Q2 Financial Results Briefing for FY2023

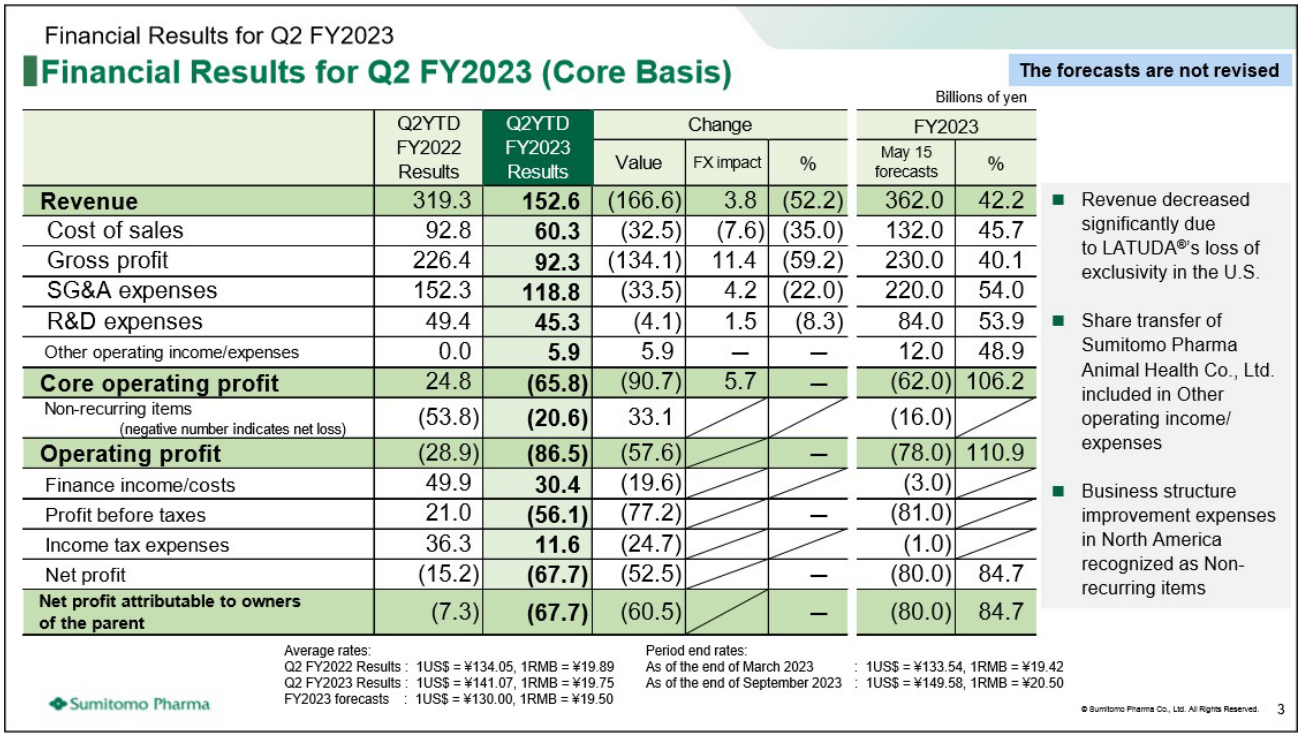
[Date]	October 31, 2023	
[Time]	16:30 – 17:55 (Total: 85 minutes, Presentation: 37 minutes, Q&A: 48 minutes)	
[Venue]	Tokyo Head Office and Webcast	
[Number of Speakers]	4	
	Hiroshi Nomura	Representative Director, President and CEO
	Toru Kimura	Representative Director, Senior Managing Executive Officer
	Yoshiharu Ikeda	Member, Board of Directors, Managing Executive Officer
	Naoki Noguchi	Executive Officer, Vice President, Head of Corporate Communications

Presentation

Noguchi: Now we will now begin the financial results briefing for Q2 FY2023.

Thank you very much for joining us today.

Mr. Nomura will now explain the financial results for Q2 FY2023. Mr. Nomura, over to you.



Financial Results for Q2 FY2023

Financial Results for Q2 FY2023 (Core Basis)

The forecasts are not revised

Billions of yen

	Q2YTD FY2022 Results	Q2YTD FY2023 Results	Change			FY2023	
			Value	FX impact	%	May 15 forecasts	%
Revenue	319.3	**152.6**	(166.6)	3.8	(52.2)	362.0	42.2
Cost of sales	92.8	**60.3**	(32.5)	(7.6)	(35.0)	132.0	45.7
Gross profit	226.4	**92.3**	(134.1)	11.4	(59.2)	230.0	40.1
SG&A expenses	152.3	**118.8**	(33.5)	4.2	(22.0)	220.0	54.0
R&D expenses	49.4	**45.3**	(4.1)	1.5	(8.3)	84.0	53.9
Other operating income/expenses	0.0	**5.9**	5.9	—	—	12.0	48.9
Core operating profit	24.8	**(65.8)**	(90.7)	5.7	—	(62.0)	106.2
Non-recurring items (negative number indicates net loss)	(53.8)	**(20.6)**	33.1			(16.0)	
Operating profit	(28.9)	**(86.5)**	(57.6)		—	(78.0)	110.9
Finance income/costs	49.9	**30.4**	(19.6)			(3.0)	
Profit before taxes	21.0	**(56.1)**	(77.2)		—	(81.0)	
Income tax expenses	36.3	**11.6**	(24.7)			(1.0)	
Net profit	(15.2)	**(67.7)**	(52.5)		—	(80.0)	84.7
Net profit attributable to owners of the parent	(7.3)	**(67.7)**	(60.5)		—	(80.0)	84.7

- 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 items

Average rates:
Q2 FY2022 Results : 1US$ = ¥134.05, 1RMB = ¥19.89
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
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 September 2023 : 1US$ = ¥149.58, 1RMB = ¥20.50

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Nomura: Thank you all very much for joining us today.

Given the time constraints, I would like to quickly explain the financial results.

As usual, this slide is a comparison with the same period of the previous year. As you all know, there are some major comparative obstacles, which I would like to explain separately. I would especially like to mention here that the other operating income and expenses here is the gain from the sale of Sumitomo Pharma Animal Health Co., Ltd.

Of the JPY20.6 billion non-recurring items, JPY20.3 billion consists of business structure improvement expenses in North America, which were incurred in the process of bringing the eight companies together.

The large amount of JPY30.4 billion in finance income and costs is due to foreign exchange gains on assets denominated in foreign currencies, which are arising from the weakening of the exchange rate.

Financial Results for Q2 FY2023

Financial Results for Q2 FY2023 (Core Basis) - vs. Q2 YTD FY2023 Plans

Billions of yen

	Q2YTD FY2023 Plans	**Q2YTD FY2023 Results**	Change			
			Value	%	FX impact	% (w/o FX)
Revenue	166.2	**152.6**	(13.6)	91.8	6.3	88.0
Cost of sales	60.6	**60.3**	(0.2)	99.6	2.2	96.0
Gross profit	105.7	**92.3**	(13.3)	87.4	4.1	83.5
SG&A expenses	116.1	**118.8**	2.6	102.3	6.8	96.4
R&D expenses	44.3	**45.3**	1.0	102.3	2.3	97.0
Other operating income/expenses	7.0	**5.9**	(1.1)	84.4	–	84.4
Core operating profit	(47.8)	**(65.8)**	(18.1)	–	(5.0)	–

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

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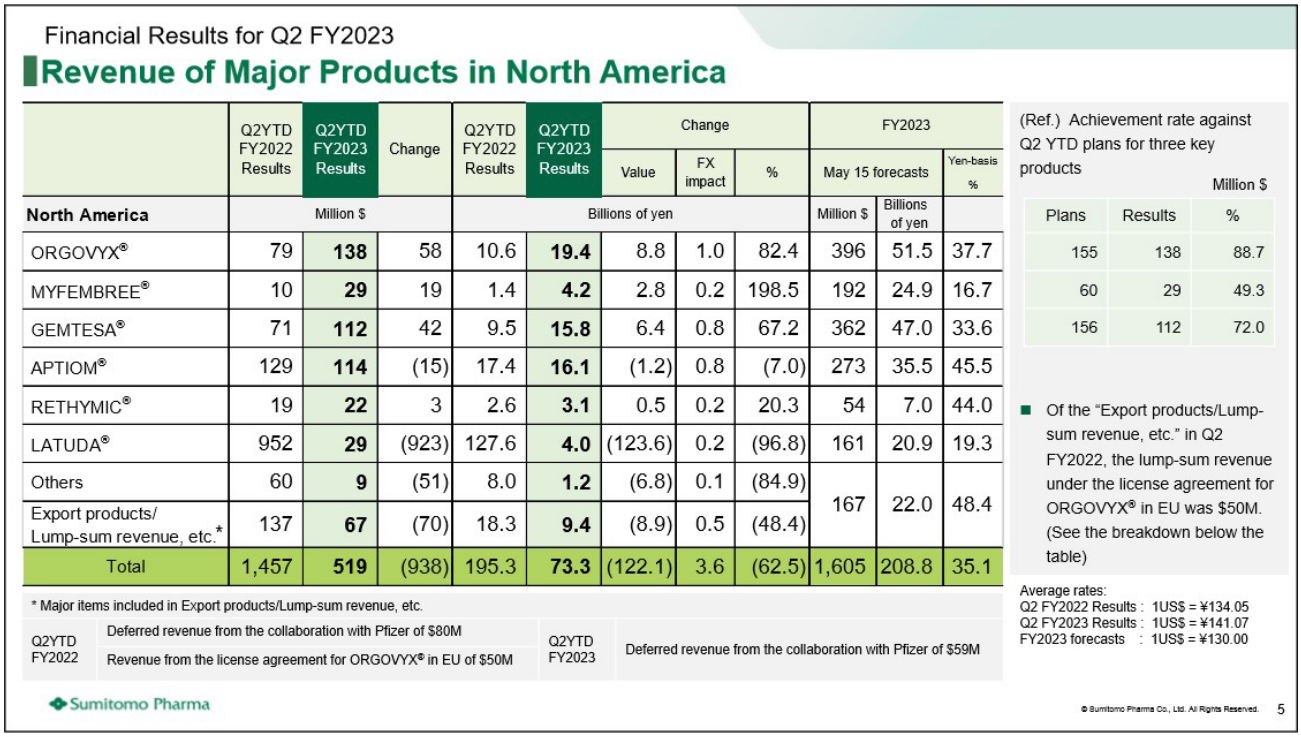
The figures on the leftmost side of the table are a cumulative plan that we have internally until Q2 FY2023, although this is a figure that we have not made public. Next figures are the results.

Here is the exchange rate. The plan is calculated at JPY130, and the results use the figure of JPY141 against U.S. dollar, so there is an exchange difference. If you look at the percentage of achievement here, which is real, sales revenue is 88%, which is a bit disappointing. I will come back to this later.

Gross profit was 83.5% of the forecast figure. Selling, general and administrative expenses were 96.4% of the forecast figure, a little higher than planned. Research and development expenses were also lower than anticipated. As I mentioned earlier, we sold Sumitomo Pharma Animal Health. We have a few more asset sales in the works, so part of our activity in this area has not materialized yet.

Looking in terms of the actual rate of achievement, if you look at it in monetary terms, the gross profit was down JPY13.3 billion compared to the plan, with most of that attributable to North America. In SG&A expenses, we see a figure of JPY2.6 billion above the plan. This increase includes foreign exchange, and again, North America is a significant factor.

The change for North America was JPY3.9 billion down, which means that the change is mostly in North America. In Japan and Asia, the actual results are roughly on par with the plan, with a large difference in North America, or rather, a negative difference in terms of sales revenue. As for SG&A expenses, this means that there is a positive difference in real terms.



Financial Results for Q2 FY2023

Revenue of Major Products in North America

North America	Q2YTD FY2022 Results (Million $)	Q2YTD FY2023 Results (Million $)	Change (Million $)	Q2YTD FY2022 Results (Billions of yen)	Q2YTD FY2023 Results (Billions of yen)	Change Value	Change FX impact	Change %	FY2023 May 15 forecasts Million $	FY2023 May 15 forecasts Billions of yen	FY2023 Yen-basis %
ORGOVYX®	79	**138**	58	10.6	**19.4**	8.8	1.0	82.4	396	51.5	37.7
MYFEMBREE®	10	**29**	19	1.4	**4.2**	2.8	0.2	198.5	192	24.9	16.7
GEMTESA®	71	**112**	42	9.5	**15.8**	6.4	0.8	67.2	362	47.0	33.6
APTIOM®	129	**114**	(15)	17.4	**16.1**	(1.2)	0.8	(7.0)	273	35.5	45.5
RETHYMIC®	19	**22**	3	2.6	**3.1**	0.5	0.2	20.3	54	7.0	44.0
LATUDA®	952	**29**	(923)	127.6	**4.0**	(123.6)	0.2	(96.8)	161	20.9	19.3
Others	60	**9**	(51)	8.0	**1.2**	(6.8)	0.1	(84.9)	167	22.0	48.4
Export products/ Lump-sum revenue, etc.*	137	**67**	(70)	18.3	**9.4**	(8.9)	0.5	(48.4)			
Total	1,457	**519**	(938)	195.3	**73.3**	(122.1)	3.6	(62.5)	1,605	208.8	35.1

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

Q2YTD FY2022	Deferred revenue from the collaboration with Pfizer of $80M Revenue from the license agreement for ORGOVYX® in EU of $50M
Q2YTD FY2023	Deferred revenue from the collaboration with Pfizer of $59M

(Ref.) Achievement rate against Q2 YTD plans for three key products

Million $

Plans	Results	%
155	138	88.7
60	29	49.3
156	112	72.0

- Of the "Export products/Lump-sum revenue, etc." in Q2 FY2022, the lump-sum revenue under the license agreement for ORGOVYX® in EU was $50M. (See the breakdown below the table)

Average rates:
Q2 FY2022 Results : 1US$ = ¥134.05
Q2 FY2023 Results : 1US$ = ¥141.07
FY2023 forecasts : 1US$ = ¥130.00

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This is revenue by product.

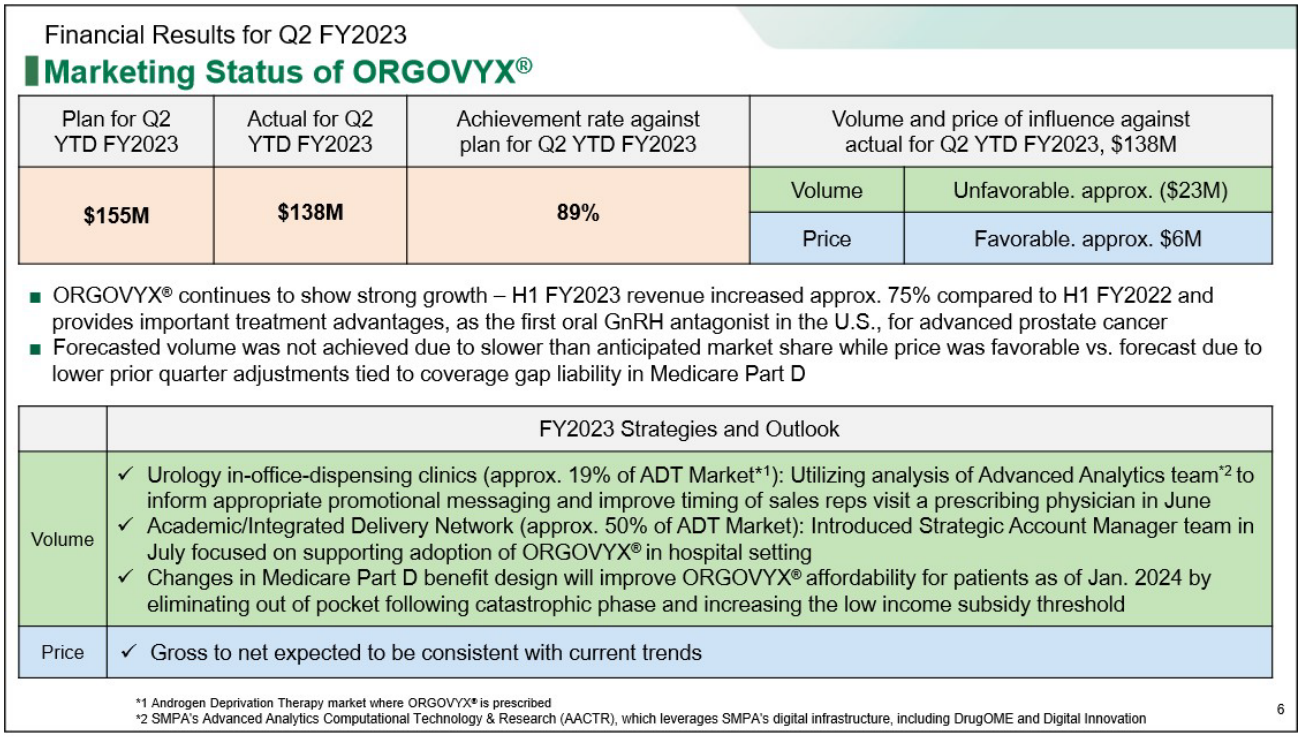
Comparing it to the same period last year, it looks like it has grown very much. This is as planned. This is the cumulative amount in U.S. dollars through Q2 FY2023. Revenue for ORGOVYX® is USD138 million, which is 88.7% of our Q2 YTD plan.

MYFEMBREE® is at roughly half of its USD60 million target. GEMTESA® is at 72% of its $156 million Q2 YTD plan, at $112 million.

The numbers are a little low based on the full-year forecasts, because we are anticipating stronger figures in H2. This is how our cumulative H1 figures tend to look. In particular, GEMTESA® is a little low for various reasons, which I will explain later. ORGOVYX® is just about right. And as for MYFEMBREE®, this level of sales suggests some attention is necessary.

Then on this table, I just want to make a small comment that LATUDA® has now had its LOE, so this is the kind of difference. There is a bit of a difference in Others, because XOPENEX®, BROVANA®, and others have already been divested. It is structured in such a way that it was included until last year, but since it is no longer there, we can see that difference.

We have seen a very large decrease in yen terms compared to the previous year. The figure for LATUDA® has almost completely fallen off.



Financial Results for Q2 FY2023

Marketing Status of ORGOVYX®

Plan for Q2 YTD FY2023	Actual for Q2 YTD FY2023	Achievement rate against plan for Q2 YTD FY2023	Volume and price of influence against actual for Q2 YTD FY2023, $138M	
$155M	**$138M**	**89%**	Volume	Unfavorable. approx. ($23M)
			Price	Favorable. approx. $6M

- ORGOVYX® continues to show strong growth – H1 FY2023 revenue increased approx. 75% compared to H1 FY2022 and provides important treatment advantages, as the first oral GnRH antagonist in the U.S., for advanced prostate cancer
- Forecasted volume was not achieved due to slower than anticipated market share while price was favorable vs. forecast due to lower prior quarter adjustments tied to coverage gap liability in Medicare Part D

	FY2023 Strategies and Outlook
Volume	✓ Urology in-office-dispensing clinics (approx. 19% of ADT Market*1): Utilizing analysis of Advanced Analytics team*2 to inform appropriate promotional messaging and improve timing of sales reps visit a prescribing physician in June ✓ Academic/Integrated Delivery Network (approx. 50% of ADT Market): Introduced Strategic Account Manager team in July focused on supporting adoption of ORGOVYX® in hospital setting ✓ Changes in Medicare Part D benefit design will improve ORGOVYX® affordability for patients as of Jan. 2024 by eliminating out of pocket following catastrophic phase and increasing the low income subsidy threshold
Price	✓ Gross to net expected to be consistent with current trends

*1 Androgen Deprivation Therapy market where ORGOVYX® is prescribed
*2 SMPA's Advanced Analytics Computational Technology & Research (AACTR), which leverages SMPA's digital infrastructure, including DrugOME and Digital Innovation

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I would now like to explain each of these three key products individually.

As I mentioned earlier, for ORGOVYX®, the actual result was USD138 million against a plan of USD155 million, which means that we achieved almost 89% of our sales plan for Q2 YTD FY2023. In volume terms, it is negative USD23 million. In price terms, it is positive USD6 million.

It is about 85% of the budget for Q2 YTD FY2023 in volume terms.

In price terms it is a bit positive. It says that this is due to lower prior quarter adjustments tied to coverage gap liability in Medicare Part D. In essence, it is due to the payer mix, which is why it is a bit price-positive.

We have to decide what we will do in the future, and we have to adopt a marketing strategy to increase sales by volume. Some points are written here, but for urology clinics with in-office dispensing, it is used in 19% of ADT market.

This came from an analysis by our digital team. This is because the sales reps will be informed by prescription data that a patient has been prescribed a GnRH antagonist, or that a patient with prostate cancer has visited, and this information will be passed on to the sales reps in that area. The reps can then make sure to visit the doctor at the right time.

We also know in advance what kind of patients are prescribed GnRH antagonists. ORGOVYX® is tablet, but competitor treatment is injectable. We know in advance what kind of treatment they are receiving, which is very useful in terms of talking with doctors about various things.

In addition, we have not had sufficient access to academic and integrated delivery network, which account for 50% of the ADT market, so we have appointed strategic account managers and are actively working on this issue.

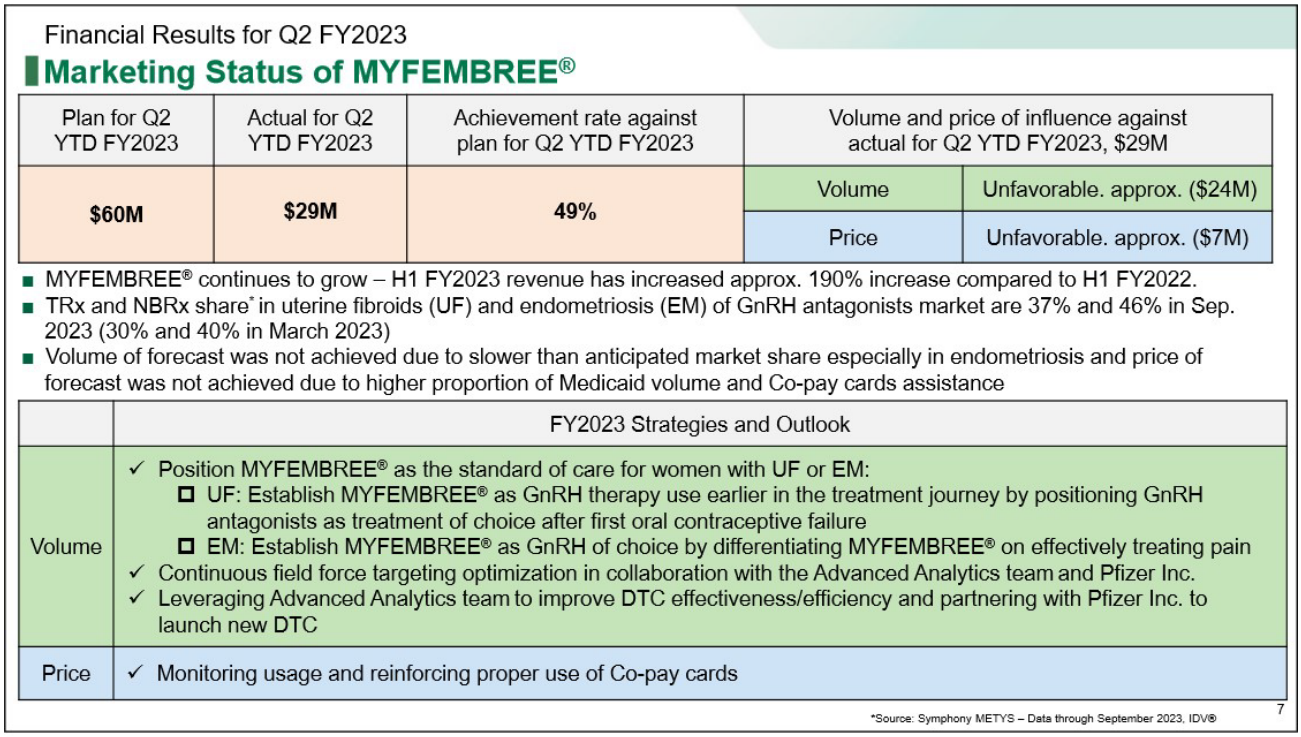
However, for hospital purchasing, we are not dealing with doctors, but with purchasing managers of treatments. Since we are trying to access such people and have them use ORGOVYX®, in short, I am not sure if it will be effective immediately, since there will be various timing issues, such as the revision of hospital formularies and so on. We are working very hard in this area, and I think it will produce results.

We are also working with urology clinics, for example, that have only been providing injectable treatments, and are very familiar with Medicare Part B insurance claims, while ORGOVYX® is a Medicare Part D insurance claim. We are working to support the procedural aspects relating to these different types of insurance claims.

Also, some of these insurance policies require prior approval. We are also working to support such procedures in effort to reduce barriers to prescriptions.

At the bottom of the page is the elimination of out of pocket for medical expenses in catastrophic coverage starting next year. Catastrophic coverage, at the top of the list, has a 5% personal contribution until this year, but not after next year. So, since the drug costs are such and such, and this is for cancer treatment, if the drug costs are somewhat higher than the individual cost, once you get through to some extent, then the individual cost will no longer be incurred. In that sense, we believe that this kind of thing would also make it easier to prescribe ORGOVYX®.

As for price, since this is a payer mix, I believe that the current trend for gross to net will continue. However, that is beyond our control, so we are taking measures to somehow increase the volume in this way.



Financial Results for Q2 FY2023

Marketing Status of MYFEMBREE®

Plan for Q2 YTD FY2023	Actual for Q2 YTD FY2023	Achievement rate against plan for Q2 YTD FY2023	Volume and price of influence against actual for Q2 YTD FY2023, $29M	
$60M	**$29M**	**49%**	Volume	Unfavorable. approx. ($24M)
			Price	Unfavorable. approx. ($7M)

- MYFEMBREE® continues to grow – H1 FY2023 revenue has increased approx. 190% increase compared to H1 FY2022.
- TRx and NBRx share* in uterine fibroids (UF) and endometriosis (EM) of GnRH antagonists market are 37% and 46% in Sep. 2023 (30% and 40% in March 2023)
- Volume of forecast was not achieved due to slower than anticipated market share especially in endometriosis and price of forecast was not achieved due to higher proportion of Medicaid volume and Co-pay cards assistance

	FY2023 Strategies and Outlook
Volume	✓ Position MYFEMBREE® as the standard of care for women with UF or EM: ☐ UF: Establish MYFEMBREE® as GnRH therapy use earlier in the treatment journey by positioning GnRH antagonists as treatment of choice after first oral contraceptive failure ☐ EM: Establish MYFEMBREE® as GnRH of choice by differentiating MYFEMBREE® on effectively treating pain ✓ Continuous field force targeting optimization in collaboration with the Advanced Analytics team and Pfizer Inc. ✓ Leveraging Advanced Analytics team to improve DTC effectiveness/efficiency and partnering with Pfizer Inc. to launch new DTC
Price	✓ Monitoring usage and reinforcing proper use of Co-pay cards

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*Source: Symphony METYS – Data through September 2023, IDV®

The sales figure of MYFEMBREE® is almost half the plan for Q2 YTD FY2023. Sales are minus USD24 million by volume, and minus USD7 million by price.

In volume terms, we achieved roughly 64% of the budget for Q2 YTD FY2023. Again, this is almost half in the plan for Q2 YTD FY2023, which means that in price terms it was considerably below plan.

The reason for this is described here. MYFEMBREE® is covered by commercial and Medicaid and prescribing on Medicaid increased more than expected in commercial. We also use Co-pay cards to make it easier for patients to use MYFEMBREE®, but the Co-pay card program is used in a slightly different way than we intended, and this has caused the prices to deteriorate a little. This is the reason for the reduction in price terms.

However, as mentioned below, monitoring of Co-pay card usage and reinforcing of proper use have been progressing, and I believe such concerns are gradually disappearing.

In the area of GnRH antagonists for NBRx, MYFEMBREE® has a very large share of the market for uterine fibroids (85%), but the share for endometriosis is still not as large as it should be. There was also a bit of a delay in getting to market.

The market for GnRH antagonists related to uterine fibroids is growing as expected, but not as fast as we had hoped, which we believe is another reason why we have not achieved our volume target.

In line with our strategy and outlook, we believe MYFEMBREE® has the potential to be the standard of care for uterine fibroids and endometriosis, and we are working hard to achieve this.

Uterine fibroids are associated with hypermenorrhea, so oral contraceptives such as pill are typically used firstly. We continue to drive awareness of MYFEMBREE® as the first management option where treatment is not effective by oral contraceptives.

This is especially important because it is very important to know when to use MYFEMBREE®. As part of this, we continue to drive patient awareness and educational materials easy-to-understand instructions to ensure the best possible understanding and appropriate use of these products.

Since pain is a main complaint of endometriosis, we want to make sure patients are aware of their options, including MYFEMBREE® which can effectively treat associated pains with proper use. We plan to continue efforts of communicating treatment benefits to key HCPs in this space to increase awareness of MYFEMBREE® which we believe will also support uptake efforts.

We will also work with Pfizer Inc. and the Advanced Analytics team, a DX initiative, to optimize in terms of field force deployment and targeting.

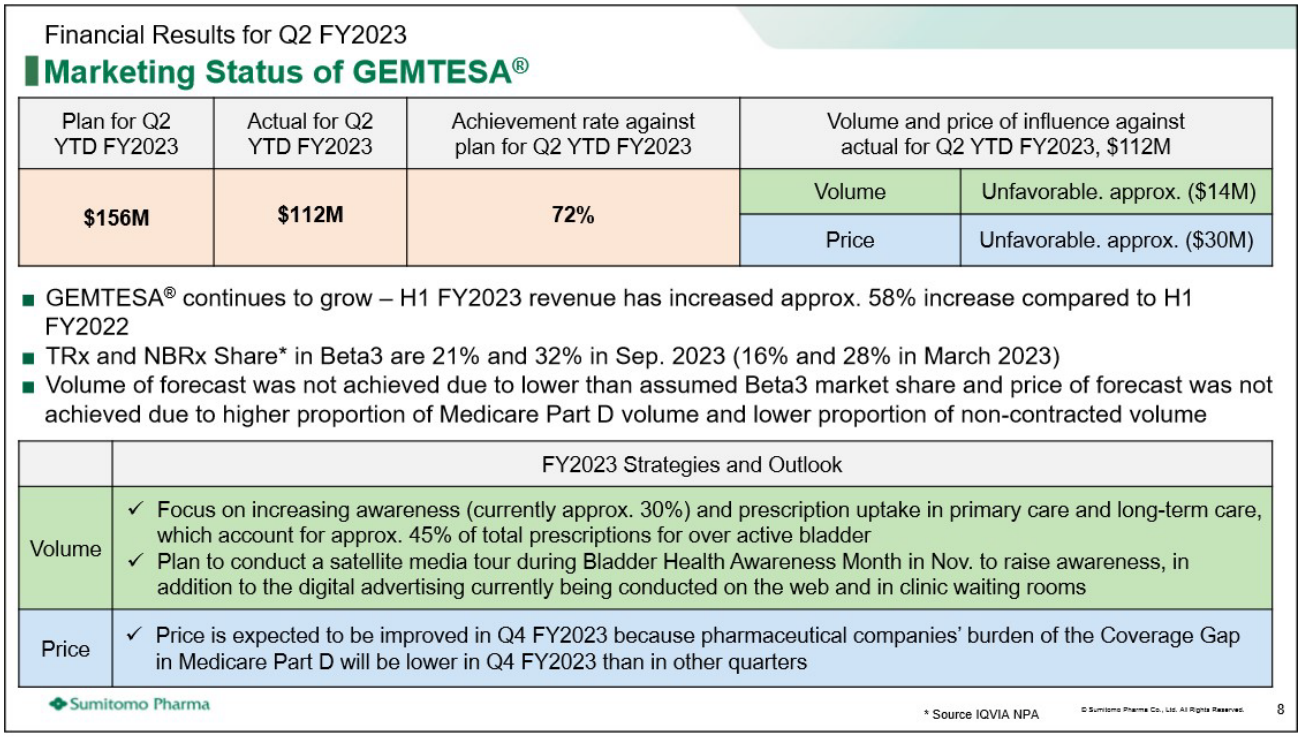
I have found that it is not always appropriate to have sales reps at doctors' offices a lot, or to have sales reps placed where there are a lot of patients. We are aiming to ensure this is still handled well. However, this has to be done together with Pfizer, so it will take some time. This will actually be deployed in around Q4 FY2023.

In the meantime, we are also considering the possibility of supplementing our efforts by bringing in virtual sales reps for certain territories where current capabilities may be stretched a bit thin.

We have expanded our focus to both uterine fibroids and endometriosis to support addressing unmet patient needs in these key areas. We will work with Pfizer to make sure that we can do that as effectively as possible.

Also, although it is not mentioned here, there is also the issue of prior approval as a barrier to prescriptions. We are considering providing support for procedures relating to this.

Through this kind of activity, we aim to increase awareness as well as market share of MYFEMBREE®.



Financial Results for Q2 FY2023

Marketing Status of GEMTESA®

Plan for Q2 YTD FY2023	Actual for Q2 YTD FY2023	Achievement rate against plan for Q2 YTD FY2023	Volume and price of influence against actual for Q2 YTD FY2023, $112M	
$156M	**$112M**	**72%**	Volume	Unfavorable. approx. ($14M)
			Price	Unfavorable. approx. ($30M)

- GEMTESA® continues to grow – H1 FY2023 revenue has increased approx. 58% increase compared to H1 FY2022
- TRx and NBRx Share* in Beta3 are 21% and 32% in Sep. 2023 (16% and 28% in March 2023)
- Volume of forecast was not achieved due to lower than assumed Beta3 market share and price of forecast was not achieved due to higher proportion of Medicare Part D volume and lower proportion of non-contracted volume

	FY2023 Strategies and Outlook
Volume	✓ Focus on increasing awareness (currently approx. 30%) and prescription uptake in primary care and long-term care, which account for approx. 45% of total prescriptions for over active bladder ✓ Plan to conduct a satellite media tour during Bladder Health Awareness Month in Nov. to raise awareness, in addition to the digital advertising currently being conducted on the web and in clinic waiting rooms
Price	✓ Price is expected to be improved in Q4 FY2023 because pharmaceutical companies' burden of the Coverage Gap in Medicare Part D will be lower in Q4 FY2023 than in other quarters

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* Source IQVIA NPA

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Next, GEMTESA®.

GEMTESA® is a bit disappointing seeing that the achievement rate is 72% against plan for Q2 YTD FY2023. In volume terms, this is minus USD14 million. In price terms it is minus USD30 million. However, in volume terms it is 98% of budget for Q2 YTD FY2023.

We are losing out in price terms because of the increase in the percentage of volume in Medicare Part D here and the fact that but commercial has decreased and Medicare Part D has increased.

As I mentioned earlier, the payer mix in terms of price is not controllable, so we have to find solutions to potentially increase the volume. We recognize that awareness levels are not what they should be for this product.

Primary care and long-term care facilities account for 45% of prescriptions for overactive bladder, and we will raise awareness here.

We are also considering the use of additional digital media to provide information on how patients use GEMTESA®, as well as share impressions of the product, similar to ongoing digital advertising efforts we perform via the web and in clinics. We also plan to enhance awareness raising activities in key areas as part of Bladder Health Awareness Month in November 2023 which is not only for overactive bladder, but also for bladder cancer and many other related diseases.

We will also work to raise awareness among doctors, patients, as well as additional long-term care facilities to support increase in volume.

In terms of prices in the future, this is a little complicated, but prices are expected to improve to some degree as the Coverage Gap in Medicare Part D lowers in Q4 of FY2023 compared to other quarters. After one year, Medicare is expected to be refreshed and we will start from the deductible again from scratch. This means that the Company contribution will be less than in other quarters. We think that the so-called average price will improve, and that this price will move somewhat in a positive direction.

As for the three key products, the results for Q2 FY2023 are as you have just seen. We are now working hard on the ground to achieve improvement, especially in terms of volume, through various measures.

Some people have asked whether we are going to revise our forecast, but it is difficult to say what kind of forecast we should make at this stage, so we have left the current forecast unchanged as for the end of Q2 FY2023.

However, while recognizing that there are various downside risks, we are firmly committed to implementing our strategy for the three products I just mentioned.

Financial Results for Q2 FY2023

Revenue of Major Products in Japan & Asia

Billions of yen

	Q2YTD FY2022 Results	Q2YTD FY2023 Results	Change		FY2023	
			Value	%	May 15 forecasts	%
Japan						
Equa®/EquMet®	17.3	**15.8**	(1.5)	(8.7)	32.4	48.7
TRERIEF®	8.6	**8.5**	(0.0)	(0.5)	15.0	57.0
LATUDA®	4.6	**5.7**	1.1	23.3	12.5	45.8
METGLUCO®	4.0	**3.7**	(0.2)	(5.8)	7.5	49.6
TWYMEEG®	0.5	**2.6**	2.1	420.7	4.2	62.9
LONASEN® Tape	1.4	**1.8**	0.4	31.7	3.3	55.5
AG products	4.6	**4.6**	(0.0)	(0.7)	8.6	53.5
Trulicity®*	16.7	**—**	(16.7)	—	—	—
Others	8.7	**10.9**	2.1	24.5	30.6	51.3
Export products/ Lump-sum revenue, etc.	9.6	**3.5**	(6.1)	(63.6)		
Non-pharmaceutical operations	22.1	**1.3**	(20.8)	(94.1)		
Total	98.1	**58.5**	(39.5)	(40.3)	114.1	51.3
Asia						
MEROPEN® (China)	18.7	**10.2**	(8.5)	(45.3)	18.7	54.8
Others	7.1	**10.6**	3.4	48.4	20.4	51.8
Total	25.9	**20.8**	(5.0)	(19.5)	39.1	53.2

Japan
- Progress is fundamentally on track in total
- Sales of TWYMEEG®, LATUDA®, and LONASEN® Tape continue to grow
- Of the "Export products/Lump- sum revenue, etc." in Q2 FY2022, the lump-sum revenue under the license agreement for DSP-0187 was ¥6.1B
- NHI drug price revision effect (¥2.0B) in total

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

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

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This is main sales items in Japan and Asia.

This is also a YoY comparison, so there are some comparative obstacles. If you look at the comparison with the forecast, you will see that Equa®/EquMet® is a bit low. I think we are a little behind in this area.

The achievement rate for TWYMEEG® is 62.9% of the forecast, which gives us the impression that we are making a bit of progress against forecast while we are very inconvenienced by the limited shipments. These shipment issues are of course an inconvenience to medical institutions and patients. We have managed to

procure APIs with the cooperation of API manufacturers, and we are also working in three shifts at the Suzuka Plant to build up inventory, including formulations and packing.

We hope you will understand that we are working hard to improve the situation by the end of December 2023.

In Asia such as China, sales are down YoY, especially in terms of volume, due to system of volume-based procurement.

Financial Results for Q2 FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
Q2 YTD FY2023 Results	Revenue	58.5	73.3	20.8	152.6
	Cost of sales	28.0	27.0	5.3	60.3
	Gross profit	30.6	46.3	15.5	92.3
	SG&A expenses	24.7	88.4	5.6	118.8
	Core segment profit	5.9	(42.2)	9.9	(26.4)
	R&D expenses				45.3
	Core operating profit				(65.8)
Q2 YTD FY2022 Results	Revenue	98.1	195.3	25.9	319.3
	Cost of sales	56.0	31.2	5.7	92.8
	Gross profit	42.1	164.2	20.2	226.4
	SG&A expenses	29.2	116.9	6.1	152.3
	Core segment profit	12.9	47.3	14.0	74.2
	R&D expenses				49.4
	Core operating profit				24.8
Change	Revenue	(39.5)	(122.1)	(5.0)	(166.6)
	SG&A expenses	(4.5)	(28.5)	(0.5)	(33.5)
	Core segment profit	(7.1)	(89.4)	(4.2)	(100.6)
	R&D expenses				(4.1)
	Core operating profit				(90.7)

- **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

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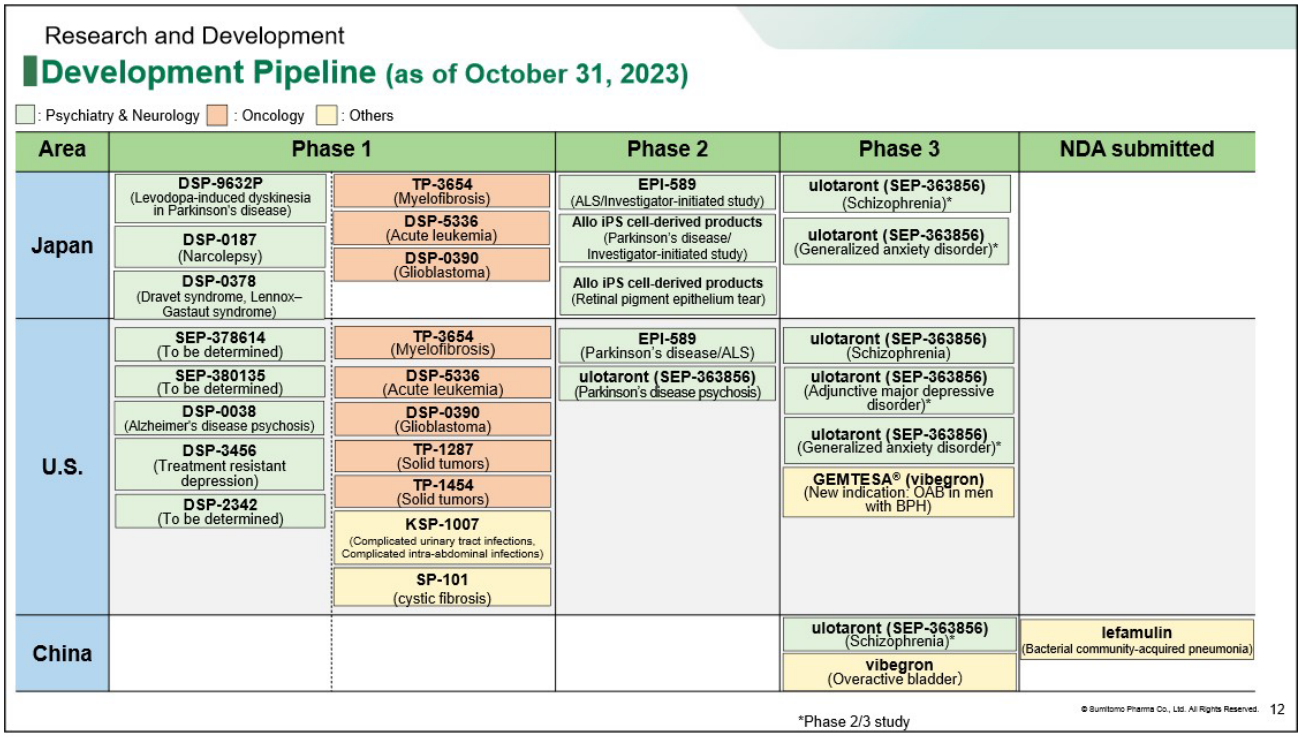
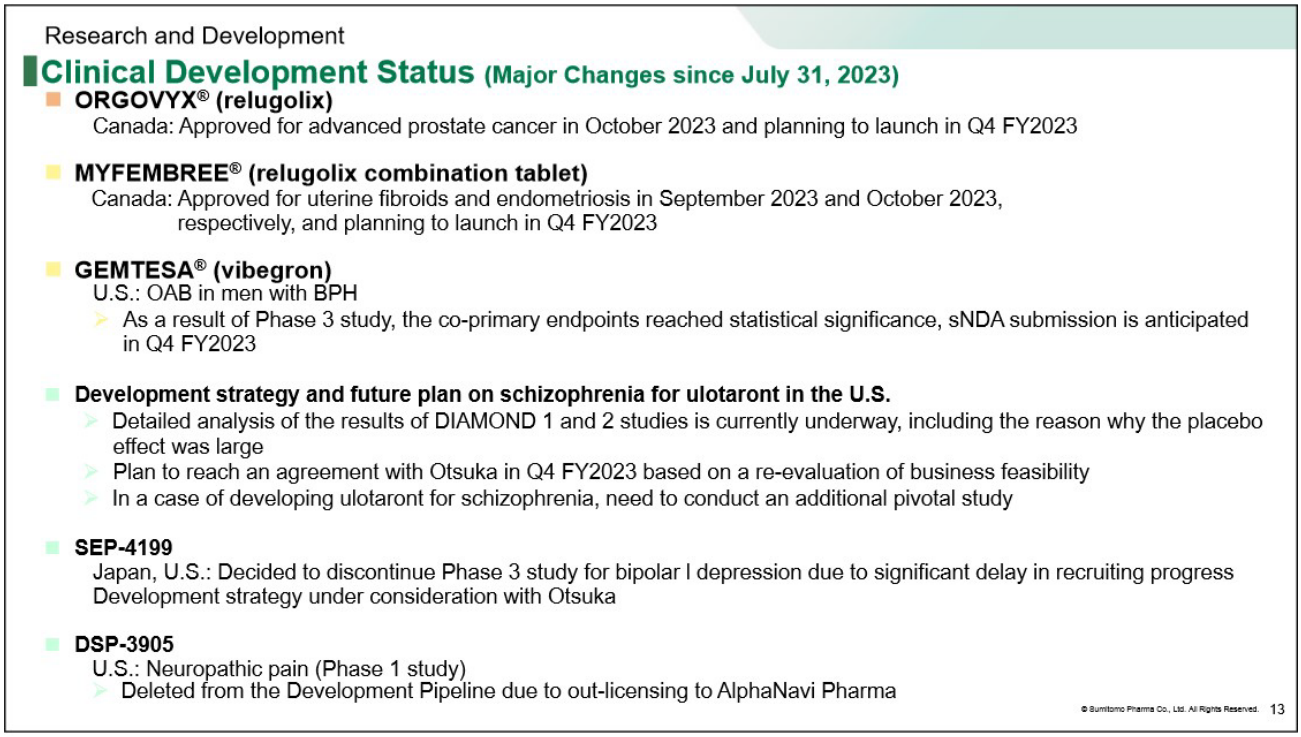
This is by segment, but since this is also a comparison with the same period last year, I do not have much to comment on. As I mentioned earlier, the difference is mostly in North America.



This is a list of development items. Regarding lefamulin, we are now expecting that it will be approved by the end of December 2023. This has been held up by public holidays in China and other factors.



ORGOVYX® and MYFEMBREE® were approved in Canada.

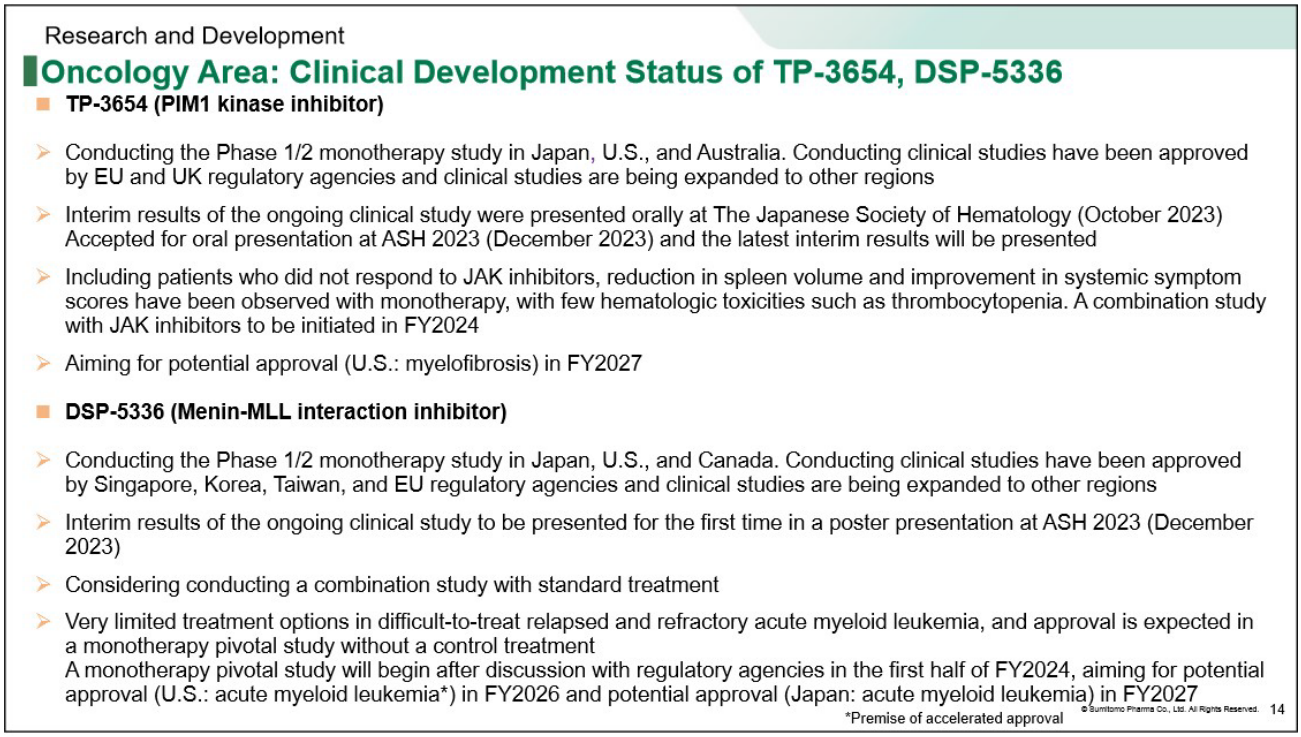
As for GEMTESA®, we have announced that the results of Phase 3 study for the indication of overactive bladder with benign prostatic hyperplasia. I would like to proceed sNDA of the indication in Q4 FY2023.

As for ulotaront, regarding the future plan of the development strategy for schizophrenia in the U.S., I have already told you many times, and I may be scolded for not knowing the details yet, but it is not a simple matter. We are still in the process of analyzing the situation.

We are trying to reach an agreement with Otsuka Pharmaceutical Co., Ltd. by the end of FY2023, considering the business case for this, including the launch of delay. If we are going to develop for schizophrenia, additional clinical study is of course necessary. There was some talk previously about whether we could somehow negotiate with the FDA on the current Phase 3 studies data, but that is essentially impossible. We believe that additional clinical study will be necessary.

As for SEP-4199, recruitment has been delayed for various reasons. We are already years behind. This is the first pivotal study. If we wanted to do one later, it would delay the market launch for a long time. In this sense, we have decided to discontinue this Phase 3 study and will discuss future development with Otsuka Pharmaceutical in light of the business potential of the compound.

At the very bottom is DSP-3905, and there is not much to say here.



In the Oncology area, we have two promising compounds, TP-3654 and DSP-5336. Although it is early, we are seeing a variety of evidence.

We gave an oral presentation at annual meeting of the Japanese Society of Hematology in October 2023, and we will be giving an oral presentation at the ASH meeting in December. For patients, including those who have not shown any effect on the JAK inhibitor, we are thinking that it is quite good at the moment in terms of items such as reduction in splenic volume, systemic symptom scores, and platelet reduction, and we are aiming to start a combination study with JAK inhibitor in FY2024. We are aiming for approval by the end of FY2027.

As for DSP-5336, we are seeing good results in the course of study, and we will be presenting a poster on this at ASH2023.

The treatment options for relapsed and refractory acute myeloid leukemia are very limited, so we are very hopeful that the monotherapy pivotal study will be approved.

We are aiming for approval by the end of FY2026 in the U.S., and in Japan by the end of FY2027. Based on the information we have now, our compound is the third in this area, following on from those by companies such as Syndax Pharmaceuticals, Inc. and Kura Oncology, Inc. We believe that our compound has a number of potential strengths.

This concludes my presentation. Thank you very much for your attention.

Noguchi: Thank you, Mr. Nomura.

Question & Answer

Noguchi [M]: I would now like to move on to the Q&A session.

Sakai, UBS Securities Japan [Q]: I have two questions. You did not mention much about H2, but since you have not changed your forecast, I am wondering if you are assuming that the second half of the year will be close to the forecast if things continue as they are. I would appreciate any additional comments you may have on this. Thank you.

Nomura [A]: Yes, thank you. I cannot be too specific about H2, but the assumption is that sales will increase in volume more in H2. We would like to catch up as much as possible with the measures in North America, as I explained earlier. We also expect that the effects of the combination of group companies in North America will be felt even more in H2. Thank you.

Sakai [Q]: Yes, thank you. In relation to this, you have explained various measures to be taken for the three key products in North America, and I think this is especially true of MYFEMBREE®, but without drastic measures, it is difficult for us to see a chance for them to generate strong results in H2 and the next fiscal year.

I'm wondering if there is any kind of plan B in place for these key products? If things continue as they are, I think there is a possibility that these three key products will fall in cost terms in H2 as well.

Nomura [A]: Indeed, the situation for MYFEMBREE® is difficult. As I mentioned earlier, the new system started in July, so we have already begun to take various measures, and the effects of these measures will not be immediately apparent.

We are expecting the effects to appear, however. We would hope to see a steepening of the trend line in the future, as this will show the true potential of MYFEMBREE®. We are watching to see how the trend changes in H2.

I am not saying that we have not considered any kind of plan B, but first of all, we would like to consider how the trend changes in H2. We want to take a hard look at that first to see if we can change that trend a bit.

Sakai [Q]: Regarding MYFEMBREE®, is the level of collaboration with Pfizer satisfactory from your Company's point of view? Or is there room for something more to be done?

Nomura [A]: I think that when Myovant Sciences Ltd. was doing this before, the relationship was still like something between a large company and a venture. However, this is not the case now as feel our relationship with Pfizer has become much better with both teams working hard to support common goals Adele Gulfo, our CEO of the Biopharma Commercial Unit, has a great former career history with Pfizer with many relationships that continue to this day as part of our collaboration efforts, so in that sense, we are in a situation where things are running smoothly.

Sakai [M]: I understand. Thank you very much.

Wakao, JPMorgan Securities Japan [Q]: The first question overlaps a bit with Mr. Sakai's question. Looking at the current performance, I get the impression that achieving JPY460 billion in revenue and JPY40 billion in core operating profit for the next fiscal year is becoming more difficult, but you mentioned just now you are not considering a plan B.

If the H2 results are much lower than your forecasts, and if a plan B is implemented, will it be possible to achieve the JPY40 billion in core operating profit for the next fiscal year? Could you please tell us how a plan B fits in with the targets for the next fiscal year?

Nomura [A]: We just announced the Mid-term Business Plan (MTBP) 2027 this past April, and it is difficult to say something like this less than a year later. With the top line already showing some difference from the forecast, I think it will be quite difficult to achieve what we have said in the MTBP 2027 in the same form.

Therefore, we are aiming to achieve positive core operating profit in FY2024, as I explained at the time of the MTBP 2027. I can't tell you at this point what measures we will take to somehow make that happen, or what kind of plan B we would consider, but we are looking at various contingency plans depending on the sales situation. We are now considering measures to see if we can somehow achieve a surplus in core operating profit in FY2024.

Wakao [Q]: Okay. If so, it may be difficult to achieve JPY40 billion in core operating profit, but it would mean that a turnaround would occur, and also, is plan B a plan that would play out reasonably quickly?

Nomura [A]: We will aim to achieve a surplus in FY2024, as we originally said. As for plan B, there are still various moving parts, so I cannot say at this point what we are going to do and how we are going to do it.

We are of course considering our options in different circumstances. We are thinking carefully about various issues and are discussing what concrete measures should be taken to address them.

Wakao [Q]: Okay. Second, I would like to know a little bit about cash flow.

I think that the operating cash flow for Q2 is already negative JPY160 billion or JPY170 billion, but I think that you said that you can raise funds through bank loans this fiscal year, so I am not particularly concerned about the cash flow. I would like to know if you will be able to do so in the next fiscal year and beyond.

If the top line continues at its current pace, it will be difficult to increase cash flow. In that case, I think there were about JPY60 billion in bonds with a maturity date next fiscal year, so looking at the next fiscal year, I think the current cash flow situation will be quite difficult. I wonder if there will be any additional borrowing capacity for the next fiscal year and beyond.

Nomura [A]: Yes, thank you. Rather than additional borrowing, we would sell our shares of Roivant Sciences Ltd. That would be a better first step. This would of course cover the JPY60 billion.

Wakao [Q]: Yes, I understand. Thank you very much. As for SEP-363856, even if additional analysis is done, or rather detailed analysis is done, and an additional study is conducted, I still feel a bit of risk even if they are implemented, unless it is clear that the reason for not meeting the endpoints was the influence of the coronavirus pandemic. As you proceed with this detailed analysis, is it becoming clear that the coronavirus pandemic was a major factor? Thank you.

Nomura [A]: Yes, thank you. I explained at the Q1 briefing in July and said that the coronavirus pandemic may have had an effect. It was at that point that the pre-coronavirus and post-coronavirus data were compared, and although the pre-coronavirus sample population was not large, the figure was statistically significant.

Post-coronavirus was problematic, so it came down to comparison of pre-coronavirus and post-coronavirus. However, in terms of what changed with the coronavirus, there is the question of the strengthening of the placebo effect. We are deepening our analysis, and I will hand over to Dr. Ikeda to talk about that.

Ikeda [A]: As Mr. Nomura has just explained, we are working on the analysis of various parameters. I can't present the details as of today, but there has been considerable analysis of the high placebo response.

However, we have not yet reached the point where this is absolutely the case, so we will continue to analyze the results, and we are currently discussing with Otsuka Pharmaceutical what kind of studies we can conduct and what type of patients we should recruit, if we decide to conduct the next study, for example, for schizophrenia.

Wakao [Q]: So, if you see factors such as effects of the coronavirus pandemic, you would consider doing a study, and if you don't see them, you may not?

Ikeda [A]: We have made some assumptions about the factors, but we are getting the impression that this is the case. As for not implementing the study, there is the economic aspect, in particular. As Mr. Nomura may have mentioned earlier, based on evaluations of economic feasibility by Otsuka Pharmaceutical and ourselves, we are considering various options, including whether we should conduct a clinical study for schizophrenia, and whether we should focus on 2nd indication or 3rd indication.

Wakao [M]: Yes, I understand. Thank you very much. That is all.

Muraoka, Morgan Stanley MUFG Securities [Q]: Regarding the sale of shares of Roivant that you mentioned earlier, when I looked at the cash flow chart for Q1, I thought that you sold about JPY20 billion. At the end of Q2 of this fiscal year, the sale has not progressed very much, and I don't mean to imply that you should proceed, but it seems that you are not making much progress. Can you give me your thoughts on this?

Nomura [A]: We have various commitments with Roivant, so there are factors to consider, such as the timing of the sale. The sale will begin by the end of FY2023.

Muraoka [Q]: Oh, I'm sorry, I must be mistaken, I thought a sale was made in Q1, for about JPY23 billion.

Nomura [A]: Yes, we sold some in Q1 FY2023. There is still a substantial amount of the remaining portion, and we expect to be able to begin selling the remaining portion in Q4 FY2023.

Muraoka [Q]: I see, that's what you mean, I understand. So, by the next fiscal year, as you mentioned earlier about the cash flow for the next fiscal year, I imagine that a significant portion of the shares will be liquidated.

Nomura [A]: Yes, we will monetize it. Because of the various restrictions imposed by my position on the board of directors of Roivant, we did not immediately sell the shares.

I had no problem selling some shares in the Q1 FY2023 because of the various things they were going to do together in issuing the shares. If we try to sell a large amount, we will not be able to do so immediately due to various issues, so we are planning to do so in Q4 FY2023.

Muraoka [Q]: Okay, thank you. Next, I would like to ask about the three key products in the U.S. You mentioned that there are six months left. After H2 is over, do you feel that you will rethink your strategy again around next May? Or will you consider that more drastic action needs to be taken, and review the situation in December? In other words, will it be three months, six months, or nine months before some drastic change in thinking takes place, or will it not happen at all?

Nomura [A]: In many ways, it is a bit late to start thinking about it after the closing of accounts at the end of March next year. We are constantly monitoring the sales of these three key products, so we will come up with various plans when necessary.

Therefore, we would like to proceed on an on-going basis, rather than aim at a specific point in the future.

Muraoka [M]: Okay. Thank you very much. That is all.

Yamaguchi, Citigroup Global Markets Japan [Q]: I am sorry to ask another similar question. I would like to go over one more time your thoughts on the Company forecast.

The interim results were not disclosed, but now they have been disclosed, and the results were not achieved. Since the full-year forecast is unchanged, it would normally mean that the H2 forecast would have to be revised upward to meet the full-year forecast.

Is it correct to say that you are only going to focus on the full-year results now, without thinking too much about the bumps on the way? I would like to ask this with respect to the three key products in particular. Thank you.

Nomura [A]: Yes, thank you. We explained in the interim briefing that, in accordance with our custom, a comparison with the same period of the previous year would be meaningless, so we thought it would be better to show you how we think things will look at the end of H2 and explain how the difference is compared with the same period of the previous year. We did this because we thought it would be easier for you to understand if we explained what the difference would be.

Of course, as you said, if we could talk about making up for this dip with a corresponding bump in H2, that would be great. As I mentioned earlier, there is a time lag between the effects of the various initiatives for these three key products and the results, so it is difficult for us to make predictions. Under these circumstances, I hope you will understand that we have decided not to revise the forecast this time.

Yamaguchi [Q]: Okay. I would like to ask you a question. You mentioned that you are using digital a lot, and I think you have presented some information to us about it. I don't mean to preach to the choir, but I think the good thing about digital is that you can immediately tell if the situation is good or bad and take countermeasures.

I suppose changes to the plan in that sense are being made to some extent by the team during the term, but as for drastic changes, it seems you are letting the system run for a while before considering it. I'm sorry if this overlaps with the previous question.

Nomura [A]: Yes, as you said, I think that the marketing strategy that I mentioned earlier should be revised as we find more and more data. However, it is difficult for people in North America alone to come up with drastic measures for this major trend, so we will have to join in and think about it. But if you ask me what exactly that is, I can't give you any specifics yet.

Yamaguchi [Q]: Thank you very much. One more, please. You mentioned that your Company and Otsuka Pharmaceutical are planning to reach an agreement on ulotaront. At the moment, I felt that the issue is what to do about schizophrenia study in the future, but I am not sure if that framing is correct. Also, since other indications are already in progress, I don't think we can do anything now, but what about the possibility of other studies being affected in the same way as this one, and whether such things could also be items for consideration in the reevaluation of business feasibility?

Nomura [Q]: Your question now is about whether other studies have been affected like this one, do you mean the placebo effect?

Yamaguchi [A]: Yes, yes.

Nomura [A]: That is probably not the case. One of the reasons is that it takes time and money to conduct a study, for example, for schizophrenia, which delays the timing of the launch of the product.

There may also be other things to consider, such as adjunctive Major Depressive Disorder and Generalized Anxiety Disorder, which we are currently doing as planned, but I think this must be considered in a comprehensive manner.

At least for us, we wanted to get the product on the market for the indication of schizophrenia as soon as possible, and establish the potential of ulotaront as much as possible within the anti-psychotic area before moving on to the next phase. We will fully consider with Otsuka Pharmaceutical what options are available in the event that this is no longer possible.

Therefore, in many ways, we would like to continue to think about whether or not to do schizophrenia on a blank slate.

Yamaguchi [M]: Yes, thank you very much. That is all.

Hashiguchi, Daiwa Securities [Q]: There are several things, the first of which is the development of ulotaront for adjunctive Major Depressive Disorder and Generalized Anxiety Disorders.

I understand that the Phase 2 part of the Phase 2/3 study is currently underway.

When will the data from the Phase 2 part be compiled? When evaluating business feasibility and deciding the future policy that you mentioned earlier, are you making those decisions with the Phase 2 data in hand? Or is that not a factor in your decision-making?

Nomura [M]: Dr. Ikeda will answer.

Ikeda [A]: As for adjunctive Major Depressive Disorder, Otsuka Pharmaceutical is in charge, so I cannot give you the details about that, but I have been informed that recruitment is going smoothly.

We are also involved in Generalized Anxiety Disorders, which started out a little late, but we are now gradually catching up.

We are now considering the schedule for both studies, which I think are positioned as Phase 2/3, with the expectation that the results will be available approximately by 2025, or the last patient in, as the case may be. We are considering the schedule for that period.

Hashiguchi [Q]: The year 2025 or so you just mentioned is as a Phase 2/3 study, right? How about the timing of the results of the Phase 2 part?

Ikeda [A]: I believe that we are currently in Phase 2/3 of this study, so we are thinking that by conducting the current study and another Phase 3 study, we will be able to take the compound to the stage where we can apply for approval. I do not mean just Phase 2, but Phase 2/3.

Hashiguchi [Q]: To ask another question, when do you think you will decide when to add the other Phase 3 study?

Ikeda [A]: If we want to be sure about that, I think we should wait until we get the results of the first study at the timing I just mentioned. At the same time, however, we are considering various ways to be more aggressive with our schedule.

Therefore, we are currently unable to give an answer as to when the second study will be conducted.

Hashiguchi [Q]: I understand. I would also like to ask about GEMTESA®'s QoQ sales. I believe that sales for Q2 were slightly lower in U.S. dollar terms than Q1 sales. If you could explain the reasons for this, I would appreciate it.

Nomura [A]: I'm sorry, we can't answer that question at this time.

Hashiguchi [M]: Yes, I understand. That is all. Thank you very much.

Sakaguchi, Iyakukeizai [Q]: I understand that you have left the full-year forecast unchanged, but in terms of individual products, you have indicated a figure of JPY20.9 billion yen for LATUDA® in North America. How do you rate your ability to achieve this?

Nomura [A]: It is difficult to answer whether or not we will achieve this. LATUDA® is a useful drug, and one of the reasons for the results is that generic drugs are encroaching more rapidly than we had anticipated.

In addition, there are various past rebate settlements that came in this fiscal year, which have had a very negative impact.

Sakaguchi [M]: Thank you very much.

Tsubokura, The Chemical Daily [Q]: I would like to ask you about a few updates in the area of cellular medicine. First of all, in the checklist of major events/goals for FY2023 on page 18 of the presentation material, the section on the commencement of clinical studies in the U.S. for products derived from iPS cells for Parkinson's disease has not been checked yet. I remember that you said in this summer that you hoped to start a study by the end of September. I would like to ask about the situation here.

Kimura [A]: Yes, I will answer your question. Regarding the U.S. clinical study for Parkinson's disease, we are actually in the process of submitting an IND now and are responding to inquiries. We are working with a university in the U.S. to conduct a clinical study that is almost identical to the one at Kyoto University, and I will be able to provide more details once it is cleared.

Tsubokura [Q]: Do you expect to be able to start approximately by the end of the year?

Kimura [A]: In light of our conversations with the FDA, we can't say exactly when, but we think we will be able to start soon. We would like to make it a goal to start by the end of the year.

Tsubokura [Q]: Okay. Thank you very much. I would also like to ask you about the iPS cell clinical study for retinal pigment epithelium tear. I believe you have started the clinical study, but when do you expect to find out the new target date for the review of the launch plan?

Kimura [A]: We have started the clinical study, but we are still in the process of surgery site setup. After that is setup, we need to see how many patients come. We will be in a better position to set the end date of the study at that time.

It will probably take another year or so. Since this is a very rare disease, we are taking various steps, including increasing the number of surgical sites, to see how many patients we can attract.

Tsubokura [Q]: So, it's going to take about a year until a target date is announced.

Kimura [A]: Yes, the clinical study itself has begun, so we just have to proceed steadily, but I think it will be about that time when we set the actual target date.

Tsubokura [M]: Okay. Thank you very much.

Kamio, MIX, Inc. [Q]: I would like to ask you about North America and Japan. You explained earlier about the three key products in North America, and I think you have been very active in digital marketing and using digital technology. I was wondering if you could tell us more about the various things that have been done so far, such as for ORGOVYX®, which was mentioned here today on page 6 of the presentation material. In this respect, what will be changed in H2?

Nomura [Q]: Could you clarify what you mean by "so far"?

Kamio [A]: In H1.

Nomura [A]: This was not done during the Myovant Sciences period. In short, we didn't receive much in terms of data disclosure, analysis, or data-based marketing strategy, so these are measures that we took after we had 100% control. It is relatively new and had only been implemented in FY2023.

Kamio [Q]: Okay. I would also like to ask you about your business in Japan. I think you have stated in the past that you have a policy of not reducing the number of MRs. I think you mentioned that you might be able to collaborate with other companies, including tie-ins with other companies' products, to make use of your Company's sales force. Can you give us any information about developments in this area?

Nomura [A]: Of course, I can't tell you which companies we are working with or what we are doing. We have various strengths. We have been discussing various ways to make the best use our sales force and the power of our MRs. I still think it will take a bit more time to make a final decision. However, we are trying to make sure that such partnerships are firmly established, and we hope to be able to talk about them by the end of FY2023, if possible.

Ishii, Iyakutsushin [Q]: About ulotaront, how are the clinical study for bipolar disorder going to proceed?

Ikeda [A]: Regarding ulotaront, we are not conducting a clinical study for bipolar disorder.

Ishii [Q]: So, there is no plan to do so?

Ikeda [A]: We are considering it as a possibility, but at least we have not done it so far.

Ishii [Q]: Okay. I would like to know the number of sales reps for GEMTESA®, ORGOVYX® and MYFEMBREE®.

Nomura [Q]: Understood. Should I be precise?

Ishii [A]: Ballpark figures are fine.

Nomura [A]: Roughly speaking, ORGOVYX® and MYFEMBREE® have about 100 people each, and GEMTESA® has about 200. This includes managers.

Ishii [Q]: Okay. Is that something that can be increased or reduced?

Nomura [A]: We believe we have sufficient human resources in place at this time.

Ishii [M]: Thank you very much.

Jimbo, Nikkei Inc. [Q]: This is just for confirmation. I believe you mentioned earlier that the core operating profit for the next fiscal year, FY2024, will be in the black. How about the net profit attributable to owners of the parent company?

Nomura [A]: We can't say anything about that at this point. We can't say anything without more precise accumulation of data, but at least at this stage, we would like to proceed in the direction of bringing core operating profit into the black.

Jimbo [M]: Okay. Thank you very much.

Suwa, The Asahi Shimbun Company [Q]: I would like to ask two minor questions here as well. Looking at the current interim results, SG&A expenses totaled JPY118.8 billion, and I think that this is not decreasing as expected. Is this made up of items independent of sales, that is, fixed costs?

Nomura [A]: Thank you for your question. This is a little higher than we had expected due to the foreign exchange rate, but as to your question about whether we can reduce SG&A expenses if sales decrease, I think that under the circumstances where sales are not increasing at all, we can still consider cost reductions, such as reducing the number of employees, in order to improve profitability.

However, we are now in the process of allocating the right people to the right positions in the right functions, based on the assumption that the sales of these three key products will continue to grow, and that we need the necessary personnel.

However, as many people have asked earlier, if there are any major changes in the situation, we will have to be flexible in our thinking.

Suwa [Q]: Okay. Also, one more thing, the parent company, Sumitomo Chemical Co., Ltd., holds 51.73% of the Company. Since it is now fully consolidated, does this mean that the group will be effective as it is?

Nomura [A]: The core operating profit is fully consolidated, but the attributable to the owners of the parent company is equity.

Suwa [M]: Okay. Thank you very much.

Hyodo, TOYO KEIZAI INC. [Q]: When you were talking earlier about the progress of the three key products, I think you mentioned that there is the potential for some kind of leverage or concrete measures prior to next year's financial results. What kind of concrete measures could you take? What kind of ways are there to sell these three key products or supplement them with other products?

Nomura [A]: I can't be specific about our plan B right now. As mentioned in an earlier question, we are constantly monitoring the sales situation, and all I can say at this point is that we would like to have a system in place so that we can take the necessary measures when necessary.

Hyodo [M]: Thank you very much.

Kakei, Yakuji Nippo, Limited [Q]: Please tell us whether you expect to achieve your forecast for FY2023, which remains unchanged. I would like to know the scenarios in which it would be possible to achieve it, and the scenarios in which it would not be possible to achieve it.

Nomura [A]: As I mentioned earlier, the reason we are leaving the forecast unchanged is not because we think we can achieve it. It is not necessarily clear to us what figures we should revise.

We have not made any changes at this time because we believe that it is difficult to predict the effects of the various measures we will take for the three key products I mentioned earlier until we see how they will manifest themselves, So, we have not made any changes at this point in time.

As for what will happen to the annual performance for FY2023, for various reasons, the forecast performance in the MTBP 2027 was not that strong. Based on that, we have been asked by some people about our outlook for FY2024. We will carefully assess what measures can be taken in FY2024 and beyond during FY2023.

Kakei [M]: Thank you.

Matsuda, The Yomiuri Shimbun [Q]: What was the reason for the delay in starting a clinical study for the regenerative medicine for Parkinson's disease in the U.S.?

Kimura [A]: It is a little later than originally planned, and that's really for administrative reasons, such as the work required to get the documents together.

Matsuda [Q]: Okay. Another point, regarding the clinical study for retinal pigment epithelium tear, is it my understanding that the target medical institutions and the actual transplantation of the first case have not yet been decided?

Kimura [A]: We have not yet transplanted the first patient. We are now in the process of gradually establishing a hub-and-spoke model where at least three surgery sites, each of which is surrounded by a diagnostic and care site for patients, will be set up in Japan. I think Kyushu University will be the first to launch a surgical site.

Matsuda [Q]: When the first patient is completed, do you plan to make some kind of a press release?

Kimura [A]: I will consider that, but I think it would be very rare for a Company clinical study to issue a press release for that kind of milestone. However, I would be happy to report that at our financial results briefing.

Matsuda [M]: Thank you very much.

Noguchi [M]: This concludes Sumitomo Pharma's financial results briefing for the second quarter of FY2023.

[END]