

# **Investors Meeting Presentation for FY2022 (Year ended March 31, 2023)**

Hiroshi Nomura, President and CEO

Sumitomo Pharma Co., Ltd.

May 15, 2023

## ■ 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 and medical devices (including compounds under development) contained herein is not intended as advertising or as medical advice.



# Financial Results for FY2022

## Financial Results for FY2022

# Financial Results for FY2022 (Core Basis)

Billions of yen

	FY2021 Results	FY2022 Results	Change			FY2022 Jan. 31 forecasts
			Value	FX impact	%	
<b>Revenue</b>	560.0	<b>555.5</b>	(4.5)	60.5	(0.8)	<b>563.0</b>
Cost of sales	157.1	<b>176.7</b>	19.6	18.4	12.5	173.0
Gross profit	402.9	<b>378.8</b>	(24.1)	42.1	(6.0)	390.0
SG&A expenses	251.6	<b>305.6</b>	54.1	39.7	21.5	308.0
R&D expenses	94.0	<b>106.1</b>	12.1	12.7	12.8	98.0
Other operating income/expenses	1.2	*1 <b>49.2</b>	48.0	4.2	—	50.0
<b>Core operating profit</b>	<b>58.5</b>	<b>16.4</b>	(42.1)	(6.2)	(72.0)	<b>34.0</b>
Changes in fair value of contingent consideration (negative number indicates loss)	3.3	<b>3.4</b>	0.1			1.0
Other non-recurring items (negative number indicates loss)	(1.6)	*2 <b>(96.7)</b>	(95.2)			(62.0)
<b>Operating profit</b>	<b>60.2</b>	<b>(77.0)</b>	(137.2)		—	<b>(27.0)</b>
Finance income/costs	22.7	<b>29.1</b>	6.3			
Profit before taxes	83.0	<b>(47.9)</b>	(130.9)		—	
Income tax expenses	42.4	<b>48.8</b>	6.4			
Net profit	40.6	<b>(96.7)</b>	(137.3)		—	
<b>Net profit attributable to owners of the parent</b>	<b>56.4</b>	<b>(74.5)</b>	(130.9)		—	<b>(35.0)</b>

### (Ref.) Earnings related to Sumitovant

Billions of yen

	FY21	FY22
<b>Revenue</b>	<b>35.7</b>	<b>89.7</b>
SG&A expenses *	90.3	139.5
R&D expenses	24.3	33.7
<b>Core operating profit</b>	<b>(86.9)</b>	<b>(96.8)</b>
<b>Operating profit</b>	<b>(86.5)</b>	<b>(97.7)</b>
Net profit	(87.4)	(103.9)
<b>Net profit attributable to owners of the parent</b>	<b>(71.6)</b>	<b>(81.7)</b>

The figures include intra-group transaction

\* Include amortization of patent rights

\*1 Breakdown of other operating income/expenses

- ① Share transfer of Sumitomo Pharma Food & Chemical
- ② Sale of Priority Review Voucher
- ③ Divestiture of BROVANA® and XOPENEX HFA®
- ④ Divestiture of LUNESTA®

\*2 Breakdown of other non-recurring items

- ① Impairment loss on KYNMOBI® : ¥55.6B
- ② Impairment loss on TP-0903 : ¥20.6B
- ③ Restructuring expenses in North America : ¥12.7B

Average rates:

FY2021 Results : 1US\$ = ¥112.40, 1RMB = ¥17.52

FY2022 Results : 1US\$ = ¥135.51, 1RMB = ¥19.75

FY2022 forecasts : 1US\$ = ¥135.00, 1RMB = ¥19.50

Period end rates:

As of the end of March 2022 : 1US\$ = ¥122.41, 1RMB = ¥19.26

As of the end of March 2023 : 1US\$ = ¥133.54, 1RMB = ¥19.42

## Financial Results for FY2022

# Revenue of Major Products in Japan

Billions of yen

	FY2021 Results	FY2022 Results	Change	
			Value	%
Equa <sup>®</sup> /EquMet <sup>®</sup>	37.5	<b>33.6</b>	(4.0)	(10.5)
Trulicity <sup>®</sup> *	33.6	<b>24.8</b>	(8.8)	(26.2)
TRERIEF <sup>®</sup>	16.4	<b>16.7</b>	0.3	1.8
LATUDA <sup>®</sup>	6.9	<b>9.6</b>	2.7	39.3
METGLUCO <sup>®</sup>	8.1	<b>7.7</b>	(0.4)	(5.5)
LONASEN <sup>®</sup> Tape	2.1	<b>2.9</b>	0.9	42.8
TWYMEEG <sup>®</sup>	0.2	<b>2.2</b>	2.0	—
AG products	9.7	<b>9.2</b>	(0.5)	(5.2)
Others	35.5	<b>19.5</b>	(16.0)	(45.1)
<b>Total</b>	<b>149.9</b>	<b>126.1</b>	<b>(23.8)</b>	<b>(15.9)</b>

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

- Sales collaboration of Trulicity<sup>®</sup> terminated at the end of December 2022
- LATUDA<sup>®</sup> showing steady growth
- Prescription days limit of TWYMEEG<sup>®</sup> was lifted in September 2022
- Sale of REPLAGAL<sup>®</sup> included in “Others” decreased (FY2021: ¥12.4B)
- NHI price revision affected (¥10.9B) the Japan segment total

## Financial Results for FY2022

# Revenue of Major Products in North America & China

	FY2021 Results	FY2022 Results	Change	FY2021 Results	FY2022 Results	Change		
						Value	FX impact	%
<b>North America</b>	Million \$			Billions of yen				
LATUDA®	1,816	1,465	(351)	204.1	198.5	(5.6)	33.9	(2.8)
APTIOM®	241	249	8	27.1	33.7	6.6	5.8	24.4
RETHYMIC®	3	33	30	0.3	4.4	4.1	0.8	—
BROVANA®	129	21	(108)	14.5	2.8	(11.7)	0.5	(80.7)
KYNMOBI®	5	3	(2)	0.6	0.4	(0.2)	0.1	(29.1)
ORGOVYX®	83	182	99	9.3	24.7	15.4	4.2	164.9
MYFEMBREE®	6	33	27	0.7	4.5	3.8	0.8	528.8
GEMTESA®	63	182	119	7.1	24.7	17.5	4.2	246.0
Others *	498	256	(242)	56.0	34.7	(21.2)	5.9	(38.0)
<b>Total</b>	<b>2,845</b>	<b>2,424</b>	<b>(421)</b>	<b>319.8</b>	<b>328.5</b>	<b>8.7</b>	<b>56.0</b>	<b>2.7</b>
<b>China</b>	Million RMB			Billions of yen				
MEROPEN®	1,708	1,445	(263)	29.9	28.5	(1.4)	3.2	(4.6)
Others	478	550	72	8.4	10.9	2.5	1.2	29.7
<b>Total</b>	<b>2,186</b>	<b>1,995</b>	<b>(191)</b>	<b>38.3</b>	<b>39.4</b>	<b>1.1</b>	<b>4.4</b>	<b>2.9</b>

\* Lump-sum revenue included in "Others"

FY2021	Revenue from the alliance with Otsuka of \$270M	FY2022	Revenue from the license agreement for ORGOVYX® of \$50M
			Milestone revenue from approval of endometriosis of \$38M

### North America segment

Revenue increased due to the impact of fluctuations in FX rates and products of Sumitovant and its subsidiaries

- LATUDA® revenue decreased due to a decrease in shipment volume due to the end of the exclusivity sales period in February 2023 and a decrease in selling prices due to changes in the payer mix
- BROVANA® revenue decreased due to loss of exclusivity in June 2021
- Revenue from license agreements included in "Others" decreased (See the breakdown below the table)
- **China segment**

MEROPEN® revenue decreased due to the impact of Volume-Based Procurement application

FX rates:

FY2021 Results : 1US\$ = ¥112.40, 1RMB = ¥17.52  
 FY2022 Results : 1US\$ = ¥135.51, 1RMB = ¥19.75

## Financial Results for FY2022

# Segment Information (Core Basis)

Billions of yen

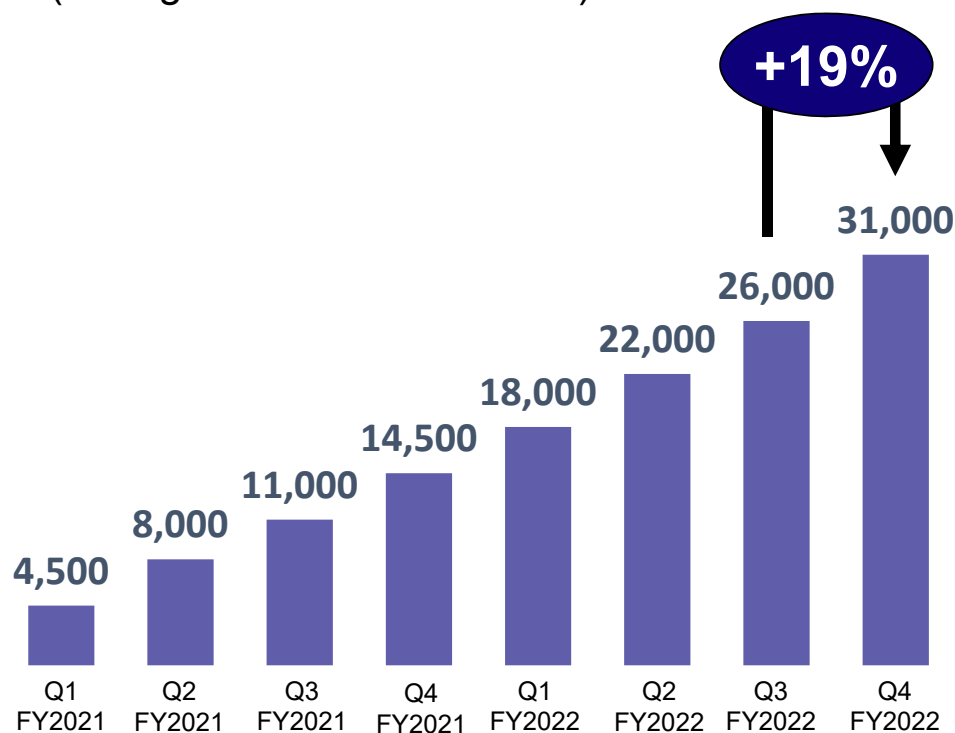
		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2022 Results	Revenue (Sales to customers)	126.1	328.5	39.4	16.8	510.7	44.8	555.5	
	Cost of sales	65.3	62.4	8.4	5.1	141.3	35.4	176.7	
	Gross profit	60.9	266.0	31.0	11.6	369.5	9.3	378.8	
	SG&A expenses	51.8	233.8	11.4	1.6	298.7	7.0	305.6	
	Core segment profit	9.1	32.2	19.5	10.0	70.8	2.4	73.2	
	R&D expenses						103.2	2.8	106.1
	Core operating profit						(8.0)	24.3	16.4
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						91.7	2.3	94.0
	Core operating profit						57.3	1.2	58.5
Change	Revenue (Sales to customers)	(23.8)	8.7	1.1	4.6	(9.5)	5.0	(4.5)	
	SG&A expenses	0.1	53.0	0.1	(0.7)	52.6	1.5	54.1	
	Core segment profit	(10.5)	(73.1)	(0.0)	6.7	(77.0)	(1.1)	(78.1)	
	R&D expenses						11.6	0.5	12.1
	Core operating profit						(65.3)	23.2	(42.1)

- **Japan:** Lower profit due to declined gross profit
- **North America:** Profit decreased since the impact of higher expenses in Sumitovant Group and forex situation exceeded increased revenue
- **China:** Profit decreased since the impact of higher expenses in forex situation
- **Other Regions:** Profit includes the revenue of \$50M under the license agreement for DSP-0187

## Financial Results for Q4 FY2022

### Marketing Status of ORGOVYX®

- Approx. 5,000 new patients started treatment with ORGOVYX® in Q4 FY2022 (19% growth vs. Q3 FY2022)



### Estimated Cumulative Patients Treated with ORGOVYX®

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

- The market for androgen deprivation therapy targeted by ORGOVYX® is over 200 billion yen/year (gross conversion), and recently expanded by approx. 20% annually\*
- Established broad health plan coverage (Percentage of coverage obtained as of April 2023: total of Medicare Part D lives was approx. 100%, total of commercial lives was >90%)
- Gathering new evidence for further potential utility (Use in combination therapy and cardiovascular event risks)

\*Source IQVIA

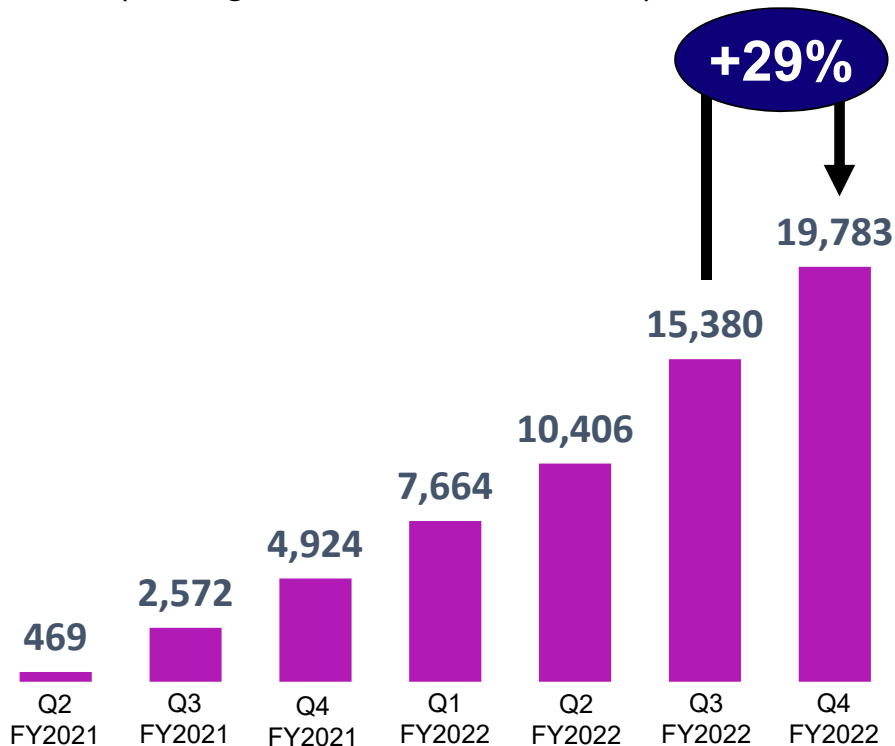
\*NSP sales for RELUGOLIX, DEGARELIX, GOSERELIN, LEUPROLIDE, and TRIPTORELIN for the 12 months ended Feb. 2023 were \$1,612M (130yen/\$), which reflects a 21% growth vs the 12 months ended Feb. 2022



## Financial Results for Q4 FY2022

### Marketing Status of MYFEMBREE®

■ Approx. 19,700 total prescriptions (TRx) in Q4 FY2022 (29% growth vs. Q3 FY2022)



Number of prescriptions per quarter with MYFEMBREE®\*

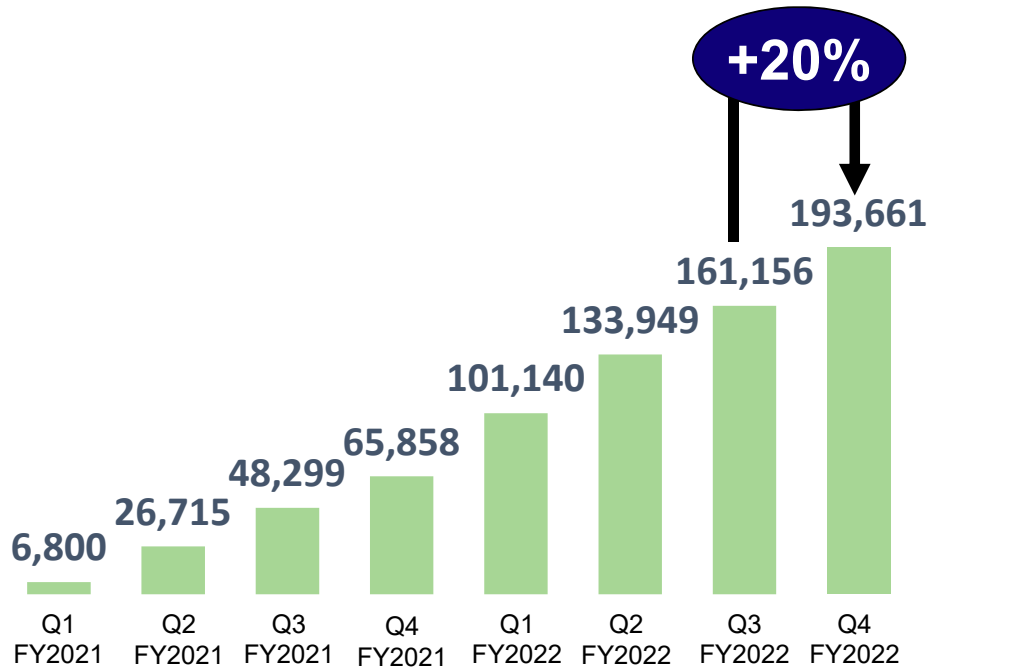
- The market targeted by MYFEMBREE® is approx. 63 billion yen/year (gross conversion), and recently expanded by approx. 20% annually\*\*  
Also focus on switching from oral contraceptives, NSAIDs, and surgery to MYFEMBREE®
- Established broad health plan coverage (Percentage of total commercial lives as primary coverage obtained as of March 2023; for UF was >90% and endo. was >80%)
- Gathering new evidence for further potential utility (To leverage data of long-term administration for endo. and verify contraceptive efficacy)
- Continue to improve Gross to Net

\*Source Symphony Health, an ICON plc Company, IDV®  
\*\*Source IQVIA NSP sales as of end of Feb. 2023 and TRx as of end of Mar. 2023. Sales for MYFEMBREE®, ORIAHNN, ORLISSA, Lupron Depot 3.75MG/11.25MG, and Lupaneta Pack for the 12 months ended Feb. 2023 were \$481M (130yen/\$), which reflects a 19% growth vs 12 months ended Feb. 2022

## Financial Results for Q4 FY2022

### Marketing Status of GEMTESA®

- Approx. 190,000 TRx in Q4 FY2022, which is greater than our FY2022 forecast (20% growth vs. Q3 FY2022)



Number of prescriptions per quarter with GEMTESA®\*

- The market for overactive bladder (OAB) of GEMTESA® is over 400 billion yen/year (gross conversion), and recently expanded by 8% annually\*
- Established broad health plan coverage (Percentage of coverage obtained as of April 2023: total of Medicare Part D lives was approx. 80%, total of commercial lives was >70%)
- Phase 3 study results for OAB associated with benign prostatic hyperplasia will be obtained in 1H FY2023, and sNDA will be submitted in 2H FY2023

\*Source IQVIA

\*NSP sales as of end of Feb. 2023 and TRx as of end of Mar. 2023. Sales for GEMTESA®, MYRBETRIQ, TOVIAZ, and Generics for the 12 months ended Feb. 2023 were \$3.1B (130yen/\$), which reflects a 8% growth vs 12 months ended Feb. 2022



# Financial Forecasts for FY2023

## Financial Forecasts for FY2023

# Financial Forecasts for FY2023 (Core Basis)

Billions of yen

	FY2022 Results	FY2023 Forecasts	Change		
			Value	FX	%
Revenue	555.5	362.0	(193.5)	(9.5)	(34.8)
Cost of sales	176.7	132.0	(44.7)	(3.0)	(25.3)
Gross profit	378.8	230.0	(148.8)	(6.5)	(39.3)
SG&A expenses	305.6	220.0	(85.6)	(6.7)	(28.0)
R&D expenses	106.1	84.0	(22.1)	(2.3)	(20.8)
Other operating income and expenses (Core basis)	49.2	12.0	(37.2)	(0.2)	(75.6)
<b>Core operating profit</b>	<b>16.4</b>	<b>(62.0)</b>	<b>(78.4)</b>	<b>2.3</b>	<b>—</b>
Non-recurring item (negative number indicates loss)	(93.3)	(16.0)	77.3		
<b>Operating profit</b>	<b>(77.0)</b>	<b>(78.0)</b>	<b>(1.0)</b>		<b>1.3</b>
Income tax expenses	48.8	(1.0)	(49.8)		
<b>Net profit</b>	<b>(96.7)</b>	<b>(80.0)</b>	<b>16.7</b>		
Net profit attributable to owners of the parent	(74.5)	(80.0)	(5.5)		7.4
R O E (%)	(14.7%)	(21.9%)			
R O I C (%)	(3.9%)	(8.5%)			

### FX rates:

FY2022 Results : 1US\$ = ¥135.51, 1RMB = ¥19.75

FY2023 Forecasts : 1US\$ = ¥130.00, 1RMB = ¥19.50

## Expect both revenue and profit down for FY2023

- **Revenue:** Japan (¥21.1B), North America (¥119.7B), China (¥6.4B), Other Business (¥43.3B)
  - Japan will be affected by termination of sales collaboration of Trulicity®, NHI price revision
  - North America will be affected by loss of exclusivity of LATUDA®, while ORGOVYX®, MYFEMBREE®, GEMTESA® will grow
  - China will decrease due to the growing impact of Volume-Based Procurement application for MEROPEN®
  - Other Business will decrease due to the transfer of subsidiaries
- **SG&A and R&D expenses:**
  - SG&A and R&D will decrease mainly due to the Combination of Group Companies in the U.S.
- **Other operating income and expenses (Core basis):**
  - Sale of assets will decrease
- **Non-recurring item:**
  - Temporary expenses associated with the Combination of Group Companies in the U.S. are expected

## Financial Forecasts for FY2023

# Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2023 Forecasts	Revenue (Sales to customers)	105.0	208.8	33.0	13.7	360.5	1.5	362.0	
	Cost of sales	48.1	68.8	7.4	6.8	131.1	0.9	132.0	
	Gross profit	56.9	140.0	25.6	6.9	229.4	0.6	230.0	
	SG&A expenses	46.1	160.3	10.6	1.8	218.8	1.2	220.0	
	Core segment profit	10.8	(20.3)	15.0	5.1	10.6	(0.6)	10.0	
	R&D expenses						82.0	2.0	84.0
	Core operating profit						(65.4)	3.4	(62.0)
FY2022 Results	Revenue (Sales to customers)	126.1	328.5	39.4	16.8	510.7	44.8	555.5	
	Cost of sales	65.3	62.4	8.4	5.1	141.3	35.4	176.7	
	Gross profit	60.9	266.0	31.0	11.6	369.5	9.3	378.8	
	SG&A expenses	51.8	233.8	11.4	1.6	298.7	7.0	305.6	
	Core segment profit	9.1	32.2	19.5	10.0	70.8	2.4	73.2	
	R&D expenses						103.2	2.8	106.1
	Core operating profit						(8.0)	24.3	16.4
Change	Revenue (Sales to customers)	(21.1)	(119.7)	(6.4)	(3.1)	(150.2)	(43.3)	(193.5)	
	SG&A expenses	(5.7)	(73.6)	(0.8)	0.2	(79.9)	(5.8)	(85.6)	
	Core segment profit	1.7	(52.5)	(4.5)	(4.9)	(60.2)	(3.0)	(63.2)	
	R&D expenses						(21.2)	(0.8)	(22.1)
	Core operating profit						(57.4)	(21.0)	(78.4)

- **Japan segment:** Profit will increase due to the effects of reduced SG&A expenses, while revenue will decrease
- **North America segment:** Gross profit will decrease significantly due to the decrease in revenue. Profit is expected to decline significantly, while cost reduction through streamlining is expected
- **China segment:** Profit will decrease because revenue decrease largely
- **Other Regions segment:** Decreased revenue and profit due to one-time payments based on out-licensing agreements in FY2021
- **Other Business:** Revenue will decrease due to the transfer of two subsidiaries and profit will decrease due to a decrease in transfer gains

## Financial Forecasts for FY2023

# Revenue of Major Products in Japan

Billions of yen

	FY2022 Results	FY2023 Forecasts	Change	
			Value	%
Equa <sup>®</sup> /EquMet <sup>®</sup>	33.6	<b>32.4</b>	(1.2)	(3.4)
TRERIEF <sup>®</sup>	16.7	<b>15.0</b>	(1.7)	(10.0)
LATUDA <sup>®</sup>	9.6	<b>12.5</b>	2.9	30.5
METGLUCO <sup>®</sup>	7.7	<b>7.5</b>	(0.2)	(2.6)
TWYMEEG <sup>®</sup>	2.2	<b>4.2</b>	2.0	89.3
LONASEN <sup>®</sup> Tape	2.9	<b>3.3</b>	0.4	12.2
AG products	9.2	<b>8.6</b>	(0.6)	(6.1)
Trulicity <sup>®</sup> *	24.8	—	(24.8)	—
Others	19.5	<b>21.5</b>	2.0	10.3
<b>Total</b>	<b>126.1</b>	<b>105.0</b>	<b>(21.1)</b>	<b>(16.7)</b>

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

- Revenue will decrease ¥21.1B on Japan segment total
- Sales of LATUDA<sup>®</sup> and TWYMEEG<sup>®</sup> are expected to increase
- Sales collaboration of Trulicity<sup>®</sup> was terminated in December 2022
- NHI price revision impact in FY2023 (approx.¥5.0B)

## Financial Forecasts for FY2023

# Revenue of Major Products in North America & China

	FY2022 Results	FY2023 Forecasts	Change	FY2022 Results	FY2023 Forecasts	Change		
						Value	FX impact	%
<b>North America</b>	Million \$			Billions of yen				
ORGOVYX®	182	396	214	24.7	51.5	26.8	(2.2)	108.5
MYFEMBREE®	33	192	159	4.5	24.9	20.4	(1.1)	454.1
GEMTESA®	182	362	180	24.7	47.0	22.3	(2.0)	90.5
APTIOM®	249	273	24	33.7	35.5	1.8	(1.5)	5.3
RETHYMIC®	33	54	21	4.4	7.0	2.6	(0.3)	57.7
LATUDA®	1,465	161	(1,304)	198.5	20.9	(177.6)	(0.9)	(89.5)
Others	280	167	(113)	38.0	22.0	(16.0)	(0.9)	(42.0)
<b>Total</b>	<b>2,424</b>	<b>1,605</b>	<b>(819)</b>	<b>328.5</b>	<b>208.8</b>	<b>(119.7)</b>	<b>(8.8)</b>	<b>(36.4)</b>
<b>China</b>	Million RMB			Billions of yen				
MEROPEN®	1,445	958	(487)	28.5	18.7	(9.8)	(0.2)	(34.5)
Others	550	737	187	10.9	14.3	3.4	(0.2)	31.6
<b>Total</b>	<b>1,995</b>	<b>1,695</b>	<b>(300)</b>	<b>39.4</b>	<b>33.0</b>	<b>(6.4)</b>	<b>(0.4)</b>	<b>(16.2)</b>

\* Lump-sum revenue included in "Others"

FY2022	Deferred revenue from the collaboration with Pfizer of \$138M	FY2023	Deferred revenue from the collaboration with Pfizer of \$117M
	Revenue from the license agreement for ORGOVYX® of \$50M		

### North America segment

Due to loss of exclusivity of LATUDA® in February 2023, revenue will decrease significantly in FY2023

ORGOVYX® and MYFEMBREE® will accelerate the efficiency of sales activities with the acquisition of Myovant as a wholly owned subsidiary

GEMTESA® is expected continued steady growth

KYNMOBI® and LONHALA® MAGNAIR® have been decided to discontinue sales

### China segment

Revenue of MEROPEN® will be expected to decrease due to the growing impact of Volume-Based Procurement application

FX rates:

FY2022 Results : 1US\$ = ¥135.51, 1RMB = ¥19.75  
 FY2023 Forecasts : 1US\$ = ¥130.00, 1RMB = ¥19.50



# Research and Development



# Research and Development

## Development Pipeline (as of May 15, 2023)

: Psychiatry & Neurology
  : Oncology
  : Others

Revisions since the announcement of January 2023 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA submitted
<b>Japan</b>	<b>DSP-9632P</b> (Levodopa-induced dyskinesia in Parkinson's disease)	<b>TP-3654</b> (Myelofibrosis)	<b>EPI-589</b> (ALS/Investigator-initiated study)	<b>ulotaront (SEP-363856)</b> (Schizophrenia)	
	<b>DSP-0187</b> (Narcolepsy)	<b>DSP-5336</b> (Acute leukemia)	<b>Allo iPS cell-derived products</b> (Parkinson's disease/ Investigator-initiated study)	<b>ulotaront (SEP-363856)</b> (Generalized anxiety disorder)*	
	<b>DSP-0378</b> (Dravet syndrome, Lennox-Gastaut syndrome)	<b>DSP-0390</b> (Glioblastoma)		<b>SEP-4199</b> (Bipolar I depression)	
<b>U.S.</b>	<b>DSP-3905</b> (Neuropathic pain)	<b>TP-3654</b> (Myelofibrosis)	<b>EPI-589</b> (Parkinson's disease/ALS)	<b>ulotaront (SEP-363856)</b> (Schizophrenia)	
	<b>SEP-378614</b> (To be determined)	<b>DSP-5336</b> (Acute leukemia)	<b>ulotaront (SEP-363856)</b> (Parkinson's disease psychosis)	<b>ulotaront (SEP-363856)</b> (Adjunctive major depressive disorder)*	
	<b>SEP-380135</b> (To be determined)	<b>DSP-0390</b> (Glioblastoma)	<b>rodatristat ethyl</b> (Pulmonary arterial hypertension)	<b>ulotaront (SEP-363856)</b> (Generalized anxiety disorder)*	
	<b>DSP-0038</b> (Alzheimer's disease psychosis)	<b>TP-1287</b> (Solid tumors)	<b>URO-902</b> (Overactive bladder)	<b>SEP-4199</b> (Bipolar I depression)	
	<b>DSP-3456</b> (Treatment resistant depression)	<b>TP-1454</b> (Solid tumors)		<b>GEMTESA® (vibegron)</b> (New indication: OAB in men with BPH)	
	<b>DSP-2342</b> (To be determined)	<b>KSP-1007</b> (Complicated urinary tract infections, Complicated intra-abdominal infections)			
	<b>SP-101</b> (cystic fibrosis)				
<b>China</b>				<b>ulotaront (SEP-363856)</b> (Schizophrenia)	<b>lefamulin</b> (Bacterial community-acquired pneumonia)
				<b>vibegron</b> (Overactive bladder)	

\*Phase 2/3 study

## Clinical Development Status (Major Changes since January 31, 2023)

### ■ DSP-2342

U.S.: Started Phase 1 study (Proposed indication: To be determined)

### ■ SEP-378608

U.S.: Discontinued development for bipolar disorder (Phase 1 study)

### ■ Vibegron

China: Started Phase 3 study (Overactive bladder)

### ■ SP-101

U.S.: Started Phase 1 study (Proposed indication: cystic fibrosis)

### ■ URO-902

U.S.: Discontinued in-house development for overactive bladder (OAB) (Phase 2 study), out-licensing under consideration

■ Decided to discontinue development of DSP-0509, which was under consideration for development strategy

## **Ulotaront: Development Progress and Future Plans** (Co-Development with Otsuka Pharmaceutical)

### **Schizophrenia:**

- Clinical program lead: Sunovion/Sumitomo Pharma  
Phase 3 DIAMOND clinical study program on-track  
Results from the efficacy studies (DIAMOND 1 and DIAMOND 2 studies) anticipated in H1 FY2023  
NDA submission to the U.S. FDA is anticipated in FY2023

### **Adjunctive treatment of major depressive disorder (aMDD):**

- Clinical program lead: Otsuka Pharmaceutical  
First patient randomized in November 2022  
Phase 2/3 study is ongoing

### **Generalized Anxiety Disorder (GAD):**

- Clinical program lead: Sunovion/Sumitomo Pharma  
First patient randomized in April 2023  
Phase 2/3 study is ongoing

## Research and Development

### Main Events / Targets for FY2023 (as of May 15, 2023)

#### Psychiatry & Neurology

- ❑ ulotaront : ❑ Obtain results from two Phase 3 studies for schizophrenia ( ❑ DIAMOND 1 ❑ DIAMOND 2 ) (SEP-363856) ❑ Submit NDA for schizophrenia in the U.S.
  - ❑ Advance Phase 2/3 study in Japan and China for schizophrenia
  - ❑ Advance Phase 2/3 studies for two additional indications (aMDD, GAD)
- ❑ SEP-4199: Advance Phase 3 studies for Bipolar I depression
- ❑ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear) : Start clinical study in Japan
- ❑ Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S.
- ❑ Complete manufacturing plant in the U.S. (for RETHYMIC® and allogeneic iPS cell-derived products)

#### Oncology

- ❑ Advance early Phase studies

#### Others

- ❑ relugolix: Obtain approval for endometriosis in Europe
- ❑ vibegron: Obtain results from Phase 3 study and submit sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S.
- ❑ rodatristat ethyl: Obtain results from Phase 2 study for pulmonary arterial hypertension (PAH)
- ❑ universal influenza vaccine, malaria vaccines : Promote joint research and development projects

#### Frontier

- ❑ Launch product: (Japan) Automated blood collection/stabilization device
- ❑ Promoting the current themes and generating evidence data for maximizing the value of the launched products

# Appendix

## <Contents>

P.21	FY2022	Financial Results (Full Basis)
P.22	FY2022	Financial Position
P.23	R&D	Main Events/Targets for FY2022
P.24	R&D	Product Launch Target
P.25	R&D	Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline
P.26	R&D	Product Launch Target (Frontier Business)
P.27	R&D	New Chemical Entity: DSP-2342
P.28	R&D	New Chemical Entity: SP-101

Appendix (Financial Results for FY2022)

## Financial Results for FY2022 (Full Basis)

Billions of yen

	FY2021 Results	FY2022 Results	Change	
			Value	%
Revenue	560.0	555.5	(4.5)	(0.8)
Cost of sales	157.1	178.9	21.8	13.9
Gross profit	402.9	376.6	(26.3)	(6.5)
SG&A expenses	249.1	373.3	124.2	49.9
R&D expenses	94.9	131.9	37.0	38.9
Other operating income and expenses	1.3	51.6	50.3	
Operating profit	60.2	(77.0)	(137.2)	—
Finance income and costs	22.7	29.1	6.3	
Profit before taxes	83.0	(47.9)	(130.9)	—
Income tax expenses	42.4	48.8	6.4	
Net profit	40.6	(96.7)	(137.3)	—
Net profit attributable to owners of the parent	56.4	(74.5)	(130.9)	—

## Appendix (Financial Results for FY2022)

### Financial Position

Billions of yen

B / S	As of March 2022	As of March 2023	Change
<b>Assets</b>	<b>1,308.0</b>	<b>1,134.7</b>	<b>(173.3)</b>
Goodwill / Intangible assets	593.8	538.7	(55.1)
Other financial assets (Non-current)	115.8	134.0	18.2
Trade and other receivables	151.4	95.9	(55.5)
Cash and deposit / Short-term loan receivable	230.2	153.5	(76.7)
<b>Liabilities</b>	<b>634.4</b>	<b>728.0</b>	<b>93.5</b>
Bonds and borrowings	269.0	334.7	65.7
Fair value of contingent consideration (Other financial liabilities)	4.4	1.5	(2.9)
Deferred tax liabilities	26.6	36.5	10.0
Income taxes payable	7.6	24.1	16.5
<b>Equity</b>	<b>673.6</b>	<b>406.8</b>	<b>(266.8)</b>
Attributable to owners of the parent	607.9	406.7	(201.1)
(Ratio of equity attributable to owners of the parent) to total assets	46.5%	35.8%	

Impairment losses

Increase due to changes in valuation of securities

Decrease due to loss of exclusivity of LATUDA®

Payment for making Myovant a wholly owned subsidiary

Financing to make Myovant a wholly owned subsidiary

Impact of making Myovant a wholly owned subsidiary

C / F	FY2021	FY2022	Change
Operating CF	31.2	11.9	(19.3)
Investment CF	(18.3)	52.4	70.7
Financial CF	(21.4)	(146.8)	(125.4)
Cash and cash equivalents	203.0	143.5	(59.5)
(Operating funds)	234.9	158.0	(76.9)

Proceeds from sales of the share of Sumitomo Pharma Food & Chemical Co., Ltd. and intangible assets etc.

Decrease in payment for making Myovant a wholly owned subsidiary

## Appendix (Research and Development)

### Main Events / Targets for FY2022 (as of May 15, 2023)

✓ Completed action / target    Revisions since the announcement of January 2023 are shown in red

Psychiatry & Neurology	<ul style="list-style-type: none"> <li>✓ ulotaront (SEP-363856) : ✓ Start clinical studies for two new indications (               <ul style="list-style-type: none"> <li>✓ Adjunctive major depressive disorder</li> <li>✓ Generalized anxiety disorder</li> </ul> )             </li> <li>✓ Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia</li> <li>✓ SEP-4199: Advance Phase 3 studies for Bipolar I depression</li> </ul>
Oncology	<ul style="list-style-type: none"> <li>✓ relugolix : (Europe) Obtain approval for prostate cancer</li> <li>✓ Advance early Phase studies</li> </ul>
Regenerative medicine / Cell therapy	<ul style="list-style-type: none"> <li><input type="checkbox"/> Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study in Japan</li> <li><input type="checkbox"/> Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S.</li> <li>✓ Start construction of manufacturing plant in the U.S (for RETHYMIC® and allogeneic iPS cell-derived products)</li> </ul>
Infectious Diseases	<ul style="list-style-type: none"> <li>✓ KSP-1007 (Antimicrobial resistance) : Complete Phase 1 study in the U.S.</li> <li>✓ universal influenza vaccine, malaria vaccines : Promote joint research and development projects</li> </ul>
Others	<ul style="list-style-type: none"> <li>✓ relugolix : (U.S.)    ✓ Obtain approval for endometriosis (Europe)    ✓ Submit MAA for endometriosis</li> </ul>
Frontier	<ul style="list-style-type: none"> <li>✓ Launch products: ✓ (Japan) MELTz Neurorehabilitation device for hand/fingers</li> <li>✓ (U.S.) VR contents for mental health (brand name: First Resort, general wellness product)</li> <li>✓ Promoting the current themes and generating evidence data for maximizing the value of the launched products: Digital device for relieving BPSD, etc.</li> </ul>



Appendix (Research and Development)

**Product Launch Target (as of May 15, 2023)**

■ Psychiatry & Neurology
 ■ Oncology
 ■ Others

	FY2023	FY2024	FY2025	FY2026	FY2027	
<b>ulotaront</b> (TAAR1 agonist)		<b>Schizophrenia</b> 			<b>Schizophrenia</b> 	Expand indications
<b>Allogeneic iPS cell-derived dopaminergic neural progenitor cells (DSP-1083)</b>		<b>Parkinson's disease*1</b> 				Development in the U.S.
<b>Allogeneic iPS cell-derived retinal pigment epithelial cells (HLCR011)</b>			<b>Retinal pigment epithelium tear*1</b> 			Expand indications
<b>DSP-5336</b> (menin and MLL inhibitor)				<b>Acute myeloid leukemia*2</b> 	<b>Acute myeloid leukemia</b> 	Expand indications
<b>TP-3654</b> (PIM kinases inhibitor)					<b>Myelofibrosis</b> 	Expand sales countries
<b>GEMTESA®</b> (β3-adrenergic receptor agonist)			<b>Overactive bladder with BPH</b> 		<b>Overactive bladder</b> 	
<b>rodatristat ethyl</b> (tryptophan hydroxylase inhibitor)					<b>Pulmonary arterial hypertension</b> 	
<b>lefamulin</b> (antimicrobial agent of pleuromutilin class)		<b>Bacterial community-acquired pneumonia</b> 				

\*1 Launch schedule is based on our goal pending agreement with partners

\*2 Premise to utilize an application of accelerated approval program  
 (Plan to consult with the FDA)

## Appendix (Research and Development)

### Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of May 15, 2023)

Revisions since the announcement of January 2023 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.)
<b>RPE tear</b> AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium cells	Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor cells	In progress: investigator-initiated study (Phase 1/2 study) (Japan) Preparing to start clinical study (U.S.)
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 cells	In progress: clinical research (Sub-Acute Phase) In progress: pre-clinical study (Chronic Phase)
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 **FY2023**

Aim to launch in FY2024 (Japan)\*









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

Appendix (Research and Development)

## Frontier Business Product Launch Target (as of May 15, 2023)

 : Non-medical device

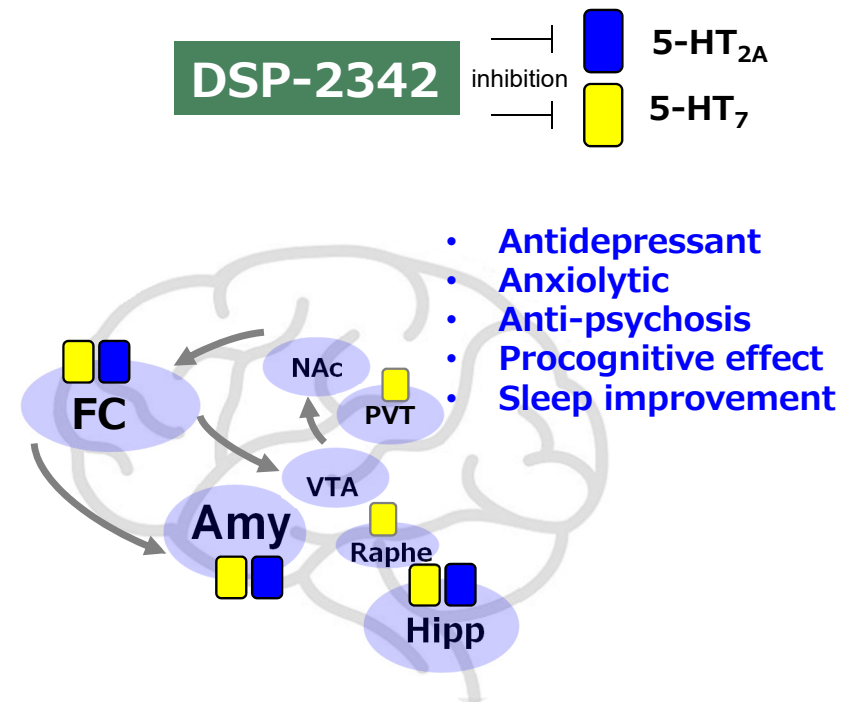
 : Medical device

	FY2023	FY2024	FY2025	FY2026	FY2027
<b>VR contents</b> (BehaVR, Inc.)				<b>Social Anxiety Disorder</b> 	<b>VR contents in other disease area</b>
<b>MELTz®</b> (MELTIN)			<b>"MELTz® Portable"</b> (finger exercise training system) 		<b>Neurorehabilitation device for hand/fingers</b> 
<b>Wearable EEG meter</b> (NeuroSky Co., Ltd.)		<b>Depression</b> 			<b>Depression</b> 
<b>Violet Light</b> (Tsubota Laboratory Incorporated)			<b>Depression / Dementia</b> 		<b>Depression / Dementia</b> 
<b>Automated blood collection/stabilization device</b> (Drawbridge Health, Inc.)	<b>Self-management solutions for metabolic diseases*</b> 				

\* At the start of the business, we plan to provide management solutions for metabolic disease management

## New Chemical Entity: DSP-2342

- ✓ Target indication: To be determined
- ✓ Origin: In-house (Joint research with Exscientia)
- ✓ Mechanism of action: Serotonin 5-HT<sub>2A</sub> and 5-HT<sub>7</sub> receptor antagonist
- ✓ Stage: Phase 1 in the U.S.
- ✓ Expected profile:
  - DSP-2342 is a novel compound discovered at Sumitomo Pharma using Exscientia's AI technologies, and is expected to demonstrate a broad effect on psychiatric symptoms which include psychosis, anxiety and depression, based on the additive effect of 5-HT<sub>2A</sub> and 5-HT<sub>7</sub> receptor antagonist
  - DSP-2342 has high selectivity for 5-HT<sub>2A</sub> and 5-HT<sub>7</sub> receptors, which can be expected to show a high safety and tolerability



## **New Chemical Entity: SP-101**

- ✓ Target indication: Cystic Fibrosis
- ✓ Origin: In-house (Spirovant Sciences, Inc.)
- ✓ Mechanism of action: CFTR gene transfer to lung
- ✓ Stage: Phase 1/2 in the U.S.
- ✓ Expected profile:
  - SP-101 is a novel adeno-associated viral (AAV) vector engineered to efficiently transduce human airway epithelia from the apical (lumen) surface. It is designed to deliver a shortened but fully functional cystic fibrosis transmembrane conductance regulator (CFTR) gene to the airways of people living with Cystic Fibrosis (CF)
  - Based on preclinical data, the addition of doxorubicin substantially improves SP-101 transduction and subsequent expression of the CFTR gene. SP-101 followed by doxorubicin administered via a nebulizer is being developed as a combination product for the treatment of CF. SP-101 is expected to restore CFTR function and halting disease progression in the lungs of people living with CF

