

# Sumitomo Pharma Co., Ltd.

## Transcript Q1 FY2022 Conference Call

<b>[Date]</b>	July 29, 2022	
<b>[Time]</b>	17:00 – 17:35	
	(Total: 35 minutes, Presentation: 10 minutes, Q&A: 25 minutes)	
<b>[Venue]</b>	Conference call	
<b>[Number of Speakers]</b>	4	
	Toru Kimura	Representative Director, Executive Vice President
	Yoshiharu Ikeda	Member, Board of Directors, Senior Executive Officer
	Hisayoshi Kashima	Senior Director, Finance & Accounting
	Yusuke Mori	Corporate Communications

### Disclaimer:

This is a summary of the Q1 FY2022 call and clarifies certain information provided. Myovant Sciences Ltd. (“Myovant”) is listed on the New York Stock Exchange, and the Sumitomo Pharma Group holds approximately 52% of the outstanding shares of Myovant. ORGOVYX® (relugolix), MYFEMBREE® /RYEQO® (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com>.

# Presentation

**Mori:** This is Sumitomo Pharma. Thank you for taking time out of your busy schedule today to participate in our FY2022 Q1 conference call.

We would like to present our Q1 results and the current status of clinical development.

Joining us from the Company are Dr. Kimura, Representative Director and Executive Vice President; Dr. Ikeda, Senior Executive Officer; Mr. Kashima, Senior Director, Finance and Accounting; and myself, Mori, the moderator for today's session.

Today's presentation will be based on the presentation materials sent to you via e-mail, so you are welcome to follow along. The presentation materials are also available on our website.

After the presentation, there will be time for questions and answers. We would be happy to answer any questions you may have. Please note that today's conference call will be recorded and will be available on the web at a later date. Thank you.

First of all, Mr. Kashima will explain our Q1 results and the current status of clinical development. Mr. Kashima, over to you.

Financial Results for Q1 FY2022							Billions of yen	
<b>Financial Results for Q1 FY2022 (Core Basis)</b>							The forecasts are not revised	
	Q1YTD FY2021 Results	Q1YTD FY2022 Results	Change			FY2022		
			Value	FX impact	%	May 13 forecasts	%	
<b>Revenue</b>	131.2	<b>159.9</b>	28.7	16.4	21.9	550.0	29.1	
Cost of sales	38.5	<b>46.1</b>	7.6	4.0	19.7	164.5	28.0	
Gross profit	92.7	<b>113.8</b>	21.1	12.4	22.8	385.5	29.5	
SG&A expenses	62.0	<b>76.0</b>	14.1	9.2	22.7	283.5	26.8	
R&D expenses	22.4	<b>24.4</b>	2.0	2.9	8.9	93.0	26.3	
Other operating income/expenses	0.2	<b>0.0</b>	(0.2)	—	—	21.0	—	
<b>Core operating profit</b>	8.5	<b>13.4</b>	4.9	0.3	57.2	30.0	44.6	
Changes in fair value of contingent consideration (negative number indicates loss)	(0.1)	<b>(0.1)</b>	0.0			(0.5)		
Other non-recurring items (negative number indicates loss)	(0.1)	<b>1.3</b>	1.4			(5.5)		
<b>Operating profit</b>	8.3	<b>14.6</b>	6.3		75.9	24.0	60.9	
Finance income/costs	(0.3)	<b>32.0</b>	32.3					
Profit before taxes	8.0	<b>46.6</b>	38.7		485.8			
Income tax expenses	7.2	<b>18.5</b>	11.4					
Net profit	0.8	<b>28.1</b>	27.3		—			
<b>Net profit attributable to owners of the parent</b>	4.8	<b>31.1</b>	26.3		547.8	22.0	141.4	

(Ref.) Earnings related to Sumitovant		
Billions of yen		
	Q1 FY21	Q1 FY22
<b>Revenue</b>	<b>5.8</b>	<b>20.7</b>
SG&A expenses *	19.9	29.8
R&D expenses	5.9	7.1
<b>Core operating profit</b>	<b>(20.7)</b>	<b>(20.8)</b>
<b>Operating profit</b>	<b>(20.7)</b>	<b>(20.8)</b>
Net profit	(21.0)	(23.8)
<b>Net profit attributable to owners of the parent</b>	<b>(17.0)</b>	<b>(20.7)</b>

The figures include intra-group transaction  
\* Include amortization of patent rights

Average rates:  
Q1FY2021 Results : 1US\$ = ¥109.5, 1RMB = ¥17.0  
Q1FY2022 Results : 1US\$ = ¥129.7, 1RMB = ¥19.6  
FY2022 forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

Period end rates:  
As of the end of March 2022 : 1US\$ = ¥122.4, 1RMB = ¥19.3  
As of the end of June 2022 : 1US\$ = ¥136.6, 1RMB = ¥20.4

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**Kashima:** Thank you. Kashima here.

I would like to report on the Q1 results for FY2022 and the current status of clinical development.

Let's start with page three.

This slide shows a summary of our Q1 financial results. Figures are shown on a core IFRS basis.

Revenues totaled JPY159.9 billion, an increase of JPY28.7 billion from the same period last year. Sales in the Japan segment declined due to the impact of the NHI drug price revision and other factors. On the other hand, sales in the North America, China, and other regions segments increased due to the impact of foreign currency translation and the recording of one-time revenues.

Selling, general and administrative expenses and R&D expenses also increased due to the effect of foreign currency exchange. Core operating profit increased JPY4.9 billion year over year (YoY) to JPY13.4 billion, largely due to the increase in gross profit from higher sales.

Non-recurring items, such as changes in the fair value of conditional consideration, did not change significantly in the previous or current fiscal years. Operating profit increased YoY by JPY6.3 billion to JPY14.6 billion.

Income before tax increased YoY by JPY38.7 billion to JPY46.6 billion. This was due to a large foreign exchange gain resulting from the yen's depreciation at the end of the quarter.

As a result, income attributable to owners of the parent also increased significantly, rising JPY26.3 billion to JPY31.1 billion.

In terms of progress toward the full year forecast, although sales revenue and profit markers in Q1 have progressed slightly ahead of schedule, there has been no significant change from our assumptions. The full-year forecast has not been revised at this time. We maintain our exchange rate assumption of JPY125 to the dollar.

Financial Results for Q1 FY2022

## Revenue of Major Products in Japan

Billions of yen

	Q1 YTD FY2021 Results	Q1 YTD FY2022 Results	Change		FY2022	
			Value	%	May 13 forecasts	%
Equa®/EquMet®	9.8	<b>8.8</b>	△1.0	△10.4	34.9	25.2
Trulicity®*	8.8	<b>8.6</b>	△0.2	△2.2	31.0	27.8
TRERIEF®	4.3	<b>4.4</b>	0.1	2.7	17.3	25.6
LATUDA®	1.4	<b>2.3</b>	0.9	65.5	9.9	23.2
METGLUCO®	2.1	<b>2.0</b>	△0.1	△5.2	7.8	25.5
LONASEN® Tape	0.5	<b>0.7</b>	0.2	41.6	2.7	24.4
TWYMEEG®	—	<b>0.1</b>	0.1	—	1.5	6.9
AG products	2.4	<b>2.3</b>	△0.1	△4.4	9.7	23.9
Others	9.3	<b>4.5</b>	△4.9	△52.1	15.2	29.4
合計	38.7	<b>33.7</b>	△5.0	△12.9	130.0	25.9

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

- Progress is almost as forecasted in the segment total
- LATUDA® showing steady growth
- Prescription days limit of TWYMEEG® will be lifted in September 2022
- Sale of REPREGAL® included "Others" decreased (Q1 YTD FY2021: ¥3.5B)
- NHI price revision affected (¥3.2B) on Japan segment total

Page four shows sales revenue for the Japan segment.

Revenue decreased JPY5 billion from the same period last year to JPY33.7 billion.

Although sales of LATUDA® increased, overall segment sales declined due to the NHI price revision and the impact of the transfer of sales of REPLAGAL®. Progress against the full-year forecast was 25.9%, with progress as expected in the segment as a whole.

Financial Results for Q1 FY2022

**Revenue of Major Products in North America & China**

	Q1 YTD FY2021 Results	Q1 YTD FY2022 Results	Change	Q1 YTD FY2021 Results	Q1 YTD FY2022 Results	Change			FY2022		
						Value	FX Impact	%	May 13 forecasts		Yen-basis %
<b>North America</b>	Million \$			Billions of yen			Million \$	Billions of yen			
LATUDA®	469	482	13	51.4	62.5	11.1	9.7	21.7	1,726	215.8	29.0
APTIOM®	63	65	2	6.9	8.4	1.5	1.3	21.3	255	31.8	26.4
RETHYMIC®	—	5	5	—	0.7	0.7	0.1	—	48	6.0	11.8
BROVANA®	51	14	△37	5.6	1.8	△3.8	0.3	△68.6	26	3.2	54.7
KYNMOBI®	2	△0	△2	0.2	△0.0	△0.3	△0.0	△110.9	18	2.3	△1.1
ORGOVYX®	11	36	25	1.2	4.7	3.5	0.7	293.5	601	75.2	29.0
MYFEMBREE®	1	4	3	0.1	0.5	0.4	0.1	339.8			
GEMTESA®	7	34	27	0.8	4.4	3.6	0.7	454.4			
Others	48	94	47	5.2	12.2	7.0	1.9	135.2			
<b>Total</b>	<b>652</b>	<b>733</b>	<b>82</b>	<b>71.4</b>	<b>95.2</b>	<b>23.8</b>	<b>14.8</b>	<b>33.3</b>	<b>2,674</b>	<b>334.3</b>	<b>28.5</b>
<b>China</b>	Million RMB			Billions of yen			Million RMB	Billions of yen			
MEROPEN®	392	464	72	6.6	9.1	2.5	1.2	37.7	863	16.8	54.1
Others	111	129	19	1.9	2.5	0.6	0.3	31.9	553	10.8	23.5
<b>Total</b>	<b>503</b>	<b>594</b>	<b>91</b>	<b>8.5</b>	<b>11.6</b>	<b>3.1</b>	<b>1.6</b>	<b>36.4</b>	<b>1,416</b>	<b>27.6</b>	<b>42.1</b>

- **North America segment**  
Revenue increased due to the impact of fluctuations in FX rates and products of Sumitovant
- Sale of LATUDA® is in line with forecasts
- BROVANA® decreased due to loss of exclusivity in June 2021
- Revenue of \$50M from the license agreement for ORGOVYX® in EU is recorded in "Others"
- **China segment**  
MEROPEN® increased continuously

FX rates:  
Q1FY2021 Results : 1US\$ = ¥109.5, 1RMB = ¥17.0  
Q1FY2022 Results : 1US\$ = ¥129.7, 1RMB = ¥19.6  
FY2022 forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5



Page five shows revenue from the North America and China segments.

The North America segment reported sales of JPY95.2 billion on a yen basis, an increase of JPY23.8 billion from the same period last year.

Sales in LATUDA amounted to JPY62.5 billion, an increase of 21.7%. In dollar terms, revenues increased by USD13 million, or 2.7%. Although progress against the annual plan appears to be strong, we believe that progress is on schedule as we enter the loss of exclusivity (LOE) in the second half of the fiscal year.

Sales of BROVANA®, which had an exclusivity period that ended last June, declined by JPY3.8 billion.

In the Sumitovant-related business, sales of ORGOVYX®, MYFEMBEE®, and GEMTESA® combined totaled JPY9.6 billion, a YoY increase of JPY7.5 billion.

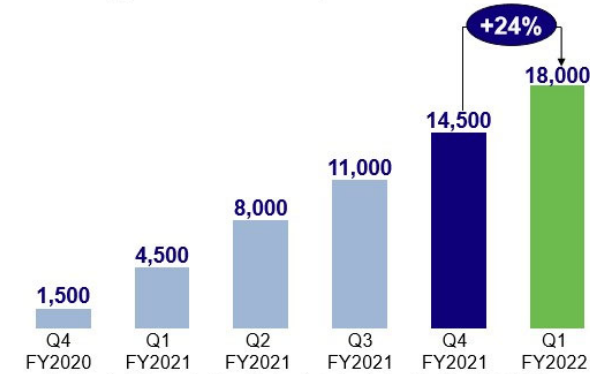
The upfront payment associated with Myovant’s exclusive license agreement with Accord Healthcare for the sale of ORGOVYX in Europe is included in the other segment.

In the China segment, MEROPEN® continued to grow, with sales of JPY11.6 billion, up 36.4%. Progress toward the full-year forecast is at 42.1%.

MEROPEN has been selected for Volume Based Procurement in 2022. This is expected to be implemented in October, a few months later than expected. The delay in implementation results in an upside to the FY2022 results compared with the forecast.

## Marketing Status of ORGOVYX®

- Obtained approx. 3,500 new patient starts in Q1 FY2022 (24% growth vs. Q4 FY2021)



**Estimated Cumulative Patients Treated with ORGOVYX®**  
(includes patients on free and commercial drug, excludes patients utilizing product samples)

- Prescribed approx. 18,000 patients since launch
- Prescribed approx. 80% of the total at Dispensing Clinics, Academic, etc.
- Secured broad payer coverage continues  
Commercial – 81% of lives  
Medicare Part D – 99% of lives

- 75% of patients pay less than \$60 out of pocket per month
- Gross to Net remains in the low-to-mid 40% range

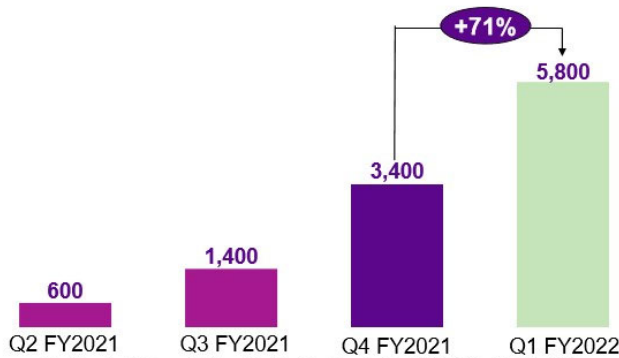
Page six presents the marketing status of ORGOVYX.

ORGOVYX has been prescribed to approximately 18,000 patients since its launch. Approximately 3,500 patients received the medicine in Q1 of FY2022. Approximately 80% of all prescriptions are dispensed at Dispensing Clinics and Academic. There is extensive coverage, with 81% commercial and 99% Medicare Part D.

Gross to net has been in the low-to-mid 40% range.

## Marketing Status of MYFEMBREE®

- Obtained approx. 2,400 new patient starts in Q1 FY2022 (71% growth vs. Q4 FY2021)



Estimated Cumulative Patients Treated with MYFEMBREE®  
(includes patients on free and commercial drug, excludes patients utilizing product samples)

- Prescribed approx. 5,800 patients since launch
- Achieved 2.8 times class growth in TRx for GnRH antagonists therapies for uterine fibroids since MYFEMBREE® launch
- Secured broad payer coverage continues Commercial – 94% of lives

- Obtained 51% total prescriptions (TRx) share and 57% new-to-brand prescription (NBRx) share among GnRH antagonists therapies for uterine fibroids in June 2022

- 75% of patients pay \$5 or less out of pocket per month

Page seven presents the marketing status of MYFEMBREE.

MYFEMBREE has been prescribed to approximately 5,800 patients since its launch, with approximately 2,400 patients receiving doses in Q1 of FY2022. The number of prescriptions for GnRH antagonist medicines for uterine fibroids has increased by a factor of approximately 2.8 times since the launch of MYFEMBREE. MYFEMBREE continues to have extensive coverage, with 94% of commercial insurers.

Prescriptions of MYFEMBREE are trending upwards, with a 51% share of total prescriptions and 57% share of new to brand prescription in GnRH antagonists for uterine fibroids in June 2022.

## Marketing Status of GEMTESA®

- Prescribed 38,100 TRx in June 2022 and ahead of our FY2022 forecast

	GEMTESA®	
	March 2022	June 2022
TRx Share in Beta 3	6.4%	9.3%
Monthly TRx numbers	26,145	38,100

- Coverage has not expanded since March 2022. Plan to secure most of peak coverage during FY2022

	GEMTESA®	
	March 2022	June 2022
All of commercial lives (Approx. 180 million)	55%	55%
All of Medicare Part D lives (Approx. 48 million)	30%	30%

- Entered into an exclusive license agreement with Pierre Fabre to commercialize vibegron in Europe (July 2022)  
Urovant to receive compensation of up to USD \$75 million including upfront payment, regulatory and sales milestones as well as royalties



Page eight summarizes the marketing status of GEMTESA and the licensing agreement signed in Europe.

GEMTESA's marketing status is progressing well against the FY2022 plan, with 38,100 monthly prescriptions in June 2022.

Coverage has not expanded since March 2022. Urovant anticipates that it will approach peak coverage during FY2022.

In July 2022, Urovant signed an exclusive European marketing license agreement with Pierre Fabre of France for vibegron, a treatment for overactive bladder. Urovant will receive up to USD75 million in total up front and milestone payments, plus royalties, as consideration for this agreement.



Financial Results for Q1 FY2022

**Segment Information (Core Basis)**

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q1 YTD FY2022 Results	Revenue (Sales to customers)	33.7	95.2	11.6	8.4	148.9	11.0	159.9
	Cost of sales	19.1	13.5	3.7	1.2	37.5	8.5	46.1
	Gross profit	14.6	81.7	7.9	7.2	111.4	2.5	113.8
	SG&A expenses	13.0	58.6	2.6	0.4	74.6	1.4	76.0
	Core segment profit	1.6	23.1	5.3	6.8	36.8	1.0	37.8
	R&D expenses					23.8	0.6	24.4
	Core operating profit				13.0	0.4	13.4	
Q1 YTD FY2021 Results	Revenue (Sales to customers)	38.7	71.4	8.5	2.7	121.3	9.9	131.2
	Cost of sales	20.0	8.0	1.6	1.3	30.9	7.6	38.5
	Gross profit	18.7	63.4	6.9	1.4	90.5	2.3	92.7
	SG&A expenses	11.9	45.3	2.7	0.8	60.7	1.3	62.0
	Core segment profit	6.7	18.1	4.3	0.6	29.8	1.0	30.8
	R&D expenses					22.3	0.2	22.4
	Core operating profit				7.7	0.9	8.5	
Change	Revenue (Sales to customers)	(5.0)	23.8	3.1	5.6	27.5	1.1	28.7
	SG&A expenses	1.1	13.3	(0.1)	(0.4)	13.9	0.2	14.1
	Core segment profit	(5.2)	4.9	1.1	6.2	7.0	0.0	7.0
	R&D expenses					1.5	0.5	2.0
	Core operating profit				5.3	(0.4)	4.9	

- **Japan:** Lower profit due to declined sales by NHI price revision and increased expenses
- **North America:** Profit increased since the impact of higher revenue exceeded increased expenses
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Profit includes the revenue of \$50M from the license agreement for DSP-0187

Page nine shows operating results by segment.

In the Japan segment, core segment income decreased JPY5.2 billion to JPY1.6 billion due to lower sales and higher selling, general and administrative expenses.

In the North America segment, core segment profit increased by JPY4.9 billion to JPY23.1 billion. The increase in gross profit due to higher sales exceeded the increase in Sumitovant Group expenses and the increase in selling, general and administrative expenses due to currency exchange.

In the China segment, the figure increased by JPY1.1 billion due to higher sales.

The Other Regions segment reported an increase in both revenue and income due to the significant impact of one-time revenues from out-licensing.

Research and Development

## Development Pipeline (as of July 29, 2022)

■ : Psychiatry & Neurology 
 ■ : Oncology 
 ■ : Regenerative medicine / Cell therapy 
 ■ : Others 
 ■ : Frontier business 
 ■ : No revisions since the announcement of May 2022

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

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See page 11.

Next, an explanation of the development status.

This table lists the status of our development items. There are no changes from May of this year.

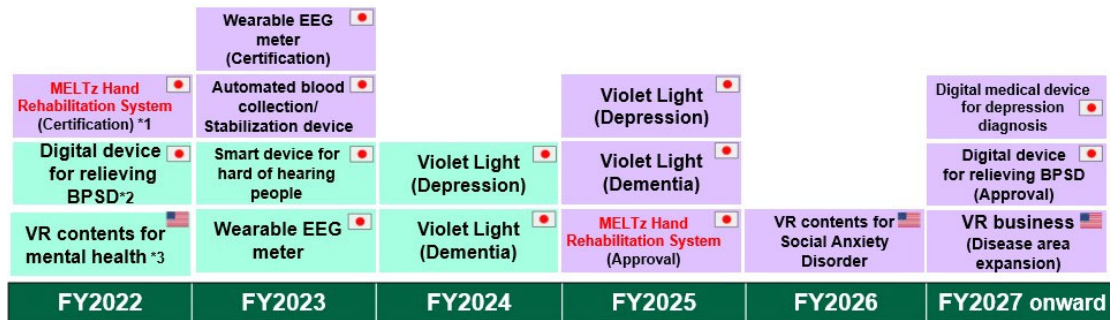
We expect to prepare to start clinical studies in the US for ulotaront in what would be its second indication, as adjunctive therapy for major depressive disorder. In addition, discussions with Otsuka Pharmaceutical are ongoing regarding a third indication.

Research and Development

**Product Launch Target (Frontier business) (as of July 29, 2022)**

Revisions since the announcement of May 2022 are shown in red

Medical device  
Non-medical device



\*1 Certified medical device named "Active extension / flexion / extension rotation exercise device" (Accepted name for medical devices), plan to launch in August 2022 by Sumitomo Pharma

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

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

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

See page 12.

Regarding the product launch target of the Frontier Business, we plan to launch the MELTz Hand Rehabilitation System as a medical device in August of this year. After the product is launched for sale, we aim to accumulate evidence in clinical studies. We will then aim for approval and launch of the product as a new or improved medical device in FY2025. This concludes my presentation.

**Mori:** Thank you very much, Mr. Kashima.

## Question & Answer

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

**Sakai, Credit Suisse Securities (Japan)** : Regarding ulotaront, I think you mentioned last time that the read-out, or rather, the data retrieval was a bit delayed due to the situation in Ukraine and Russia. In the Otsuka Pharmaceutical conference call that ended a little while ago, there was a statement that there has been no change in the outlook for sales and market launch in, FY2025 was it? Can you give us an update from your point of view?

**Ikeda** : Regarding your question, Otsuka Pharmaceutical and our company have different fiscal years. Therefore, in terms of our company's fiscal year, we are aiming for launch in FY2024.

**Sakai, Credit Suisse Securities (Japan)** : So, the difference is between a January start and an April start?

**Ikeda** : That's right.

**Sakai, Credit Suisse Securities (Japan)** : Okay. Next, I'd like to ask about this Q1 financial statement. As a whole, given the Q1 results, are there any plans to review the situation with respect to cost containment and so forth depending on performance from Q2 to Q4?

Sorry, it would be really helpful if you could give me a quick summary of that, since I didn't hear it the first time. Thank you.

**Kashima** : Kashima here. Thank you very much.

Please see page three for an overview. On the far right, you will see our forecast for FY2022 and our progress toward that goal. Progress toward the full year forecast for sales is 29.1%, while for core operating profit the figure is 44.6%. First, on the sales side, there were two one-time revenue items.

The contract with Jazz Pharmaceuticals for DSP-0187 and Myovant's agreement to commercialize ORGOVYX in Europe have a combined total of USD100 million in upfront revenues. Also, the rate of progress has been high due to the impact of foreign exchange conversion and the depreciation of the yen.

Therefore, core operating profit is high, but because this is due in part to one-time revenue, we have chosen not to revise our full year forecast at Q1 of FY2022.

**Sakai, Credit Suisse Securities (Japan)** : Okay. Was this USD100 million already included in the plan?

**Kashima** : The USD50 million with Jazz was included. In the European part of Myovant's ORGOVYX business, a one-time lump-sum payment of USD50 million was recorded, but the plan was a bit conservative: it was assumed that the payment would be deferred and recognized as revenue over a number of years, so this is a slight positive factor.

**Sakai, Credit Suisse Securities (Japan)** : I'm sorry to be persistent.

Is it correct to say that the USD50 million for ORGOVYX is the final payment in this matter?

**Kashima** : Yes, that's right.

**Sakai, Credit Suisse Securities (Japan)** : Understood. Thank you very much.

**Yamaguchi, Citigroup Global Markets Japan** : Thank you.

I just wanted to follow up on what you just said. Subtracting the one-time factor of JPY10 billion from the core operating profit of JPY13.4 billion leaves us with JPY3.4 billion, but multiplying it by four and adding JPY10 billion, it seems to me that we are now short by JPY30 billion. I wonder if there are a few expenses or other items that are throwing off the calculations? That, JPY13.4 billion multiplied by four, of course, doesn't work, but if you subtract JPY10 billion, you get JPY3.4 billion. How about that?

**Kashima** : Yes, this is also on page three.

In the FY2022 section of other income and expenses, the JPY21 billion figure is included. This has not occurred yet. Regarding this point, as I mentioned in May, we are thinking of selling a priority review voucher or assets. We have not yet received anything in that area in Q1.

We hope you understand that this area, if implemented, will be a positive factor.

**Yamaguchi, Citigroup Global Markets Japan** : Understood. I'd just like to confirm one thing. Jazz was included, but the USD50 million for ORGOVYX was only partially included. Part of that USD50 million, maybe USD30 million, or USD40 million, is in there as savings, is that correct?

**Kashima** : Yes, that's right.

**Yamaguchi, Citigroup Global Markets Japan** : Okay, thank you.

Has the timing of ulotaront read-out been finalized yet?

**Ikeda** : As for the read-out, including the subsequent work, our goal to launch in FY2024 has not changed. The status remains unchanged at this time.

**Yamaguchi, Citigroup Global Markets Japan** : So, the timing of the read-out hasn't changed. That seems a bit unusual.

**Ikeda** : Regarding the read-out, the situation in Ukraine is having a slight influence. However, we already have sites up and running in different countries, so we feel there is a fair chance of catching up there.

The current plan is to shorten the read-out period to ensure we keep to the market launch timetable.

**Yamaguchi, Citigroup Global Markets Japan** : Understood. Thank you. That's all from me.

**Wakao, JP Morgan Securities Japan** : Thank you.

The first question is about the one-time revenues you just described. You said that you have not announced it yet, but I do recall talk of selling the priority review voucher in Q1. Has anything changed in this respect? Can these really be sold?

**Kimura** : Yes, regarding the priority review voucher, it is a sale, and we think we can sell it for around JPY10 billion. There is a market for these, and they are sold in order. The order for ours has not come up yet.

However, we are already thinking about where to sell the voucher. So please be assured that we are able to sell these Priority Review voucher.

**Wakao, JP Morgan Securities Japan** : So, we can assume that there won't be a big delay?

**Kimura** : Yes.

**Wakao, JP Morgan Securities Japan** : Okay. Thank you very much.

I would like to ask about the progress of MYFEMBREE. I still feel like, somehow, the sales base is not that large.

Looking at the number of patients, I think it is still small in terms of sales. From your Company's point of view, do you expect that sales will accelerate once you obtain approval not only for uterine fibroids but also for endometriosis?

**Kimura** : Yes, as you have just mentioned, the GnRH mechanism that MYFEMBREE uses has not yet fully penetrated the market. Since Myovant has the leading market share in this field, they know that they have to further develop the market in the future.

In this context, there are two major areas that have not been fully extended, exactly as you mentioned. One is long-term prescriptions. Myovant is aiming to obtain approval for long-term prescriptions. By securing indications for both endometriosis and uterine fibroids, we hope that more women will be able to benefit from this medicine. Myovant is also working to educate physicians.

The PDUFA for endometriosis is coming up soon, and we are looking forward to the results.

**Wakao, JP Morgan Securities Japan** : Understood. Thank you very much.

I think the PDUFA date is next week, or August 6. What about if your company's approval is not granted as expected, and the treatment is indicated only for uterine fibroids? When its long-term prescriptions become available, as you have just explained, even if the other one is not approved, is it correct to think that a certain level of sales can be expected over time, even for uterine fibroids alone?

**Kimura** : Of course, Myovant can expect a certain level of sales. For our part, even if the endometriosis indication is not approved at this time, Myovant has enough data. Although there will be delays, Myovant believes that they will be able to obtain approval.

**Wakao, JP Morgan Securities Japan** : Understood. Thank you very much. That is all.

**Muraoka, Morgan Stanley MUFG Securities**: Thank you very much. I know we've been talking about the recording of one-time revenues, but I'd like to ask a further question on this topic.

The GEMTESA item put out to Pierre Fabre in Europe is USD75 million, including milestone. Will this be a lump sum up-front in Q2? Or will this be deferred? Also, is this included in the forecast? Thank you.

**Kashima** : Kashima here. We will record a lump sum in Q2 of FY2022. However, the amount will not be the full USD75 million.

**Muraoka, Morgan Stanley MUFG Securities** : So, we should think of it as a third or a quarter of 75 million, or something like that?

**Kashima** : Maybe a little less, but roughly in the range of single-digit millions.

**Muraoka, Morgan Stanley MUFG Securities** : I see. Understood. Thank you very much. Also, I'm not sure how to ask this question.

I'd like to ask about Trulicity®. I think that the performance of Trulicity is strong. Regarding the second-generation drug from Eli Lilly Japan K.K., tirzepatide, I thought your company was going to acquire it, but it looked as if Mitsubishi Tanabe took it.

I was wondering if, given your company's relationship with Eli Lilly Japan, you might have had some priority status in negotiations. Even though the profit margin was a little low, the amount of profit was large. Could you please explain the background, or rather, the reason why this was not taken?

**Kimura :** We don't have anything to say about the background, or rather, on Eli Lilly Japan's consideration here, but it was a little disappointing.

**Muraoka, Morgan Stanley MUFG Securities :** This is a product that your company had already gone all out to get.

**Kimura :** Our company has a very strong sales force in the diabetes area, and we have a very good track record. I think we would have been a natural choice for this treatment. Again, this was Eli Lilly Japan's consideration, and we have nothing to say about it.

**Muraoka, Morgan Stanley MUFG Securities :** Thank you very much. Finally, regarding voucher, please explain a little bit about the sale of PRV, because I'm afraid I don't know much about this.

As mentioned earlier in the Q&A, the sale of the voucher is being done in order and your company's turn has not yet come. Sorry, I didn't realize that was how it worked. It would be reassuring if we knew, for example, how many companies have already sold this year and how many more to go before your company. Thank you.

**Kimura :** Voucher, as you said, are not issued in large numbers, they come out in order. It's strange to say that vendors that handles vouchers, or rather the voucher market, has its own rules, but it's not a formal rule, vouchers are sold in order.

Otherwise, it would end up being a price competition between vouchers. That is my understanding.

**Muraoka, Morgan Stanley MUFG Securities :** So, you don't know how many vouchers are ahead of your company's in the queue?

**Kimura :** Apparently it is not that far off.

**Muraoka, Morgan Stanley MUFG Securities :** Okay. Thank you very much. By the way, if you sell the voucher, will you issue a press release?

**Kimura :** Excuse me. We have not decided yet.

**Muraoka, Morgan Stanley MUFG Securities :** So, you are undecided whether to announce it or not?

**Kimura :** Yes, we are undecided whether to announce it or not.

**Muraoka, Morgan Stanley MUFG Securities :** Understood. That is all. Thank you very much.

**Hashiguchi, Daiwa Securities :** Thank you.

I have a few questions. The first is about ulotaront's clinical studies as adjunctive therapy for major depressive disorder. Is this planned from the beginning to be a Phase III study like the one that will be the basis of the application? For example, will it be done once an exploratory study has been conducted to establish dosage and administration? What is your outlook at this time?

**Ikeda** : Otsuka Pharmaceutical will take the lead in announcing the expansion of the adjunctive therapy for MDD indication.

Therefore, I am not sure how much we can say. I can say that we expect there may be two studies, although I do not know whether they will be Phase II/III or Phase III studies.

**Hashiguchi, Daiwa Securities** : Is it correct to say that one of those two will begin in the near future?

**Ikeda** : Yes, that is my understanding.

**Hashiguchi, Daiwa Securities** : Thank you very much.

The second question is about initial sales of RETHYMIC®. It seems to me that your results for Q1 have not yet progressed in line with your full-year forecast. I would like to know your outlook for the full year. What are your thoughts, and what are your current plans for the development of this treatment outside the US?

**Kimura** : Indeed. As for RETHYMIC I am aware that the number of transplant cases has not grown that much yet. We are aiming to support 15 to 20 transplants per year in this year, and we are working to have this level of support ready for this year.

**Hashiguchi, Daiwa Securities** : Is it correct to say that preparations are underway to accumulate the number of cases in accordance with the plan, the JPY6 billion that you have indicated?

**Kimura** : Yes, that's right. The start of the project has been delayed slightly. The production system has not yet been fully established as we initially expected, but we have heard from the site that they will be able to catch up in the near future.

**Hashiguchi, Daiwa Securities** : Thank you very much. What about overseas, or rather, outside the US?

**Kimura** : Yes, there are patients outside the US, so we would like to expand the scope. There are two issues: one is obtaining approval in each country. The other is that since the product is a biomedical product, there are logistical questions such as whether or not the product can withstand a long transportation time.

**Hashiguchi, Daiwa Securities** : Thank you very much. Finally, I would like to know how the failure to obtain the marketing rights to tirzepatide affects your company's strategy. I would like to know about the competitive environment in the diabetes field, and how you think it will affect your products. Also, how it will affect your strategy to maintain the number one sales force in Japan in the diabetes field and to continue to focus on maintaining and strengthening your sales force there.

**Kimura** : In terms of the drug's mechanism of action, it will compete with Trulicity, so we would like to develop a strategy for the future, depending on how well it is accepted in the market.

**Hashiguchi, Daiwa Securities** : Understood. That is all. Thank you very much.

**Sakai, Credit Suisse Securities (Japan)** : I understand that TWYMEEG® has only been launched in Japan. It has been launched recently, and long-term prescriptions are not yet available, so I think we can expect sales to start off slowly. Am I correct in saying that your company own 100% of the rights to this?

How do you plan to expand overseas in the future?

**Ikeda** : This product was introduced from Poxel, and we have the rights for Japan and some countries in Southeast Asia.



**Sakai, Credit Suisse Securities (Japan)** : Okay. So, your Company is looking at sales at the regional level?

**Ikeda** : Indeed.

**Sakai, Credit Suisse Securities (Japan)** : Understood. Thank you very much.

**Mori** : Since there seem to be no other questions, I will now close the Q&A session. This concludes the conference call. Thank you very much for your time today.

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