



Sumitomo Dainippon  
Pharma

Innovation today, healthier tomorrows

# **Q1 FY2020 (April 1 to June 30, 2020) Conference Call**

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July 30, 2020

Sumitomo Dainippon Pharma Co., Ltd.

## Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

# Financial Results for Q1 FY2020

## Financial Results for Q1 FY2020

# Financial Results for Q1 FY2020 (Core Basis)



Billions of yen

	Q1 FY2019 Results	Q1 FY2020 Results	Change			FY2020	
			Value	FX impact	%	Previous forecasts	%
<b>Revenue</b>	117.5	133.9	16.4	(1.9)	13.9	510.0	26.2
Cost of sales *1	28.8	36.0	7.1	(0.6)	24.7	145.0	24.8
Gross profit	88.6	97.9	9.2	(1.2)	10.4	365.0	26.8
SG&A expenses *1	46.3	47.8	1.4	(0.8)	3.1	229.0	20.9
R&D expenses *1	20.0	25.7	5.7	(0.4)	28.4	103.0	25.0
<b>Core operating profit</b>	22.3	24.4	2.1	(0.1)	9.4	33.0	73.8
Changes in fair value of contingent consideration (negative number indicates loss)	18.5	(1.2)	(19.7)			(24.0)	
Other non-recurring items *2 (negative number indicates loss)	(0.3)	0.1	0.5			15.0	
<b>Operating profit</b>	40.4	23.3	(17.2)		(42.4)	24.0	97.0
Profit before taxes	36.9	22.0	(14.9)		(40.4)	24.0	91.6
Income tax expenses	30.2	6.4	(23.8)			38.0	
Net profit	6.7	15.6	8.9		132.2	(14.0)	-
<b>Net profit attributable to owners of the parent</b>	6.7	18.3	11.6		172.4	7.0	260.8

### Results of Sumitovant:

Revenue	3.7
SG&A expenses	6.4
R&D expenses	7.3
Core operating profit	(10.0)
Operating profit	(10.0)
Net profit	(10.2)
Net profit attributable to owners of the parent	(7.5)

\*1 Exclude non-recurring items (impairment losses, changes in fair value of contingent consideration, etc.)

\*2 Non-recurring items (Other operating income and expenses, impairment losses, etc.)

FX rates: Q1FY2019 Results : 1US\$ = ¥ 109.9, 1RMB = ¥16.1  
 Q1FY2020 Results : 1US\$ = ¥ 107.6, 1RMB = ¥15.2  
 FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

## Financial Results for Q1 FY2020

# Revenue of Major Products in Japan



Billions of yen

	Q1 FY2019	Q1 FY2020	Change		FY2020	
	Results	Results	Value	%	Previous forecasts	%
Equa <sup>®</sup> /EquMet <sup>®</sup>	—	10.3	10.3	—	40.5	25.4
Trulicity <sup>®</sup> *	7.2	8.4	1.2	16.0	36.6	22.9
TRERIEF <sup>®</sup>	4.2	4.3	0.0	0.2	17.0	25.0
REPLAGAL <sup>®</sup>	3.4	3.5	0.1	2.3	13.3	26.0
METGLUCO <sup>®</sup>	2.5	2.5	(0.0)	(0.4)	7.8	31.6
AmBisome <sup>®</sup>	1.0	0.9	(0.1)	(11.2)	4.0	22.0
LATUDA <sup>®</sup>	—	0.5	0.5	—	2.2	23.6
LONASEN <sup>®</sup> Tape	—	0.3	0.3	—	5.3	4.9
<b>Promoted products Total</b>	<b>18.3</b>	<b>30.5</b>	<b>12.2</b>	<b>66.6</b>	<b>126.7</b>	<b>24.1</b>
AMLODIN <sup>®</sup>	2.1	1.7	(0.4)	(19.9)	6.1	28.1
SUREPOST <sup>®</sup>	1.8	1.8	0.1	4.3	3.0	61.4
AG products	2.0	1.9	(0.1)	(5.0)	9.4	20.2
Others	8.4	3.8	(4.6)	(55.2)	9.2	40.9
<b>Total</b>	<b>32.6</b>	<b>39.7</b>	<b>7.1</b>	<b>21.8</b>	<b>154.4</b>	<b>25.7</b>

Note: Sales of each product are shown by invoice price (\* Trulicity<sup>®</sup> is shown by NHI price)

Equa<sup>®</sup>/EquMet<sup>®</sup> contributed to increased revenue with sales recorded from November 2019

LATUDA<sup>®</sup> was launched in June 2020

LONASEN<sup>®</sup> Tape showed slow progress

## Financial Results for Q1 FY2020

# Revenue of Major Products in North America & China



	Q1 FY2019 Results	Q1 FY2020 Results	Change	Q1 FY2019 Results	Q1 FY2020 Results	Change			FY2020		
						Value	FX impact	%	Previous forecasts		Yen-basis %
<b>North America</b>	Million \$			Billions of yen			Million \$	Billion yen			
LATUDA®	445	493	47	49.0	53.0	4.1	(1.1)	8.3	1,798	194.2	27.3
BROVANA®	74	72	(2)	8.1	7.8	(0.3)	(0.2)	(4.2)	288	31.1	25.0
APTIOM®	48	63	15	5.3	6.8	1.5	(0.1)	27.8	216	23.3	29.1
LONHALA® MAGNAIR®	6	5	(1)	0.7	0.5	(0.1)	(0.0)	(20.1)	35	3.8	13.9
XOPENEX®	8	13	5	0.8	1.3	0.5	(0.0)	61.9	38	4.1	32.9
Sunovion Others	19	9	(10)	2.1	1.0	(1.1)	(0.0)	(52.9)	69	7.5	13.2
Sumitovant	—	34	34	—	3.7	3.7	(0.1)	—	37	4.0	91.9
<b>Total</b>	<b>600</b>	<b>689</b>	<b>88</b>	<b>66.0</b>	<b>74.1</b>	<b>8.1</b>	<b>(1.6)</b>	<b>12.3</b>	<b>2,481</b>	<b>268.0</b>	<b>27.7</b>
<b>China</b>	Million RMB			Billions of yen			Million RMB	Billion yen			
MEROPEN®	364	260	(104)	5.9	3.9	(1.9)	(0.2)	(32.7)	1,632	25.3	15.6
Others	61	78	17	1.0	1.2	0.2	(0.1)	20.5	355	5.5	21.6
<b>Total</b>	<b>425</b>	<b>338</b>	<b>(87)</b>	<b>6.8</b>	<b>5.1</b>	<b>(1.7)</b>	<b>(0.3)</b>	<b>(25.0)</b>	<b>1,987</b>	<b>30.8</b>	<b>16.6</b>

North America sales were in line with forecasts, COVID-19's impact on Q1 actual is not seen

Myovant recorded revenue of out-licensing relugolix in Europe and other areas

In China, MEROPEN® sales showed slow progress due to COVID-19

FX rates: Q1FY2019 Results : 1US\$ = ¥ 109.9, 1RMB = ¥16.1  
 Q1FY2020 Results : 1US\$ = ¥ 107.6, 1RMB = ¥15.2  
 FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

## Financial Results for Q1 FY2020

### Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Q1 FY2020 Results	Revenue (Sales to customers)	39.7	74.1	5.1	5.5	124.5	9.3	133.9	
	Cost of sales	20.4	5.4	0.8	2.4	29.0	7.0	36.0	
	Gross profit	19.4	68.8	4.3	3.1	95.6	2.3	97.9	
	SG&A expenses	11.4	32.9	1.6	0.7	46.5	1.2	47.8	
	Core segment profit	8.0	35.9	2.7	2.4	49.0	1.1	50.1	
	R&D expenses						25.6	0.2	25.7
	Core operating profit						23.4	0.9	24.4
Q1 FY2019 Results	Revenue (Sales to customers)	32.6	66.0	6.8	2.5	107.9	9.6	117.5	
	Cost of sales	13.4	6.3	1.0	0.8	21.4	7.4	28.8	
	Gross profit	19.3	59.7	5.8	1.7	86.5	2.1	88.6	
	SG&A expenses	12.0	30.2	2.0	0.8	45.1	1.3	46.3	
	Core segment profit	7.3	29.5	3.8	0.9	41.5	0.8	42.3	
	R&D expenses						19.8	0.2	20.0
	Core operating profit						21.7	0.6	22.3
Change	Revenue (Sales to customers)	7.1	8.1	(1.7)	3.0	16.6	(0.2)	16.4	
	SG&A expenses	(0.6)	2.7	(0.4)	(0.1)	1.5	(0.1)	1.4	
	Core segment profit	0.8	6.4	(1.1)	1.5	7.6	0.3	7.8	
	R&D expenses						5.8	(0.1)	5.7
	Core operating profit						1.8	0.3	2.1

Japan:  
Profit increased due to increased revenue and decreased cost

North America:  
Profit increased since increased revenue and cost reduction in Sunovion covered incremental cost of Sumitovant newly consolidated

China:  
Decreased revenue largely affected to decreased profit

# Financial Forecasts for FY2020



## Financial Forecasts for FY2020

# Financial Forecasts for FY2020 (Core Basis)



Billions of yen

	FY2020 Previous forecasts	FY2020 Revised forecasts	Change
Revenue	510.0	<b>495.0</b>	(15.0)
Cost of sales	145.0	<b>140.0</b>	(5.0)
Gross profit	365.0	<b>355.0</b>	(10.0)
SG&A expenses	229.0	<b>219.0</b>	(10.0)
R&D expenses	103.0	<b>103.0</b>	—
Core operating profit	33.0	<b>33.0</b>	—
Changes in fair value of contingent consideration (negative number indicates loss)	(24.0)	<b>(24.0)</b>	—
Other non-recurring items (negative number indicates loss)	15.0	<b>15.0</b>	—
Operating profit	24.0	<b>24.0</b>	—
Income tax expenses	38.0	<b>35.0</b>	(3.0)
Net profit	(14.0)	<b>(12.0)</b>	2.0
Net profit attributable to owners of the parent	7.0	<b>9.0</b>	2.0
R O E (%)	1.3	<b>1.7</b>	
R O I C (%)	(0.6)	<b>(0.2)</b>	

FX rates: Unchanged

FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

### Revised full-year forecasts including assumed impact of COVID-19

- Revenue revised down in North America and other segment (¥15.0b)
- SG&A expenses revised down owing to restrictions on business activities because of the COVID-19 (¥10.0b)

⇒ Core operating profit unchanged

- Income tax expenses revised down
- ⇒ Net profit attributable to owners of the parent revised up by ¥2.0b

## Financial Forecasts for FY2020

### Segment Information (Core Basis)



Billions of yen

Includes assumed impact of COVID-19 in FY2020 forecasts

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Revised forecasts	FY2020	Revenue (Sales to customers)	153.1	258.5	28.5	16.9	457.0	38.0	495.0
		Cost of sales	77.9	22.5	5.3	5.0	110.7	29.3	140.0
		Gross profit	75.2	236.0	23.2	11.9	346.3	8.7	355.0
		SG&A expenses	52.5	148.2	9.4	3.2	213.3	5.7	219.0
		Core segment profit	22.7	87.8	13.8	8.7	133.0	3.0	136.0
		R&D expenses					102.0	1.0	103.0
		Core operating profit					31.0	2.0	33.0
Previous forecasts	FY2020	Revenue (Sales to customers)	154.4	268.0	30.8	18.8	472.0	38.0	510.0
		Cost of sales	80.0	23.0	5.8	6.9	115.7	29.3	145.0
		Gross profit	74.4	245.0	25.0	11.9	356.3	8.7	365.0
		SG&A expenses	55.0	154.3	10.4	3.6	223.3	5.7	229.0
		Core segment profit	19.4	90.7	14.6	8.3	133.0	3.0	136.0
		R&D expenses					102.0	1.0	103.0
		Core operating profit					31.0	2.0	33.0
Change		Revenue (Sales to customers)	(1.3)	(9.5)	(2.3)	(1.9)	(15.0)	—	(15.0)
		SG&A expenses	(2.5)	(6.1)	(1.0)	(0.4)	(10.0)	—	(10.0)
		Core segment profit	3.3	(2.9)	(0.8)	0.4	—	—	—
		R&D expenses					—	—	—
		Core operating profit					—	—	—

#### Japan segment

- Profit revised up due to decreased SG&A and other factors though revenue will decrease

#### North America segment

- Profit revised down because revenue including LATUDA® will decrease though SG&A is also expected to decrease

#### China segment

- Counted decrease in MEROPEN® sales and decrease in SG&A expenses in the forecasts

#### Other regions segment

- Export of MEROPEN® will decrease

# Execution of Hybrid Finance

## Issuance of Hybrid Bonds (Max ¥120 billion)

- Finance the funds for partial repayment of bridge loan (¥270b) raised for the Strategic Alliance with Roivant
- Maintain our long-term financial integrity

### Hybrid Bonds

A form of hybrid financing that form a hybridization of equity and debt. There is no dilution of the equity value, whereas they are similar to equity in features and characteristics, such as an option to defer interest payments, extremely long-term redemption periods, and subordination in liquidation or bankruptcy proceedings

<b>Total amount of issue</b>	Maximum ¥120 billion (Total of 1st and 2nd series)
<b>Issue date</b>	September, 2020 (Earliest)
<b>Redemption period</b>	30 years
<b>First call date</b>	The 1st series : After 7 years      The 2st series : After 10 years
<b>Equity credit</b>	Expected equity credit 50 (Rating and Investment Information, Inc.)

- ✓ The balance of the bridge loan will be refinanced by bank loan, etc.

# Research and Development

## Research and Development

# Development Pipeline (as of July 30, 2020)



  : Psychiatry & Neurology
   : Oncology
   : Regenerative medicine / cell therapy
   : Others

Revisions since the announcement of May 2020 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	<b>SEP-363856</b> (Schizophrenia)	<b>dubermatinib (TP-0903)</b> (Solid tumors)	<b>SEP-4199</b> (Bipolar I depression)	<b>EPI-743</b> (Leigh syndrome)	<b>imeglimin</b> (Type 2 diabetes)
	<b>EPI-589</b> (ALS)		<b>DSP-7888</b> (Solid tumors)	<b>napabucasin</b> (Colorectal cancer)	
	<b>DSP-1181</b> (Obsessive compulsive disorder)		<b>Allo iPS cell-derived products</b> (Parkinson's disease) Investigator-initiated clinical study		
U.S.	<b>DSP-6745</b> (Parkinson's disease psychosis)	<b>alvocidib</b> (MDS)	<b>EPI-589</b> (Parkinson's disease/ALS)	<b>SEP-363856</b> (Schizophrenia)	<b>relugolix</b> (Prostate cancer)
	<b>SEP-378608</b> (Bipolar disorder)	<b>dubermatinib (TP-0903)</b> (Solid tumors)	<b>SEP-363856</b> (Parkinson's disease psychosis)	<b>napabucasin</b> (Colorectal cancer)	<b>RVT-802</b> (Pediatric congenital athymia) Received Complete Response Letter
	<b>DSP-3905</b> (Neuropathic pain)	<b>DSP-0509</b> (Solid tumors)	<b>SEP-4199</b> (Bipolar I depression)	<b>relugolix</b> (Endometriosis)	<b>vibegron</b> (OAB)
	<b>SEP-378614</b> (Treatment resistant depression)	<b>TP-0184</b> (Solid tumors / Hematologic malignancies)	<b>alvocidib</b> (AML)	<b>vibegron</b> (OAB in men with BPH)	<b>relugolix</b> (Uterine fibroids)
	<b>SEP-380135</b> (Agitation in Alzheimer's disease)	<b>DSP-0337</b> (Solid tumors)	<b>DSP-7888</b> (Solid tumors)		
		<b>TP-1287</b> (Solid tumors)	<b>vibegron</b> (IBS-associated pain)		
		<b>TP-3654</b> (Solid tumors/ Hematologic malignancies)	<b>rodatristat ethyl</b> (Pulmonary arterial hypertension)		
		<b>TP-1454</b> (Solid tumors)	<b>URO-902</b> (Overactive bladder)		
Europe					<b>relugolix</b> (Uterine fibroids)

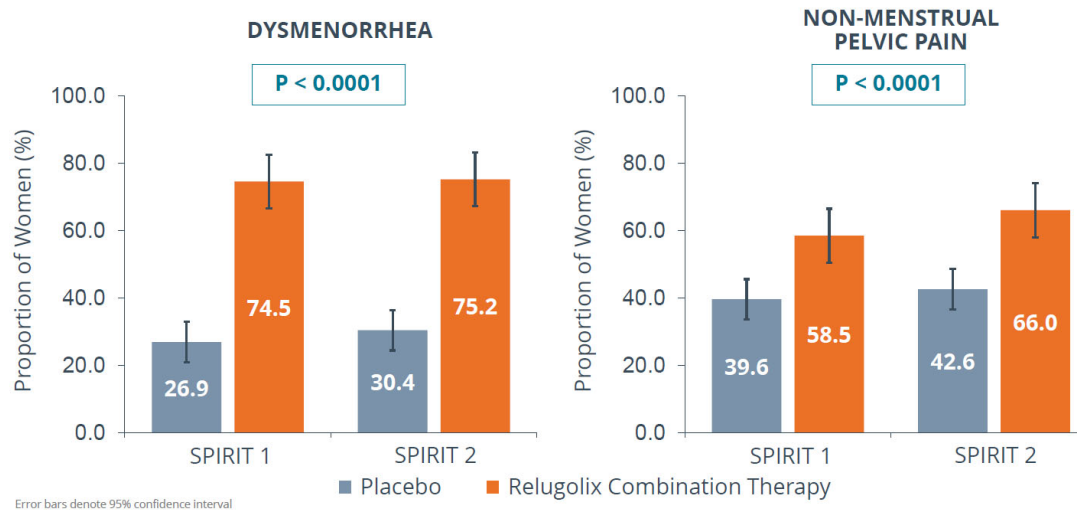
# Clinical Development Status (Major Changes since May 13, 2020)

- **KYNMOBI™** (apomorphine sublingual film)  
U.S. : Approved for OFF episodes associated with Parkinson's disease in May 2020
- **SEP-4199** (A non-racemic mixture of amisulpride enantiomers)  
U.S., etc. : Obtained results from global Phase 2 study for Bipolar I depression and consider to start Phase 3 studies
  - The primary endpoint did not reach statistical significance, however, clinically meaningful improvement in depressive symptoms was observed  
(Primary endpoint : change from baseline in total MADRS score at 6 weeks)
- **Relugolix**  
U.S. : Accepted for Priority Review of NDA for prostate cancer in June 2020
  - Expected action date by FDA : December 20, 2020
- **Relugolix**  
U.S. : Submitted NDA for uterine fibroids in May 2020  
U.S., etc. : Obtained results from global Phase 3 study (SPIRIT 1) for endometriosis
- **Imeglimin**  
Japan : Submitted NDA for Type 2 diabetes in July 2020
- **Impact on clinical studies associated with the spread of COVID-19**  
Prioritize patient safety and continue clinical studies wherever possible consistent with the latest regulations and guidelines
  - Enrollment of new patients was suspended in some clinical studies but has been carefully resumed
  - Results from Phase 3 study of napabucasin with colorectal cancer have been delayed, and expected to be after this autumn

# Relugolix : Endometriosis Phase 3 Study Results (SPIRIT 1 & 2)

- **Study design:** Randomized, double-blind, placebo-controlled studies  
Relugolix Combination Therapy : relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

- **Efficacy:**
  - Achieved co-primary endpoints with significant pain reduction ( $p < 0.0001$ )  
(Co-primary endpoints : proportion of women with clinically meaningful reduction in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain as assessed using the Numerical Rating Scale (NRS))
  - Achieved seven key secondary endpoints in SPIRIT 1
  - Two consistent positive studies in SPIRIT program



- **Safety:** Generally well tolerated including minimal bone mineral density loss, adverse events were similar to placebo
- **Future plan:** One-year extension-study results to be available in Q4 FY2020  
Plan to submit NDA with safety and efficacy results from SPIRIT 1 & 2 and one-year extension-study results

# Appendix

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## Appendix (Financial Results for Q1 FY2020)

# Financial Results for Q1 FY2020 (Full Basis)



Billions of yen

	Q1 FY2019 Results	Q1 FY2020 Results	Change	
			Value	%
Revenue	117.5	133.9	16.4	13.9
Cost of sales	29.0	36.0	7.0	24.2
Gross profit	88.5	97.9	9.4	10.6
SG&A expenses	27.9	49.0	21.1	75.8
R&D expenses	20.1	25.7	5.7	28.4
Other operating income and expenses	(0.2)	0.1	0.3	
Operating profit	40.4	23.3	(17.2)	(42.4)
Finance income and costs	(3.5)	(1.3)	2.2	
Income tax expenses	30.2	6.4	(23.8)	
Net profit	6.7	15.6	8.9	132.2
Net profit attributable to owners of the parent	6.7	18.3	11.6	172.4

## Appendix (Financial Results for Q1 FY2020)

# Adjustments to Core Operating Profit



### Q1 FY2020 Results

Billions of yen

	IFRS Full Basis	Adjusted amount	IFRS Core Basis	Adjusted items
Revenue	133.9	-	133.9	
Cost of sales	36.0	-	36.0	
Gross profit	97.9	-	97.9	
SG&A expenses	49.0	(1.2)	47.8	Changes in fair value of contingent consideration (1.2)
R&D expenses	25.7	-	25.7	
Other operating income and expenses	0.1	(0.1)	(0.0)	Share of profit/loss of associates accounted for using equity method included in other operating income and expenses (Positive number indicates profit)
Operating profit	23.3	1.1	24.4	Core operating profit

IFRS Full Basis : Each item is shown by original financial value under IFRS

IFRS Core Basis : Each item is shown by value after adjustment for calculating core operating profit

## Appendix (Financial Forecasts for FY2020)

# Revenue of Major Products in Japan



Billions of yen

	FY2020 Previous forecast	FY2020 Revised forecasts	Change
Equa <sup>®</sup> /EquMet <sup>®</sup>	40.5	40.5	—
Trulicity <sup>®</sup> *	36.6	36.6	—
TRERIEF <sup>®</sup>	17.0	17.0	—
REPLAGAL <sup>®</sup>	13.3	13.3	—
METGLUCO <sup>®</sup>	7.8	8.8	1.0
LONASEN <sup>®</sup> Tape	5.3	2.5	(2.8)
AmBisome <sup>®</sup>	4.0	4.0	—
LATUDA <sup>®</sup>	2.2	2.2	—
<b>Promoted products Total</b>	<b>126.7</b>	<b>124.9</b>	<b>(1.8)</b>
AMLODIN <sup>®</sup>	6.1	6.1	—
SUREPOST <sup>®</sup>	3.0	3.5	0.5
AG products	9.4	7.2	(2.2)
Others	9.2	11.4	2.2
<b>Total</b>	<b>154.4</b>	<b>153.1</b>	<b>(1.3)</b>

Revised up  
METGLUCO<sup>®</sup> and SUREPOST<sup>®</sup>

Revised down  
LONASEN<sup>®</sup> Tape and AG products

Impact of NHI price revision :  
About ¥10 billion  
(Change from April 2019 price, FY2020 forecast basis)

Note: Sales of each product are shown by invoice price (\* Trulicity<sup>®</sup> is shown by NHI price)

## Appendix (Financial Forecasts for FY2020)

# Revenue of Major Products in North America & China



	FY2020 Previous forecasts	FY2020 Revised forecasts	Change	FY2020 Previous forecasts	FY2020 Revised forecasts	Change
<b>North America</b>	Million \$			Billions of yen		
LATUDA®	1,798	1,740	(58)	194.2	187.9	(6.3)
BROVANA®	288	275	(13)	31.1	29.7	(1.4)
APTIOM®	216	216	—	23.3	23.3	—
LONHALA®MAGNAIR®	35	28	(7)	3.8	3.0	(0.8)
XOPENEX®	38	43	5	4.1	4.6	0.5
KYNMOBI™	10	10	—	1.1	1.1	—
Sunovion Others	59	45	(14)	6.4	4.9	(1.5)
Sumitovant	37	37	—	4.0	4.0	—
<b>Total</b>	<b>2,481</b>	<b>2,394</b>	<b>(87)</b>	<b>268.0</b>	<b>258.5</b>	<b>(9.5)</b>
<b>China</b>	Million RMB			Billions of yen		
MEROPEN®	1,632	1,484	(148)	25.3	23.0	(2.3)
Others	355	355	—	5.5	5.5	—
<b>Total</b>	<b>1,987</b>	<b>1,839</b>	<b>(148)</b>	<b>30.8</b>	<b>28.5</b>	<b>(2.3)</b>

Includes impacts of COVID-19 on sales of several products including LATUDA®

MEROPEN® sales in China have been affected by COVID-19 significantly

FX rates: Unchanged

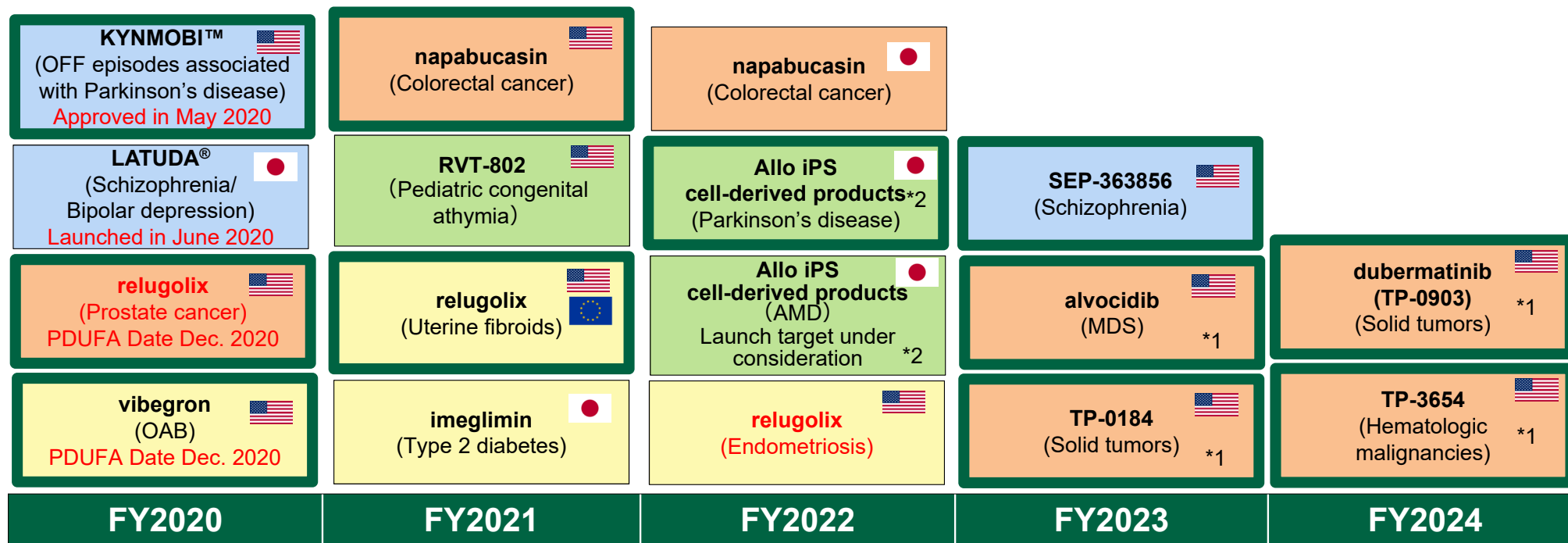
FY2020 Forecasts : 1US\$ = ¥ 108.0, 1RMB = ¥15.5

## Appendix (Research and Development)

# Product Launch Target (as of July 30, 2020)



Revisions since the announcement of May 2020 are shown in red



: Psychiatry & Neurology : Oncology

: Regenerative medicine / cell therapy : Others



Expect peak annual sales to be 50 billion yen or more (described in the first launch)

\*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

\*2 Launch schedule is based on our goal pending agreement with partners

## Appendix (Research and Development)



# Main Event / Target for FY2020 (as of July 30, 2020)

✓ Completed action / target    Revisions since the announcement of May 2020 are shown in red

<b>Psychiatry &amp; Neurology</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Apomorphine : Obtain approval for OFF episodes associated with Parkinson's disease in the U.S.</li> <li><input type="checkbox"/> SEP-363856 : <input type="checkbox"/> Determine new indication for development (global study)                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Start Phase 2/3 study for schizophrenia in Asia including Japan and China</li> </ul> </li> <li><input checked="" type="checkbox"/> SEP-4199 : Obtain results from Phase 2 study for Bipolar I depression</li> </ul>
<b>Oncology</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Napabucasin : Obtain results from global Phase 3 study for colorectal cancer</li> <li><input checked="" type="checkbox"/> Relugolix : Submit NDA for prostate cancer in the U.S.</li> </ul>
<b>Regenerative medicine / Cell therapy</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> RVT-802 : Resubmit BLA for pediatric congenital athymia in the U.S.</li> <li><input type="checkbox"/> Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study</li> <li><input type="checkbox"/> Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated clinical study</li> </ul>
<b>Infectious Diseases</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines (transmission-blocking/blood-stage) : Promote research and development projects</li> </ul>
<b>Others</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Vibegron : Obtain approval for overactive bladder in the U.S.</li> <li><input type="checkbox"/> Relugolix : <input checked="" type="checkbox"/> Obtain results from Phase 3 study for endometriosis (SPRIT 1, SPIRIT 2)                             <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Submit NDA for uterine fibroids in the U.S.    <input type="checkbox"/> Obtain approval for uterine fibroids in Europe</li> </ul> </li> <li><input checked="" type="checkbox"/> Imeglimin : Submit NDA for type 2 diabetes in Japan</li> </ul>
<b>Frontier</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Promotion of the current themes (MELTIN, Aikomi, Drawbridge and internal themes), development of new themes</li> </ul>

## Appendix (Research and Development)

### Regenerative Medicine/Cell Therapy Business Plan (as of July 30, 2020)



Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
<b>Pediatric congenital athymia (RVT-802)</b>	Duke University	Global	Cultured thymus tissue	<b>Under consideration to resubmit BLA</b>
<b>AMD (age-related macular degeneration)</b>	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	<b>In progress: clinical research Preparing to start clinical study (Japan)</b>
<b>Parkinson's disease (Designated as a "SAKIGAKE")</b>	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	<b>In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)</b>
<b>Retinitis pigmentosa</b>	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	<b>In progress: clinical research</b>
<b>Spinal cord injury</b>	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	<b>In progress: clinical research</b>
<b>Kidney failure</b>	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	<b>In progress: pre-clinical study</b>

**Aim to start clinical study in FY2020**

**Aim to launch in FY2022 \***

\* Launch schedule is based on our goal pending agreement with partners



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