

## Institutional investors, analysts, and the press Meeting of Financial Results for FY2022

<b>[Date]</b>	May 15, 2023
<b>[Time]</b>	15:00 – 16:15 (Total: 75 minutes, Presentation: 17 minutes, Q&A: 58 minutes)
<b>[Venue]</b>	Webinar
<b>[Number of Speakers]</b>	4
	Hiroshi Nomura Representative Director, President and CEO
	Toru Kimura Representative Director, Executive Vice President
	Yoshiharu Ikeda Member, Board of Directors, Senior Executive Officer
	Naoki Noguchi Executive Officer, Senior Director, Corporate Communications

### Presentation

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**Noguchi:** We will begin the presentation of Sumitomo Pharma Co., Ltd.'s financial results for FY2022.

Thank you very much for joining us today. This presentation will be streamed live via Zoom from our Tokyo Head Office. After the presentation, there will be time for a Q&A session.

Let me now introduce today's attendees. Mr. Nomura, President and CEO; Dr. Kimura, Representative Director and Executive Vice President; Dr. Ikeda, Director and Senior Executive Officer. I am Noguchi, and I will serve as moderator today. Thank you.

Now, Mr. Nomura will present the financial results for FY2022. Mr. Nomura, please go ahead.

Financial Results for FY2022

**Financial Results for FY2022 (Core Basis)**

	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



**Nomura:** Good afternoon. Thank you for taking time out of your busy schedule to attend our financial results meeting today. As time is limited, I will try to concisely explain.

First of all, the actual results are exactly the same as the forecast that we already announced at the end of April 2023. Therefore, I will omit a detailed explanation, but core operating profit has fallen significantly from JPY34 billion to JPY16.4 billion compared to the forecast as of the end of January, which was originally forecasted.

This is partly due to LATUDA®'s gross profit, which decreased significantly when it reached LOE. Another factor is higher shift in the payer mix than forecasted leading toward lower product prices, as well as lower sales by volume than forecasted. Unfortunately, we were not able to achieve our goal of JPY34 billion in core operating profit due to a slight increase in expenses.

Other non-recurring items, minus JPY62 billion. This includes an impairment loss on assets such as KYNMOBI®. The impairment loss of goodwill of oncology area and compound TP-0903 has also had an impact, as well as restructuring expenses in North America.

As a result, operating profit is minus JPY77 billion. In the area of financial income and costs, there was a foreign exchange gain of more than JPY26 billion.

On the other hand, income tax expenses, which is a large amount due to profit in Japan, resulted in a net profit for the period of minus JPY96.7 billion. Net profit attributable to owners of the parent was minus JPY74.5 billion.

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)

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- 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

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Regarding sales in Japan, there is a year-over-year decrease of JPY23.8 billion, as you can see on the right side of the slide. This was due to the loss of sales of REPLAGAL<sup>®</sup> and the termination of sales collaboration of Trulicity<sup>®</sup> in December 2022.

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>

**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

\* 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

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

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As for sales in North America, unfortunately, LATUDA® sales were lower than the previous year, even in dollar basis. The third one from the top, the RETHYMIC®, in 12 patients, has permitted surgery. I hope that we can make progress so that patients will not have to wait for surgery.

Then for ORGOVYX®, MYFEMBREE®, and GEMTESA®, naturally, there was an increase over the previous year. Regarding ORGOVYX®, while we haven't attained sales of 20% our original forecast, in terms of the payer mix, Medicare Part D accounted for a large percentage of the total sales. There are not many cases of office dispensing for tablets, and considering issues such as the handling of health insurance, or supplier authorization, there are some doctor's offices not well versed in that. As a result, it has not gone as smoothly as we would have liked.

In the case of MYFEMBREE®, use of the Co-pay Card was greater than we had forecasted, which led to a decrease in the average price. One positive point to note is that MYFEMBREE® gained the indication of endometriosis during the period.

GEMTESA® is doing very well, and sales have already increased more than we originally forecasted.

## 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)	

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- **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

I will now present results by segment. The most notable feature is that selling, general and administrative expenses in North America have increased significantly. Most of the increase is due to expenses in the Sumitovant Group, while some is due to exchange rate fluctuations. Another factor behind the increase is costs associated with Myovant Sciences Ltd. becoming 100% owned by Sumitovant Biopharma Ltd.

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

I have prepared specific data on ORGOVYX®, MYFEMBREE® and GEMTESA®, but I won't spend much time on them. I can tell you that the number of patients is steadily increasing. The other two are the number of prescriptions, but this one is in the form of estimated number of patients, as it is difficult to tell the number of prescriptions, as it also includes office dispensing.

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, ORILISSA, 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

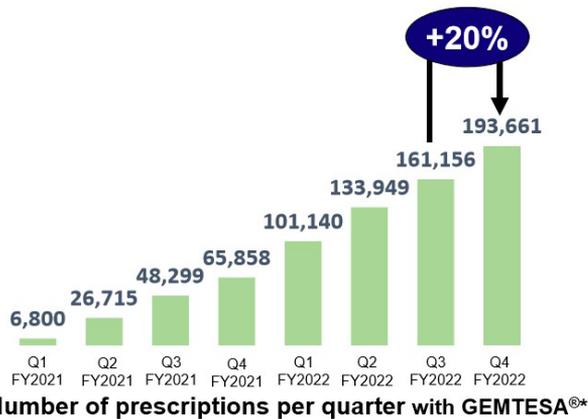
As you can see, the figure for MYFEMBREE® is increasing steadily. The market is also expanding. The key point of this MYFEMBREE® is that the right-hand side of the slide is an appeal for further potential utility by gathering new evidence. We will submit this long-term endometriosis administration safety data with the FDA in Q1 FY2023. We are very interested in how it will be handled.

The verification of contraceptive efficacy is currently being studied, with last patient out expected in April 2025.

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)



- 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

Performance of GEMTESA® is also solid. The middle of the slide on the right shows insurance coverage, which previously accounted for 55% of the commercial coverage. The figure is now over 70%.

Below that, we expect to know the results of the Phase 3 study for overactive bladder associated with benign prostatic hyperplasia in H1 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)
Core operating profit	16.4	(62.0)	(78.4)	2.3	—
Non-recurring item (negative number indicates loss)	(93.3)	(16.0)	77.3		
Operating profit	(77.0)	(78.0)	(1.0)		1.3
Income tax expenses	48.8	(1.0)	(49.8)		
Net profit	(96.7)	(80.0)	16.7		
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

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Next, I will present the forecast. We have already explained the financial forecast up to the point of core operating profit when presenting the Mid-term Business Plan (MTBP) 2027. Today, I would like to explain the core operating profit results in a little more detail. I will also give a breakdown of the JPY362 billion figure for sales.

SG&A expenses are forecasted to decrease significantly to the JPY220 billion level and R&D expenses to the JPY84 billion level.

The minus JPY16 billion in non-recurring items is mainly due to the costs associated with employees who will leave the North American subsidiaries or retention expenses for employees in FY2023 as a result of the combination in North America.

The loss is JPY80 billion, which is the amount of net profit attributable to owners of the parent.

## 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
					(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
					(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)
					(57.4)	(21.0)	(78.4)	

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- **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

As for the financial forecast by segment, I will show you the sales goals later on, but in North America there has been a decrease in SG&A expenses of JPY73.6 billion. This is due to the decrease in sales reps at Sunovion Pharmaceuticals Inc. as a result of the LATUDA® LOE, as well as a reduction in the number of SG&A personnel. An additional reduction of personnel related to the combination in North America is scheduled for FY2023, so related expenses will be reduced in comparison to the previous year.

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)

This equates to a decrease in sales of JPY21.1 billion compared to the previous year, which means that the impact of Trulicity<sup>®</sup> is significant. The impact of the NHI price revision is also noted at the bottom right of this page.

## 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	FY2023
Deferred revenue from the collaboration with Pfizer of \$138M	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

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ORGOVYX® sales in North America, in dollar basis, were USD396 million, MYFEMBREE® USD192 million, and GEMTESA® USD362 million.

Looking at the results from the previous year, we are forecasting that the goal for ORGOVYX® will double, MYFEMBREE® will increase by a factor of five, and GEMTESA® will also double. For example, if calculating this based on shipments at the end of March 2023, and if the March shipment pace continues for 12 months, there will not be much difference in GEMTESA®. The goal for ORGOVYX® will be a little less challenging, although not as much as double. The goal for MYFEMBREE® is still a challenge, but we will have to see how much it grows after this fiscal year.

From my point of view, these numbers could be a bit of a stretch for MYFEMBREE®, but I don't think it would be that difficult to say about ORGOVYX® and GEMTESA®.

With LATUDA®, of course, LOE means a large decrease. The decrease in other areas is due to the one-time payment for endometriosis from Pfizer Inc. in the previous year, licensing, and the loss of sales of BROVANA® and XOPENEX®. The result was a negative figure of about USD100 million.

In China, there has been a significant decrease in MEROPEN® sales. This is due to the impact of volume-based procurement.

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

\*Phase 2/3 study

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Next, I will talk about research and development.

In research and development, we have classified areas on Psychiatry & Neurology, Oncology, Others, Regenerative Medicine/Cell Therapy, and Frontier business. As I explained in the meeting for the MTBP 2027, we have reorganized the categories a little, so that the Regenerative medicine/cell therapy field is now included in the Psychiatry & Neurology area. The Frontier business is also included in the Psychiatry & Neurology area, now being the area as a modality.

The areas shown here in red are the changed portions.

## 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

This shows progress in clinical development.

## **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

As for ulotaront, I believe Otsuka Pharmaceutical Co., Ltd. has already explained it, so I will omit the explanation here as well.

We have high expectations for the results of the DIAMOND 1 and 2 studies for schizophrenia in H1 of fiscal year 2023. We hope to submit the applications as soon as possible so that they can be placed on the market, pending regulatory review and decision.

Research and Development

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

<b>Psychiatry &amp; Neurology</b>	<ul style="list-style-type: none"><li>❑ ulotaront : ❑ Obtain results from two Phase 3 studies for schizophrenia ( ❑ DIAMOND 1 ❑ DIAMOND 2 ) (SEP-363856) ❑ Submit NDA for schizophrenia in the U.S.</li><li>❑ Advance Phase 2/3 study in Japan and China for schizophrenia</li><li>❑ Advance Phase 2/3 studies for two additional indications (aMDD, GAD)</li><li>❑ SEP-4199: Advance Phase 3 studies for Bipolar I depression</li><li>❑ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear) : Start clinical study in Japan</li><li>❑ Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S.</li><li>❑ Complete manufacturing plant in the U.S. (for RETHYMIC® and allogeneic iPS cell-derived products)</li></ul>
<b>Oncology</b>	<ul style="list-style-type: none"><li>❑ Advance early Phase studies</li></ul>
<b>Others</b>	<ul style="list-style-type: none"><li>❑ relugolix: Obtain approval for endometriosis in Europe</li><li>❑ vibegron: Obtain results from Phase 3 study and submit sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S.</li><li>❑ rodatristat ethyl: Obtain results from Phase 2 study for pulmonary arterial hypertension (PAH)</li><li>❑ universal influenza vaccine, malaria vaccines : Promote joint research and development projects</li></ul>
<b>Frontier</b>	<ul style="list-style-type: none"><li>❑ Launch product: (Japan) Automated blood collection/stabilization device</li><li>❑ Promoting the current themes and generating evidence data for maximizing the value of the launched products</li></ul>

This is the last slide in my explanation, and I would like to talk about the main events. I have just mentioned ulotaront for schizophrenia. In the Psychiatry & Neurology area, we are planning to submit an IND of clinical study for retinal pigment epithelium tear using iPS cells in Japan in May, and to start an investigator-initiated study for Parkinson's disease in the US in June. We hope to move forward with a clinical study in the US by the end of this fiscal year.

That is all from me.

**Noguchi:** Thank you very much, Mr. Nomura.

## Question & Answer

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**Noguchi:** I would now like to move on to the question-and-answer session.

**Muraoka, Morgan Stanley MUFG Securities:** I was going to ask you if, in your product-specific forecasts, the figures for ORGOVYX® and MYFEMBREE® in particular might not be a little too high. However, you said they are supposed to be challenging, so I think that's what you mean.

For example, if you fall short of your sales plan of USD396 million and USD192 million by, say, 20% or 30%, I am sorry to be a little blunt, but in that case, the patent rights shown on the balance sheet at the end of March, 2023 which are for these two products, amount to a little over JPY200 billion. Would it be correct to assume that if you fail to achieve sales by a margin of about 20%, an impairment loss would be incurred?

**Nomura:** Thank you for your question. As far as MYFEMBREE® is concerned, I think there is a possibility of a certain amount of impairment by a little less than the amount written here. I don't know if the figure is 20% or not, but it could be a certain amount of impairment.

**Muraoka, Morgan Stanley MUFG Securities:** Should we worry too much about ORGOVYX®?

**Nomura:** I am not too worried about ORGOVYX®.

**Muraoka, Morgan Stanley MUFG Securities:** Understood. I could tell because the intangible amount of goodwill is also by far the most for MYFEMBREE®. I guess the timing of this guidance will change when this guidance needs to be changed appropriately as quarter of the year goes on.

**Nomura:** Yes, that's right. I am sure that you are very interested in the sales of these three products, and us even more so. We will continue to monitor them very closely.

During this one-year period, we will take various marketing measures, including those that we have not been able to do in the past.

**Muraoka, Morgan Stanley MUFG Securities:** I'm sorry to be so hypothetical, but if those sales were to fall short, is there any option to reduce the impact on core operating profit by further cutting costs elsewhere? Or would it be a case of covering it with sale of assets?

**Nomura:** We will monitor FY2023 closely. At the end of Q2 or Q3, for example, we will be able to see whether or not we can achieve this goal. As I mentioned in the MTBP 2027, we will consider what we can do to achieve a surplus in FY2024 rather than FY2023, and we will come up with additional plans.

**Muraoka, Morgan Stanley MUFG Securities:** I see. Rather than focusing on this fiscal year's numbers, you will take steps in H2 of this fiscal year to contribute to profitability in the next fiscal year, if necessary.

**Nomura:** Of course, we are focused on the figures for the current fiscal year, but we would like to avoid two consecutive years of deficits, so we will do what we can in FY2024 within FY2023. If the situation becomes as bad as you just mentioned, we will consider what we can do.

**Muraoka, Morgan Stanley MUFG Securities:** Understood. Sorry. This is an extension of the same question, but if these two products are insufficient this fiscal year, is there any need to think that this will lead to the risk of reducing or not receiving the milestone that is a major prerequisite to achieving profitability next fiscal year?

**Nomura:** This is, of course, because these are the figures that are assumed for sales in FY2024. We do not expect to be suddenly hitting this goal in FY2024, so we will continue to make steady growth from FY2023.

However, as I mentioned earlier, this forecast is very much double the result numbers from last year, both ORGOVYX® and GEMTESA® appear to be doubling, but the trend is gradually growing. So, I'm not sure if the March 2023 shipments, for example, reflect the normal trend, but if you look at it that way, it's not that big of a gap. Considering that sales of these products are going to grow, I don't think it will be that difficult to achieve for ORGOVYX® and GEMTESA®. However, I would say for MYFEMBREE®, I still think it is a stretch.

One of the reasons for this is that awareness among patients and doctors is still relatively low. We are trying to raise awareness about MYFEMBREE® as a treatment for uterine fibroids and endometriosis among patients through various media, including TV commercials.

**Yamaguchi, Citigroup Global Markets Japan:** As you explained earlier, the forecast costs in North America for the fiscal year ending March 31, 2024 were reduced by about JPY70 billion. The figure was JPY73.6 billion. Can you please give a breakdown of that figure?

**Nomura:** What do you mean by breakdown?

**Yamaguchi, Citigroup Global Markets Japan:** In short, what does this decrease of JPY73.6 billion represent? I wonder if your company's LATUDA®-related MRs are decreasing, or if there was some kind of synergy.

**Nomura:** It's not just LATUDA®'s sales staff that is being reduced, but SG&A staff is also being reduced at the same time. And we are also reducing personnel in North America. Therefore, when all of these items are added together, the decrease on an individual company basis would be a little over JPY60 billion. The rest is made up of things like reduced amortization of patent rights.

So, this is mostly made up of cost reductions through reductions in staffing. If you compare, for example, the end of March 2022 in North America with the end of this combination in the end of March 2024, there will be roughly 1,000 fewer people.

However, just the first LATUDA® and SG&A alone have already reduced by just under 500 people. The remaining 500 or so will be reduced gradually during FY2023. By the end of next March, most of the planned 500 or so people will have already left.

**Yamaguchi, Citigroup Global Markets Japan:** I see. However, if 1,000 employees quit and the cost in the US is about JPY30 million/employee, the actual cost is much larger than JPY30 billion. It seems to me that at JPY60 billion, the bulk of this JPY73 billion can be explained by a reduction in headcount.

**Nomura:** There is the cost of labor plus the cost of various activities that are carried out by these employees. As a result, there are also decreases in other areas. It is a mistake to say that in North America, unlike in Japan, it is quite easy to lay off personnel. The reality is that it is quite difficult and involves a considerable amount of cost.

However, the effects will be seen in the future, and we will make sure to discuss them.

**Yamaguchi, Citigroup Global Markets Japan:** Understood. Conversely, from the current fiscal year to the next fiscal year, I think that the profit recovery will be driven by the growth of three products, as you mentioned earlier. Comparing the current and next fiscal year, would it be correct to say that the current year has the biggest reduction in personnel costs, and that the benefits of synergies will come about next year and beyond, or sometime in the near future?

**Nomura:** Could you be more specific about what you mean by "synergies?"

**Yamaguchi, Citigroup Global Markets Japan:** Synergies that will be achieved by group integration, by reducing the number of companies. Are the benefits of that already included in the results for this fiscal year?

**Nomura:** It is included to some extent in this fiscal year, but I think we will see the full effect from FY2024.

**Yamaguchi, Citigroup Global Markets Japan:** I see, I understand. I understand that the current forecast for MYFEMBREE® is in place, but I have the feeling that the original plan is still running, although I am not sure of how realistic it is. I feel that it would be more reassuring externally if you made some revisions to the MTBP 2027, but I guess you have decided that it is not the right time yet.

**Nomura:** Regarding ORGOVYX® and MYFEMBREE®, I don't think that we have done enough compared to GEMTESA®. GEMTESA®, with Urovant Sciences, Inc., was made it 100% subsidiary. We have a history of achieving a stretched goal with marketing reflects our intention.

However, as for Myovant, until March 2023, in essence, as a publicly traded company, they have been working with a view to minority shareholders, not us. Moreover, they are not sharing marketing data with us. Some others do, though. Therefore, in many ways, we were not able to provide support for marketing activities.

Of course, we do not have the know-how in itself, but the Sumitovant staff in the US have a great deal of know-how in this area, so I think the first step would be to do ORGOVYX® and MYFEMBREE® utilizing their strength. We will examine our future measure based on the results, or rather the outcome, to some extent. At this stage, I think it is still too early for us to make a decision on what we think is right or wrong.

**Wakao, JPMorgan Securities Japan:** The first question is a continuation of what you just said about MYFEMBREE®.

I understand the forecast is stretch, but I was just curious about the premise of this forecast. Even if we simply look at the growth of prescriptions in the quarter you just showed us, and the volume grew by 1.3 times for every quarter in FY2023, the volume itself would only increase by about two times. On the other hand, there was the use of Co-pay Card last year and new applications will be made in Q1 FY2023, so I think there are some positive factors. Please tell us the assumptions for this forecast, such as how much the volume is assumed and what the price is, and at what timing the volume will grow in each quarter.

In addition, I think Pfizer was working with you on MYFEMBREE®. Can you also tell me how Pfizer has positioned it? This is the first question.

**Nomura:** I can't give you detailed figures, but at least in the previous fiscal year, for example, we thought the use of Co-pay Card was about 30%, but it was about 50%. We will need to monitor the situation closely.

We are concerned about the market growth of gonadotropins in this class, since we have heard that AbbVie Inc. has not been focusing much on this area recently.

However, comparing the start and the end of the previous fiscal year, I feel that the momentum became very strong in the direction of MYFEMBREE® being prescribed for uterine fibroids and endometriosis. As I mentioned earlier, we will also include TV commercials to raise awareness of the product.

Also, while this will take some time, in Q1 FY2023 we intend to submit an sNDA for endometriosis long-term safety data to the FDA. One of the key points will be how that will be described in the label.

Pfizer is also doing a good job with both ORGOVYX® and MYFEMBREE®. However, I understand that up until now, Myovant has not been able to make sufficient requests to Pfizer, partly because Myovant is the company that has been doing the work.

After the combination, we will have Ms. Adele Gulfo, a former Pfizer executive, who will be working more closely with Pfizer. She will provide a communications channel for us with those on the Pfizer side, helping to communicate our viewpoint to them and facilitate our work together.

I believe that there are still areas that we can approach with Pfizer's resources, such as relationships with various patient groups and KOLs, and we are planning to do so under a new leader.

**Wakao, JPMorgan Securities Japan:** Thank you very much. Regarding ulotaront, I think there is readout data for schizophrenia, and I have some level of expectation for that.

Since the indication is schizophrenia, I think the Company has told us from LATUDA® that the scale of sales for the first indication is not that large.

So, I was thinking that in the US, sales for the indication of schizophrenia would be about USD300 million, is that correct? I would like to confirm that.

**Nomura:** Opinion about LATUDA® was divided. As you say, a lot of people felt that sales would only attain a certain level if it was just schizophrenia. However, as you know, ulotaront is not a D<sub>2</sub> receptor antagonist, unlike conventional anti-psychotics, so the side effect profile is different in many ways.

We believe it is very easy to use for patients. We believe that it will perform strongly on the market thanks to its novel mechanism of action.

In general, schizophrenia is covered by Medicaid, so the product price is low, but from our point of view, this is a different class of product. We expect that prescribing will be different from that of conventional schizophrenia products.

**Wakao, JPMorgan Securities Japan:** Understood. In the image of the MTBP 2027, the contribution of the first new product to sales was not so large. However, from your explanation of ulotaront, I think it has potential, depending on the data that comes out, so I have high expectations for it. Thank you.

**Nomura:** Thank you. As you said, the data that will come out will be very important. We have high expectations for the results of the DIAMOND 1 and 2 studies.

**Haruta, Credit Suisse Securities (Japan):** You will reduce SG&A expenses for the fiscal year ending March 2024. How much of this reduction can be considered optimization in the US, or a lean state, and how much will be spent and how many people will be hired for ulotaront's launch in FY2024?

**Nomura:** Thank you. Regarding ulotaront, it would have been better if the LATUDA® sales reps could have been used as is, but there is a time lag. Some of LATUDA®'s excellent sales reps are handling some of other products, although they are a bit different.

If ulotaront is approved in FY2024, we are likely to hire new sales reps at that time. The scale of the project is included in the MTBP 2027, but we have not yet had a full discussion with Otsuka Pharmaceutical, so I cannot give any specifics. We would like to have about the same number of sales reps as we had for LATUDA®, about 300.

**Haruta, Credit Suisse Securities (Japan):** I'm sorry. Incidentally, in terms of something like optimization before the ulotaront launch of personnel in the US, should we expect that to be completed during the fiscal year ending March 2024?

**Nomura:** If we talk about optimization, the optimization will be completed in the period from this April to the end of March next year.

**Ishii, Iyakutsushin:** I would like to ask about the distribution status of TWYMEEG®.

**Nomura:** We are very concerned about the current situation regarding TWYMEEG®, and are currently proceeding with limited shipments. Currently, we are preparing to increase production of APIs, formulations, and packaging. We are now working diligently to see if we will be able to normalize the situation by summer.

The sales goal for this year is JPY4.2 billion. We have had a great deal of interest from clinicians. As a result, you can imagine how disappointed we are about the shipping issues. We are addressing the limited shipments, however, and we are doing all we can to increase production.

**Ishii, Iyakutsushin:** Thank you. This is a bit of a tangent to my earlier question, but what is the forecast for the number of sales reps and other personnel in the US going forward?

**Nomura:** Is that for this fiscal year?

**Ishii, Iyakutsushin:** Can you give us an estimate of how the number of sales reps and other personnel will change, both in this fiscal year and a bit further into the future?

**Nomura:** For the time being, I think that by the end of March 2024, we will have about 1,800 employees in North America. The head count will increase again with the approval of ulotaront.

However, unlike LATUDA®, ulotaront is a 50-50 profit share with Otsuka Pharmaceutical, so we have to manage the costs. Even if we increase the number of employees to some extent, we will not be able to get a sufficient return on our investment in ulotaront unless we manage our SG&A expenses well.

**Takahashi, Nikkei Biotechnology & Business:** I have two main questions.

DSP-2342, which is starting Phase 1 study, is a compound that utilizes Exscientia Ltd.'s AI technology. I would like to confirm that there are two compounds using Exscientia's AI technology that have entered clinical studies. Also, I believe DSP-1181, which was also created using AI, was discontinued because it did not achieve the evaluation criteria in the Phase 1 study. The first point is that we would like to know if you have made any improvements in the creation of this compound after the previous discontinuation. Thank you.

**Ikeda:** First of all, we have DSP-2342, which has entered the Phase 1 study. As you mentioned, this is developed with Exscientia with AI, just at the point of finding the first compound. We also have DSP-0038 as the second joint research with Exscientia and DSP-2342 is the third compound with Exscientia.

DSP-1181 has a completely different target. DSP-1181 did not achieve the criteria for the Phase 1 study based on that target mechanism.

The mechanism of DSP-2342 is completely different. I believe it was mentioned in the Supplementary Financial Data, but it is a serotonin system. We will make a decision based on the results of the Phase 1 study.

**Takahashi, Nikkei Biotechnology & Business:** Thank you. Second, I would like to ask about the timing of the start of a clinical study in Japan for allogeneic iPS cell-derived dopamine neural progenitor cells for Parkinson's disease.

Since the target is to launch the product in fiscal year 2024, I am wondering if the clinical study in Japan is about to start. Today, since the development timing was announced earlier in the US, please tell us specifically, first of all, the current status of the investigator-initiated clinical studies and when you expect the clinical study to start in Japan. Thank you.

**Kimura:** First of all, we are not currently considering a clinical study in Japan for Parkinson's disease. We will apply with the results of the investigator-initiated study. After that, we expect that the product will probably be approved with conditional and time-limited approval. We plan to conduct post-marketing clinical study in consultation with the PMDA.

In this sense, our plan is that the follow-up period for the last patient will be over by the end of this year, and we will then prepare and submit an application.

**Misumi, Nikkei:** This overlaps a bit with a previous question, but I think that the MYFEMBREE® forecast for FY2023 would indicate the expectation of a significant increase in earnings.

A while ago, at the end of March 2023, you mentioned that the momentum for various prescriptions was getting stronger. Are you forecasting this level of sales growth at this point, or are you saying that given the promotion activities you are doing, this level of sales growth is very much achievable?

**Nomura:** Thank you for your question. This is due to the fact that we have made various demand forecasts during the last fiscal year as we considered the possibility of Myovant becoming 100% owned by Sumitovant. In this context, we have set a certain goal of sales that we believe is possible. Of course, I know it is a stretch, but that is the way it came out.

However, as I mentioned earlier, we are still aiming to increase awareness among doctors and patients through TV commercials and various other media. Recently, there has been a lot of connectivity, or rather, a variety of media. We are also using social media to increase patient or doctor awareness in this product.

Especially now, oral contraceptives are being used, including off-label, for uterine fibroids and endometriosis. We are trying to promote appropriate treatment to patients and obstetricians and gynecologists. It will be a challenge to achieve 100% sales, but we believe that we will be able to reach a point close to that level.

As I mentioned earlier about the use of the Co-pay Card, although it is covered by insurance, it is still a burden for patients, and it is very difficult for them to bear. We are trying to increase the number of patients who can use MYFEMBREE® as much as possible, while still allowing a certain amount of Co-pay Card use.

**Misumi, Nikkei:** Thank you. Sorry. One more point: I assume that the president or board members have decided to return remuneration in light of the recent business situation. Hypothetically, and I am very sorry to say this is also hypothetical, but if you are unable to turn a profit in FY2024, is there any possibility of returning additional remuneration or announcing any additional such measures?

**Nomura:** The reduction in remuneration this time was done in such a way as to bring some degree of management closure to the situation that has already occurred. Therefore, as for the current fiscal year, you mentioned that it is still hypothetical, but we will make a rational decision based on the outcome of the discussion.

I cannot say at this stage how much we will reduce the amount again, but I think it is necessary to convey that message in various ways. This will be considered separately.

I believe Dr. Kimura would like to say a few words in response to your previous question.

**Kimura:** I would like to add one more thing about whether the current year's sales forecast of MYFEMBREE® could be seen as too bullish.

Last fiscal year, for MYFEMBREE®, our plan was to obtain an approval for endometriosis at the beginning of May, and we included that in our sales forecast for last fiscal year. However, there was a delay until August.

According to our calculations, two thirds of the reason that MYFEMBREE® did not achieve its goal was insufficient sales volume. It is my understanding that much of the delay in getting those numbers out can be explained by the delay in getting the endometriosis indication to market. We are in the process of promoting MYFEMBREE® for both endometriosis and uterine fibroids, and we are confident that we can make up a lot of the ground that we didn't manage to cover last fiscal year.

We have mentioned this a few times, but there is the Co-pay Card system in the US, in which the price actually paid by patients is lower than forecasted and we make up for it. The number of patients purchasing through this Co-pay Card system is higher than we had forecasted, and we are working to make up for this. We are doing this through promotional activities, and from April onward, we have been reviewing our structures.

**Tsubokura, The Chemical Daily:** I believe there have been some changes in the list of development pipeline, but I would like to ask President Nomura about the three compounds listed in red, DSP-2342, SP-101, and the GEMTESA® clinical study in China, if possible.

**Noguchi:** I guess my question is, what are our expectations for each of the compounds?

**Tsubokura, The Chemical Daily:** Yes. I would appreciate any comments you might have.

**Noguchi:** You mean comments on that added compounds.

**Tsubokura, The Chemical Daily:** Yes.

**Ikeda:** DSP-2342 is a serotonin 2A and 7 receptor antagonist.

In a nutshell, it is like taking antagonist action to dopamine D<sub>2</sub> receptor from LATUDA®, and in that sense, as written here, we can expect various effects such as antidepressant, anxiolytic, antipsychotic, cognitive function improvement, and sleep-improving effects.

We will continue to monitor the safety and tolerability of the compound during the Phase 1 study. Since we have many compounds under development in this area, we would like to select those that will be the largest or can be developed most quickly in the future, based on the applicable diseases and other factors.

Then there is SP-101, which is for cystic fibrosis. Sumitovant was originally developing for this ultra-orphan disease.

Although there are products that have been used as symptomatic treatments, there is no disease-modifying products that can cure or improve the disease. I believe that gene therapy may be able to fundamentally improve this situation.

However, this is a gene therapy using an adeno-associated virus vector. We have submitted an application to the FDA and an IND was filed by the FDA, and we will proceed with an appropriate clinical study plan in consultation with the FDA.

However, since this is forecasted to have effects not seen in existing products, we believe it has great potential.

GEMTESA® is already in China as vibegron, and is being sold in Japan and the US, so we aim to obtain an approval for GEMTESA® in China and increase sales. Does that answer your question?

**Tsubokura, The Chemical Daily:** Thank you. I'm sorry, but I would like to check that SP-101 is the only gene therapy compound currently in clinical development at your Company, is that correct? I believe URO-902 was also a gene therapy compound, although this one has also been discontinued for in-house development.

**Ikeda:** As you pointed out, we have stopped developing our own URO-902 and are now looking for a licensee. Currently, we understand that SP-101 is one of the agents that are ongoing in the Phase 1 study.

**Yoshida, The Yomiuri Shimbun:** I'm sorry if this is a repeat question, but I think there have been a number of cases recently where the potential of a product has been lower than forecasted when it is in-licensed. It may not be in-licensed for some time in the future, but do you have any plans to review the evaluation of products in order to assess their potential?

**Nomura:** Thank you for your question. Regarding lower-than-forecasted sales at in-licensed, we could talk about KYNMOBI® or LONHALA® MAGNAIR®.

**Yoshida, The Yomiuri Shimbun:** Yes.

**Nomura:** Of course, I believe that we have made the right decisions in terms of in-licensing each of them, obtaining approval, and launching them on the market. From the point of view of hindsight, I would like to say that there are times when I wish I had done it later, but when it comes to LONHALA® MAGNAIR®, the device is a very important point.

In short, the product itself is an existing product, but the vibration of the nebulizer creates a very fine mist that goes deep into the lungs, and the delivery is very good. However, this was originally on Medicare Part B, which means that we were thinking of reimbursement, and we also developed on that basis.

But if we were to make it Medicare Part B, the durability of the device itself would have to be three years. The device itself is not ours, but is provided by another company, which manufactures nebulizers, so we have been working with them with the knowledge that they are well versed in this area.

It was later discovered that the lifespan of the diaphragm, which produces a fine mist, was not that long, so it is not covered by Medicare Part B reimbursement. Under Medicare Part B, a patient only has to pay for the product, which is a very light burden.

In the end, we were unable to obtain durability status, so the device was placed under Medicare Part D. In that sense, the burden on the patient would have increased, and this probably would not have happened if the device had been initially placed under Medicare Part B.

Another thing I would like to mention is KYNMOBI®, which is a type of treatment for off-symptoms with Parkinson's disease. When we looked at the results of the Phase 2 study, there were no side effects, such as mouth ulcers, but when we started our own clinical study after conducting our due diligence, we found that such side effects appeared.

So, even though we did not find such a problem when we looked at the due diligence the Phase 2 study data, it did appear when we actually increased the number of patients. This made it difficult to use clinically.

In both of those cases, the best decisions were made at the time of each in-licensed, but later on, device issues came up, or side effects came up in the clinical study, so it is not always easy to succeed commercially.

Therefore, in in-licensing products and devices in new areas, we have to make a comprehensive judgment based on a thorough understanding of the possibilities and problems from various perspectives. I think we have no choice but to repeat this process.

The issues that LONHALA® MAGNAIR® and KYNMOBI® are facing are specific to each agent, so I don't think they are applicable here, or to what we are going to in-license in the future.

Therefore, I understand that the first step for us will be to carefully assess where these issues lie, and to cultivate an eye for them.

**Ishii, Iyakutsushin:** Second question, sorry. Regarding TWYMEEG®, given what was discussed earlier, why is it likely that the sales forecast of JPY4.2 billion will be exceeded?

**Nomura:** That is a very difficult question. We have created this situation, and we are not sure how it is viewed by healthcare professionals. We will work to get back to where we were, explain the situation to them and gain their understanding, and then encourage them to use TWYMEEG® again.

We are not concerned about sales, but rather about ensuring that our new "mode of action" product is used to patients who are well suited for TWYMEEG®. Therefore, I think it is more important for us to restore the trust of our customers rather than sales, so that we can fulfill our responsibility to supply the product.

**Kuriyama, Yakuji Nippo:** I would like to ask you a few questions in light of what you have said so far.

You mentioned that you are aiming to return to profitability in FY2024. Can you tell us what requirements you are focusing on to achieve a surplus in FY2024, or, conversely, what are your concerns about the factors that are preventing you from achieving a surplus?

**Nomura:** Thank you. First of all, since this is something that can be done under our control, the first thing we must do is to decisively reduce costs. As some of you have asked, the first priority is to create a situation where given cost reductions are possible by the end of March next year.

We will also make efforts in this direction to boost the top line. These two are the major themes of this year.

We will monitor the progress of the project and take necessary measures in a timely manner.

**Kuriyama, Yakuji Nippo:** I'm sorry. What are some of the concerns that are preventing a turnaround?

**Nomura:** The factors preventing us from turning a profit are the opposite: sales are not what we forecasted. In the case of ORGOVYX®, there are medical institutions that are not familiar with the procedures for insurance reimbursement, and so on. It is a challenge to see how much we can gain ground in such institutions.

As for MYFEMBREE®, if the Co-pay Card is used more than we expect, the top line will be reduced by that amount. I think this may be a significant obstacle.

**Noguchi:** This concludes the presentation of Sumitomo Pharma's financial results for fiscal year 2022. Thank you very much for joining us today.

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