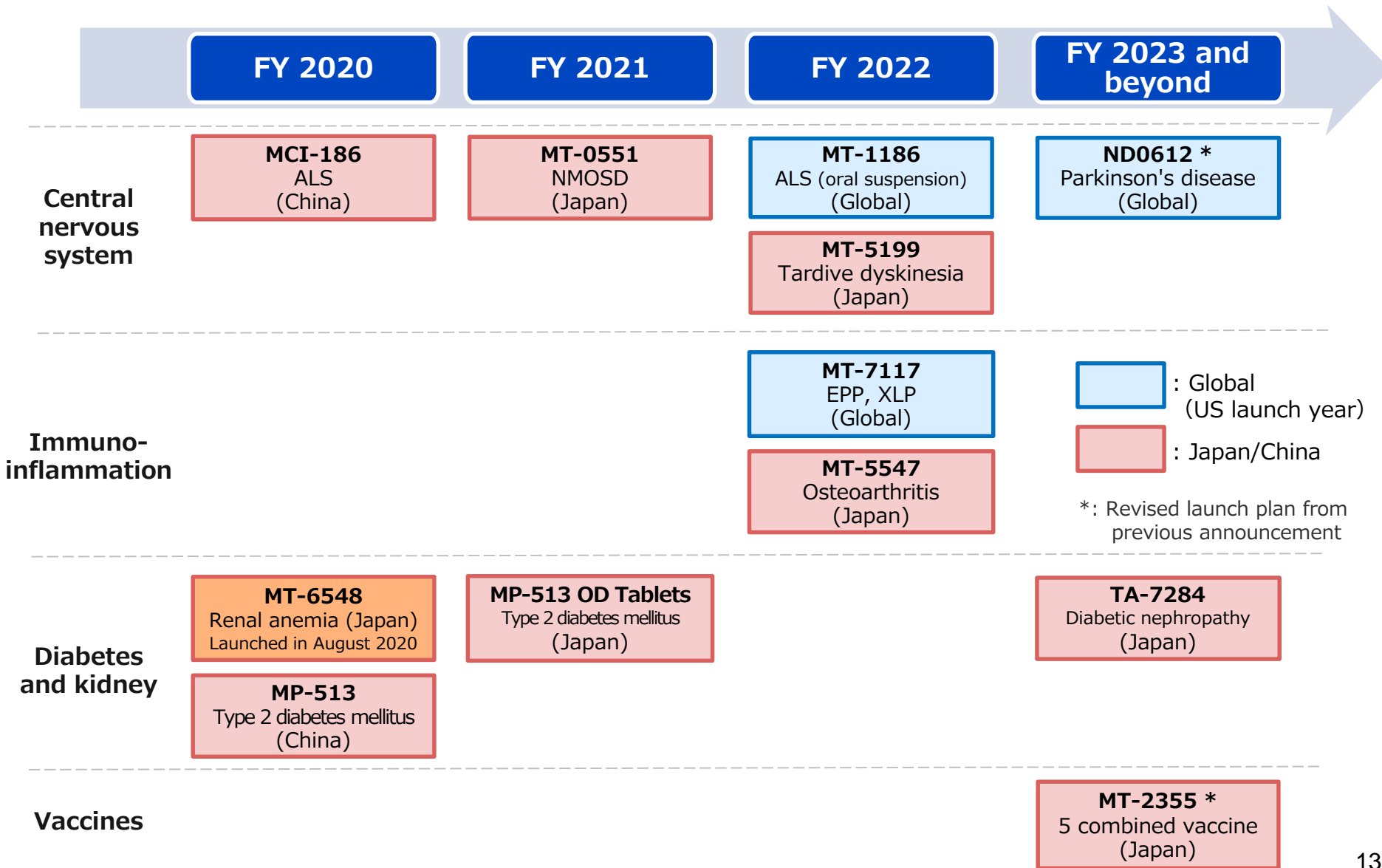
# Major Development Pipeline List

As of October 25, 2020

Priority areas	Code	Region	Indications	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global	ALS/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-8554	Global	Vasomotor symptoms associated with menopause			preparing		
	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan	Neuromyelitis Optica Spectrum Disorder(NMOSD)					
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria(EPP) X-linked protoporphyria(XLP)					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
	MT-6548	Japan	Renal anemia					June 2020
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2766	Global	Prophylaxis of COVID-19					
	MT-2355	Japan	5 combined vaccine*					

\* Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

# Launch Plan for Major Development Pipeline



## **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.**

**It contains information about pharmaceuticals including products under development, but is not intended for advertising or medical advice.**