

# **Investors Meeting Presentation for FY2021 (Year ended March 31, 2022)**

Hiroshi Nomura, President and CEO

Sumitomo Pharma Co., Ltd.

May 16, 2022

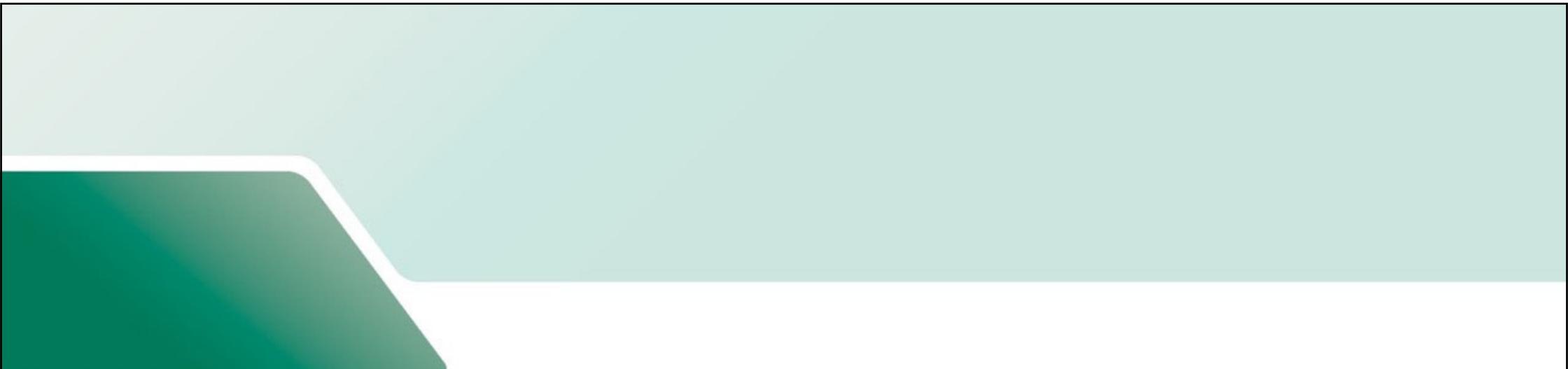
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Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group holds approximately 53% of the outstanding shares of Myovant. ORGOVYX<sup>®</sup>, MYFEMBREE<sup>®</sup> /RYEQO<sup>®</sup> (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com>.



# Financial Results for FY2021

## Financial Results for FY2021

# Major Topics in FY2021

**Revenue increased y-o-y due to lump-sum alliance revenue, profit decreased mainly due to incremental costs related to Sumitovant**

### Japan

Despite LATUDA<sup>®</sup> increase, revenue decreased largely due to NHI price revision impact on Equa<sup>®</sup> /EquMet<sup>®</sup>  
Profit decreased y-o-y due to incremental sales costs

### North America

Despite LATUDA<sup>®</sup> and BROVANA<sup>®</sup> decreases, revenue increased due to lump-sum alliance revenue, and sales of ORGOVYX<sup>®</sup>, MYFEMBREE<sup>®</sup>, GEMTESA<sup>®</sup>  
Profit decreased due to incremental costs related to Sumitovant

### China/ Other

In China, revenue increased mainly due to sales growth of MEROPEN<sup>®</sup>  
In Other Regions, lower profit due to decrease in export

### R&D

Success in three pipeline approvals

- MYFEMBREE<sup>®</sup>/ RYEQO<sup>®</sup> (relugolix combination tablet) in the U.S./ Europe: uterine fibroids
- RETHYMIC<sup>®</sup> in the U.S.: pediatric congenital athymia
- TWYMEEG<sup>®</sup> in Japan: type 2 diabetes

Three submissions for approval achieved:

- lefamulin in China (bacterial community-acquired pneumonia), MYFEMBREE<sup>®</sup> in the U.S. (endometriosis), METGLUCO<sup>®</sup> in Japan (public knowledge-based application for infertility treatment-related indications)

Entered into collaboration agreement for joint development and commercialization with Otsuka Pharmaceutical for four candidate compounds including ulotaront and SEP-4199

Started Phase 3 studies: SEP-4199 in the U.S. and Japan (bipolar I depression)

Initiated clinical studies: DSP-5336, DSP-0187, KSP-1007, DSP-3456

## Financial Results for FY2021

# Financial Results for FY2021 (Core Basis)

Billions of yen

	FY2020 Results	FY2021 Results	Change			FY2021 Jan. 31 forecasts
			Value	FX impact	%	
<b>Revenue</b>	516.0	<b>560.0</b>	44.1	21.9	8.5	<b>554.0</b>
Cost of sales	137.5	<b>157.1</b>	19.6	10.0	14.3	154.0
Gross profit	378.5	<b>402.9</b>	24.5	11.9	6.5	400.0
SG&A expenses	211.8	<b>251.6</b>	39.8	11.0	18.8	252.0
R&D expenses	97.1	<b>94.0</b>	(3.1)	3.7	(3.2)	92.0
Other operating income/expenses	(0.0)	<b>1.2</b>	1.2	—	—	1.0
<b>Core operating profit</b>	69.6	<b>58.5</b>	(11.1)	(2.8)	(15.9)	<b>57.0</b>
Changes in fair value of contingent consideration (negative number indicates loss)	① 22.5	① <b>3.3</b>	(19.2)			(1.0)
Other non-recurring items (negative number indicates loss)	②③ (20.8)	③ <b>(1.6)</b>	19.3			(1.0)
<b>Operating profit</b>	71.2	<b>60.2</b>	(11.0)		(15.4)	<b>55.0</b>
Profit before taxes	77.9	<b>83.0</b>	5.1		6.6	
Income tax expenses	41.0	<b>42.4</b>	1.3			
Net profit	36.8	<b>40.6</b>	3.8		10.2	
<b>Net profit attributable to owners of the parent</b>	56.2	<b>56.4</b>	0.2		0.3	<b>37.0</b>

- ① Revised business plans of oncology pipelines
- ② Gain on sale of former Ibaraki plant
- ③ Impairment losses on oncology pipelines

## (Ref.) Earnings related to Sumitovant

Billions of yen

	FY20	FY21
<b>Revenue</b>	<b>7.8</b>	<b>35.7</b>
SG&A expenses *	46.5	90.3
R&D expenses	24.6	24.3
<b>Core operating profit</b>	<b>(63.6)</b>	<b>(86.9)</b>
<b>Operating profit</b>	<b>(63.6)</b>	<b>(86.5)</b>
Net profit	(63.6)	(87.4)
<b>Net profit attributable to owners of the parent</b>	<b>(44.3)</b>	<b>(71.6)</b>

The figures include intra-group transaction

\* Include amortization of patent rights

FX rates:

FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

FY21 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5

FY21 Forecasts : 1US\$ = ¥110.0, 1RMB = ¥17.0

## Financial Results for FY2021

# Revenue of Major Products in Japan

Billions of yen

	FY2020 Results	FY2021 Results	Change	
			Value	%
Equa <sup>®</sup> /EquMet <sup>®</sup>	40.1	<b>37.5</b>	(2.6)	(6.5)
Trulicity <sup>®</sup> *	33.9	<b>33.6</b>	(0.3)	(0.8)
TRERIEF <sup>®</sup>	16.2	<b>16.4</b>	0.2	1.1
REPLAGAL <sup>®</sup>	13.8	<b>12.4</b>	(1.4)	(10.4)
METGLUCO <sup>®</sup>	9.1	<b>8.1</b>	(1.0)	(10.9)
LATUDA <sup>®</sup>	2.4	<b>6.9</b>	4.5	188.1
LONASEN <sup>®</sup> Tape	1.3	<b>2.1</b>	0.8	61.6
AMLODIN <sup>®</sup>	6.5	<b>5.7</b>	(0.9)	(13.5)
AG products	8.0	<b>9.7</b>	1.7	20.8
Others	21.1	<b>17.7</b>	(3.5)	(16.5)
<b>Total</b>	<b>152.5</b>	<b>149.9</b>	<b>(2.6)</b>	<b>(1.7)</b>

- Decrease in Equa<sup>®</sup>/EquMet<sup>®</sup> is attributed to NHI price revision
- Sale of REPLAGAL<sup>®</sup> was terminated in February 2022
- LATUDA<sup>®</sup> showing steady growth
- “Others” include TWYMEEG<sup>®</sup> launched in September 2021
- NHI price revision affected (¥7.4B) on Japan segment total

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

## Financial Results for FY2021

# Revenue of Major Products in North America & China

	FY2020 Results	FY2021 Results	Change	FY2020 Results	FY2021 Results	Change		
						Value	FX impact	%
<b>North America</b>	Million \$			Billions of yen				
LATUDA®	1,946	1,816	(130)	206.5	204.1	(2.3)	11.4	(1.1)
APTiom®	242	241	(1)	25.7	27.1	1.4	1.5	5.4
BROVANA®	278	129	(149)	29.4	14.5	(15.0)	0.8	(50.8)
KYNMOBI®	2	5	4	0.2	0.6	0.4	0.0	204.0
ORGOVYX®	4	83	79	0.4	9.3	8.9	0.5	2,321.5
MYFEMBREE®/ RYEQO®	—	11	11	—	1.3	1.3	0.1	—
GEMTESA®	—	63	63	—	7.1	7.1	0.4	—
Others	182	496	314	19.3	55.7	36.5	3.1	189.2
<b>Total</b>	<b>2,653</b>	<b>2,845</b>	<b>192</b>	<b>281.5</b>	<b>319.8</b>	<b>38.3</b>	<b>17.9</b>	<b>13.6</b>
<b>China</b>	Million RMB			Billions of yen				
MEROPEN®	1,435	1,708	273	22.5	29.9	7.4	3.1	33.0
Others	340	478	138	5.3	8.4	3.0	0.9	57.1
<b>Total</b>	<b>1,775</b>	<b>2,186</b>	<b>411</b>	<b>27.8</b>	<b>38.3</b>	<b>10.5</b>	<b>4.0</b>	<b>37.6</b>

### ■ North America segment

Revenue increased due to the alliance revenue, new products of Sumitovant and impact of fluctuations in FX rates

- LATUDA® decreased due largely to down-stream inventory destocking and lower price
- BROVANA® decreased due to generic products erosion

- Revenue from the alliance with Otsuka \$270M (¥30.3B) is recorded in “Others”

### ■ China segment

Increased sales by recovering from the effect of COVID-19 in previous year

FX rates:

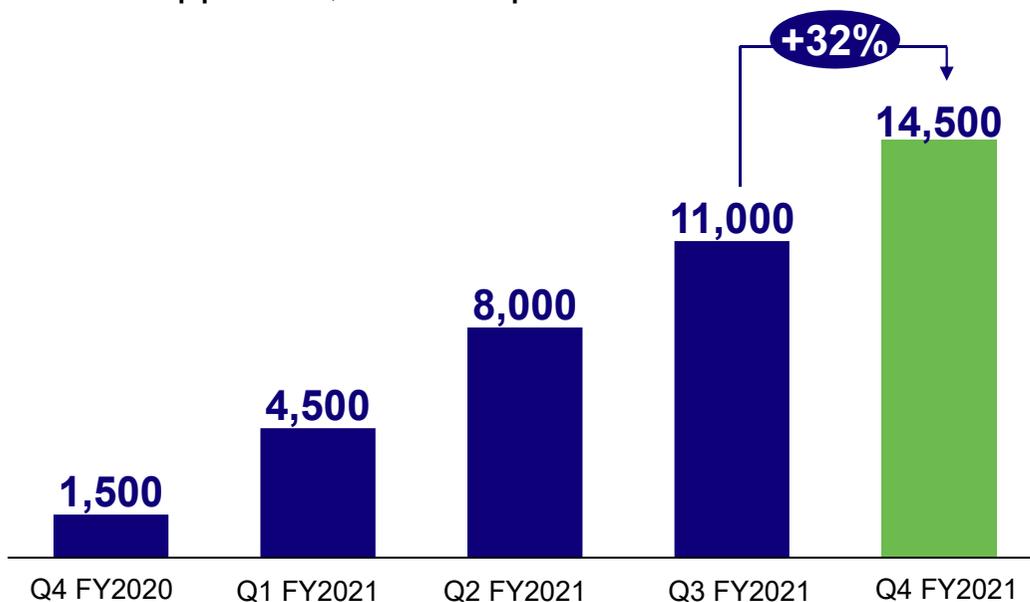
FY2020 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5

## Financial Results for FY2021

### Marketing Status of ORGOVYX®

- Obtained approx. 3,500 new patient starts in FY2021 Q4 with wide range of patients (32% growth vs. Q3)



**Estimated Cumulative Patients Treated with ORGOVYX®**

(includes patients on free and commercial drug, excludes patients utilizing product samples) \*

#### Obtained prescriptions of wide range of patients

- 60% ADT naïve / 40% ADT transition patients
- 55% with localized PC
- 32% with metastatic PC
- 20% receiving combination therapy



#### Established broad payer coverage

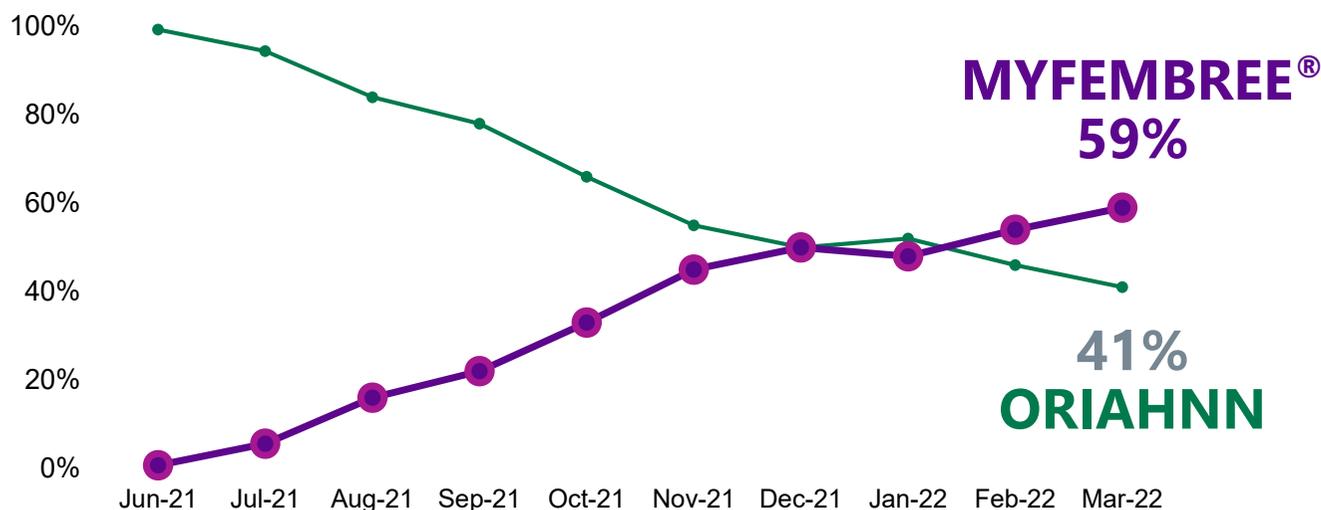
- **Commercial – 82% of lives**
- **Medicare Part D – 99% of lives (March 2022)**

- Achieved 18% commercial demand volume growth in FY2021 Q4 vs. Q3 (Prescribed approx. 80% of the total at Dispensing Clinics, Academic, etc.)
- Led to high prescriber satisfaction by no testosterone surge, profound/sustained testosterone suppression and one-pill, once-a-day (ORGOVYX® prescriber satisfaction is 73% in April 2022)

## Financial Results for FY2021

### Marketing Status of MYFEMBREE®

- Obtained 59% NBRx share among GnRH antagonists therapies for uterine fibroids in March 2022 as market leader



#### Established broad payer coverage

- **Commercial – 93% of lives (April 2022)**

NBRx share among GnRH antagonists therapies for uterine fibroids\*1

- Achieved 2.4 times class growth in TRx for GnRH antagonists therapies for uterine fibroids since MYFEMBREE® launch\*2
- Achieved 87% intent to prescribe in important targets by substantial/sustained MBL reduction, anemia improvement, one-pill, once-a-day, etc. in March 2022

## Financial Results for FY2021

### Marketing Status of GEMTESA®

- GEMTESA® was prescribed 26,145 TRx in March 2022 and ahead of our FY2021 forecast

	GEMTESA®	
	Dec. 2021	March 2022
TRx Share in Beta 3	4.7%	6.4%
Monthly TRx numbers	18,933	26,145



- Coverage continues to expand and plans to secure most of peak coverage during FY2022

	GEMTESA®	
	Jan. 2022	End of March 2022
All of commercial lives (Approx. 178 million)	34%	56%
All of Medicare Part D lives (Approx. 46million)	24%	31%

- Sales reps calls in person, promote building a strong presence at major Urology and Long Term Care conferences
- Focus on online video distribution for disease awareness and product recognition for patients, including potential patients

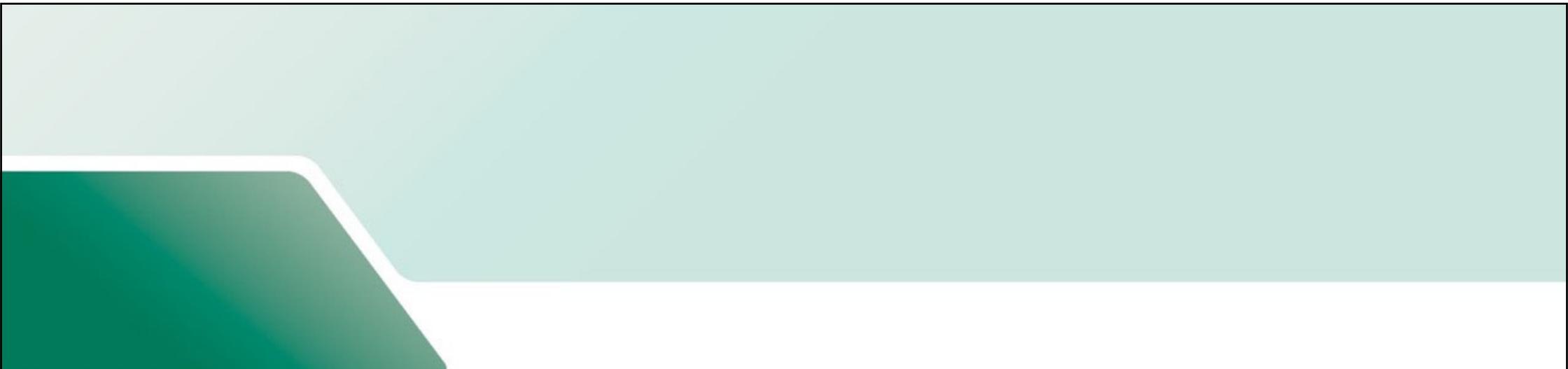
## Financial Results for FY2021

### Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2021 Results	Revenue (Sales to customers)	149.9	319.8	38.3	12.2	520.2	39.9	560.0	
	Cost of sales	78.7	33.6	7.4	6.6	126.3	30.8	157.1	
	Gross profit	71.3	286.2	30.9	5.5	393.9	9.0	402.9	
	SG&A expenses	51.7	180.8	11.3	2.3	246.1	5.5	251.6	
	Core segment profit	19.6	105.4	19.6	3.3	147.8	3.5	151.4	
	R&D expenses						93.2	0.8	94.0
	Core operating profit						55.8	2.7	58.5
FY2020 Results	Revenue (Sales to customers)	152.5	281.5	27.8	17.2	479.1	36.9	516.0	
	Cost of sales	77.5	20.8	5.4	5.7	109.4	28.1	137.5	
	Gross profit	75.1	260.7	22.5	11.5	369.8	8.7	378.5	
	SG&A expenses	50.8	143.8	9.2	2.8	206.7	5.1	211.8	
	Core segment profit	24.3	116.9	13.2	8.7	163.1	3.6	166.7	
	R&D expenses						96.2	0.9	97.1
	Core operating profit						66.9	2.7	69.6
Change	Revenue (Sales to customers)	(2.6)	38.3	10.5	(5.1)	41.1	3.0	44.1	
	SG&A expenses	0.9	37.0	2.1	(0.5)	39.4	0.4	39.8	
	Core segment profit	(4.7)	(11.5)	6.4	(5.4)	(15.3)	(0.1)	(15.3)	
	R&D expenses						(3.0)	(0.1)	(3.1)
	Core operating profit						(11.1)	0.0	(11.1)

- **Japan:** Lower profit due to declined gross profit and increased expenses resulting from the launch of TWYMEEG®
- **North America:** Lower profit mainly due to incremental costs related to Sumitovant despite higher sales from the alliance revenue and new products sales
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit due to decrease in export



# Financial Forecasts for FY2022

## Financial Forecasts for FY2022

# Financial Forecasts for FY2022 (Core Basis)

Billions of yen

	FY2021 Results	FY2022 Forecasts	Change		
			Value	FX	%
Revenue	560.0	<b>550.0</b>	(10.0)	37.5	(1.8)
Cost of sales	157.1	<b>164.5</b>	7.4	7.5	4.7
Gross profit	402.9	<b>385.5</b>	(17.4)	30.0	(4.3)
SG&A expenses	251.6	<b>283.5</b>	31.9	21.7	12.7
R&D expenses	94.0	<b>93.0</b>	(1.0)	6.5	(1.1)
Other operating income and expenses (Core basis)	1.2	<b>21.0</b>	19.8	2.1	—
<b>Core operating profit</b>	<b>58.5</b>	<b>30.0</b>	<b>(28.5)</b>	<b>3.9</b>	<b>(48.7)</b>
Changes in fair value of contingent consideration (negative number)	3.3	<b>(0.5)</b>	(3.8)		
Other non-recurring item (negative number indicates)	(1.6)	<b>(5.5)</b>	(3.9)		
<b>Operating profit</b>	<b>60.2</b>	<b>24.0</b>	<b>(36.2)</b>		<b>(60.2)</b>
<b>Net profit attributable to owners of the parent</b>	<b>56.4</b>	<b>22.0</b>	<b>(34.4)</b>		<b>(61.0)</b>
R O E (%)	9.5	<b>3.6</b>			
R O I C (%)	1.7	<b>0.7</b>			

### FX rates:

FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5

FY2022 Forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

## Expect both revenue and profit down for FY2022

- **Revenue:** Japan (¥19.9B), North America ¥14.5B  
China (¥10.7B)
  - Japan will be affected by termination of sale of REPLAGAL<sup>®</sup>, NHI price revision
  - North America will decrease on USD basis because the alliance revenue ¥30.3B was recorded in FY2021, while ORGOVYX<sup>®</sup>, MYFEMBREE<sup>®</sup>, GEMTESA<sup>®</sup> will grow
  - China is expected price down by VBP application to MEROPEN<sup>®</sup>
- **SG&A and R&D expenses:**
  - SG&A will increase mainly due to impact of FX
  - R&D will decrease despite FX impact
- **Other operating income and expenses (Core basis):**
  - Sale of priority review voucher will be assumed

(Ref.) Expenses related to Sumitovant (¥B)

	2021	2022	Change
SG&A expenses	90.3	117.9	27.6
Amortization of patent rights in above	17.4	20.8	3.4
R&D expenses	24.3	25.8	1.5

The figures are before intra-group elimination

## Financial Forecasts for FY2022

### Variance with FY2022 Target of Revised MTBP (1)

	Financial Forecasts for FY2022	Mid-term Business Plan 2022 (Revised in May 2021)
Revenue	¥550.0B	¥600.0B
SG&A expenses	¥283.5B	¥262.0B
R&D expenses	¥93.0B	¥93.0B
Core operating profit	¥30.0B	¥60.0B
ROIC	0.7 %	3 %
ROE	3.6 %	3 %
FX rate	1US\$ = ¥125.0	1US\$ = ¥110.0

#### Revenue :

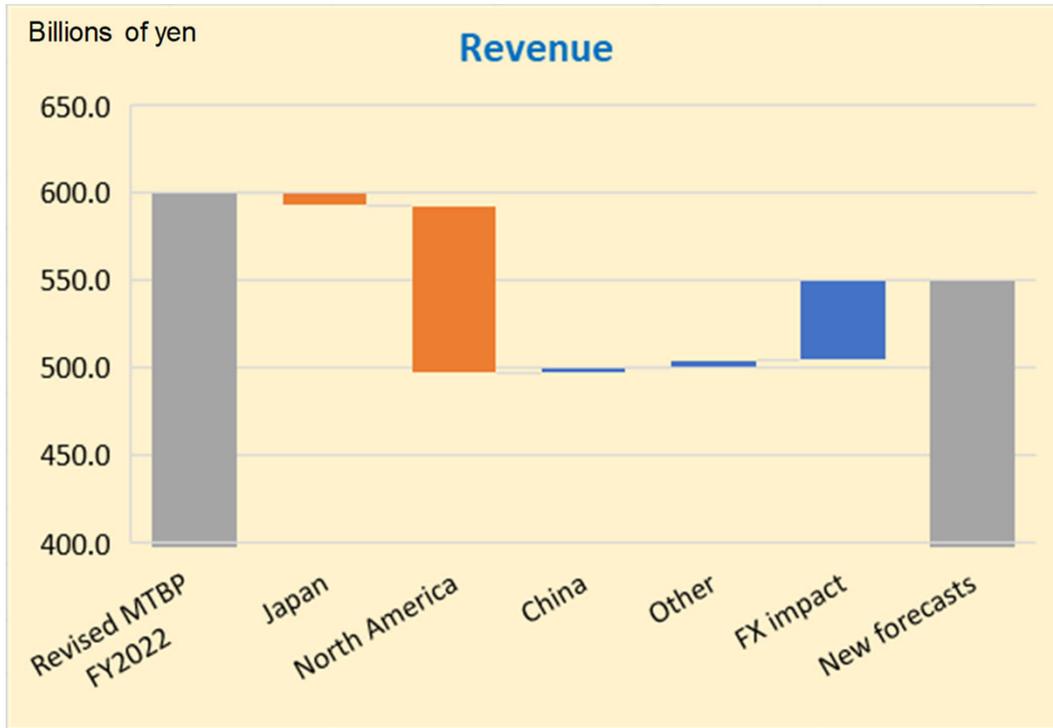
- Downward adjustment of ¥90.0B except for increased revenue by weaker yen, due to taking much time for market penetration of new products than assumption in revised MTBP because of effects of COVID-19

#### Core operating profit :

- Downward adjustment of ¥30.0B due to decrease in revenue and gross profit

## Financial Forecasts for FY2022

# Variance with FY2022 Target of Revised MTBP (2)



## Financial Forecasts for FY2022

# Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2022 Forecasts	Revenue (Sales to customers)	130.0	334.3	27.6	16.1	508.0	42.0	550.0
	Cost of sales	67.6	53.6	5.6	5.2	132.0	32.5	164.5
	Gross profit	62.4	280.7	22.0	10.9	376.0	9.5	385.5
	SG&A expenses	53.0	211.0	11.6	1.6	277.2	6.3	283.5
	Core segment profit	9.4	69.7	10.4	9.3	98.8	3.2	102.0
	R&D expenses					90.5	2.5	93.0
	Core operating profit					29.3	0.7	30.0
FY2021 Results	Revenue (Sales to customers)	149.9	319.8	38.3	12.2	520.2	39.9	560.0
	Cost of sales	78.7	33.6	7.4	6.6	126.3	30.8	157.1
	Gross profit	71.3	286.2	30.9	5.5	393.9	9.0	402.9
	SG&A expenses	51.7	180.8	11.3	2.3	246.1	5.5	251.6
	Core segment profit	19.6	105.4	19.6	3.3	147.8	3.5	151.4
	R&D expenses					93.2	0.8	94.0
	Core operating profit					55.8	2.7	58.5
Change	Revenue (Sales to customers)	(19.9)	14.5	(10.7)	3.9	(12.2)	2.1	(10.0)
	SG&A expenses	1.3	30.2	0.3	(0.7)	31.1	0.8	31.9
	Core segment profit	(10.2)	(35.7)	(9.2)	6.0	(49.0)	(0.3)	(49.4)
	R&D expenses					(2.7)	1.7	(1.0)
	Core operating profit					(26.5)	(2.0)	(28.5)

- **Japan segment:** Profit will decrease largely because of revenue decrease
- **North America segment:** Revenue will increase by FX, but decrease on USD basis  
Gross profit will decrease due to changes in component such as decrease of alliance revenue  
SG&A expenses will be the same as FY2021 except for FX impact  
Core segment profit will decrease due to decrease in Gross profit
- **China segment:** Profit will decrease largely because revenue decrease
- **Other Regions segment:** Lump-sum payment (\$50M) based on the license out contract for DSP-0187 is included
- **Other Business:** Revenue and expenses in the frontier business will be expected

## Financial Forecasts for FY2022

# Revenue of Major Products in Japan

Billions of yen

	FY2021 Results	FY2022 Forecasts	Change	
			Value	%
Equa <sup>®</sup> /EquMet <sup>®</sup>	37.5	<b>34.9</b>	(2.6)	(6.9)
Trulicity <sup>®</sup> *	33.6	<b>31.0</b>	(2.6)	(7.8)
TRERIEF <sup>®</sup>	16.4	<b>17.3</b>	0.9	5.7
LATUDA <sup>®</sup>	6.9	<b>9.9</b>	3.0	44.0
METGLUCO <sup>®</sup>	8.1	<b>7.8</b>	(0.3)	(4.3)
LONASEN <sup>®</sup> Tape	2.1	<b>2.7</b>	0.6	31.2
TWYMEEG <sup>®</sup>	0.2	<b>1.5</b>	1.3	752.2
REPLAGAL <sup>®</sup>	12.4	—	(12.4)	—
AG products	9.7	<b>9.7</b>	0.0	0.4
Others	23.1	<b>15.2</b>	(7.9)	(34.3)
<b>Total</b>	<b>149.9</b>	<b>130.0</b>	<b>(19.9)</b>	<b>(13.3)</b>

- Revenue will decrease ¥19.9B on Japan segment total
- Decrease in Equa<sup>®</sup>/EquMet<sup>®</sup> and Trulicity<sup>®</sup> are attributed to NHI price revision
- Sales of LATUDA<sup>®</sup>, LONASEN<sup>®</sup> Tape and TWYMEEG<sup>®</sup> will increase
- Sale of REPLAGAL<sup>®</sup> was terminated in February 2022
- Revenue of Agalsidase Beta BS which promotion started in April 2022 is included in “Others”
- NHI price revision impact in FY2022 (¥12.0B)

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

## Financial Forecasts for FY2022

# Revenue of Major Products in North America & China

	FY2021 Results	FY2022 Forecasts	Change	FY2021 Results	FY2022 Forecasts	Change		
						Value	FX impact	%
<b>North America</b>	Million \$			Billions of yen				
LATUDA®	1,816	1,726	(90)	204.1	215.8	11.7	21.7	5.7
APTOM®	241	255	14	27.1	31.8	4.7	3.2	17.3
RETHYMIC®	3	48	45	0.3	6.0	5.7	0.6	1,854.4
BROVANA®	129	26	(103)	14.5	3.2	(11.3)	0.3	(77.9)
KYNMOBI®	5	18	13	0.6	2.3	1.7	0.2	273.4
ORGOVYX®	83	601	(50)	9.3	75.2	2.1	7.7	2.8
MYFEMBREE®/ RYEQO®	11			1.3				
GEMTESA®	63			7.1				
Others	493			55.4				
<b>Total</b>	<b>2,845</b>	<b>2,674</b>	<b>(171)</b>	<b>319.8</b>	<b>334.3</b>	<b>14.5</b>	<b>33.7</b>	<b>4.5</b>
<b>China</b>	Million RMB			Billions of yen				
MEROPEN®	1,708	863	(845)	29.9	16.8	(13.1)	1.7	(43.8)
Others	478	553	75	8.4	10.8	2.4	1.1	28.9
<b>Total</b>	<b>2,186</b>	<b>1,416</b>	<b>(770)</b>	<b>38.3</b>	<b>27.6</b>	<b>(10.7)</b>	<b>2.8</b>	<b>(27.9)</b>

\* Even though the United States Patent and Trademark Office (USPTO) has made decision that there is no patentability of LATUDA patent for use, we are seeking the withdrawal of this decision, we consider there is no impact for the loss of exclusivity in February 2023.

FX rates:

FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5

FY2022 Forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

### ■ North America segment

Revenue will increase on JPY basis due to ¥33.7B of FX impact despite decrease on the USD basis

- LATUDA® will reach loss of exclusivity in February 2023. Considering the effect of competing products, we focus on promotion until December 2022
- BROVANA® decreased due to generic products of BROVANA® launched in June 2021

- Revenue from the alliance with Otsuka \$270M (¥30.3B) included in "Others" will decrease, deferred revenue from the alliance for relugolix will be \$100M / ¥12.5B (FY2021: \$105M / ¥11.8B)

### ■ China segment

MEROPEN® will decrease due to expected price down by VBP

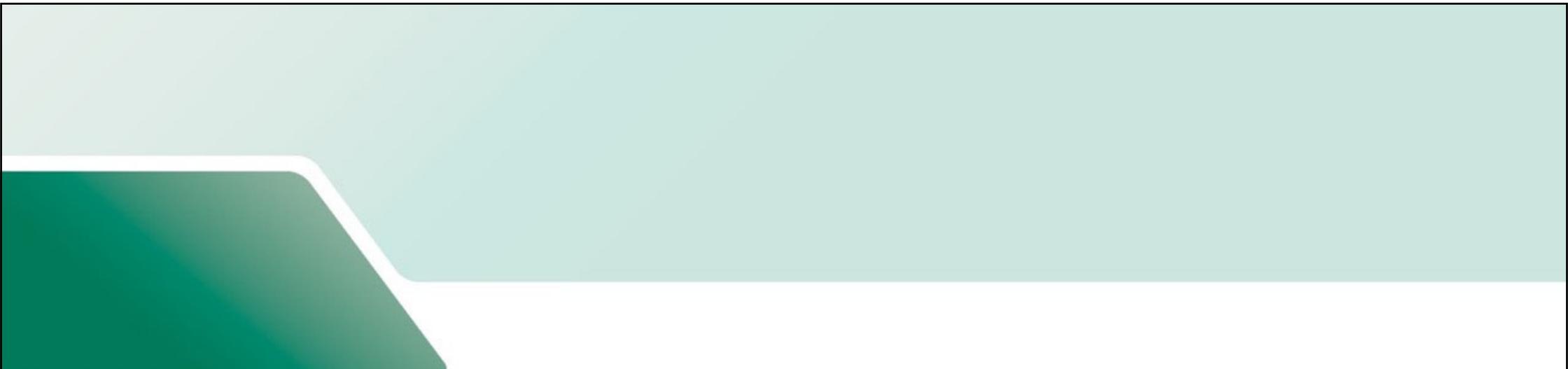
## Financial Forecasts for FY2022

### Dividend Policy

- Performance-linked dividend hike will be considered in addition to consistent dividend payments
- Current MTBP 5-year (FY2018-2022) average payout ratio: 20% or higher (expected to be 28%)

	FY2020 actual	FY2021 plan	FY2022 plan
Dividend per share (yen)	28.00	28.00	28.00
Payout ratio (%)	19.8	19.7	50.6
Return on Invested Capital (ROIC) (%)	3.1	1.7	0.7
Return on Equity (ROE) (%)	10.1	9.5	3.6

ROIC: (core operating profit – income taxes) / (total capital + interest-bearing liabilities)



# Research and Development

# Research and Development

## Development Pipeline (as of May 13, 2022)

■: Psychiatry & Neurology 
 ■: Oncology 
 ■: Regenerative medicine / Cell therapy 
 ■: Others 
 ■: Frontier business 
 ■: Revisions since the announcement of January 2022 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	DSP-9632P (Levodopa-induced dyskinesia in Parkinson's disease)	DSP-0390 (Solid tumors)	EPI-589 (ALS/Investigator-initiated study)	ulotaront (SEP-363856) (Schizophrenia)	METGLUCO® (metformin) (New indication: infertility treatment)
	DSP-0187 (Narcolepsy)	TP-3654 (Hematologic malignancies)	Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated study)	SEP-4199 (Bipolar I depression)	
		DSP-5336 (Hematologic malignancies)			
		guretolimod (DSP-0509) (Solid tumors)			
U.S.	DSP-6745 (Parkinson's disease psychosis)	guretolimod (DSP-0509) (Solid tumors)	EPI-589 (Parkinson's disease/ALS)	ulotaront (SEP-363856) (Schizophrenia)	MYFEMBREE® (relugolix) (New indication: Endometriosis) PDUFA goal date: Aug. 2022
	SEP-378608 (Bipolar disorder)	TP-1287 (Solid tumors)	ulotaront (SEP-363856) (Parkinson's disease psychosis)	SEP-4199 (Bipolar I depression)	
	DSP-3905 (Neuropathic pain)	TP-3654 (Hematologic malignancies)	dubermatinib (TP-0903) (AML/Research group-initiated study)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)	
	SEP-378614 (To be determined)	TP-1454 (Solid tumors)	DSP-7888 (Solid tumors)		
	SEP-380135 (To be determined)	DSP-0390 (Solid tumors)	rodatristat ethyl (Pulmonary arterial hypertension)		
	DSP-0038 (Alzheimer's disease psychosis)	DSP-5336 (Hematologic malignancies)	URO-902 (Overactive bladder)		
	DSP-3456 (Treatment resistant depression)	KSP-1007 (Complicated urinary tract infections, Complicated intra-abdominal infections)			
China				LATUDA® (New indication: Bipolar I depression)	lefamulin (Bacterial community-acquired pneumonia)
				ulotaront (SEP-363856) (Schizophrenia)	

## Clinical Development Status (Major Changes since January 31, 2022)

### ■ DSP-3456

U.S.: Started Phase 1 study for treatment resistant depression

### ■ Relugolix

Europe: Approved for prostate cancer in April 2022

✓ In May 2022, Myovant entered into an exclusive license agreement with Accord Healthcare, Ltd. to commercialize ORGOVYX® for the treatment of prostate cancer in Europe

Accord Healthcare is expected to launch ORGOVYX® in Europe in the second half of calendar year 2022

### ■ DSP-0509 (guretolimod)

Japan: Started Phase 1/2 study for solid tumors

### ■ TP-0184

U.S.: Discontinued development for anemia associated with myelodysplastic syndromes (Phase 1/2 study)

### ■ MYFEMBREE® (relugolix combination tablet)

U.S.: Extended PDUFA goal date of FDA (May 6, 2022→ August 6, 2022)

### ■ METGLUCO® (metformin)

Japan: Submitted additional indication for infertility treatment (“ovulation induction for patients with polycystic ovary syndrome” and “controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome”) in March 2022

## ■ Progress of ulotaront and SEP-4199 (Co-Development with Otsuka Pharmaceutical)

### ■ Progress of ulotaront

- ✓ First indication: schizophrenia (SZ)
  - Actively evaluating the impact of the situation in Russia and Ukraine on clinical study recruitment and implementing mitigation strategies
    - ⇒ New recruitment in Russia and Ukraine is on indefinite hold, and in the process of initiating new sites in other countries, including the U.S.
  
- ✓ Second indication: Adjunctive Major Depressive Disorder (aMDD)
  - Clinical program lead: Otsuka Pharmaceutical
  - Study design under review for finalization with IND planned in FY2022
  
- ✓ Third indication: Under consideration; mental health disorder synergistic with aMDD and SZ
  - Clinical program lead: Sunovion
  - Study design under consideration; disclosure of additional study details expected during FY2022

### ■ Progress of SEP-4199

- ✓ Phase 3 study and its associated Open Label Extension (OLE) for bipolar I depression are ongoing
  - FPI for the both studies occurred at a U.S. site in Q4 FY2021

## Research and Development

# Main Events / Targets for FY2022 (as of May 13, 2022)

### Psychiatry & Neurology

- ulotaront :  Start clinical studies for two new indications (SEP-363856)  Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia
- SEP-4199: Advance Phase 3 studies for Bipolar I depression

### Oncology

- relugolix : (Europe) Obtain approval for prostate cancer
- Advance early Phase studies

### Regenerative medicine / Cell therapy

- Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study
- Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S.
- Start construction of manufacturing plant in the U.S (for RETHYMIC® and allogeneic iPS cell-derived products)

### Infectious Diseases

- Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects

### Others

- relugolix : (U.S.)  Obtain approval for endometriosis (Europe)  Submit MAA for endometriosis

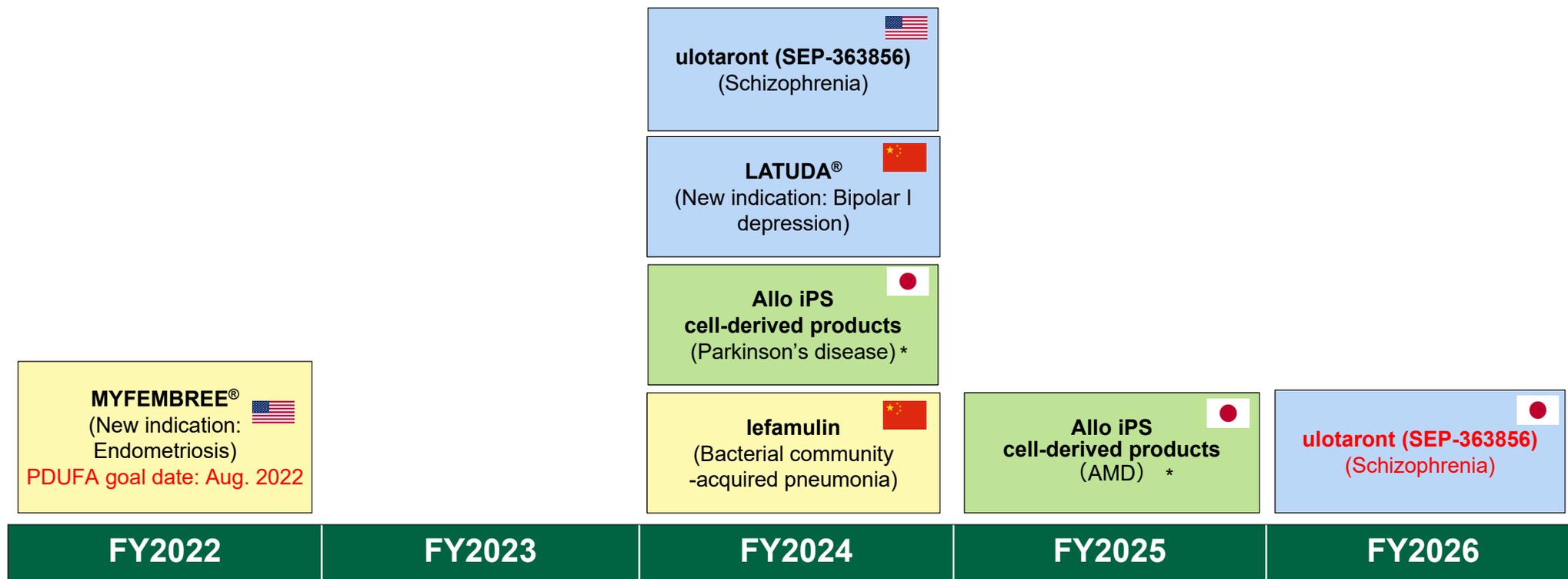
### Frontier

- Launch products:  (Japan) Neurorehabilitation device for hand/figures  (U.S.) VR contents for mental health
- Generating evidence data for maximizing the value of the launched products: Digital device for relieving BPSD, etc.
- Promote the current themes and development of new themes

Research and Development

# Product Launch Target (as of May 13, 2022)

Revisions since the announcement of January 2022 are shown in red



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

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

## Research and Development

# Product Launch Target (Frontier business) (as of May 13, 2022)

Revisions since the announcement of January 2022 are shown in red

- : Medical device
- : Non-medical device

FY2022	FY2023	FY2024	FY2025	FY2026	FY2027 onward
	Wearable EEG meter (Certification) <span style="color: red;">●</span>				
Neurorehabilitation device for hand/fingers (Certification)*1 <span style="color: red;">●</span>	Automated blood collection/Stabilization device <span style="color: red;">●</span>		Violet Light (Depression) <span style="color: red;">●</span>		Digital medical device for depression diagnosis <span style="color: red;">●</span>
Digital device for relieving BPSD (nursing care)*2 <span style="color: red;">●</span>	Smart device for hard of hearing people <span style="color: red;">●</span>	Violet Light (Depression) <span style="color: red;">●</span>	Violet Light (Dementia) <span style="color: red;">●</span>		Digital device for relieving BPSD (Approval) <span style="color: red;">●</span>
VR contents for mental health*3 <span style="color: red;">●</span>	Wearable EEG meter <span style="color: red;">●</span>	Violet Light (Dementia) <span style="color: red;">●</span>	Neurorehabilitation device for hand/fingers (Approval) <span style="color: red;">●</span>	VR contents for Social Anxiety Disorder <span style="color: red;">●</span>	VR business (Disease area expansion) <span style="color: red;">●</span>

\*1 Certified medical device named "Active extension / flexion / extension rotation exercise device" (Accepted name for medical devices), sales by Sumitomo Pharma

\*2 Full-scale sales primarily by partners (Aikomi : our associated company)

\*3 Sales primarily by partners (BehaVR) (Profit share 50-50 with both companies)

The project description varies with the product (device sales, solution business, royalties, etc.)

## Neurorehabilitation Device for Hand/Fingers

- Commercialization of neurorehabilitation device for hand/fingers paralysis which has been co-developed by MELTIN and Sumitomo Pharma
- Under application for certification as a medical device (accepted name for medical devices: Active extension/flexion/extension rotation exercise device)
- Manufacturer: MELTIN, distributor (planned): Sumitomo Pharma
- Targeting to launch in FY2022



- Even for post-stroke patients with hand/fingers paralysis, this robotic neurorehabilitation device is designed to read the patient's motion intention from biosignals with which AI will interpret them to motions and operate the device for training of hand/fingers movements in sync with the intention
- By repeating movements in sync with the patient's intention, it is aimed that the brain will learn again how to move the hand

# Appendix

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P.32	R&D	Regenerative Medicine/Cell Therapy Business Plan
P.33	R&D	New Chemical Entity: DSP-3456

Appendix (Financial Results for FY2021)

## Financial Results for FY2021 (Full Basis)

Billions of yen

	FY2020 Results	FY2021 Results	Change	
			Value	%
Revenue	516.0	560.0	44.1	8.5
Cost of sales	137.8	157.1	19.4	14.0
Gross profit	378.2	402.9	24.7	6.5
SG&A expenses	190.4	249.1	58.7	30.8
R&D expenses	132.7	94.9	(37.8)	(28.5)
Other operating income and expenses	16.1	1.3	(14.8)	
Operating profit	71.2	60.2	(11.0)	(15.4)
Finance income and costs	6.6	22.7	16.1	
Profit before taxes	77.9	83.0	5.1	6.6
Income tax expenses	41.0	42.4	1.3	
Net profit	36.8	40.6	3.8	10.2
Net profit attributable to owners of the parent	56.2	56.4	0.2	0.3

## Appendix (Financial Results for FY2021)

# Adjustments to Core Operating Profit

### FY2021 Results

Billions of yen

	IFRS Full Basis	Adjusted amount	IFRS Core Basis	Adjusted items
Revenue	560.0	-	560.0	
Cost of sales	157.1	(0.0)	157.1	
Gross profit	402.9	0.0	402.9	
SG&A expenses	249.1	2.5	251.6	Changes in fair value of contingent consideration 3.3
R&D expenses	94.9	(0.9)	94.0	
Other operating income and expenses	1.3	(0.2)	1.2	
Operating profit	60.2	(1.7)	58.5	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 Results for FY2021)

### Financial Position

B / S	As of March 2021	As of March 2022	Change
Assets	1,308.1	1,308.0	(0.1)
Goodwill / Intangible assets	559.9	593.8	33.9
Other financial assets (Non-current)	193.0	115.8	(77.2)
Trade and other receivables	135.9	151.4	15.5
Cash and deposit / Short-term loan receivable	221.4	230.2	8.8
Liabilities	659.9	634.4	(25.5)
Bonds and borrowings	273.8	269.0	(4.8)
Fair value of contingent consideration (Other financial liabilities)	8.3	4.4	(3.9)
Provisions	99.9	119.1	19.3
Deferred revenue (Other liabilities)	55.3	58.9	3.6
Equity	648.2	673.6	25.4
Attributable to owners of the parent	580.6	607.9	27.3
Ratio of equity attributable to owners of the parent to total assets	44.4%	46.5%	

Billions of yen

Foreign exchange impact

Decrease in changing securities  
valuation

Decrease in fair value mainly due to  
review of development plan

C / F	FY2020	FY2021	Change
Operating CF	135.6	31.2	(104.4)
Investment CF	8.9	(18.3)	(27.2)
Financial CF	(57.2)	(21.4)	35.8
Cash and cash equivalents	193.7	203.0	9.3
(Operating funds)	221.4	234.9	13.5

## Appendix (Research and Development)

### Main Events / Targets for FY2021 (as of May 13, 2022)

✓ Completed action / target    Revisions since the announcement of January 2022 are shown in red

<b>Psychiatry &amp; Neurology</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> ulotaront : <input type="checkbox"/> Start clinical program for the development (global study) of new indication (SEP-363856) <input checked="" type="checkbox"/> Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia</li> <li><input checked="" type="checkbox"/> SEP-4199: Start Phase 3 study for Bipolar I depression</li> </ul>
<b>Oncology</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> DSP-7888 : Advance global Phase 3 study for glioblastoma → Terminated</li> </ul>
<b>Regenerative medicine / Cell therapy</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> RVT-802 : Obtain approval 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 checked="" type="checkbox"/> Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated study</li> </ul>
<b>Infectious Diseases</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects</li> </ul>
<b>Others</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> relugolix : (U.S.) <input checked="" type="checkbox"/> Obtain approval for uterine fibroids <input checked="" type="checkbox"/> Submit NDA for endometriosis (Europe) <input checked="" type="checkbox"/> Obtain approval for uterine fibroids <input type="checkbox"/> Submit MAA for endometriosis</li> <li><input checked="" type="checkbox"/> imeglimin : Obtain approval for type 2 diabetes in Japan</li> </ul>
<b>Frontier</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Promote the current themes (Type 2 diabetes management app, Neurorehabilitation device for hand/fingers, Digital device for relieving BPSD, Automated blood collection/Stabilization device, VR contents for Social Anxiety Disorder, and internal themes, etc.) and development of new themes (Discontinued development for Type 2 diabetes management app SMC-01)</li> </ul>

Appendix (Research and Development)

## Regenerative Medicine/Cell Therapy Business Plan (as of May 13, 2022)

Revisions since the announcement of January 2022 are shown in red

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RETHYMIC®)	Duke University	Global	Cultured thymus tissue	Launched in March 2022 (U.S.)
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
Kidney failure	Jikei University Bios	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	In progress: pre-clinical study

Aim to start clinical study in FY2022

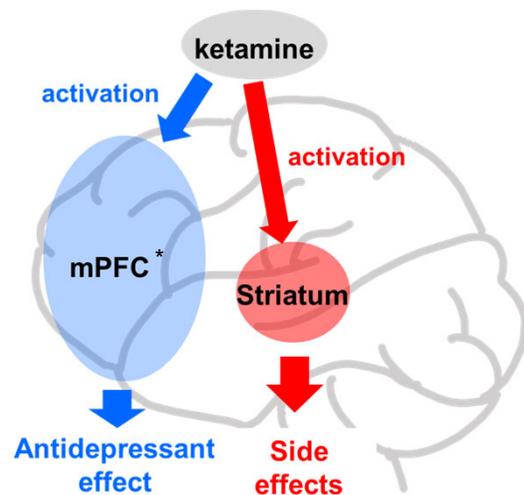
Aim to launch in FY2024 \*

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

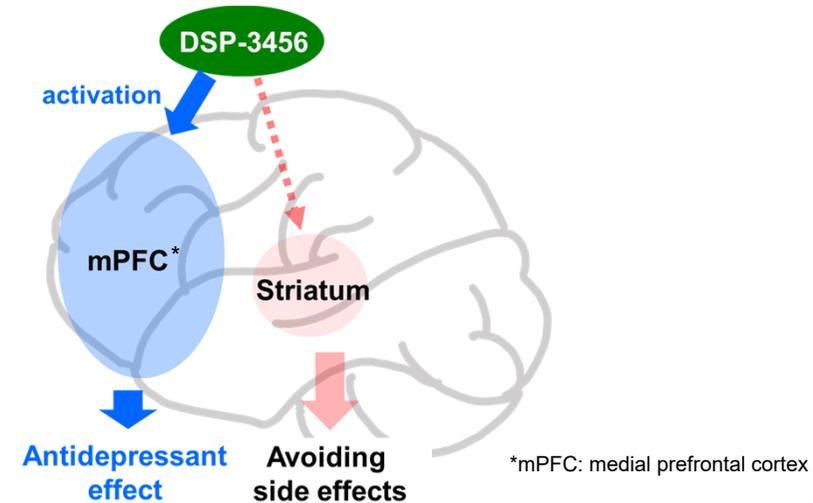
## Appendix (Research and Development)

# New Chemical Entity: DSP-3456

- ✓ Target indication: Treatment resistant depression
- ✓ Origin: In-house
- ✓ Mechanism of action: metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)  
NAM binds to a site different from the binding site of neurotransmitters and inhibits their effects to the receptor
- ✓ Stage: Phase 1 in the U.S.
- ✓ Expected profile:
  - To exhibit a ketamine-like antidepressant effect through selective activation of the prefrontal cortex by enhancing the glutamate release, while avoiding side effects (psychotic symptoms, cognitive dysfunction) caused by ketamine



Ketamine shows efficacy for treatment-resistant depression, but side effects are problems.



DSP-3456 is expected to be effective against treatment-resistant depression while avoiding side effects.

