Q1 Financial Results Briefing for FY2023

[Date]	July 31, 2023	
[Time]	17:20 – 18:10 (Total: 50 minutes, Presentation: 14 minutes, Q&A: 36 minutes)	
[Venue]	Webinar	
[Number of Speakers]	5	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Senior Managing Executive Officer
	Yoshiharu Ikeda	Member, Board of Directors, Managing Executive Officer
	Naoki Noguchi	Executive Officer, Vice President, Head of Corporate Communications
	Koji Ishida	Vice President, Head of Finance & Accounting

Presentation

Noguchi: Welcome to the financial results briefing of Sumitomo Pharma Co., Ltd. for Q1 FY2023.

Thank you very much for taking time out of your busy schedules today. Today's briefing session will proceed in accordance with the financial results briefing material on webinar, followed by the question-and-answer session.

Mr. Ishida will now give a presentation on the financial results for Q1 FY2023, and then Dr. Ikeda will give a presentation on the current status of clinical development.

Please go ahead, Mr. Ishida.

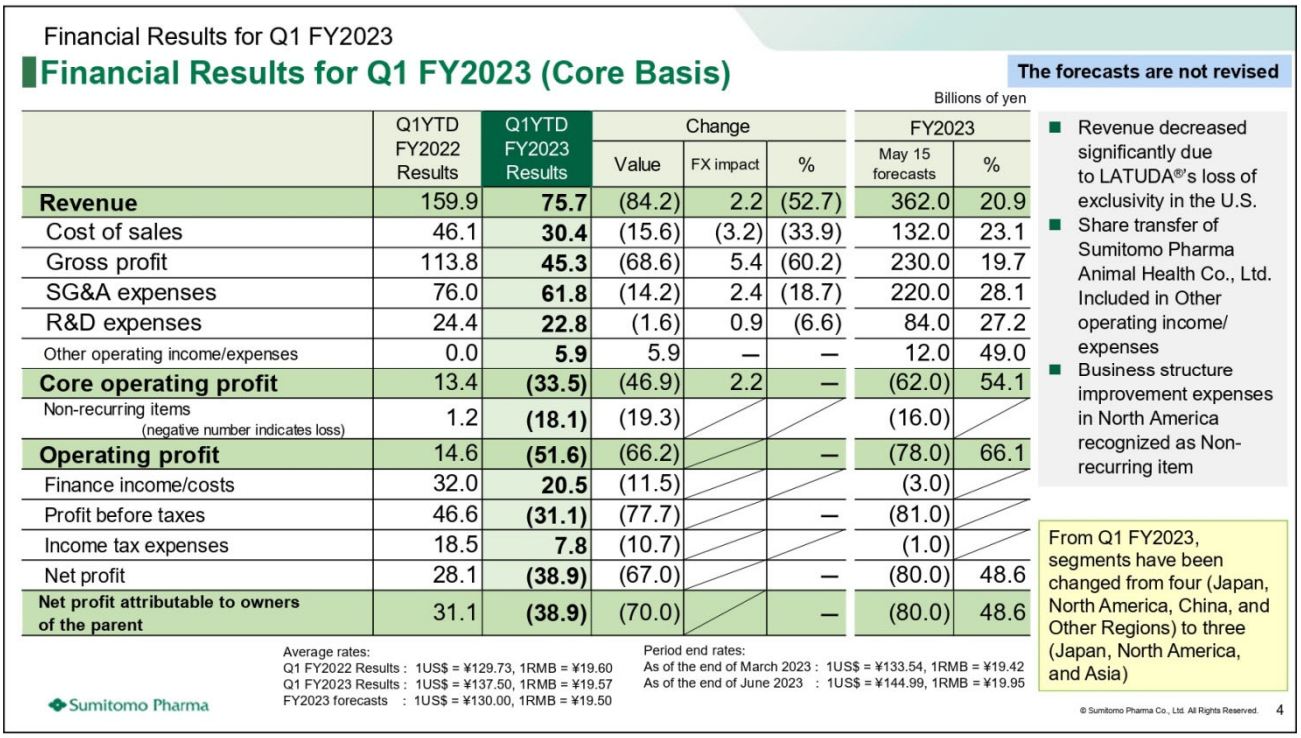
Ishida: I am Ishida. I will now explain the financial results for Q1 FY2023 based on the presentation materials.

Please turn to page three. This page summarizes the completion of the combination of U.S. group companies and the launch of Sumitomo Pharma America, Inc. (SMPA)

SMPA was established on July 1, 2023 by consolidating the functions and human resources of seven U.S. group companies including Sunovion Pharmaceuticals Inc, Sumitovant Biopharma, Inc., and Myovant Sciences Ltd.

The combination is expected to reduce the total number of employees in North America by approximately 500 by the end of FY2023 compared to the end of FY2022, and to reduce SG&A and R&D expenses by approximately USD260 million in FY2023 and USD400 million in FY2024 compared to the case where no combination was made.

SMPA, whose profile is shown on the slide, has a leadership team comprised of industry-leading experts with deep expertise in the life sciences field. Myrtle Potter, President & CEO and two others also became executive officers of Sumitomo Pharma on July 1.



Financial Results for Q1 FY2023

Financial Results for Q1 FY2023 (Core Basis)

The forecasts are not revised

Billions of yen

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change			FY2023	
			Value	FX impact	%	May 15 forecasts	%
Revenue	159.9	**75.7**	(84.2)	2.2	(52.7)	362.0	20.9
Cost of sales	46.1	**30.4**	(15.6)	(3.2)	(33.9)	132.0	23.1
Gross profit	113.8	**45.3**	(68.6)	5.4	(60.2)	230.0	19.7
SG&A expenses	76.0	**61.8**	(14.2)	2.4	(18.7)	220.0	28.1
R&D expenses	24.4	**22.8**	(1.6)	0.9	(6.6)	84.0	27.2
Other operating income/expenses	0.0	**5.9**	5.9	—	—	12.0	49.0
Core operating profit	13.4	**(33.5)**	(46.9)	2.2	—	(62.0)	54.1
Non-recurring items (negative number indicates loss)	1.2	**(18.1)**	(19.3)			(16.0)	
Operating profit	14.6	**(51.6)**	(66.2)		—	(78.0)	66.1
Finance income/costs	32.0	**20.5**	(11.5)			(3.0)	
Profit before taxes	46.6	**(31.1)**	(77.7)		—	(81.0)	
Income tax expenses	18.5	**7.8**	(10.7)			(1.0)	
Net profit	28.1	**(38.9)**	(67.0)		—	(80.0)	48.6
Net profit attributable to owners of the parent	31.1	**(38.9)**	(70.0)		—	(80.0)	48.6

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Share transfer of Sumitomo Pharma Animal Health Co., Ltd. Included in Other operating income/ expenses
- Business structure improvement expenses in North America recognized as Non-recurring item

From Q1 FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia)

Average rates:
Q1 FY2022 Results : 1US$ = ¥129.73, 1RMB = ¥19.60
Q1 FY2023 Results : 1US$ = ¥137.50, 1RMB = ¥19.57
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of June 2023 : 1US$ = ¥144.99, 1RMB = ¥19.95

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 4

Please turn to page four. We are pleased to report our Q1 operating results, which are shown on a core IFRS basis. Effective from Q1 of the current fiscal year, the Company changed its reporting segments from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia).

Revenues were JPY75.7 billion, a decrease of JPY84.2 billion from the same period last year. Sales declined in the Japan, North America, and Asia segments.

In addition to a decrease in selling, general and administrative expenses, other operating income was recorded due to the transfer of shares in Sumitomo Pharma Animal Health Co., Ltd. However, core operating profit decreased by JPY46.9 billion YoY to a core operating loss of JPY33.5 billion due to the significant impact of the decrease in gross profit caused by the decline in revenue.

Due to non-recurring items such as severance payments of JPY18.1 billion associated with the combination of group companies in North America, operating profit decreased by JPY66.2 billion from the same period last year to an operating loss of JPY51.6 billion.

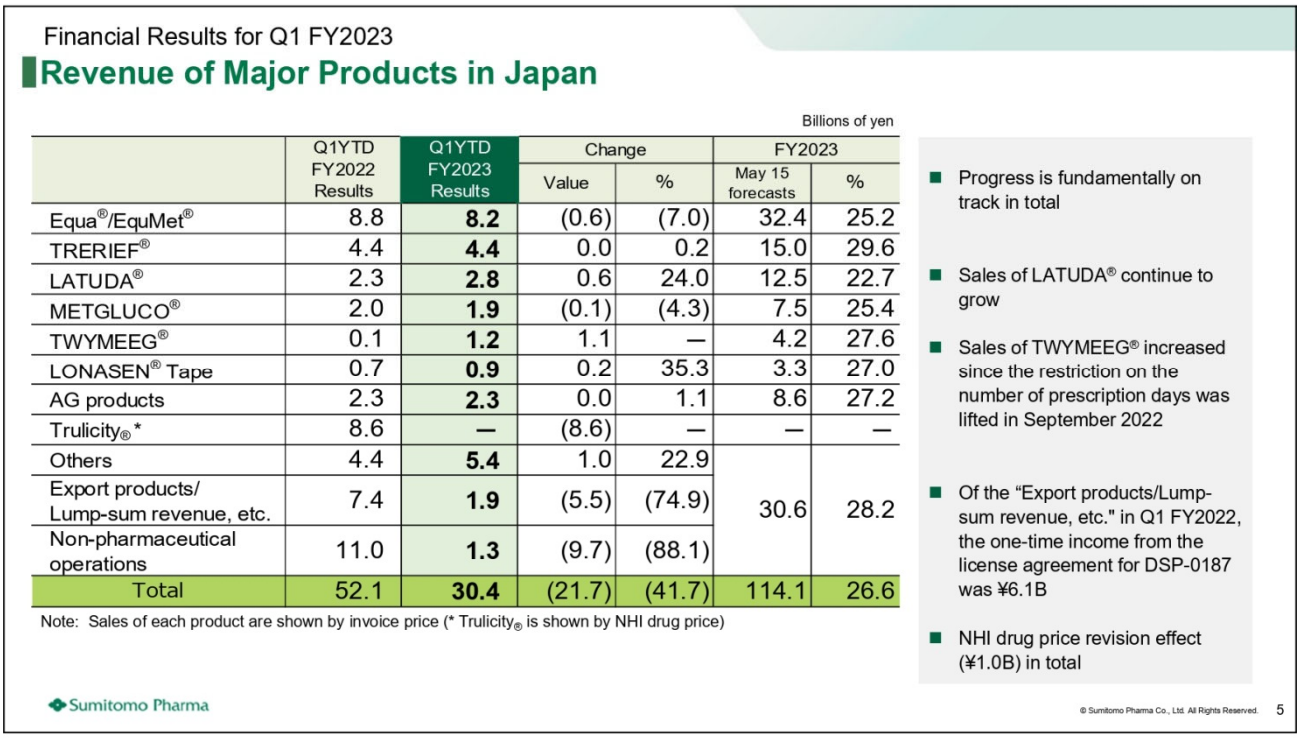
Profit before income taxes and minority interests was JPY20 billion due to a foreign exchange gain of JPY20 billion resulting from the yen's depreciation at the end of the quarter. However, the impact of the decrease in operating profit was significant, resulting in a loss before income taxes of JPY31.1 billion, a decrease of JPY77.7 billion from the same period last year.

As a result, Net profit attributable to owners of the parent also declined significantly, to a loss of JPY38.9 billion.

While the Q1 sales revenue progress is low compared to the annual forecast, each profit level is progressing at a high rate. Sales are expected to grow, while selling, general and administrative expenses are expected to

decrease from Q2 onward due to the effect of the combination of the North American subsidiaries. Since the Q1 results did not change significantly from our assumptions, we have not revised our full-year forecast at this time.

Severance and other costs associated with the combination of group companies in North America have already exceeded the planned annual loss of JPY16 billion, most of which was recorded in Q1. The assumed exchange rate of JPY130 to the U.S. dollar remains unchanged.



Financial Results for Q1 FY2023

Revenue of Major Products in Japan

Billions of yen

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change		FY2023	
			Value	%	May 15 forecasts	%
Equa®/EquMet®	8.8	**8.2**	(0.6)	(7.0)	32.4	25.2
TRERIEF®	4.4	**4.4**	0.0	0.2	15.0	29.6
LATUDA®	2.3	**2.8**	0.6	24.0	12.5	22.7
METGLUCO®	2.0	**1.9**	(0.1)	(4.3)	7.5	25.4
TWYMEEG®	0.1	**1.2**	1.1	—	4.2	27.6
LONASEN® Tape	0.7	**0.9**	0.2	35.3	3.3	27.0
AG products	2.3	**2.3**	0.0	1.1	8.6	27.2
Trulicity®*	8.6	**—**	(8.6)	—	—	—
Others	4.4	**5.4**	1.0	22.9	30.6	28.2
Export products/ Lump-sum revenue, etc.	7.4	**1.9**	(5.5)	(74.9)		
Non-pharmaceutical operations	11.0	**1.3**	(9.7)	(88.1)		
Total	52.1	**30.4**	(21.7)	(41.7)	114.1	26.6

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

- Progress is fundamentally on track in total
- Sales of LATUDA® continue to grow
- Sales of TWYMEEG® increased since the restriction on the number of prescription days was lifted in September 2022
- Of the "Export products/Lump-sum revenue, etc." in Q1 FY2022, the one-time income from the license agreement for DSP-0187 was ¥6.1B
- NHI drug price revision effect (¥1.0B) in total

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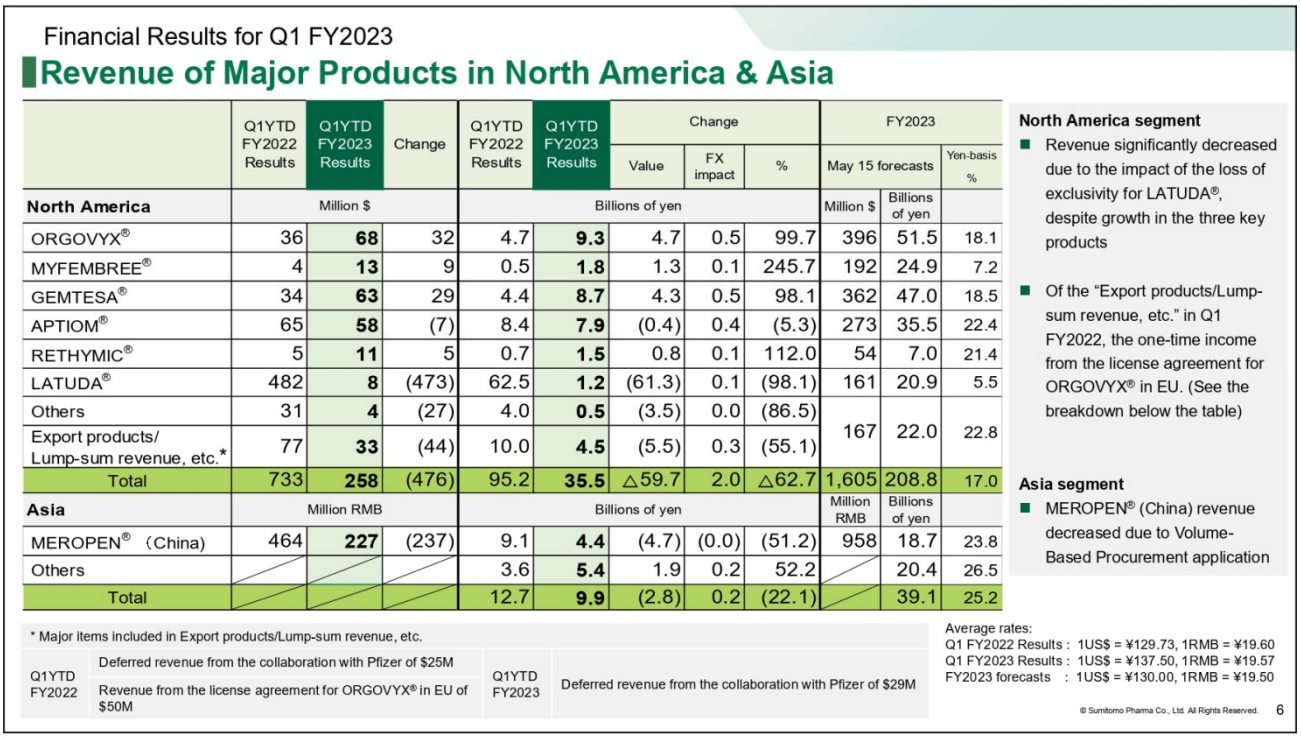
 5

Page five shows revenue from sales in Japan.

Revenues decreased by JPY21.7 billion from the same period last year to JPY30.4 billion. Sales of LATUDA® and TWYMEEG® increased but were affected by the termination of the Trulicity® sales collaboration in December 2022. It was also affected by the one-time payment of JPY6.1 billion from the out-licensing of DSP-0187 in the Japan segment, which had been recorded in the overseas and other segment in the same period of the previous year.

Revenues declined mainly because the Sumitomo Pharma Food & Chemical Co., Ltd. is no longer under the Group's umbrella following the transfer of all shares at the end of March 2023, losing its revenue recorded in the Other Regions in the same period last year.

Progress against the full-year forecast was 26.6%, with the segment as a whole progressing largely in line with expectations.



Financial Results for Q1 FY2023

Revenue of Major Products in North America & Asia

	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change	Q1YTD FY2022 Results	Q1YTD FY2023 Results	Change: Value	Change: FX impact	Change: %	FY2023 May 15 forecasts		FY2023 Yen-basis %
North America	Million $			Billions of yen					Million $	Billions of yen	
ORGOVYX®	36	**68**	32	4.7	**9.3**	4.7	0.5	99.7	396	51.5	18.1
MYFEMBREE®	4	**13**	9	0.5	**1.8**	1.3	0.1	245.7	192	24.9	7.2
GEMTESA®	34	**63**	29	4.4	**8.7**	4.3	0.5	98.1	362	47.0	18.5
APTIOM®	65	**58**	(7)	8.4	**7.9**	(0.4)	0.4	(5.3)	273	35.5	22.4
RETHYMIC®	5	**11**	5	0.7	**1.5**	0.8	0.1	112.0	54	7.0	21.4
LATUDA®	482	**8**	(473)	62.5	**1.2**	(61.3)	0.1	(98.1)	161	20.9	5.5
Others	31	**4**	(27)	4.0	**0.5**	(3.5)	0.0	(86.5)	167	22.0	22.8
Export products/ Lump-sum revenue, etc.*	77	**33**	(44)	10.0	**4.5**	(5.5)	0.3	(55.1)			
Total	733	**258**	(476)	95.2	**35.5**	△59.7	2.0	△62.7	1,605	208.8	17.0
Asia	Million RMB			Billions of yen					Million RMB	Billions of yen	
MEROPEN® （China）	464	**227**	(237)	9.1	**4.4**	(4.7)	(0.0)	(51.2)	958	18.7	23.8
Others				3.6	**5.4**	1.9	0.2	52.2		20.4	26.5
Total				12.7	**9.9**	(2.8)	0.2	(22.1)		39.1	25.2

North America segment

- Revenue significantly decreased due to the impact of the loss of exclusivity for LATUDA®, despite growth in the three key products
- Of the "Export products/Lump-sum revenue, etc." in Q1 FY2022, the one-time income from the license agreement for ORGOVYX® in EU. (See the breakdown below the table)

Asia segment

- MEROPEN® (China) revenue decreased due to Volume-Based Procurement application

* Major items included in Export products/Lump-sum revenue, etc.

Q1YTD FY2022	Deferred revenue from the collaboration with Pfizer of $25M Revenue from the license agreement for ORGOVYX® in EU of $50M
Q1YTD FY2023	Deferred revenue from the collaboration with Pfizer of $29M

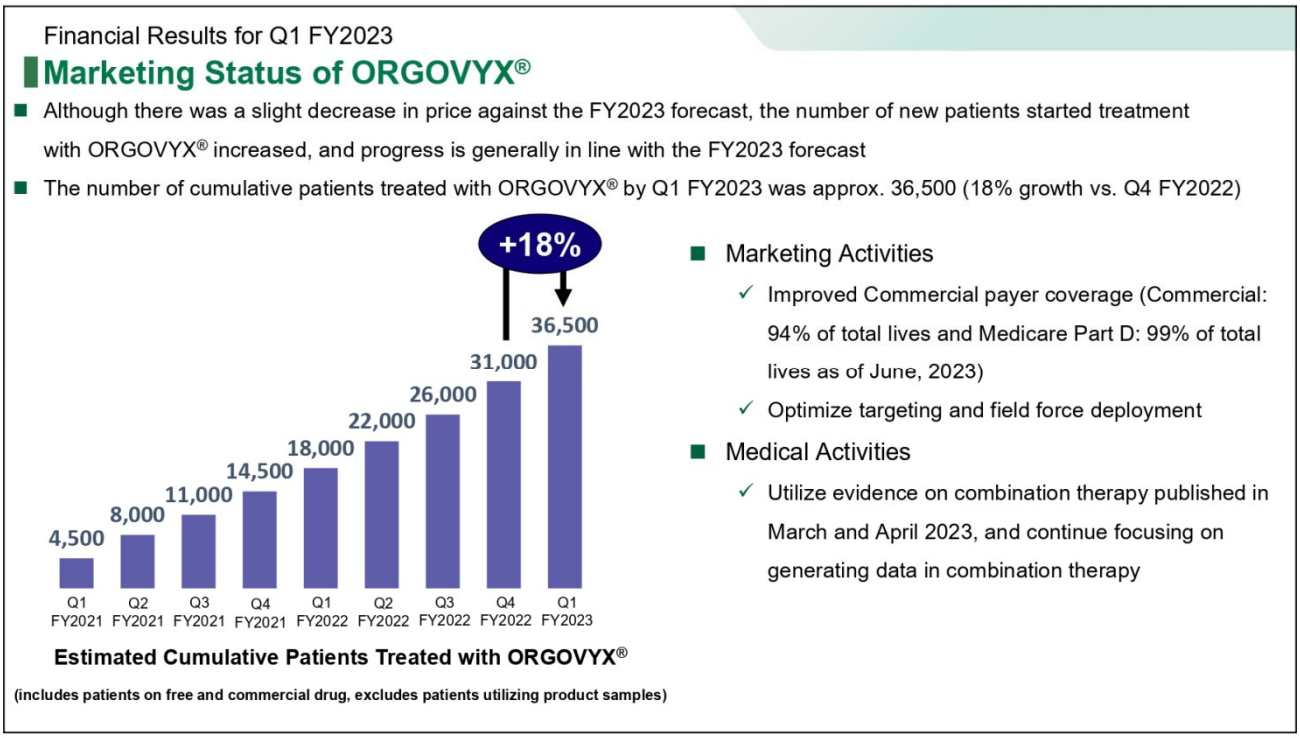
Average rates:
Q1 FY2022 Results : 1US$ = ¥129.73, 1RMB = ¥19.60
Q1 FY2023 Results : 1US$ = ¥137.50, 1RMB = ¥19.57
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

 6

Page six shows revenue from sales in North America and Asia.

In North America, sales of the three key products, ORGOVYX®, MYFEMBREE®, and GEMTESA® grew. However, the end of LATUDA®'s exclusivity period in the U.S. had a significant impact, resulting in sales of JPY35.5 billion on a yen basis, a decrease of JPY59.7 billion from the same period last year. Although progress against the full-year forecast for the three key products is low, we plan to make progress toward H2 of FY2023, and we are generally making growth as expected.

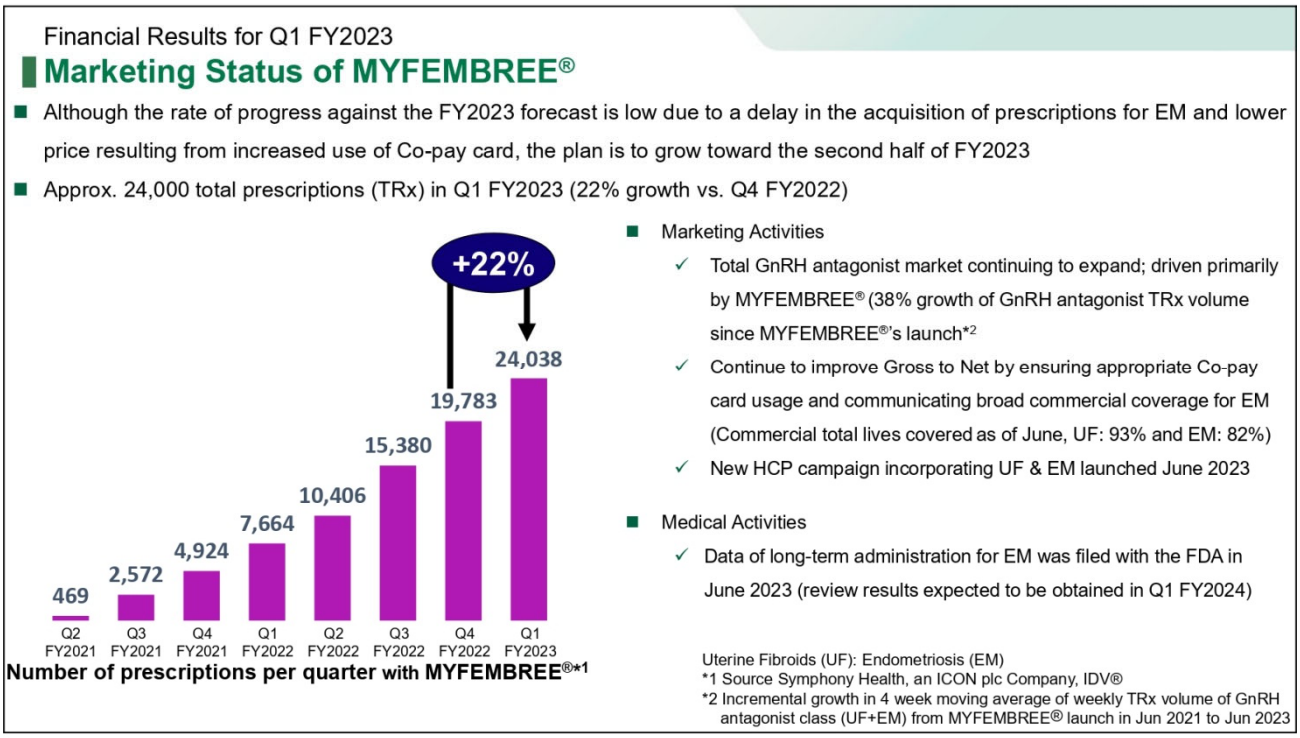
In Asia, the segment as a whole was affected by the decline in sales of MEROPEN® in China, which became subject to volume-based procurement, resulting in a JPY2.8 billion decline in sales compared to the same period last year.



Page seven shows the marketing status of ORGOVYX®.

ORGOVYX® has been administered to a cumulative total of approximately 36,500 patients through Q1 of FY2023, which is generally in line with the forecasts of FY2023, despite a slight price decline relative to the annual forecast.

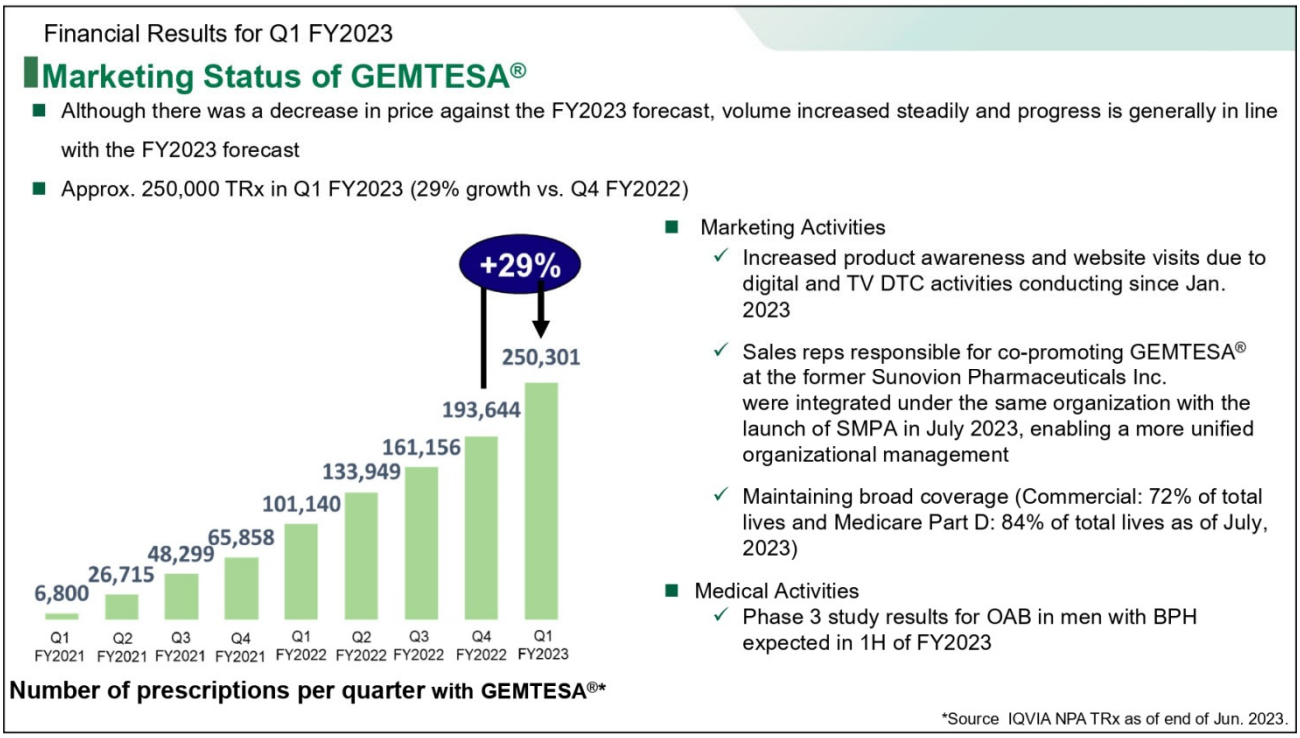
For marketing activities, the Advanced Analytics team will analyze various sales metrics and utilize real-world data to optimize targeting and field force deployment.



Page eight is the marketing status of MYFEMBREE®.

MYFEMBREE®'s progress against the annual forecast is low due to delays in obtaining prescriptions for endometriosis and lower prices due to increased use of Co-pay cards. It is planned to grow toward H2 of FY2023. In addition, we obtained approximately 24,000 prescriptions in Q1 of FY2023.

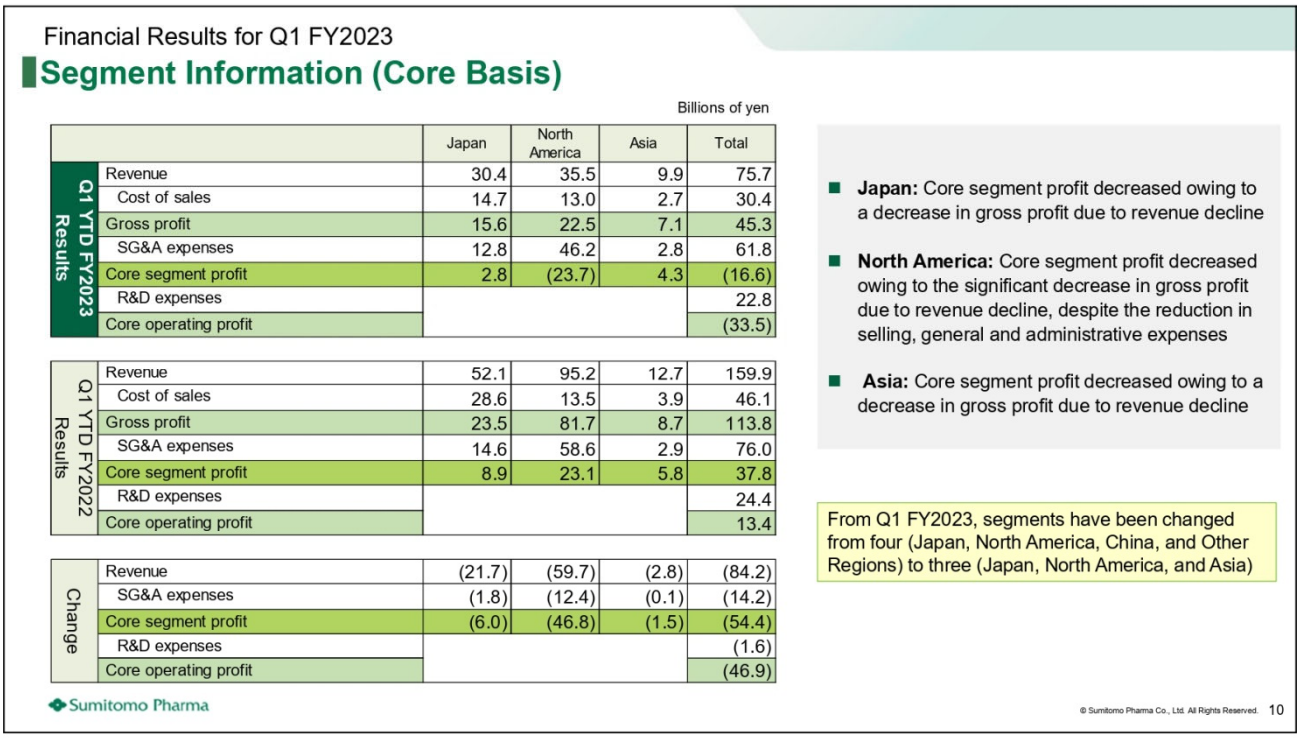
As for Co-pay cards, we will work to improve gross to net by monitoring their use for eligible patients and by suspending their use in some pharmacies to ensure appropriateness and further expanding commercial insurance coverage for endometriosis.



Page nine shows the marketing status of GEMTESA®.

GEMTESA® had lower prices versus the annual forecast due to increased rebate payments to Medicare Part D. In Q1, the number of prescriptions has increased steadily, with approximately 250,000 prescriptions obtained, and progress is generally in line with the forecasts of FY2023.

With the establishment of SMPA, the sales forces of Urovant Sciences, Inc. and Sunovion in charge of GEMTESA® were integrated, and we expect to be able to operate the organization and conduct marketing activities with a greater sense of unity.



Financial Results for Q1 FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
Q1 YTD FY2023 Results	Revenue	30.4	35.5	9.9	75.7
	Cost of sales	14.7	13.0	2.7	30.4
	Gross profit	15.6	22.5	7.1	45.3
	SG&A expenses	12.8	46.2	2.8	61.8
	Core segment profit	2.8	(23.7)	4.3	(16.6)
	R&D expenses				22.8
	Core operating profit				(33.5)
Q1 YTD FY2022 Results	Revenue	52.1	95.2	12.7	159.9
	Cost of sales	28.6	13.5	3.9	46.1
	Gross profit	23.5	81.7	8.7	113.8
	SG&A expenses	14.6	58.6	2.9	76.0
	Core segment profit	8.9	23.1	5.8	37.8
	R&D expenses				24.4
	Core operating profit				13.4
Change	Revenue	(21.7)	(59.7)	(2.8)	(84.2)
	SG&A expenses	(1.8)	(12.4)	(0.1)	(14.2)
	Core segment profit	(6.0)	(46.8)	(1.5)	(54.4)
	R&D expenses				(1.6)
	Core operating profit				(46.9)

- **Japan:** Core segment profit decreased owing to a decrease in gross profit due to revenue decline
- **North America:** Core segment profit decreased owing to the significant decrease in gross profit due to revenue decline, despite the reduction in selling, general and administrative expenses
- **Asia:** Core segment profit decreased owing to a decrease in gross profit due to revenue decline

From Q1 FY2023, segments have been changed from four (Japan, North America, China, and Other Regions) to three (Japan, North America, and Asia)

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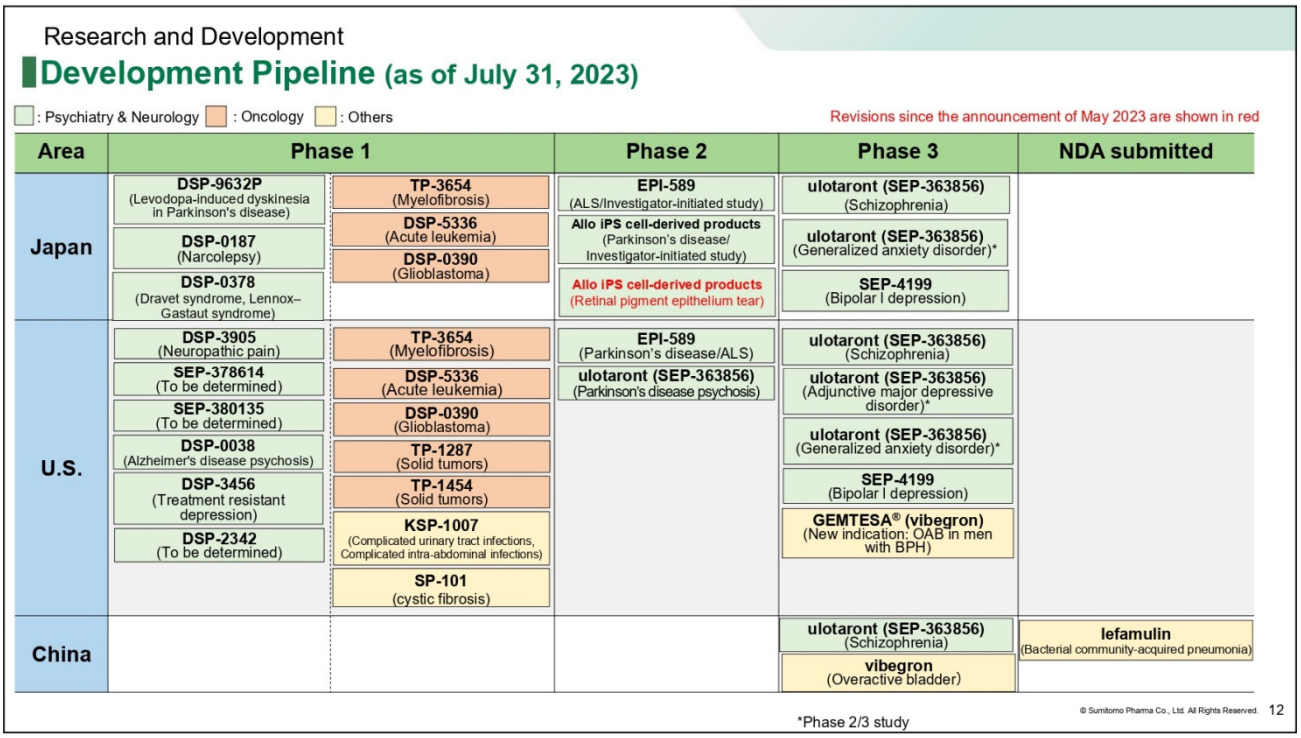
 10

Page 10 shows operating results by segment.

In Japan, core segment profit decreased by JPY6 billion to JPY2.8 billion due to a decrease in gross profit from lower sales.

In North America, core segment profit decreased by JPY46.8 billion to a loss of JPY23.7 billion due to the significant impact of lower gross profit from lower sales, despite lower selling, general and administrative expenses resulting from the end of LATUDA®'s exclusive sales period and other factors.

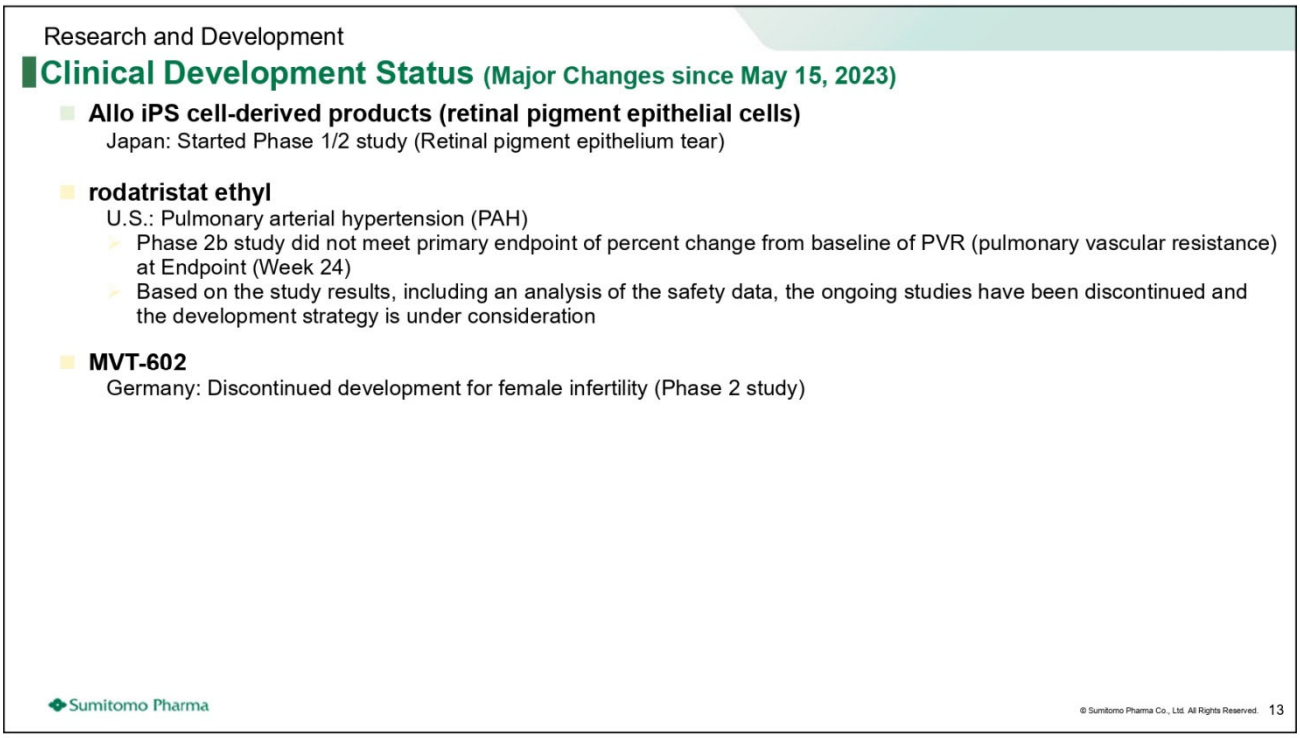
In Asia, core segment profit declined by JPY1.5 billion to JPY4.3 billion due to a decrease in gross profit from lower sales.



Ikeda: I will now explain the current status of clinical development.

Please turn to page 12. I will explain research and development. This table lists the development stages of our development pipelines.

The changes effective from May of this year are explained on the next page.

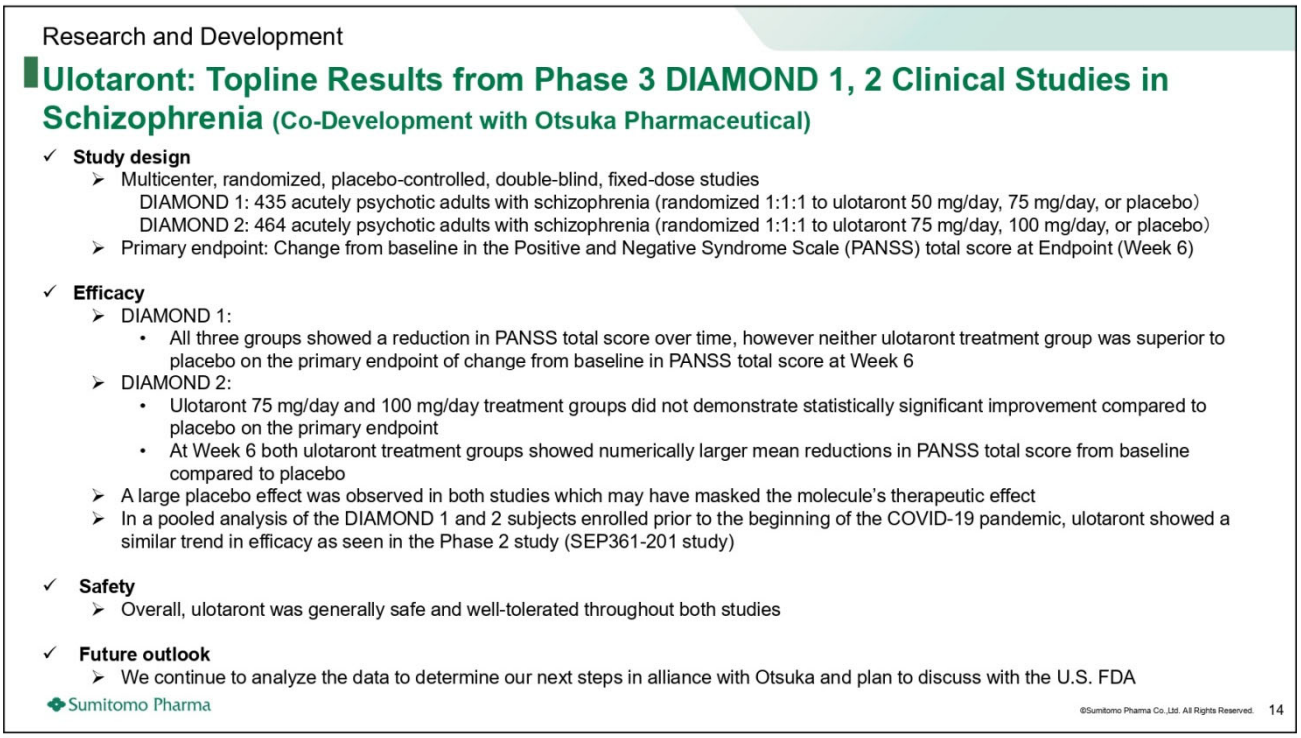


Please turn to page 13. This section summarizes the changes that have been made since May of this year.

In the Psychiatry & Neurology area, regarding retinal pigment epithelial cells that are cell therapy derived from allogeneic iPS cells, the Phase I/II study of retinal pigment epithelium tear was initiated in Japan.

In others area, the results of the Phase 2b study of rodatristat ethyl in pulmonary arterial hypertension conducted in the U.S. failed to meet its primary endpoint. Based on the results of this study and the analysis of safety data, the ongoing studies were discontinued. The future development strategy of this compound is currently under consideration.

In addition, the development of MVT-602 for infertility, which had been conducted in Germany, was discontinued.



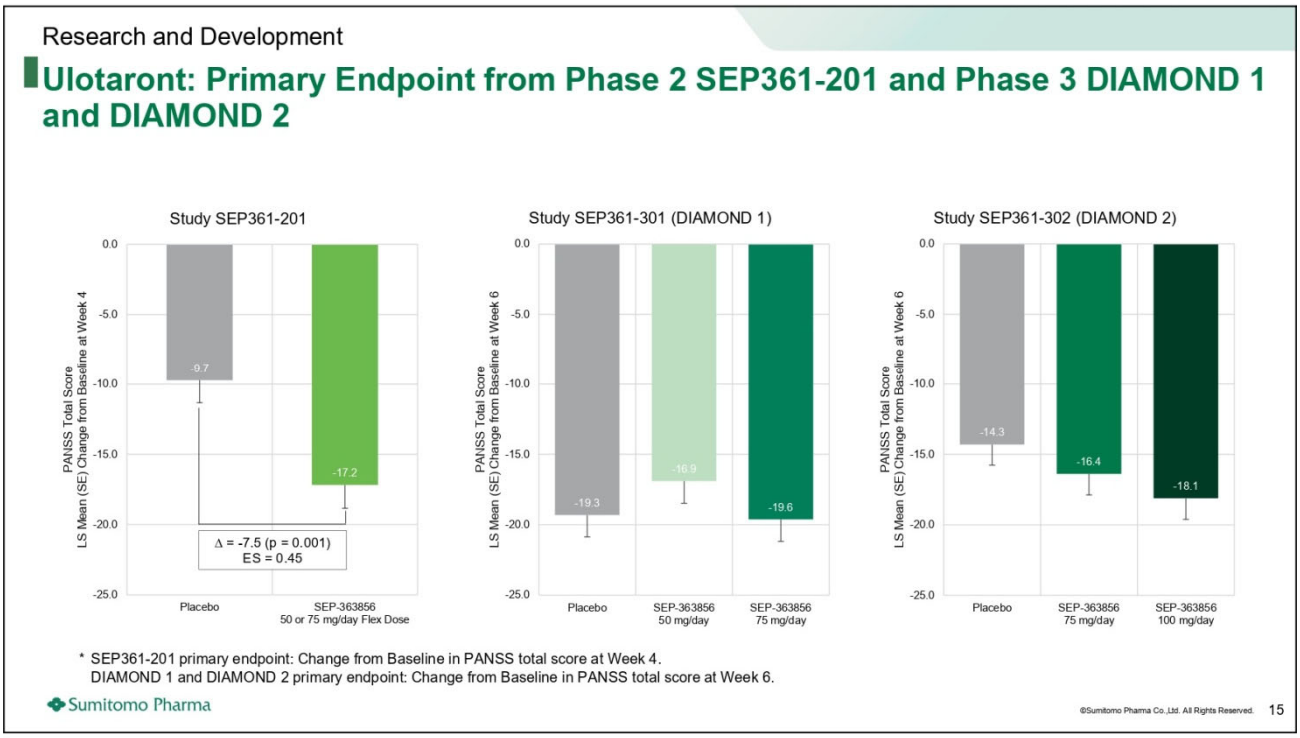
Please turn to page 14. We have obtained the results of DIAMOND 1 and DIAMOND 2, the Phase 3 schizophrenia studies of ulotaront and would like to share them.

The study design is shown on the slide.

In terms of efficacy, both studies did not demonstrate significant improvement versus placebo on the primary endpoint. Ulotaront showed improvement, but a large improvement was observed in the placebo group, which we think may have influenced the study results. In a pooled analysis of subjects enrolled prior to COVID-19 for both studies, the ulotaront group showed a similar trend in efficacy as in the Phase 2 study (SEP361-201 study).

Regarding safety, ulotaront was generally safe and well- tolerated.

Further data analysis and discussions with the FDA are planned for the future.



Please turn to page 15. The results of the primary endpoints of the Phase 2 study of ulotaront and the DIAMOND 1 and 2 studies are shown.

The top left of this page is the results of SEP361-201, Phase 2 study. Then the middle figure shows the results of the 301 study, the DIAMOND 1 study. The far-right side shows the results of the 302 study, the DIAMOND 2 study.

The DIAMOND 1 and 2 studies did not show statistically significant improvement. In general, we believe that the placebo effect was high and masked the efficacy of ulotaront compared to Phase 2 study and published reports. Further detailed analysis will be continued in the future.

This concludes the presentation.

Noguchi: Thank you, Mr. Ishida and Dr. Ikeda.

Question & Answer

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

Wakao, JPMorgan Securities Japan: First, let me ask about ulotaront. I assume that you are going to proceed with the analysis and aim to submit an application, but what scenario can you envision?

According to what you have explained, would the strategy be to collect only patients before COVID-19, collect them from Phase 3 study in Japan, and then apply for this Phase 2 study? And when will this become clear? It says that a similar trend was observed this time, but does it mean that this is a trend and not a statistically significant difference?

Ikeda: First, for the scenario, we are currently analyzing the detailed data. Based on the results, we would like to discuss this with Otsuka Pharmaceutical Co., Ltd., so at this time we are unable to present a clear scenario.

As for the timing, we will proceed with the analysis as soon as possible and consult with the FDA once complete.

Then, ulotaront showed a similar trend in efficacy at before COVID-19 of Phase 3 study as seen in the Phase 2 study. On the other hand, there is the issue of the number of subjects enrolled prior to the beginning of the COVID-19 pandemic.

Kimura: As for the analysis before COVID-19, there is a significant difference in terms of so-called p-value being 0.05. However, since we did not agree with the FDA on this type of analysis in advance, we have considered it carefully and made a qualitative comment that the results were similar to those of the Phase 2 study.

Wakao, JPMorgan Securities Japan: I see. Is it safe to assume that whether or not that will be accepted will be the focus in the future?

Kimura: Leaving aside the argument as to whether that is the only focus or not, that would be a focus. However, this will also be a matter for future discussion with Otsuka. We will discuss various options, including whether to leave it to discussions with the FDA alone or to conduct another study.

Wakao, JPMorgan Securities Japan: Okay. Thank you. My second question is about the three key products. The assumption is that the plan will go up toward H2, toward the end of the fiscal year, but I still think there are a few shades of gray.

In particular, MYFEMBREE® still seems a bit harsh. As for MYFEMBREE®, the quarterly data from Symphony Health shows a 22% growth in QoQ, while the weekly data shows a flat growth since April. How is the trend since this April analysis of the factors that are making it worse in the first place? Also, why will this volume grow in the future? Can you give us a little more background there?

Kimura: Regarding MYFEMBREE®, as you mentioned, we are expecting very positive results this year. In Q1, our calculations show that sales are more than 60% of our initial target.

Unlike, we do not recognize it being flat in April and May. We are working on gross to net, in other words, the issue of discount rates and such, and we expect sales to increase in the future.

We expect sales to grow in the future, especially in endometriosis. We have just launched a new integrated company on July 1, and we will be discussing these areas with Pfizer Inc. as we work to increase sales.

Nomura: It is true that some of the shipments were high in March 2023, decreased in April, and appear to have leveled off a bit in May and June. But, we're anticipating a little more from the start in H2.

So, once we have established a new company, SMPA, we're going to narrow down the targets. In the past, for example, the indications for uterine fibroids were women between the ages of 18 and 50, and so on. However, we will also promote narrowing down to the women with uterine fibroids or patients with such diseases, and we will also promote DTC in various ways.

Also, according to our data, we know that the frequency of detail and visits to important Tier 1 and Tier 2 doctors is still insufficient. We will improve that. In many ways, I would like to change the way we have been doing things in the past in order to promote our sales activities in a way that will help us to tap into this demand for MYFEMBREE®. Then we will take various measures, including, for example, reviewing the allocations of sales reps. But I think it will be very difficult for effects of those to appear immediately and easily. So, we hope to see such effects in Q3 and Q4.

Wakao, JPMorgan Securities Japan: I see. Thank you. That's all.

Muraoka, Morgan Stanley MUFG Securities: I agree with what you said about those three key products looking weak. I hope the Company can conduct a reanalysis of ulotaront to submit an application. However, if it is difficult to expect that to be the case, the study will have to be conducted again, and it will take a considerable amount of time to get the two together at aMDD and GAD, so I suspect that the timing of ulotaront's contribution to performance will be delayed back by four years to five years, in my opinion.

What I would like to ask you is whether the term "Plan B" is the right word, or if it is no longer "B." What are your plans for avoiding a deficit in the next fiscal year, i.e. two consecutive years? Can you please tell us what you did not say when you explained the Mid-term Business Plan (MTBP) 2027?

Nomura: Regarding the contribution of ulotaront to the performance in the indication of schizophrenia, there is certainly a milestone in terms of the application in the current fiscal year and then the approval in the next year.

However, as you know, schizophrenia has many Medicaid patients and low drug prices. On the other hand, we also need to have a certain number of sales reps, etc. Considering these factors, the contribution to profit and loss was not necessarily large during the MTBP 2027 period. Of course, beyond that, I think that beyond 2027 it will have a profit-and-loss contribution, and also an adjunctive aMDD contribution will be a significant addition.

In that sense, if we do not hire new sales reps or incur other marketing costs in the next fiscal year onward, it would curtail the incurrence of costs.

Of course, it is very unfortunate that this schizophrenia indication, or rather the clinical study, did not meet the endpoints. We are very disappointed that we could not achieve what we had hoped for, and we apologize for that. I can only say that at this point we will wait for further analysis of the data and then a new path forward. However, from a profit-and-loss perspective, during the MTBP 2027 period, as I mentioned earlier, this is the case.

Muraoka, Morgan Stanley MUFG Securities: I see. Thank you. Let me ask just one more question. In this situation, I'm actually wondering if narcolepsy royalties from Jazz Pharmaceuticals plc is becoming more important, although it's a bit further down the road.

So I would like to know a little bit about science. As much was discussed at Takeda Pharmaceutical Company Limited's meeting last week, a detailed paper of TAK-994 in *The New England Journal of Medicine* was on topic, and there was a lot of discussion about it.

Is the molecular structure of DSP-0187 that your company gave to Jazz very different from Takeda's TAK-994 or TAK-861? And there was a discussion by Takeda about metabolites affecting safety, but can we reasonably assume that this is unlikely to apply to your company? Please share any basic science findings in this area.

Ikeda: In terms of the face of the compounds, we think that our compounds and Takeda's compounds are different. Then, there was the TAK-994, I think this is the one with hepatotoxic, but the face of such parent compound to the original compound is different. Hence, hepatotoxicity due to metabolites would be different.

As for our company's drug, it is developed by Jazz, so we do not have such information at this time.

Yamaguchi, Citigroup Global Markets Japan: I would like to ask you a question or two about ulotaront.

First of all, it means that this placebo effect was very large, which of course is twice as placebo effective as the normal study. So, it seems to be more effective than the drug. Is it possible to, conversely, have a logic that could eliminate this without study? Is it still something that can only be understood by doing the study?

Kimura: That is exactly the area that we are also considering a lot right now. The placebo group dropped nearly 20 points on the PANSS. This is especially true for DIAMOND 1, and we are currently conducting a detailed analysis to determine how we can eliminate this area in advance.

But, as I said, that has not happened in patients who were enrolled before COVID-19. So, I think there must have been some kind of timing factor. However, we are in the process of doing a detailed analysis, so we are not in a position to say anything formally.

Yamaguchi, Citigroup Global Markets Japan: I see. As you mentioned earlier, what about the possibility of the same thing happening with placebo partially in other studies?

Ikeda: aMDD and GAD are in progress. I don't believe that any intermediate analysis, etc. are scheduled at this time. So, in that sense, we would like to analyze it if we have a chance at some point in the future.

However, I don't think it is impossible that other drugs may have such different results before and after the spread of COVID-19 as well. Therefore, we would like to proceed with careful analysis in this area and consider the influences of other drugs as well. However, at this point, we are honestly not sure.

Yamaguchi, Citigroup Global Markets Japan: I guess your company must have been surprised when you actually conducted the study. The placebo effect tends to appear to some extent, but it is a bit unexpected to see it appear to this extent.

Ikeda: The placebo level is generally around 10, so we have heard that it is very rare for a placebo to reach 20, even in the past. We will have to do more analysis to determine the cause of this unusual result.

Yamaguchi, Citigroup Global Markets Japan: I see. And one more thing, thank you for your comments and discussions, including MYFEMBREE®. I understand the logic of your company, but looking at it from the outside, I see that it is nevertheless starting off quite harshly. Is there still a possibility of revising this again around Q2, especially for these three key products? This includes both above and below.

Nomura: Regarding the meaning of revising, there are two elements: where we place it as a goal, and where the current achievable range is. For example, if we forecast around September, what kind of measures can we think of to make them reach our goal?

What happens when you take those measures? We do not believe that a simple sales forecast will lead to a financial forecast. So, we are taking various measures in the future, as we become a new company and as our sales executives are changing. We would like to consider what the future sales of the three drugs will be like, taking into account what kind of effect this will have.

Hashiguchi, Daiwa Securities: As for the US sales, LATUDA® is at USD8 million, which is quite low compared to your forecast for the full year. Can you tell me if this includes some sort of price retroaction for the previous year's shipment and why?

Ishida: As for LATUDA®, the payment of rebates for sales made from January to March of this year occurred in Q1, and the adjustment for this occurred in Q1.

Hashiguchi, Daiwa Securities: Is that factored into the full-year plan? Or is there a possibility that this is not in and but retroacted, and if so, is there a possibility of a downside for the full year?

Ishida: This portion has already been incorporated in the full-year plan.

Hashiguchi, Daiwa Securities: Thank you very much. My understanding is that the impact on the sales of the three key products that were retroacted in the previous fiscal year and delivered products are not included in the results for Q1. Is it correct?

Ishida: Basically, the situation of LATUDA® is a special situation because it is right after the LOE. Some adjustments, such as true-up, are naturally applied to the three key products as well, but the effect is not as great as in LATUDA®.

Hashiguchi, Daiwa Securities: Thank you very much. I was wondering if you could comment on the results of Phase 3 studies of ulotaront and how safe it was. I remember a clean profile in Phase 2 study, with almost no increase in schizophrenia possibilities or common adverse events in ulotaront compared to placebo.

This time, the observation period and administration period have been extended, and the number of cases has also increased significantly. Could you tell me how it has been changed?

Ikeda: The results on safety and tolerability are good reflections of the results that have been obtained so far.

Hashiguchi, Daiwa Securities: Thank you very much. Finally, I'm afraid this is a similar question, but do you have any hypothesis as to why the placebo effect was greater with COVID-19? Does schizophrenia have any particular features of the disease that make such things susceptible to amplification by COVID-19? Or was the change in handling of the two studies by your company an effect of the start of the COVID-19 pandemic? Is there anything you know at this point, even hypothetical, that you would be willing to share?

Ikeda: We are still analyzing the details of what you just asked. We're sorry.

Sakai, Credit Suisse Securities (Japan): I'm a little concerned about the part that was registered before the pandemic, for ulotaront. As I recall, your company stopped clinical trials for a time when there was a crisis in Ukraine, I think they were Phase 3 studies.

I can imagine that the patients would have been from different areas and their backgrounds would have been quite different. I know you probably don't have an answer to this question, but how about the impact on that area? Although it is said to be before the pandemic, do you see the so-called Ukraine crisis as having had some impact on the recombination of clinical trials? This is my first question.

Ikeda: DIAMOND 1 and then also the DIAMOND 2 studies started on September 11 or 30, 2019. Also, regarding the definition of the start date of COVID-19, we are considering March 13, 2020, the date when the emergency declaration was issued in the U.S.

The war in Ukraine started in February 2022, so in that sense, regarding your question, we believe that we can relatively distinguish between patients who were recruited before COVID-19 and after COVID-19. However, since the war in Ukraine and Russia started, we have not been recruiting patients from Ukraine and Russia, so we have shifted our recruitment to other regions.

Sakai, Credit Suisse Securities (Japan): So you are talking about patients starting in 2019 until March 2020, when the COVID-19 emergency declaration was issued.

Ikeda: Yes, I think that is correct.

Sakai, Credit Suisse Securities (Japan): I see. Thank you very much. Since the president is here, I would like to ask you a few questions. Based on the Q1 results, or rather the situation, it is said that there are delays in the three U.S. products. On the other hand, do you feel the need to review and change the operations in Japan?

Then, I wonder if it will be necessary to leverage the balance sheet in some way. Can you tell me a little bit about these two points?

Nomura: Thank you very much. I think there are many ways to leverage the Japan business. However, I have been saying this for a long time, but we believe that our first priority is to search for such opportunities to use our existing business assets.

Then, as for the balance sheet, of course, we cannot just leave it as it is. I can't give you specifics at this time, but we are considering various possibilities. I cannot be more specific, I apologize.

Ishii, Iyakutsushin: Regarding the ulotaront, you mentioned earlier that 10 is common for placebos. Is there anything other than COVID-19 that could cause that placebo effect to increase?

Ikeda: The details of how the placebo effect became such a very large value are now under analysis. We believe that COVID-19 may be one of the factors, but we are also analyzing other factors.

Ishii, Iyakutsushin: You mean you don't know yet. Also, I would like to know a little bit about the profit progress forecast for ORGOVYX®, MYFEMBREE®, and GEMTESA®, and the current response in terms of profit.

Nomura: With regard to ORGOVYX® and MYFEMBREE®, we are talking about splitting the profits with Pfizer, so from that perspective, it is as expected.

Regarding GEMTESA®, at this point, in Q1, we are at about 89% of our budgeted sales, which is a little short of what we had expected.

We expect that we will be able to achieve our annual target for the year Q1, ORGOVYX® is at 106% in yen. From this perspective, only MYFEMBREE® is still a bit weak. As I was asked by the analysts earlier, MYFEMBREE® is the only thing that I am concerned about right now.

However, since I mentioned earlier that we are considering various measures, I am very hopeful that the various sales measures we are taking now will somehow have an effect in Q3 or Q4.

Chiboshi, Jiho: I have two questions, and the first is that the part of the performance plan based on the results of the Phase 3 studies of ulotaront, my understanding is that the market for schizophrenia was not that large, and that this is not enough to change the plan for the MTBP 2027. Is this correct?

Nomura: If we take only the period of the MTBP 2027, there is no significant impact on profit and loss, so I understand that this is not a situation that would require a change in the MTBP 2027 itself.

Chiboshi, Jiho: I see. Thank you. Also, I believe that Mr. Nomura mentioned earlier that he has been looking for opportunities to introduce the sales force in the Japan business in a way that would allow them to make the best use of the sales force for some time. Is there any good progress in this area or any good news to talk about? I'd like to know about that.

Nomura: Well, I can't be more specific here, but in various ways our sales people in charge of alliances are looking for opportunities for alliances in various forms.

At this point, we do not have any specifics yet, but we are working hard to promote these activities.

Chiboshi, Jiho: Thank you. I have a feeling, even as an amateur, that the sales force in Japan may become a bit redundant if things continue as they are. What is your perception of that?

Nomura: Yes, I think you are saying that there will be a surplus in the future, for example, when the affiliated products in the diabetes area will reach LOE. Our current thinking is that we would like to take some measures to prevent such a situation from occurring.

Tsubokura, The Chemical Daily: Is the fact that LATUDA®'s Q1 results in North America are considerably less progress than the full-year forecast as expected? Or is it that the decrease was a bit unexpected and large? Can you tell us how you view that?

Ishida: To some extent, the situation in LATUDA® was within our expectations.

Tsubokura, The Chemical Daily: So you are saying that the range of 5% of the fiscal year for the April to June period is as expected?

Ishida: The progress of LATUDA®'s sales in Q1 was as shown here, and the fact that the progress was a little slower than for the full year is within the range we had expected.

Tsubokura, The Chemical Daily: Okay. So is it safe to assume that there will not be that much of an impact with respect to the full year?

Ishida: Yes, that is my understanding.

Noguchi: This concludes the financial results briefing of Sumitomo Pharma for Q1 FY2023. Thank you very much for joining us today.

[END]