

Sumitomo Pharma Co., Ltd.

Analysts Meeting of 2nd Quarter Financial Results FY2022

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[Time] 15:00 – 16:00
(Total: 60 minutes, Presentation: 29 minutes, Q&A: 31 minutes)

[Venue] Tokyo Head Office and Webcast

[Number of Speakers] 4

Hiroshi Nomura	Representative Director, President and CEO
Toru Kimura	Representative Director, Executive Vice President
Yoshiharu Ikeda	Member, Board of Directors, Senior Executive Officer
Kimihiko Kamano	Corporate Communications

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein. Information concerning pharmaceuticals and medical devices (including compounds under development) contained herein is not intended as advertising or as medical advice.

Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group beneficially owns 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>.

Additional Information and Where to Find It

This material may be deemed to be solicitation material in respect of the proposed acquisition of Myovant by Sumitovant and Sumitomo Pharma. In connection with the proposed acquisition, Sumitovant, Sumitomo Pharma and Myovant intend to file relevant materials with the SEC, including amended Schedule 13D filings and a transaction statement on Schedule 13E-3 with respect to Sumitovant and Sumitomo Pharma and a proxy statement on Schedule 14A with respect to Myovant. The definitive proxy statement and Schedule 13E-3 transaction statement will be sent to Myovant's shareholders and will contain important information about the proposed transaction and related matters. SHAREHOLDERS OF MYOVANT ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING SUMITOVANT'S AND SUMITOMO PHARMA'S TRANSACTION STATEMENT, MYOVANT'S PROXY STATEMENT AND ANY AMENDMENTS OR SUPPLEMENTS THERETO, AND ANY OTHER RELEVANT DOCUMENTS FILED OR TO BE FILED WITH THE SEC, CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain the documents free of charge at the SEC's web site, <http://www.sec.gov>, and Myovant shareholders will be able to obtain free copies of the proxy statement and Schedule 13E-3 through the Investor Relations page of Myovant's website, www.myovant.com.

Participants in the Solicitation

Sumitovant and its directors and executive officers, Sumitomo Pharma and its directors and executive officers, and Myovant and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the holders of Myovant common stock in respect of the proposed transaction. Information about the directors and executive officers of Myovant is set forth in the proxy statement for Myovant's 2022 Annual Meeting of Shareholders, which was filed with the SEC on July 28, 2022. Investors may obtain additional information regarding the interest of such participants by reading the proxy statement regarding the acquisition when it becomes available.

Presentation

Kamano: We will now begin the presentation of Sumitomo Pharma Co., Ltd.'s financial results for Q2 FY2022. Thank you very much for joining us today.

Today, we would like to proceed with our Tokyo Head Office and a live webcast and conference call from our Tokyo Head Office.

First, a point to keep in mind. Today's explanation will be based on the presentation materials posted on our website. After the presentation, there will be a question and answer session. Please understand that we may not be able to answer all questions due to time constraints.

I would now like to introduce today's attendees.

Mr. Nomura, Representative Director, President and CEO. Dr. Kimura, Representative Director, Executive Vice President. Dr. Ikeda, Member of Board of Directors, Senior Executive Officer. Finally, I am Kamano, from Corporate Communications. Thank you.

Mr. Nomura will now present the financial results for Q2 of FY2022. Mr. Nomura, thank you.

Nomura: Thank you for attending our financial results briefing.

As you are already aware, we have decided on and are forecasting a loss for Q2 and for the full year. We sincerely apologize for this loss, and for the forecast loss for the full year.

I would now like to give a presentation in line with the available slides.

Financial Results for Q2 FY2022							Revised full-year forecasts (See P.12)	
Financial Results for Q2 FY2022 (Core Basis)								
	Q2YTD FY2021 Results	Q2YTD FY2022 Results	Change			Billions of yen FY2022		
			Value	FX impact	%	May 13 forecasts	%	
Revenue	293.7	319.3	25.6	38.8	8.7	550.0	58.1	
Cost of sales	76.9	92.8	16.0	11.6	20.8	164.5	56.4	
Gross profit	216.9	226.4	9.6	27.2	4.4	385.5	58.7	
SG&A expenses	124.4	152.3	27.8	21.1	22.3	283.5	53.7	
R&D expenses	45.7	49.4	3.7	6.8	8.0	93.0	53.1	
Other operating income/expenses	1.2	0.0	(1.2)	—	—	21.0	—	
Core operating profit	47.9	24.8	(23.1)	(0.7)	(48.2)	30.0	82.8	
Changes in fair value of contingent consideration (negative number indicates loss)	(0.1)	1.3	1.4			(0.5)		
Other non-recurring items (negative number indicates loss)	(0.2)	(55.0)	(54.8)			(5.5)		
Operating profit	47.6	(28.9)	(76.5)			24.0		
Finance income/costs	1.7	49.9	48.3					
Profit before taxes	49.3	21.0	(28.2)		(57.3)			
Income tax expenses	19.3	36.3	17.0					
Net profit	30.0	(15.2)	(45.2)					
Net profit attributable to owners of the parent	36.5	(7.3)	(43.7)			22.0		

(Ref.) Earnings related to Sumitovant		
Billions of yen		
	Q2 FY21	Q2 FY22
Revenue	16.2	43.8
SG&A expenses *	41.4	62.3
R&D expenses	11.5	14.9
Core operating profit	(38.9)	(43.6)
Operating profit	(38.9)	(43.6)
Net profit	(39.5)	(50.0)
Net profit attributable to owners of the parent	(33.0)	(42.0)

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

Average rates:
Q2FY2021 Results : 1US\$ = ¥109.8, 1RMB = ¥17.0
Q2FY2022 Results : 1US\$ = ¥134.1, 1RMB = ¥19.9
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 September 2022 : 1US\$ = ¥144.8, 1RMB = ¥20.4

Sumitomo Pharma

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Please see page three.

Revenue was JPY319.3 billion, an increase of JPY25.6 billion. However, the impact of exchange rate fluctuations was JPY38.8 billion, a very large impact.

In Japan, sales have actually declined by about JPY10 billion. This is due to factors including item returns and drug price revisions.

In the US, there is a considerable foreign exchange gain. As you will see later, we received USD270 million from Otsuka Pharmaceutical in fiscal year 2021, so there is a difference in real terms. However, from the perspective of product sales, you will see that real sales are growing.

As for China, we had anticipated that volume based procurement would start in July 2022, but since it actually started in November, we have made an upward revision here.

Selling, general and administrative (SG&A) expenses grew in real terms, even excluding foreign exchange differences. This is based on an increase in sales expenses at Sumitovant.

Next, other revenues and expenses, within the core. This figure is zero because we have not yet been able to sell the assets, but it is included in the forecast.

The change in the fair value of contingent consideration is JPY1.3 billion, which is the result of a review of the fair value of contingent consideration for TP-0903, the Beat AML program, which had an investigator-initiated clinical study, which was discontinued. The results of the review of the fair value of contingent consideration were in a positive direction.

Then, regarding other non-recurring items, as you know, we have impaired the KYNMOBI® patent rights and other assets. That is JPY54.4 billion.

As a result, we are reporting an operating loss of JPY28.9 billion.

The large figure of JPY49.9 billion in financial income and expenses is due to the foreign exchange gains of JPY49.7 billion from the translation of our financial assets.

Pre-tax income is JPY21 billion, while corporate income tax is JPY36.3 billion. The situation here is a little bit irregular, but the US subsidiary has almost no taxable income, while the domestic subsidiary has taxable income. The foreign exchange gains that I explained earlier are very large, so the tax burden is large in some cases. The amount of corporate income tax is very large compared to pre-tax income.

As a result, for the second quarter of FY2022 there was a loss of JPY15.2 billion, and the loss for the quarter attributable to owners of the parent was JPY7.3 billion.

Financial Results for Q2 FY2022

Impairment loss on KYNMOBI®

Reason for impairment loss

Since market launch in September 2020, KYNMOBI® has not been performing to commercial expectations and as a result of reviewing forecast of the earnings, patent rights, etc. related to this product have been impaired, resulting in an impairment loss of approximately US\$406 million (approximately ¥54.4 billion)

> Background of Cynapsus acquisition

- ✓ Sunovion acquired KYNMOBI® from Cynapsus in October 2016. The total purchase price of the acquisition was approximately US\$635 million (approximately ¥65.9 billion)
- ✓ The apomorphine injection Apokyn was already launched in the market as a treatment for OFF episodes associated with Parkinson's disease, but an injection use was limited. It was decided to purchase KYNMOBI® to be able to help respond to the needs of patients suffering from OFF episodes

> Reasons for sluggish sales and reviewing forecast of the earnings

- ✓ Fewer Parkinson's patients in need of rescue medication than expected
- ✓ The safety profile of KYNMOBI® was different than expected., etc.

Future steps

- > Promotion of KYNMOBI® in the U.S. is being discontinued and partnerships are under consideration
- > Preparing to streamline resources and redirect efforts towards prioritized assets in the portfolio

Impact on consolidated financial results for FY2022

- > Limited impact on core operating profit. Significant decline in profit at each profit level below operating profit
- > There is no impact on cash flow

This slide covers the major impairment loss on KYNMOBI®.

It was in October 2016 when we acquired a Canadian company called Cynapsus for USD635 million. The reason for the acquisition was that there was an unmet medical need at the time: OFF episodes of Parkinson's disease. In contrast, the injectable apomorphine was available, but it was not used that much. Cynapsus anticipated that there was an opportunity and developed a sublingual film version of apomorphine. We acquired it.

The Phase III study had not yet been completed, so we continued with Phase III study. The product launched in September 2020.

In addition, under COVID-19, we have worked to provide information to hospitals despite issues with access difficulties for healthcare providers and patients. In spite of this, to date, sales have been in the single digits.

We were aiming for a peak sales level of USD500 million, but unfortunately, we were far below that level. We have been examining why this is the case.

The reason for the poor sales and the revision of the revenue forecast is that the number of Parkinson's disease patients with a need for rescue drugs was different from what we had expected.

It is true that patients who have OFF episodes usually have these OFF episodes after about five years of taking Levodopa/Carbidopa. For such patients, the frequency of Levodopa/Carbidopa administration is increased, in order to shorten the duration of OFF episodes as much as possible. We also thought that there might be a demand for this type of treatment for patients with relatively mild Parkinson's disease.

Therefore, we initially thought that there might be a great deal of unmet medical need for OFF episodes, but we found that this was not necessarily the case.

If we look at the percentage of patients with Parkinson's disease who use OFF episodes medications from January to December 2021, we find that only about 0.1% of patients use these medications, which is a very small percentage of patients.

The other thing is the safety profile, which we were very careful about during the due diligence at the time of acquisition. However, in the course of the Phase III studies, we heard that there were some patients who stopped taking this medication because of oral side effects.

These are the main factors, but in essence, KYNMOBI® was not widely taken up for treatment of OFF episodes in patients with Parkinson's disease.

On the other hand, there were competing agents. I will omit the name of the company and the product, but in FY2021, it seems to have generated sales of approximately USD30 million. We do not know whether this drug is at a very satisfactory level or not, but it is an inhaler of L-DOPA. L-DOPA was originally used for OFF episodes in Parkinson's patients, so it may have been used because of the drug's high affinity with that area.

We have not been able to fully analyze the specifics of this, but as I mentioned earlier, KYNMOBI® has been struggling for a number of reasons. Based on these circumstances, we have made a sales forecast and have come to the conclusion that even if we continue to operate at this level, we will not reach a scale that will allow us to recover our investment. We spent USD635 million on this acquisition, but unfortunately, we have been forced to write it down.

We are going to discontinue the promotion of KYNMOBI®, and we are going to look for companies that are interested in the OFF episodes of Parkinson's disease in the future.

As for the sales reps who promoted KYNMOBI®, some will move to working with GEMTESA®, and the rest, unfortunately, will leave the Company.

Financial Results for Q2 FY2022

Revenue of Major Products in Japan

Billions of yen

	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change		FY2022	
			Value	%	May 13 forecasts	%
Equa [®] /EquMet [®]	19.3	17.3	(2.0)	(10.3)	34.9	49.5
Trulicity [®] *	17.2	16.7	(0.5)	(3.1)	31.0	53.7
TRERIEF [®]	8.4	8.6	0.2	1.9	17.3	49.6
LATUDA [®]	3.0	4.6	1.6	54.3	9.9	46.9
METGLUCO [®]	4.1	4.0	(0.2)	(4.5)	7.8	50.7
LONASEN [®] Tape	1.0	1.4	0.4	45.6	2.7	51.5
TWYMEEG [®]	0.1	0.5	0.4	521.1	1.5	33.8
AG products	4.8	4.6	(0.2)	(3.9)	9.7	47.7
Others	18.7	8.9	(9.8)	(52.4)	15.2	58.6
合計	76.6	66.6	(10.0)	(13.1)	130.0	51.2

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[®] was lifted in September 2022
- Sale of REPREGAL[®] included "Others" decreased (Q2 YTD FY2021: ¥7.1B)
- NHI price revision affected (¥6.2B) on Japan segment total

These are domestic sales.

As I mentioned earlier, this is a decrease of JPY10 billion, compared to the same period last year. The other part is minus JPY9.8 billion. Since REPREGAL[®] was returned to Takeda Pharmaceutical Company Limited, there is a decrease of JPY7.1 billion. The NHI price revision has an effect of minus JPY6.2 billion overall.

As for LATUDA[®], we are seeing relatively steady growth.

We are also working to expand sales of LONASEN[®] Tape a little more by offering prescriptions that meet the needs of various patients, providing information remotely, holding lectures on the web, and providing information on skin conditions, which is the most important part of the treatment.

Financial Results for Q2 FY2022

Revenue of Major Products in North America & China

	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change			FY2022		
						Value	FX impact	%	May 13 forecasts		Yen-basis %
North America	Million \$			Billions of yen					Million \$	Billions of yen	
LATUDA®	920	952	32	101.0	127.6	26.6	23.1	26.3	1,726	215.8	59.1
APTIOM®	124	129	5	13.6	17.4	3.7	3.1	27.4	255	31.8	54.6
RETHYMIC®	—	19	19	—	2.6	2.6	0.5	—	48	6.0	42.7
BROVANA®	83	21	(62)	9.1	2.8	(6.3)	0.5	(69.0)	26	3.2	88.0
KYNMOBI®	3	2	(1)	0.3	0.2	(0.1)	0.0	(29.2)	18	2.3	10.4
ORGOVYX®	29	79	50	3.2	10.6	7.4	1.9	232.4	601	75.2	59.5
MYFEMBREE®	3	10	7	0.2	1.4	1.2	0.3	643.4			
GEMTESA®	19	71	51	2.1	9.5	7.3	1.7	344.9			
Others *	411	174	(237)	45.3	23.3	(22.0)	4.2	(48.6)			
Total	1,592	1,457	(135)	174.9	195.3	20.5	35.3	11.7	2,674	334.3	58.4
China	Million RMB			Billions of yen					Million RMB	Billions of yen	
MEROPEN®	850	942	92	14.4	18.7	4.3	2.7	29.8	863	16.8	111.6
Others	217	266	49	3.7	5.3	1.6	0.8	43.2	553	10.8	49.0
Total	1,067	1,208	141	18.1	24.0	5.9	3.5	32.5	1,416	27.6	87.1

* Lump-sum revenue included in "Others"

Q2 YTD FY2021	Revenue from the alliance with Otsuka \$270M	Q2 YTD FY2022	Revenue from the license agreement for ORGOVIX® \$50M	FX rates:
			Milestone revenue from approval of endometriosis \$29M	Q2FY2021 Results : 1US\$ = ¥109.8, 1RMB = ¥17.0
				Q2FY2022 Results : 1US\$ = ¥134.1, 1RMB = ¥19.9
				FY2022 forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

- **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 from license agreement decreased in "Others" (See the breakdown below the table)
- **China segment**
MEROPEN® increased continuously

This slide covers North America and China.

The exchange rate has a large impact on sales of LATUDA®. In US dollar terms, sales of LATUDA® are increasing.

Then there is APTIOM® and RETHYMIC®. BROVANA® has already reached LOE, which means a decrease in sales.

ORGOVYX®, MYFEMBREE®, and GEMTESA® are all seeing increasing sales.

The other part, as I mentioned earlier at the beginning, is the USD270 million that we received from Otsuka Pharmaceutical, which is written here, is the difference in comparison.

Looking at the US dollar figure alone, the decrease appears to be USD135 million, but when converted to yen, there is a foreign exchange gain of JPY35.3 billion, so the apparent increase in revenue is JPY20.5 billion.

In the China segment, as I mentioned earlier, the volume based procurement for both MEROPEN® and LATUDA®, which we had expected to start in July 2022, is starting in November, which results in a significant increase compared to our forecast.

Financial Results for Q2 FY2022

Segment Information (Core Basis)

Billions of yen

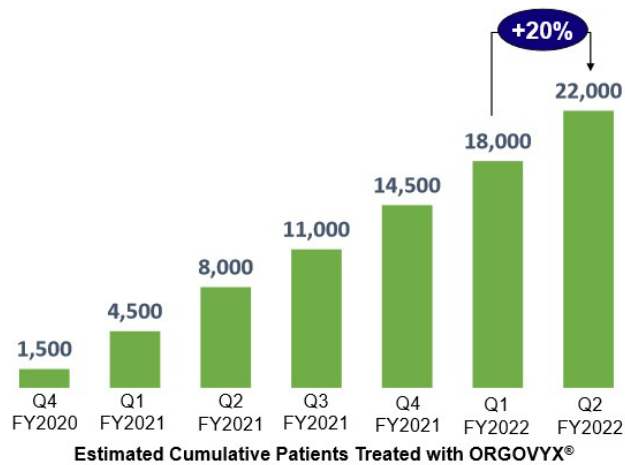
	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Q2 YTD FY2022 Results	Revenue (Sales to customers)	66.6	195.3	24.0	11.3	297.2	319.3
	Cost of sales	36.2	31.2	5.3	3.0	75.6	92.8
	Gross profit	30.4	164.2	18.7	8.3	221.6	226.4
	SG&A expenses	26.1	116.9	5.6	0.8	149.3	152.3
	Core segment profit	4.4	47.3	13.2	7.5	72.3	74.2
	R&D expenses					48.4	49.4
Core operating profit					23.9	24.8	
Q2 YTD FY2021 Results	Revenue (Sales to customers)	76.6	174.9	18.1	4.6	274.2	293.7
	Cost of sales	41.3	15.2	3.1	2.2	61.8	76.9
	Gross profit	35.3	159.6	15.0	2.4	212.4	216.9
	SG&A expenses	25.5	89.4	5.4	1.5	121.9	124.4
	Core segment profit	9.8	70.2	9.6	0.9	90.5	92.4
	R&D expenses					45.3	45.7
Core operating profit					46.4	47.9	
Change	Revenue (Sales to customers)	(10.0)	20.5	5.9	6.7	23.1	25.6
	SG&A expenses	0.5	27.5	0.1	(0.7)	27.5	27.8
	Core segment profit	(5.4)	(23.0)	3.6	6.6	(18.2)	(18.2)
	R&D expenses					3.0	3.7
Core operating profit					(22.5)	(23.1)	

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

This is a segmented comparison with the same period of the previous year, which I will not explain.

Marketing Status of ORGOVYX®

- Obtained approx. 4,000 new patient starts in Q2 FY2022 (20% growth vs. Q1 FY2022)



- Prescribed approx. 22,000 patients since launch
- Obtained the leading GnRH antagonist therapy for advanced prostate cancer with a 55% share based on months of therapy
- Since launching in January 2021, ORGOVYX® drove approx. 2.3 times increase of the GnRH antagonist market for products for the treatment of advanced prostate cancer

Source : Press release of Corporate Updates and Financial Results for Second Fiscal Quarter 2022 of Myovant Sciences Ltd.

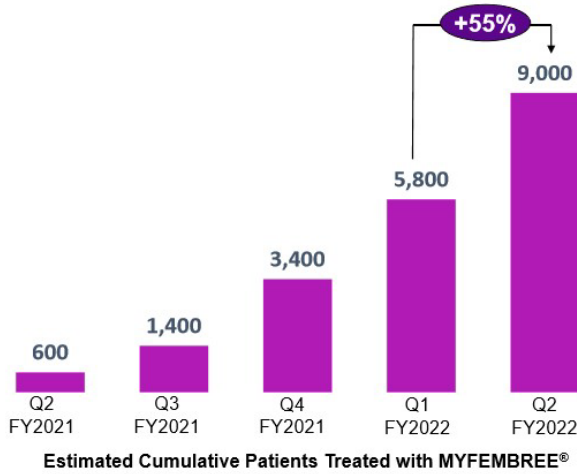
This slide covers ORGOVYX®.

There has been a 20% quarter over quarter, or QoQ, increase. The GnRH receptor antagonist formulation in advanced prostate cancer has gained a 55% monthly market share. This means that it has gained more prescriptions than the competing injectable formulation.

We are also very positive about the expansion of the market.

Marketing Status of MYFEMBREE®

- Obtained approx. 3,200 new patient starts in Q2 FY2022 (55% growth vs. Q1 FY2022)



- Prescribed approx. 9,000 patients since launch
- Obtained 54% total prescriptions (TRx) share and 67% new-to-brand prescription (NBRx) share among GnRH antagonists therapies for uterine fibroids in July 2022
- In August 2022, the FDA approved MYFEMBREE® for the endometriosis, establishing it as the first and only once-daily oral GnRH antagonist treatment in the U.S. approved for both uterine fibroids and endometriosis. MYFEMBREE® was launched in the U.S. for endometriosis as additional indication by Myovant and Pfizer in August 2022

Source : Press release of Corporate Updates and Financial Results for Second Fiscal Quarter 2022 of Myovant Sciences Ltd.

This slide covers MYFEMBREE®.

Sales have not grown that much yet, but they are up 55% QoQ. Although only one company has launched a drug in the same category, more than half of all prescriptions, that is, 67% of new patient prescriptions, are for our product. This means that we are growing relatively steadily.

We also received approval for endometriosis in August 2022, so we have been jointly promoting this with Pfizer since then.

Marketing Status of GEMTESA®

- Prescribed 47,492 TRx in Sep. 2022 and in line with FY2022 forecast

	GEMTESA®	
	June 2022	Sep. 2022
TRx Share in Beta 3	9.3%	11.3%
Monthly TRx numbers	38,100	47,492

- Coverage has not expanded since June 2022. Plan to secure most of peak coverage during FY2022 (Secured 13.6M lives of Medicare Part D, 28% of all of Medicare Part D, coverage starting in January 2023)

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

- From October 2022, increase the number of sales reps in charge of co-promotion partner Sunovion Pharmaceuticals Inc. approx. 30 (approx. 80 in total, not including managers), and engage in more activities for Primary Care Physicians (prescribe approx. 20% of beta-3 OAB treatments in the U.S.). Sales reps of Urovant Sciences Ltd. (approx. 150 in total, not including managers) will continue to focus on Urologist and Long-Term Care (prescribe approx. 45% of beta-3 OAB treatments in the U.S.)

This slide is on GEMTESA®.

The market share among beta-3 agonists, at 11.3%, has finally reached the double-digit level.

It has always been said that the GEMTESA® coverage is a little low. This is not reflected here, but starting from January 2023, the Medicare Part D coverage will be 28%, so it will be 58% here, or about 60%, and toward the end of the fiscal year 2022, we plan to increase the commercial and Medicare Part D coverage here a little more to the upside.

Also, as I mentioned earlier, starting from October 2022, we have been working with a co-promotion partner. Thirty of Sunovion’s sales reps will be assigned here, for a total of 80 people to be in charge of primary care.

We have identified approximately 8,200 targets of hospitals and clinics of primary-care physicians through targeting within Sunovion's territory. Therefore, we are going to strengthen primary care by promoting about 100 cases per person.

Financial Forecasts for FY2022

Financial Forecasts for FY2022 (Core Basis)

	FY2022 May 13 Forecasts	FY2022 Revised Forecasts	Change from Previous forecasts	
			Value	FX impact
Revenue	550.0	604.0	54.0	42.3
Cost of sales	164.5	182.0	17.5	15.5
Gross profit	385.5	422.0	36.5	26.8
SG&A expenses	283.5	312.0	28.5	25.2
R&D expenses	93.0	100.0	7.0	7.5
Other operating income and expenses (Core basis)	21.0	22.0	1.0	2.3
Core operating profit	30.0	32.0	2.0	(3.6)
Changes in fair value of contingent consideration (negative number indicates loss)	(0.5)	1.0	1.5	
Other non-recurring item (negative number indicates loss)	(5.5)	(63.0)	(57.5)	
Operating profit	24.0	(30.0)	(54.0)	
Net profit attributable to owners of the parent	22.0	(15.0)	(37.0)	
R O E (%)	3.6	(2.4)		
R O I C (%)	0.7	(1.0)		

Billions of yen

- **Revenue:** Revised up by ¥54.0B (excluding exchange rate impact)
Japan (¥4.2B)
North America +¥7.0B
China +¥8.7B
- **SG&A expenses and R&D expenses:** Increase due to FX rate impact
- **Other operating income and expenses (Core basis):** Plan to record consideration for priority review vouchers and the transfer of market rights for BROVANA® /XOPENEX HFA®, \$75M
- **Other non-recurring item:** Impairment loss on patent rights and other assets for KYNMOBI®



FX rates:
FY2022 Previous forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5
Revised forecasts : 1US\$ = ¥140.0, 1RMB = ¥20.0

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Here is the revised financial forecasts for FY2022.

The forecast for revenue is JPY604 billion. The real increase excluding the effect of exchange rate fluctuations is also shown here.

Sales in Japan are forecast to decrease. This includes those of Trulicity®, because it will end in December 2022, so comparing conventional forecast, it will decrease.

As for North America, the main products are in line with the forecast, but there are some one-time revenues that were not originally planned.

As for China, as I mentioned earlier, the increase is due to the delay in volume based procurement.

Forecast selling, general and administrative expenses have also increased. This is because Myovant will be promoting endometriosis, so there has been a slight increase in costs for that. This was not originally included in the budget.

Next, other operating income and expenses are areas where there is an increase over the FY2022 Q2 numbers. In Sunovion, LATUDA® will experience loss of exclusivity in the U.S. market in February 2023, so we will continue to promote the product in the U.S. until just before that. Therefore, in early in 2023, the LATUDA® sales force will leave the company, so these costs are also included in this figure.

Including these costs, operating profit is expected to be negative JPY30 billion, and the net loss attributable to the parent is currently projected to be a negative JPY15 billion.

Financial Forecasts for FY2022

Segment Information (Core Basis)

Billions of yen

	Pharmaceuticals Business					Other Business	Total	
	Japan	North America	China	Other Regions	Subtotal			
FY2022 Revised Forecasts	Revenue (Sales to customers)	125.8	382.3	37.2	17.0	562.3	41.7	604.0
	Cost of sales	66.1	69.9	7.9	5.6	149.5	32.5	182.0
	Gross profit	59.7	312.4	29.3	11.4	412.8	9.2	422.0
	SG&A expenses	53.0	239.0	11.9	1.9	305.8	6.2	312.0
	Core segment profit	6.7	73.4	17.4	9.5	107.0	3.0	110.0
	R&D expenses					97.4	2.6	100.0
Core operating profit					31.6	0.4	32.0	
May '13 Forecasts	Revenue (Sales to customers)	130.0	334.3	27.6	16.1	508.0	42.0	550.0
	Cost of sales	67.6	53.6	5.6	5.2	132.0	32.5	164.5
	Gross profit	62.4	280.7	22.0	10.9	376.0	9.5	385.5
	SG&A expenses	53.0	211.0	11.6	1.6	277.2	6.3	283.5
	Core segment profit	9.4	69.7	10.4	9.3	98.8	3.2	102.0
	R&D expenses					90.5	2.5	93.0
Core operating profit					29.3	0.7	30.0	
Change	Revenue (Sales to customers)	(4.2)	48.0	9.6	0.9	54.3	(0.3)	54.0
	SG&A expenses	0.0	28.0	0.3	0.3	28.6	(0.1)	28.5
	Core segment profit	(2.7)	3.7	7.0	0.2	8.2	(0.2)	8.0
	R&D expenses					6.9	0.1	7.0
	Core operating profit					2.3	(0.3)	2.0

- **Japan:** Revenue decrease due to termination of contract for Trulicity®
- **North America:** Increased revenue from lump-sum contract payments and milestone revenue exceed increased expenses
- **China:** Delay in starting VBP (volume-based procurement)

This is a segment-by-segment comparison of the forecast and revised forecast here, which I will skip over.

Acquisition of Consolidated Subsidiary Myovant as a Wholly Owned Subsidiary

- **Summary:** Entered into a definitive agreement with Myovant Sciences Ltd. to acquire all outstanding shares not already owned for \$27.00 per share
Total amount approx. \$1.7 B (approx. 250 billion yen), premium approx. 50% (compared to closing share price on Sep. 30)
- **Purpose:** Utilize cash flow generated by ORGOVYX® and MYFEMBREE®, which are expected to become major products, for Sumitomo Pharma Group and accelerate implementation of management strategies
- **Schedule:** The transaction is anticipated to close in the fourth quarter of FY2022
- **Funding:** The transaction will be financed through a combination of cash on hand and bank borrowings. A financing commitment has been received
- **Accounting:** “Non-controlling interests” in equity is reduced, and the difference between the decreasing non-controlling interests and the consideration is treated as a decrease in capital surplus
- **Impact on consolidated financial results for FY2022:** The transaction is expected to have a negative impact on each profit level below core operating profit, but the amount of impact is yet to be determined because it depends on timing of the transaction closing. Not factored it into revisions to financial forecasts

This slide covers the recent news regarding the definitive agreement with Myovant to acquire all outstanding shares already Sumitovant owned.

This is a positive initiative. In the meantime, we understand that ORGOVYX® and MYFEMBREE® are growing steadily.

As you know, although we have the majority, we are not necessarily in a position to reflect 100% of our intentions in the management of the company. If we are to use the cash flow from ORGOVYX® and MYFEMBREE® for our future growth, we have no choice but to increase the share to 100%. We have been working to achieve this 100% conversion.

We have agreed with the special committee of the other party to a definitive agreement at a price of USD27 per share.

The key funds will be provided in the short term by cash on hand and borrowing from the bank. The acquisition will not generate goodwill, but rather the difference between the non-controlling interest in Myovant and the consideration paid, which is probably more than the consideration paid, and will be treated as a decrease in capital surplus, so there will be no impact on the P&L in the future.


I did not include the impact of this acquisition of Myovant as a wholly owned subsidiary in the earnings forecast I mentioned earlier. Depending on the timing of the closing, various expenses, such as contingency fees to advisors or liquidation of equity compensation earned by employees, will be determined at that time. At this point, we believe this will happen in Q1 of calendar year 2023. If that timing is shifted, it will be in FY2023. At the moment, we are not necessarily clear on the timing of this, so it is not included in the forecast.

Research and Development

Development Pipeline (as of October 31, 2022)

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

Area	Phase 1	Phase 2	Phase 3	NDA submitted	
Japan	DSP-9632P (Levodopa-induced dyskinesia in Parkinson's disease)	DSP-0390 (Glioblastoma)	EPI-589 (ALS/Investigator-initiated study)	ulotaront (SEP-363856) (Schizophrenia)	
	DSP-0187 (Narcolepsy)	TP-3654 (Myelofibrosis)	Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated study)	SEP-4199 (Bipolar I depression)	
	DSP-0378 (Dravet syndrome, Lennox-Gastaut syndrome)	DSP-5336 (Acute leukemia)			
	guretolimod (DSP-0509) (Solid tumors)				
U.S.	SEP-378608 (Bipolar disorder)	guretolimod (DSP-0509) (Solid tumors)	EPI-589 (Parkinson's disease/ALS)	ulotaront (SEP-363856) (Schizophrenia)	
	DSP-3905 (Neuropathic pain)	TP-1287 (Solid tumors)	ulotaront (SEP-363856) (Parkinson's disease psychosis)	ulotaront (SEP-363856) (Adjunctive major depressive disorder)	
	SEP-378614 (To be determined)	TP-3654 (Myelofibrosis)	rodatristat ethyl (Pulmonary arterial hypertension)	SEP-4199 (Bipolar I depression)	
	SEP-380135 (To be determined)	TP-1454 (Solid tumors)	URO-902 (Overactive bladder)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)	
	DSP-0038 (Alzheimer's disease psychosis)	DSP-0390 (Glioblastoma)			
	DSP-3456 (Treatment resistant depression)	DSP-5336 (Acute leukemia)			
	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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Research and development.

The red text indicates that changes have been made in that area. Regarding the Oncology area, you see many programs in the red. While we previously grouped all solid tumors together, we now classify based on cancer type.

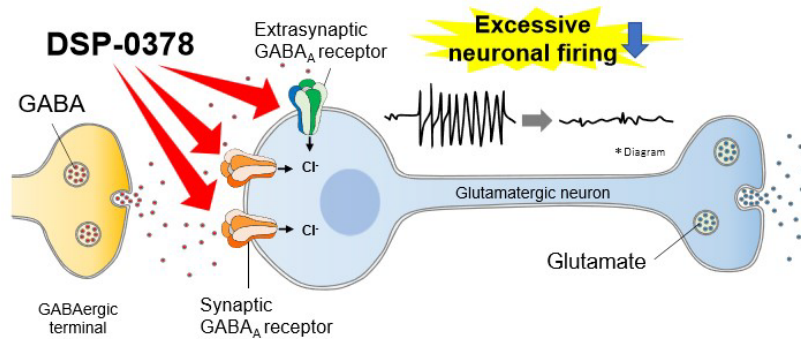
We have a number of programs, but here I would like to focus on the TP-3654 program and the DSP-5336 program.

Appendix (Research and Development)

New Chemical Entity: DSP-0378

- ✓ Target indication: Dravet syndrome* and Lennox-Gastaut syndrome* *Treatment-resistant epilepsy with onset in infancy or early childhood
- ✓ Origin: in-house
- ✓ Mechanism of action: gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator
Compound by itself does not activate the receptors, but potentiates the effect of GABA only when GABA binds to its receptors
- ✓ Stage: Phase 1 in Japan
- ✓ Expected profile:

- To exhibit a potent antiepileptic effect against broad epilepsies through inhibition of excessive neuronal firing via potentiation of various subtypes of GABA_A receptors expressed in synaptic and extrasynaptic regions
- Different mode of action from common GABA_A receptor potentiators such as benzodiazepines and neurosteroids



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In the Psychiatry and Neurology area, we have DSP-0378. Details are attached to the document, so I hope you will take a look at them later.

Clinical Development Status (Major Changes since July 29, 2022)

- **ulotaront**
U.S.: Started Phase 2/3 study for Adjunctive Major Depressive Disorder (aMDD)
- **DSP-0378**
Japan: Started Phase 1 study for Dravet syndrome and Lennox–Gastaut syndrome
- **DSP-6745**
U.S.: Discontinued development for Parkinson's disease psychosis (Phase 1 study)
- **DSP-7888**
U.S.: Discontinued Phase 1/2 study for solid tumors
Development strategy under consideration
- **TP-0903**
U.S.: Discontinued Phase 1/2 study (Research group-initiated study) for acute myeloid leukemia (AML)
Development strategy under consideration
- **MYFEMBREE® (relugolix combination tablet)**
U.S.: Approved additional indication for endometriosis in August 2022
- **METGLUCO® (metformin)**
Japan: Approved additional indication for infertility treatment ("ovulation induction for patients with polycystic ovary syndrome" and "controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome") in September 2022
- **KSP-1007**
U.S.: Obtained designation of Qualified Infectious Disease Product (QIDP) and Fast Track

This is the development status.

This is something that everyone already knows, and I will omit it because it will appear later, but this is the first time DSP-0378 has been listed here. DSP-6745, which is for psychiatric symptoms associated with Parkinson's disease, has been discontinued.

DSP-7888 is a cancer peptide vaccine. We have decided to stop the ongoing solid cancer studies and will consider the future development policy.

The status of TP-0903 is as I mentioned earlier. The development policy for this agent itself is currently under review.

As for METGLUCO®, this indication was obtained through a public knowledge application in the context of making infertility treatment covered by insurance.

KSP-1007 is a drug for AMR. It has the status of a qualified infectious disease product, QIDP, which means that the approval review will be shortened, and the so-called data protection period will be extended for five years, if it is approved.

Progress of ulotaront (Co-Development with Otsuka Pharmaceutical)

■ First indication: Schizophrenia

- Top-line results for pivotal studies in the U.S. expected CY2023

■ Second indication: Adjunctive Major Depressive Disorder (aMDD)

- Clinical program lead: Otsuka Pharmaceutical
- Started Phase 2/3 study in the U.S., and plan to dose the first patient by the end of CY2022
- Study design:

Patients	Adults between 18-65 years of age with major depressive disorder with inadequate response to antidepressant therapy (ADT)
Arms	• ulotaront + ADT • Placebo + ADT
Primary endpoint	Change from the baseline to week 14 in MADRS total score

■ Third indication: Generalized Anxiety Disorder (GAD)

- Clinical program lead: Sunovion/Sumitomo Pharma
- Start Phase 2/3 study by the end of CY2022. More information to be forthcoming on study design

This is a joint development with Otsuka Pharmaceutical.

There was some concern that the first indication, schizophrenia, might be impacted because of the delay in recruiting patients due to Russia's invasion of Ukraine, but we are now evaluating the possibility that the top line will be released by the end of CY2023. According to this plan, the market launch would be in FY2024, so it is expected to proceed as scheduled.

The second indication, adjunctive major depressive disorder, has already been announced, and we are expecting that a two-group studies will be conducted.

We are planning to conduct a study for the third indication of generalized anxiety disorder, in which we will take the lead.

Research and Development

Main Events / Targets for FY2022 (as of October 31, 2022)

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

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

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This slide covers major events in FY2022.

In the Psychiatry and Neurology area, as I mentioned earlier, a study of adjunctive major depressive disorder has begun.

In the field of Regenerative medicine/Cell therapy, we began construction of a CPC in the US in August 2022 to manufacture products derived from RETHYMIC® and other iPS cells. We intend to start manufacturing products using this equipment in FY2024.

Next is the news of endometriosis approval.

In Frontier Business, we have launched the MELTz® Neurorehabilitation device for hand/fingers. Regarding the VR contents for mental health, there are some delays here.

That concludes my explanation based on the materials. Thank you for your attention.

Kamano: Thank you very much, Mr. Nomura.

Question & Answer

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

Hashiguchi, Daiwa Securities : Thank you for your presentation. My name is Hashiguchi from Daiwa Securities. First of all, regarding the revised forecasts for this fiscal year, I understand that you have revised the US sales upward in US dollar terms, but I think you explained that this was mainly due to the change in assumption regarding the one-time payment. I was wondering if you could comment to the best of your ability on how you have raised or lowered your forecast for MYFEMBREE®, ORGOVYX®, and GEMTESA®.

Nomura : Yes, thank you. There is no specific change for MYFEMBREE®, ORGOVYX®, or GEMTESA®.

Hashiguchi, Daiwa Securities : You mean you haven't changed it?

Nomura : That's right.

Hashiguchi, Daiwa Securities : Yes, thank you. Also, I believe that you have indicated in the past that you would consider various measures to support earnings in FY2023, when performance is expected to be at its worst. Since you are forecasting a loss for the current fiscal year as well, is there a possibility that such things will be implemented ahead of schedule in H2 of this fiscal year and beyond? Also, is there a possibility that some upward swing factor will emerge in the future that is not included in the current forecast?

I think there are a lot of projects that will take place this year and next year, and depending on the deal, there may be other parties, so the timing may be this year or next year. What are your thoughts at this point in time on what you are going to do from this year to next year, and how you are going to tackle these projects that are not extensions of past projects?

Nomura : Yes, in terms of the upside to core operating profit, I didn't go into detail about the asset sales earlier in the forecast, but we have already sold USD75 million worth of assets, and we have already sold the Sunovion LOE products. We have also mentioned that we will be selling priority review vouchers.

We are also considering the sale of assets, although I cannot be more specific. This is the upside.

Then, as for the potential downside, as I mentioned a little earlier in the section on making Myovant a wholly-owned subsidiary, depending on the potential timing of the transaction closing, we may have to purchase the potential shares held by employees, which would be an expense.

Then there will be things like employee retention, one-time success fees for advisors, and so on.

Therefore, there are two possibilities: one is to slightly increase the upside, and the other is to increase the costs.

Hashiguchi, Daiwa Securities : In what you just said, I got the impression that the upside was already in your forecast.

Nomura : There are some asset sales that are not included in our forecasts. As you mentioned earlier, we are in the process of discussing this matter with the other party, but whether it will be resolved by the end of this fiscal year is still an undetermined factor. So, as I mentioned earlier, the sale of Sunovion's products that have already reached LOE, and the sale of priority review vouchers are already in our forecasts. In addition, we are in the process of selling other assets.

Hashiguchi, Daiwa Securities : My last question is about the sales structure of the Japanese business. I've asked about this before, but your products are being returned to the originator. Do you have any ideas on how to prevent contraction of the business?

Or, when considering the regional balance between the US and Japan, do you think that Japan has no choice but to have a reduced role to some extent? Could you tell us your thoughts on this?

Nomura : I don't necessarily think it's the case that the Japan business will contract. Yesterday, we had such questions from the press. The contract with Eli Lilly Japan K.K. will expire at the end of December 2022, but I believe that the capabilities of our sales force, or rather our MRs, are well understood by our partners. Therefore, I believe that there may be more opportunities for this partnership.

However, if there is a time when a partnership will eventually run out or come to an end, I think it will be difficult to continue such a thing.

This may not be immediate, but in the long run, we will have our own products coming out for the Psychiatry and Neurology area. While launching our own products, we will also launch product of the Regenerative medicine/Cell therapy in FY2024, if all goes well, and then the Frontier Business products will also emerge. In this context, I think that gradually shifting the business type a little bit over a long period of time is one option to consider.

Hashiguchi, Daiwa Securities : Thank you very much.

Yamaguchi, Citigroup Global Markets Japan : I am Yamaguchi from Citigroup. Thank you very much. My first question: I think there are a lot of activities taking place right now in the mid-term business plan, and you mentioned that the next fiscal year will be tough after factoring in these activities. I guess it depends on M&A activities, but could you tell us when you expect to announce the mid-term business plan?

Nomura : Yes, as you just pointed out, it depends on the M&A. So, for example, I think they usually happen in February 2023, but in this case that may not be possible. Therefore, we expect to have an opportunity to explain the new Mid-Term Business Plan when we announce our financial results in May.

Yamaguchi, Citigroup Global Markets Japan : Also, the Myovant contract is already signed, and I think it is almost completed, but you also bought Urovant in the process. Could you talk about any possible plans to make Myovant a subsidiary if the timing was right?

I'm not sure about the timing of the decision given the Company is still in the red and buying would rather reduce profits. What was the reason for the decision?

Nomura : Thank you. The timing of this is that we originally thought that, while ORGOVYX® was fine, for MYFEMBREE®, uterine fibroids and endometriosis would be roughly one-to-one sales. Therefore, if we did not get approval for endometriosis, MYFEMBREE® would only go about half as far as we had thought it would.

Although it turned out not to be the case, we thought it would be very important to get this approval.

Therefore, we made preparations from the time when approval was obtained or not and were ready to take action as soon as the approval was obtained.

Yamaguchi, Citigroup Global Markets Japan : Okay. And lastly, regarding ulotaront, is it likely that the top line will be available in H2 of 2023?

Nomura : Dr. Ikeda, would you like to take this question?

Ikeda : Yes, it will be in 2023.

Yamaguchi, Citigroup Global Markets Japan : In H2 of the year?

Ikeda : Yes. The market launch will be in FY2024.

Yamaguchi, Citigroup Global Markets Japan : You mean within FY2024, the fiscal year to March 31, 2025?

Ikeda : Yes.

Yamaguchi, Citigroup Global Markets Japan : So probably in early 2025?

Ikeda : In terms of calendar years, we believe so.

Yamaguchi, Citigroup Global Markets Japan : OK. I understand. In addition to schizophrenia, there is also adjunctive major depressive disorder and GAD. I understand that schizophrenia is small in terms of patients and potential, but I would appreciate it if you could give me a rough idea of the potential market for the major depressive disorder and also generalized anxiety disorder.

Nomura : In the case of major depressive disorder, it is not necessarily true that there is satisfaction with existing medications. With existing drugs, simply raising the dosage can lead to various safety issues and other problems. However, since ulotaront has a mechanism of action that is different from existing drugs, it is expected to have a sufficient add-on effect, and I believe that it will be able to capture a large market in the adjunctive major depressive disorder.

As for generalized anxiety disorder, I think there are still many issues with existing drugs in terms of their safety profile. We believe that ulotaront will be able to solve such problems to some extent, and we believe that it will be sufficient to meet unmet medical needs in terms of efficacy and safety.

Kimura : As Mr. Nomura explained, in terms of future importance, of course it depends on the drug price and insurance coverage, so I will refrain from mentioning numbers now, but in terms of the number of patients, there are solid statistics. For example, schizophrenia, as you know, is around 1% of the total population, and in the US, it is estimated that 1.6 million or 1.7 million people have been diagnosed with the disease.

In contrast, for MDD or major depression, the number is 17 million in the US and 2 million in Japan. For GAD or generalized anxiety disorder, the number is about the same, although slightly less, 13 million in the US and over 1 million in Japan. For each of these, satisfaction with existing drugs is very low.

In the case of GAD in particular, there is still a lack of a proper brand drug, so we are in agreement with Otsuka Pharmaceutical that if ulotaront can demonstrate the pharmacological effects we expect and prove its safety, it will lead to a major business.

Yamaguchi, Citigroup Global Markets Japan : Finally, just briefly, I think you took breakthrough therapy designation, is it still going? If so, is there some way you can make use of it, or use it to accelerate development?

Kimura : With breakthrough therapy designation, it is possible to speed up the regulatory review process after the application is submitted. In our case, revenue of LATUDA® will be gone in the US, and we are in a very difficult situation, but I think that the place where we can get such a review more quickly than with ordinary drugs is the place where we can see the most visible effects in enabling advancement of timelines.

Yamaguchi, Citigroup Global Markets Japan : The breakthrough therapy designation is still valid, right?

Kimura : Of course.

Yamaguchi, Citigroup Global Markets Japan : Thank you very much.

Sakai, Credit Suisse Securities (Japan) : My name is Sakai from Credit Suisse. What is the route that the funds will be used to make Myovant a wholly owned subsidiary, and will this be funded in the US or in Japan? Naturally, with interest rates rising, I don't think it is possible to arrange financing as in the past.

I know that the next fiscal year is a difficult time, but I wonder if raising these funds will weigh on your ability to hold off on so-called strategic investments. Could you first tell us how you are thinking about this area, including the use of the balance sheet?

Nomura : Yes, the procurement route, and we have quite a bit of US dollar funds for this. We receive transfer pricing adjustments and other payments in the form of US dollars from the sale of LATUDA[®]. In addition, we have US dollars, the consideration for the sale of LATUDA[®] from Japan in US dollars, so we have US dollars in some of our own funds. The rest of the money is in yen and then borrowed from banks, which are yen funds.

Interest rates are lower in Japan, but the yen is very weak at the moment, so there is a weight on that side of the equation. Therefore, we will probably be able to verify the efficiency of our investment in Myovant under the weak yen situation.

As for your mention of strategic investment, I think it will be very difficult to make large investments, at least around 2023 to 2025.

For our part, we are working to bring ORGOVYX[®], MYFEMBREE[®], and GEMTESA[®] to the blockbuster level, and we are also working to bring ulotaront to market.

In FY2024, in Japan, we will commercialize the treatment of Parkinson's disease using iPS cells. We also have a variety of Frontier Business products, and we are planning to bring these to market as well. We will focus on doing those things first.

We will also continue to grow programs that will support the mid-2030s and beyond, such as those at the Phase I study or preclinical stage. We will continue to develop our own products during this period while conducting selective primary oligonucleotide therapy, although we must also ensure that this is done properly. At this point in time, I think it is unlikely that such a major investment of money in other areas will occur.

Sakai, Credit Suisse Securities (Japan) : Okay, thank you. Also, regarding your R&D portfolio, you have announced the discontinuation of several development projects. I think the risk of development in the area of Oncology and Psychiatry and Neurology was an issue. I think the idea is to share risk with Otsuka Pharmaceutical as a partner, and I wonder if with ulotaront, you will continue to focus on these two core areas in the future.

I don't mean to say that this is a contraction, but I think it would be a good time to reevaluate investment in general, not just in Japan.

Nomura : Yes, thank you. Let me start with the Oncology area, there seems to be a lot in the pipeline. As I mentioned earlier, we have TP-3654 and DSP-5336, and we will focus on these two.

Within the data, we are working to move forward with the signal areas. We have several other drugs in the pipeline, and we will administer them to a small number of patients, and if they do not produce a strong signal, we will stop using them as soon as possible.

Therefore, I hope you understand that we are already doing almost all of the two things I mentioned earlier with regard to the Oncology area. It is particularly challenging, but we have set a goal to obtain approval for these two compounds within five years.

As for the Psychiatry and Neurology area, of course, it would be difficult for us to do everything, or to do everything that has gone up to Phase I study in this order, as we have done in the past.

So, we will identify the pipeline in roughly three categories: those that we manage ourselves, those that we advance with a third party, and those that we license to a third party.

Ulotaront is in the second category, as I mentioned earlier, and the orexin receptor agonist is in the third. As for the first area, we will now proceed to carefully assess what to do with this category. If you have anything to add regarding research, Dr. Ikeda, please do so.

Ikeda : As Mr. Nomura just mentioned, our strategy is to properly assess each clinical signal, prioritize them, and select the items to invest in.

Sakai, Credit Suisse Securities (Japan) : Yes, thank you.

Muraoka, Morgan Stanley MUFG Securities : Hello, Muraoka, Morgan Stanley. Thank you. What will happen to the goodwill or other intangible assets associated with Myovant when it becomes 100% owned by your company? The IR person also explained that goodwill and intangibles do not increase, but I'm not sure how to sort that out. If there is a change in the amount of goodwill/intangibles, this will have an effect on core operating profit, so I would appreciate some clarification on this.

Nomura : Yes, thank you very much. There is no impact on goodwill. In short, as I mentioned earlier, this is the equity section of the balance sheet, I believe.

I guess you would call it a controlling interest, and that is the part of Myovant's business that we do not have. The amount we are acquiring this time is USD1.7 billion, which will be converted into yen, and the difference between that amount and the non-controlling interest will be deducted from capital surplus. Therefore, I think the current exchange rate would probably mean that the capital surplus would be negative.

However, there are several ways to present this information. In the case of a negative capital surplus, some companies carry it over from retained earnings to erase the negative capital surplus, while others present it as it is. I think this area is still a matter for further consideration.

Therefore, there is no impact on goodwill.

Muraoka, Morgan Stanley MUFG Securities : Current amortization is about JPY20 billion to JPY30 billion every year, and I think this is affecting core operating profit. Exchange rate fluctuations will have an effect in the future too, but would it be correct to assume that it will not significantly change?

Nomura : Yes, I think it is correct to say that there is no change in the current patent rights or goodwill.

Muraoka, Morgan Stanley MUFG Securities : Thank you very much. Also, you mentioned earlier that the next fiscal year will be tough, and that is only natural, but I think you mentioned before during the small meeting with Mr. Nomura that you expect to see a recovery in the following fiscal year, the fiscal year ending March 2025, because sales of new products in the US will exceed JPY100 billion. Am I correct in my understanding that a deficit in core operating profit for two consecutive fiscal years is unlikely?

Nomura : Yes, the scenario I am currently envisioning is that the sales structure in North America will also change, in other words, the position of Sunovion, which has been dependent on the Company, will now

changeto Sumitovant. In this sense, I believe that selling, general, and administrative expenses will also change to some extent.

Then, ORGOVYX®, MYFEMBREE®, and GEMTESA® will also have a hard time during FY2023, but will show some growth once FY2024 comes around. In this context, we believe that if we can achieve growth in sales, rationalize expenses to some extent, and adjust R&D expenses appropriately, we should be able to achieve profitability in core operating profit in FY2024.

This is also something we are considering in our current mid-term business plan, and we are in the process of confirming the projected figures.

Muraoka, Morgan Stanley MUFG Securities : Okay. Thank you very much. Lastly, regarding the additional indication for ulotaront, I missed it the other day with Otsuka Pharmaceutical, but why is agitation of Alzheimer's disease not included among the indications?

Kimura : Yes, the most important feature of ulotaront is that it suppresses the negative symptoms, which is now attracting attention.

We also considered that it would be easier to expand our business if we could broaden the scope of our activities into the area of depression rather than the peripheral symptoms of Alzheimer's disease, as I mentioned. There are difficulties in the regulatory path for peripheral symptoms, including clinical studies, and so we decided to work with Otsuka Pharmaceutical on the development of these two diseases. In addition, Otsuka Pharmaceutical will be in charge of adjunctive MDD, which is their specialty, and we will be in charge of GAD operations.

Muraoka, Morgan Stanley MUFG Securities : Okay. Thank you very much. Did you say that the agitation of Alzheimer's disease is difficult because of regulatory issues?

Kimura : Yes, that's right.

Muraoka, Morgan Stanley MUFG Securities : I'm sorry, but when you say that Alzheimer's agitation is difficult from a regulatory standpoint, do you mean that you are aware of the various problems that other companies are having with it?

Kimura : That's part of it, yes. It is not easy to define a regulatory path, but if there is a precedent, we know that we can get an indication if we conduct a clinical study and obtain data in a certain way. However, there are many things that we have to consider when taking on a new challenge or taking on a challenge with a new mechanism. In the case of Alzheimer's agitation, there is a great medical need, and we would like to do something about it in another program, but we have decided that it is not appropriate for ulotaront.

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

Kamano : Thank you. There being no other questions, we will now conclude the question-and-answer session.

This concludes the presentation of the financial results. Thank you very much for your time today.

[END]