Sumitomo Pharma

Sumitomo Pharma Co., Ltd.

Conference on FY2023 Financial Results and Press Conference on Change of President and CEO

May 14, 2024

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
[Company ID]	4506-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement, Press Conference on Change of President and CEO
[Event Name]	Conference on FY2023 Financial Results, Press Conference on Change of President and CEO
[Fiscal Period]	FY2024 Annual
[Date]	May 14, 2024
[Time]	15:10 –17:06 (Total: 116 minutes, Presentation:24 minutes, Q&A: 92 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 Corporate Governance; Corporate Communications Vice President, Head of Corporate Communications

[Analyst Names]

Kazuaki Hashiguchi	Daiwa Securities
Fumiyoshi Sakai	UBS Securities Japan
Shinichiro Muraoka	Morgan Stanley MUFG Securities
Hidemaru Yamaguchi	Citigroup Global Markets Japan
Seiji Wakao	JPMorgan Securities Japan
Hiroshi Wada	SMBC Nikko Securities

Presentation

Noguchi: We would now like to begin the conference regarding Sumitomo Pharma Co., Ltd.'s financial results for the fiscal year ended March 2023, as well as the change of representative directors and the change of president. Thank you very much for joining us today despite your busy schedule and the short notice regarding the change of representative directors. This conference is held at our Tokyo Head Office and delivered via live streaming through Zoom webinar.

I would like to explain a few points that we would like you to keep in mind. In today's financial results presentation, we will explain the results in accordance with the financial results presentation material posted on our website, followed by a question-and-answer session. We would be happy to answer any questions regarding the change of representative directors during the question-and-answer session following the presentation of financial results. Please understand that we may not be able to answer all questions due to time constraints.

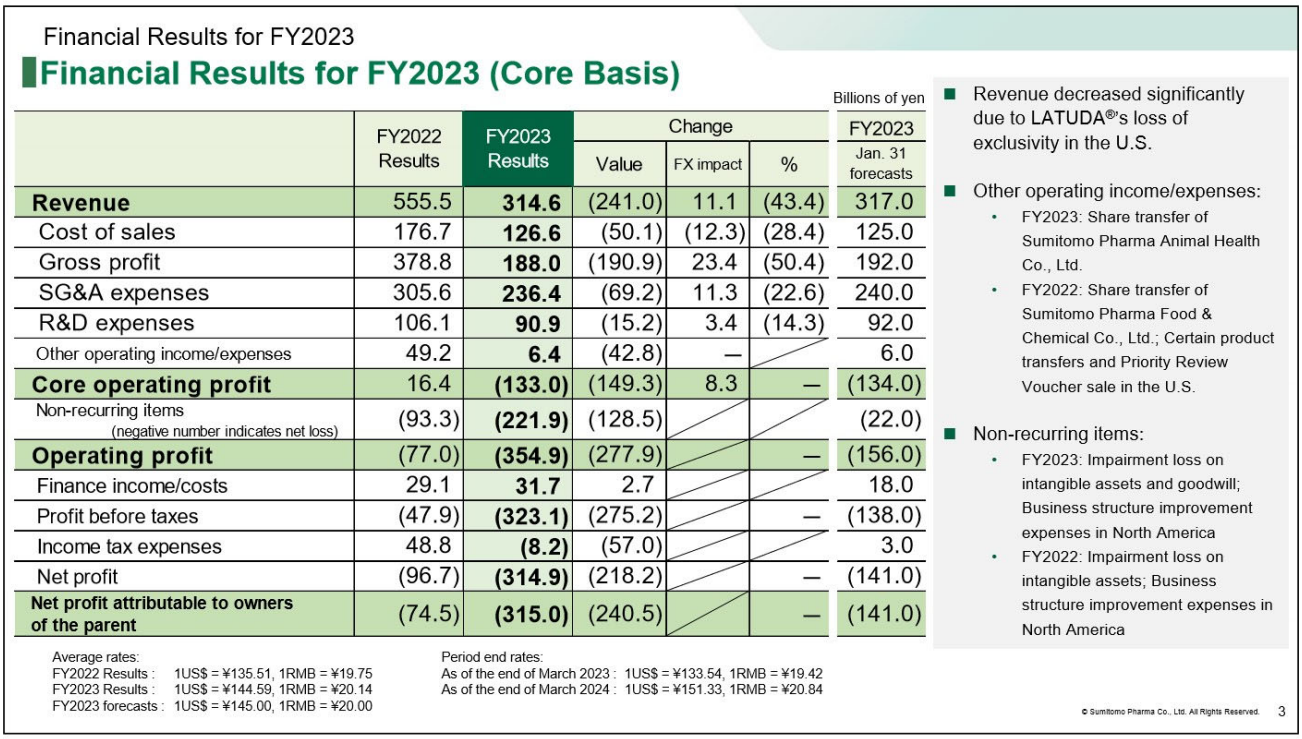
If you are attending via Zoom, please change the participant information displayed on your Zoom screen to your company name and your name. This briefing will be recorded for distribution on our website at a later date. Please understand this in advance.

We would also appreciate it if you could fill out the questionnaire to help us in our future IR activities.

Present today are Mr. Nomura, Representative Director, President and CEO; Dr. Kimura, Representative Director, Senior Managing Executive Officer; Dr. Ikeda, Member, Board of Directors, Managing Executive Officer; and I, Noguchi, moderator.

Mr. Nomura will now explain the financial results for FY2023. Mr. Nomura, could you please?

Nomura: Thank you very much.



Financial Results for FY2023

Financial Results for FY2023 (Core Basis)

Billions of yen

	FY2022 Results	FY2023 Results	Change			FY2023 Jan. 31 forecasts
			Value	FX impact	%	
Revenue	555.5	**314.6**	(241.0)	11.1	(43.4)	317.0
Cost of sales	176.7	**126.6**	(50.1)	(12.3)	(28.4)	125.0
Gross profit	378.8	**188.0**	(190.9)	23.4	(50.4)	192.0
SG&A expenses	305.6	**236.4**	(69.2)	11.3	(22.6)	240.0
R&D expenses	106.1	**90.9**	(15.2)	3.4	(14.3)	92.0
Other operating income/expenses	49.2	**6.4**	(42.8)	—		6.0
Core operating profit	16.4	**(133.0)**	(149.3)	8.3	—	(134.0)
Non-recurring items (negative number indicates net loss)	(93.3)	**(221.9)**	(128.5)			(22.0)
Operating profit	(77.0)	**(354.9)**	(277.9)		—	(156.0)
Finance income/costs	29.1	**31.7**	2.7			18.0
Profit before taxes	(47.9)	**(323.1)**	(275.2)		—	(138.0)
Income tax expenses	48.8	**(8.2)**	(57.0)			3.0
Net profit	(96.7)	**(314.9)**	(218.2)		—	(141.0)
Net profit attributable to owners of the parent	(74.5)	**(315.0)**	(240.5)		—	(141.0)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Other operating income/expenses:
  - FY2023: Share transfer of Sumitomo Pharma Animal Health Co., Ltd.
  - FY2022: Share transfer of Sumitomo Pharma Food & Chemical Co., Ltd.; Certain product transfers and Priority Review Voucher sale in the U.S.
- Non-recurring items:
  - FY2023: Impairment loss on intangible assets and goodwill; Business structure improvement expenses in North America
  - FY2022: Impairment loss on intangible assets; Business structure improvement expenses in North America

Average rates:
FY2022 Results : 1US$ = ¥135.51, 1RMB = ¥19.75
FY2023 Results : 1US$ = ¥144.59, 1RMB = ¥20.14
FY2023 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of March 2024 : 1US$ = ¥151.33, 1RMB = ¥20.84

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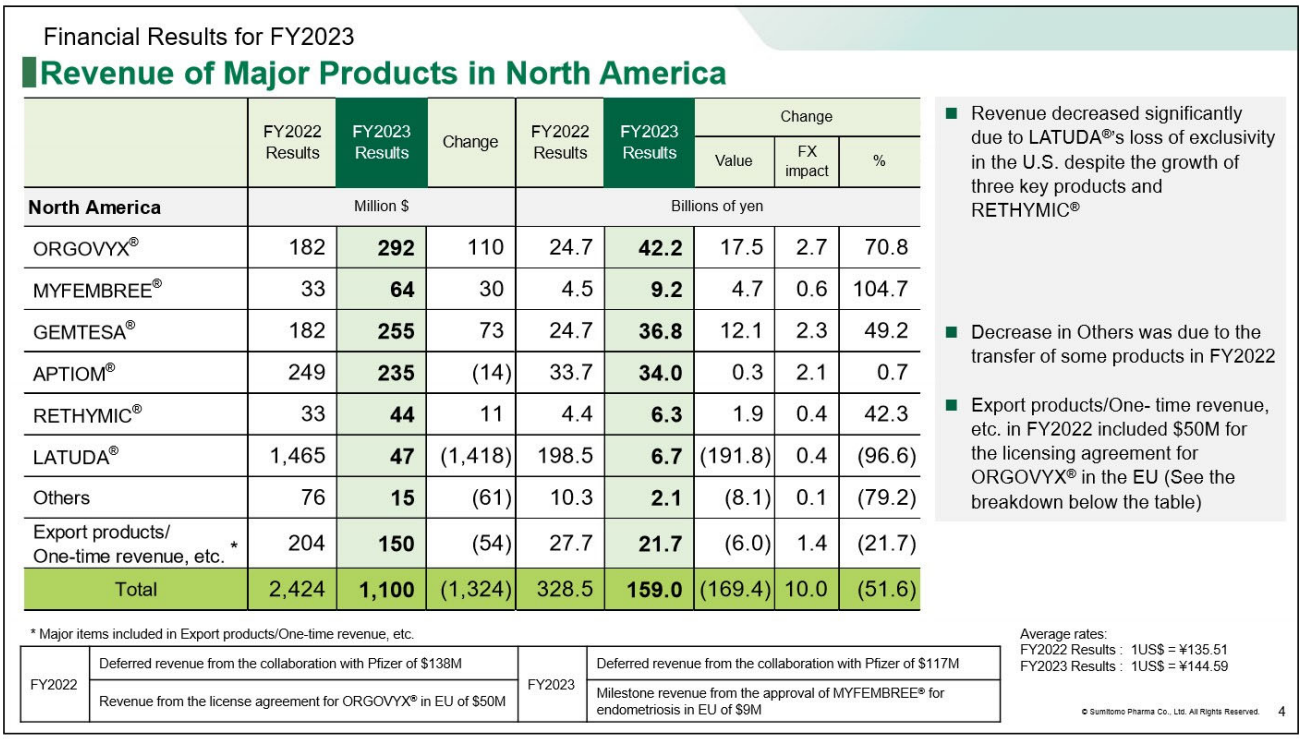
I would now like to explain the financial results.

The information on this page will be omitted since it was announced and explained to you on May 1.



Financial Results for FY2023

Revenue of Major Products in North America

	FY2022 Results	FY2023 Results	Change	FY2022 Results	FY2023 Results	Change		
						Value	FX impact	%
North America	Million $			Billions of yen				
ORGOVYX®	182	**292**	110	24.7	**42.2**	17.5	2.7	70.8
MYFEMBREE®	33	**64**	30	4.5	**9.2**	4.7	0.6	104.7
GEMTESA®	182	**255**	73	24.7	**36.8**	12.1	2.3	49.2
APTIOM®	249	**235**	(14)	33.7	**34.0**	0.3	2.1	0.7
RETHYMIC®	33	**44**	11	4.4	**6.3**	1.9	0.4	42.3
LATUDA®	1,465	**47**	(1,418)	198.5	**6.7**	(191.8)	0.4	(96.6)
Others	76	**15**	(61)	10.3	**2.1**	(8.1)	0.1	(79.2)
Export products/ One-time revenue, etc. *	204	**150**	(54)	27.7	**21.7**	(6.0)	1.4	(21.7)
Total	2,424	**1,100**	(1,324)	328.5	**159.0**	(169.4)	10.0	(51.6)

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S. despite the growth of three key products and RETHYMIC®
- Decrease in Others was due to the transfer of some products in FY2022
- Export products/One- time revenue, etc. in FY2022 included $50M for the licensing agreement for ORGOVYX® in the EU (See the breakdown below the table)

* Major items included in Export products/One-time revenue, etc.

FY2022	Deferred revenue from the collaboration with Pfizer of $138M	FY2023	Deferred revenue from the collaboration with Pfizer of $117M
	Revenue from the license agreement for ORGOVYX® in EU of $50M		Milestone revenue from the approval of MYFEMBREE® for endometriosis in EU of $9M

Average rates:
FY2022 Results : 1US$ = ¥135.51
FY2023 Results : 1US$ = ¥144.59

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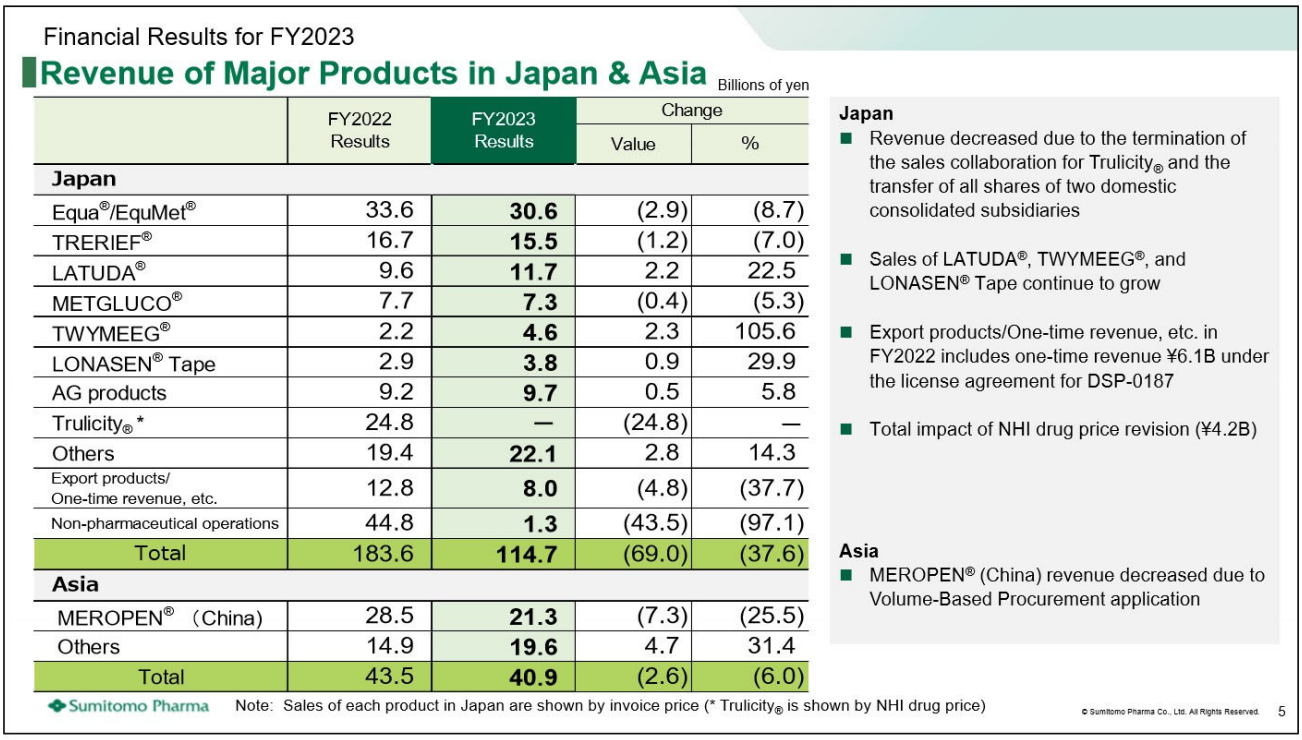
Here you see the financial results by product.

Of course, in yen terms, there is a slight currency effect, but revenue from ORGOVYX, MYFEMBREE, and GEMTESA has grown 71%, 105%, and 49%, respectively, over the previous quarter.

We have not reached the level of our expectations, but I think you can see that we are growing well.



Financial Results for FY2023

Revenue of Major Products in Japan & Asia

Billions of yen

	FY2022 Results	FY2023 Results	Change	
			Value	%
Japan				
Equa®/EquMet®	33.6	**30.6**	(2.9)	(8.7)
TRERIEF®	16.7	**15.5**	(1.2)	(7.0)
LATUDA®	9.6	**11.7**	2.2	22.5
METGLUCO®	7.7	**7.3**	(0.4)	(5.3)
TWYMEEG®	2.2	**4.6**	2.3	105.6
LONASEN® Tape	2.9	**3.8**	0.9	29.9
AG products	9.2	**9.7**	0.5	5.8
Trulicity® *	24.8	**—**	(24.8)	—
Others	19.4	**22.1**	2.8	14.3
Export products/ One-time revenue, etc.	12.8	**8.0**	(4.8)	(37.7)
Non-pharmaceutical operations	44.8	**1.3**	(43.5)	(97.1)
Total	183.6	**114.7**	(69.0)	(37.6)
Asia				
MEROPEN® (China)	28.5	**21.3**	(7.3)	(25.5)
Others	14.9	**19.6**	4.7	31.4
Total	43.5	**40.9**	(2.6)	(6.0)

Japan

- Revenue decreased due to the termination of the sales collaboration for Trulicity® and the transfer of all shares of two domestic consolidated subsidiaries
- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Export products/One-time revenue, etc. in FY2022 includes one-time revenue ¥6.1B under the license agreement for DSP-0187
- Total impact of NHI drug price revision (¥4.2B)

Asia

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

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

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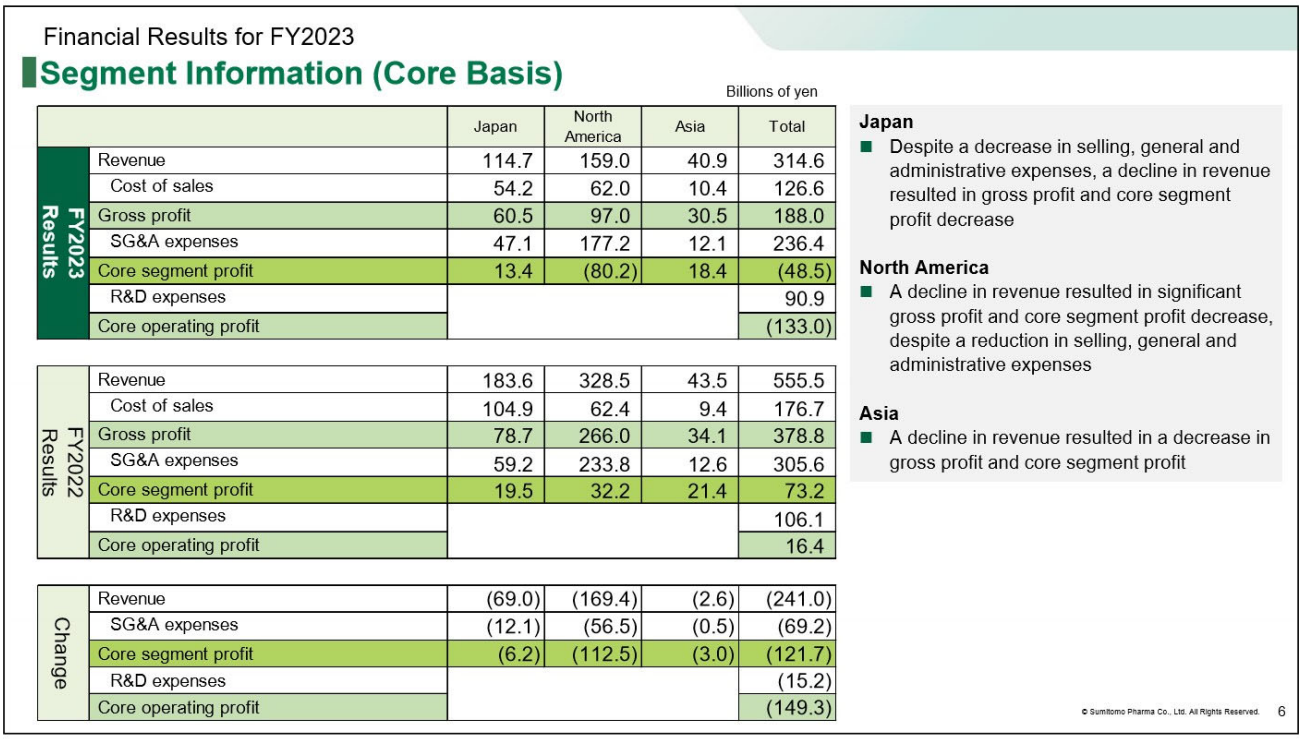
Here you see revenue in Japan.

The sale of two subsidiaries, Sumitomo Pharma Food & Chemical Co., Ltd. and Sumitomo Pharma Animal Health Co., Ltd., resulted in a significant decrease in consolidated revenue. The termination of the sales collaboration for Trulicity, which was already announced, has also resulted in a decrease in revenue. These are the major differences from the previous period.



Financial Results for FY2023

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2023 Results	Revenue	114.7	159.0	40.9	314.6
	Cost of sales	54.2	62.0	10.4	126.6
	Gross profit	60.5	97.0	30.5	188.0
	SG&A expenses	47.1	177.2	12.1	236.4
	Core segment profit	13.4	(80.2)	18.4	(48.5)
	R&D expenses				90.9
	Core operating profit				(133.0)
FY2022 Results	Revenue	183.6	328.5	43.5	555.5
	Cost of sales	104.9	62.4	9.4	176.7
	Gross profit	78.7	266.0	34.1	378.8
	SG&A expenses	59.2	233.8	12.6	305.6
	Core segment profit	19.5	32.2	21.4	73.2
	R&D expenses				106.1
	Core operating profit				16.4
Change	Revenue	(69.0)	(169.4)	(2.6)	(241.0)
	SG&A expenses	(12.1)	(56.5)	(0.5)	(69.2)
	Core segment profit	(6.2)	(112.5)	(3.0)	(121.7)
	R&D expenses				(15.2)
	Core operating profit				(149.3)

Japan
- Despite a decrease in selling, general and administrative expenses, a decline in revenue resulted in gross profit and core segment profit decrease

North America
- A decline in revenue resulted in significant gross profit and core segment profit decrease, despite a reduction in selling, general and administrative expenses

Asia
- A decline in revenue resulted in a decrease in gross profit and core segment profit

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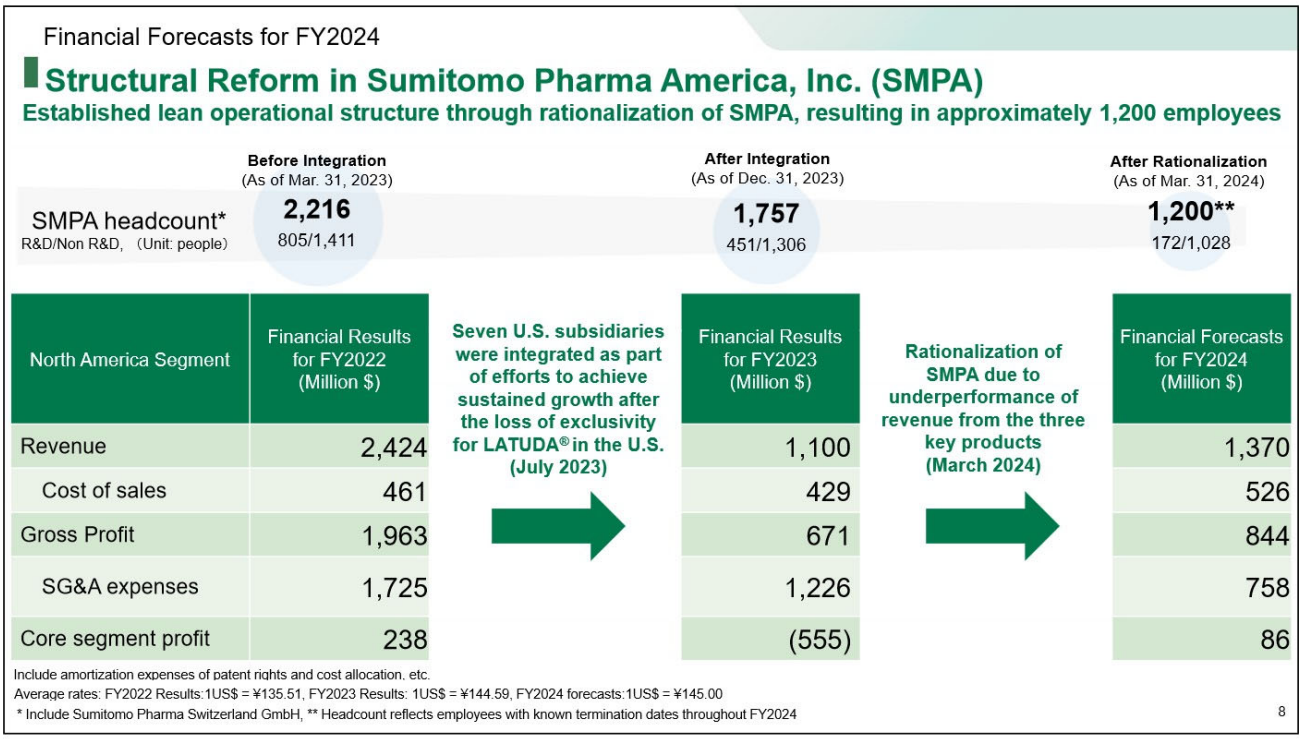
Here is a comparison of the FY2023 results with the FY2022 results.

The revenue figures are as you have just seen. SG&A expenses in Japan have decreased significantly. This is due to a decrease in SG&A expenses as a result of the sale of the two subsidiaries I mentioned, as well as a decrease in bonuses and other expenses due to very poor performance in FY2023.

In North America, we have substantially reduced our workforce. In FY2023, we have reduced 7 North American companies into one company, and we have reduced a lot of personnel, especially those in higher CxO positions.

In addition to this, there was a significant decrease in LATUDA sales promotion and other expenses, resulting in a decrease of JPY56.5 billion. This is the trend in SG&A expenses compared to the previous year.

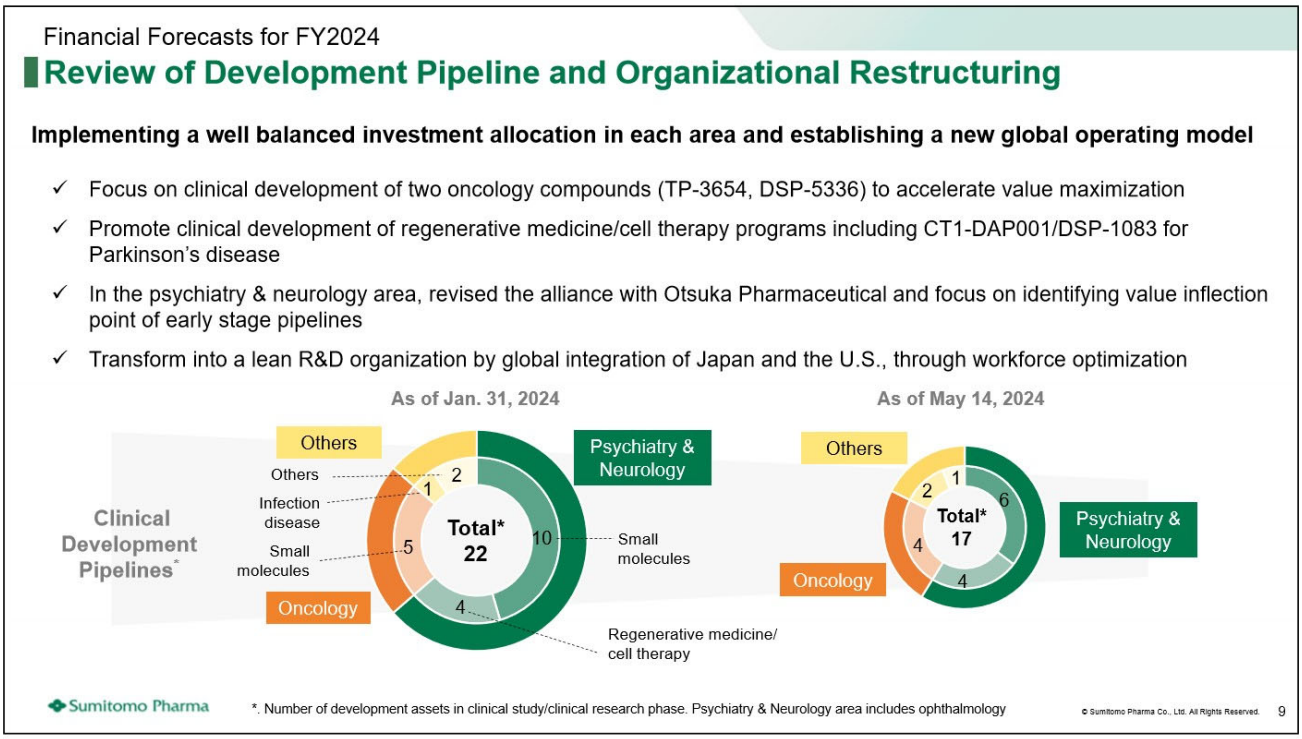


Forecasts for FY2024.

Before I talk about that, first of all, we have made structural reforms in the United States. As I have mentioned many times, if you look at our SG&A expenses in dollar terms compared to our FY2022 results, you will see that they are down about USD500 million in FY2023.

In addition, we expect SG&A expenses in dollar terms to decrease by about another USD500 million due to headcount reductions. Staffing has been drastically reduced from 2,200 to 1,200 employees.

However, as I mentioned at the May 1 conference, we are reducing our workforce to the extent that it does not impede our sales activities.



As we have told you, we will also drastically reduce R&D expenses.

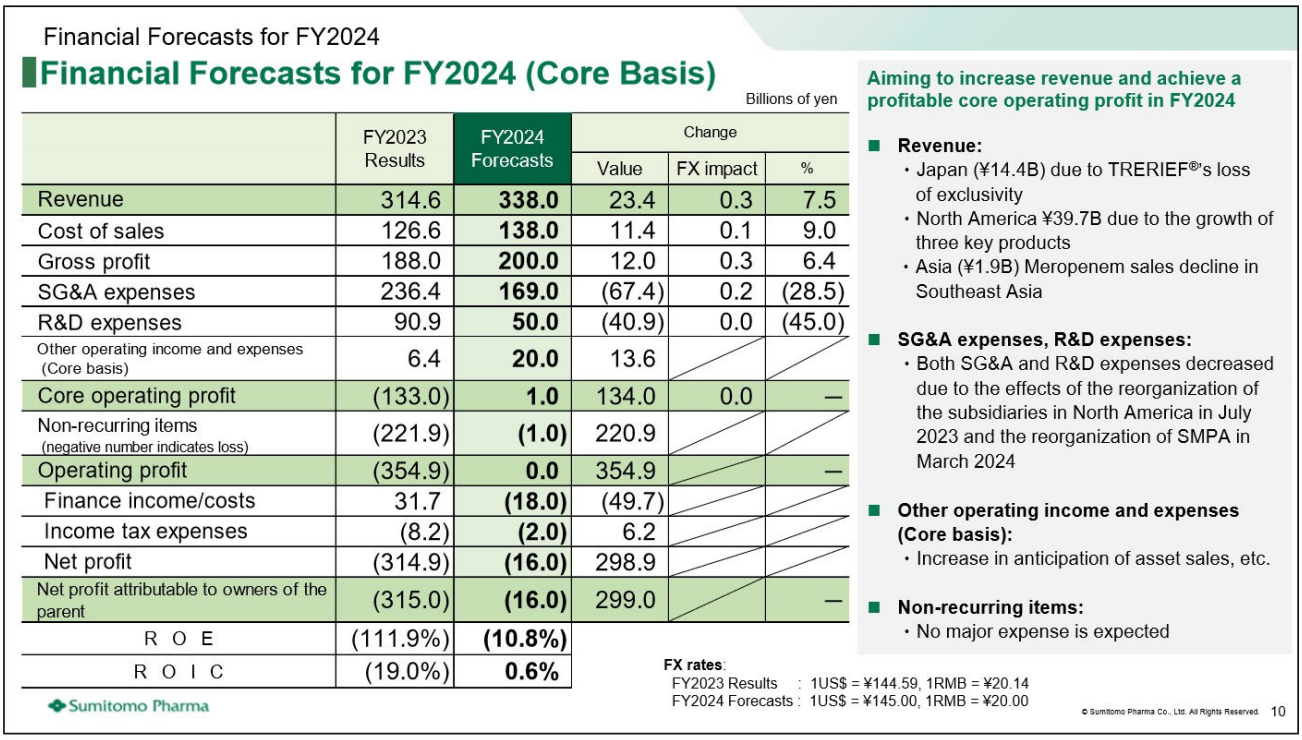
In this context, we will focus on the development of two pipelines in the area of oncology by implementing a well-balanced investment allocation.

We will also focus on non-cryopreserved and cryopreserved cells for Parkinson's disease.

In the Psychiatry & Neurology area, unfortunately, we have decided to out-license ulotaront and the other compound to Otsuka Pharmaceutical Co., Ltd., and we will continue to assess the potential of the early stage compounds in Phase I.

Overall, we are reducing the number of pipelines under development. Compared to 22 pipelines at the end of January, there are now 17 pipelines. We still have six pipelines in the Psychiatry & Neurology area, but these are still in the early stages of development. We will be examining which pipelines we will develop further.

As such, we will focus on very limited pipelines. In line with that base, we will proceed from FY2024 onward in North America, while working to optimize our workforce, make our organization leaner, and select our pipeline very selectively.



As I may have already indicated, we are projecting core operating profit of JPY1 billion. Revenue is projected at JPY338 billion, with gross profit of JPY200 billion. As already explained on May 1, SG&A expenses will be reduced by JPY67 billion from the previous year through reducing personnel and other expenses.

We will also narrow down our R&D expenses by JPY41 billion to JPY50 billion, as we reported on May 1, 2024.

The forecast for other operating income and expenses is JPY20 billion, which is due to an expected gain from asset sales.

In the May 1 material, the rationalization impact of SG&A and R&D expenses was JPY108 billion, the impact of increased gross profit from the three key products was JPY24 billion, and the increase from other factors was JPY2 billion. The JPY2 billion was the net of other operating income and expenses, JPY13.6 billion and the decrease in gross profit in Japan.

Non-recurring items are expected to be about JPY1 billion, with operating profit almost zero. This is due to the fact that the yen happened to depreciate to a little over JPY151 at the end of March, and the exchange rate forecast for FY2024 is set at a stronger yen of JPY145. This is a very technical calculation and we do not yet know what will actually happen.

However, under that assumption, the bottom line is expected to be a deficit of about JPY16 billion. However, we will aim for a significant improvement compared to the previous year.

Financial Forecasts for FY2024

Segment Information (Core Basis)

Billions of yen

		Japan	North America	Asia	Total
FY2024 Forecasts	Revenue	100.3	198.7	39.0	338.0
	Cost of sales	52.7	76.3	9.0	138.0
	Gross profit	47.6	122.4	30.0	200.0
	SG&A expenses	46.6	109.9	12.5	169.0
	Core segment profit	1.0	12.5	17.5	31.0
	R&D expenses				50.0
	Core operating profit				1.0
FY2023 Results	Revenue	114.7	159.0	40.9	314.6
	Cost of sales	54.2	62.0	10.4	126.6
	Gross profit	60.5	97.0	30.5	188.0
	SG&A expenses	47.1	177.2	12.1	236.4
	Core segment profit	13.4	(80.2)	18.4	(48.5)
	R&D expenses				90.9
	Core operating profit				(133.0)
Change	Revenue	(14.4)	39.7	(1.9)	23.4
	SG&A expenses	(0.5)	(67.3)	0.4	(67.4)
	Core segment profit	(12.4)	92.7	(0.9)	79.5
	R&D expenses				(40.9)
	Core operating profit				134.0

Japan
- Gross profit is expected to fall sharply due to the decline in sales, resulting in a decline in profits

North America
- In addition to increased sales, cost reductions through rationalization are expected to contribute to increased profits

Asia
- Profits are expected to decrease due to the impact of decreased revenue

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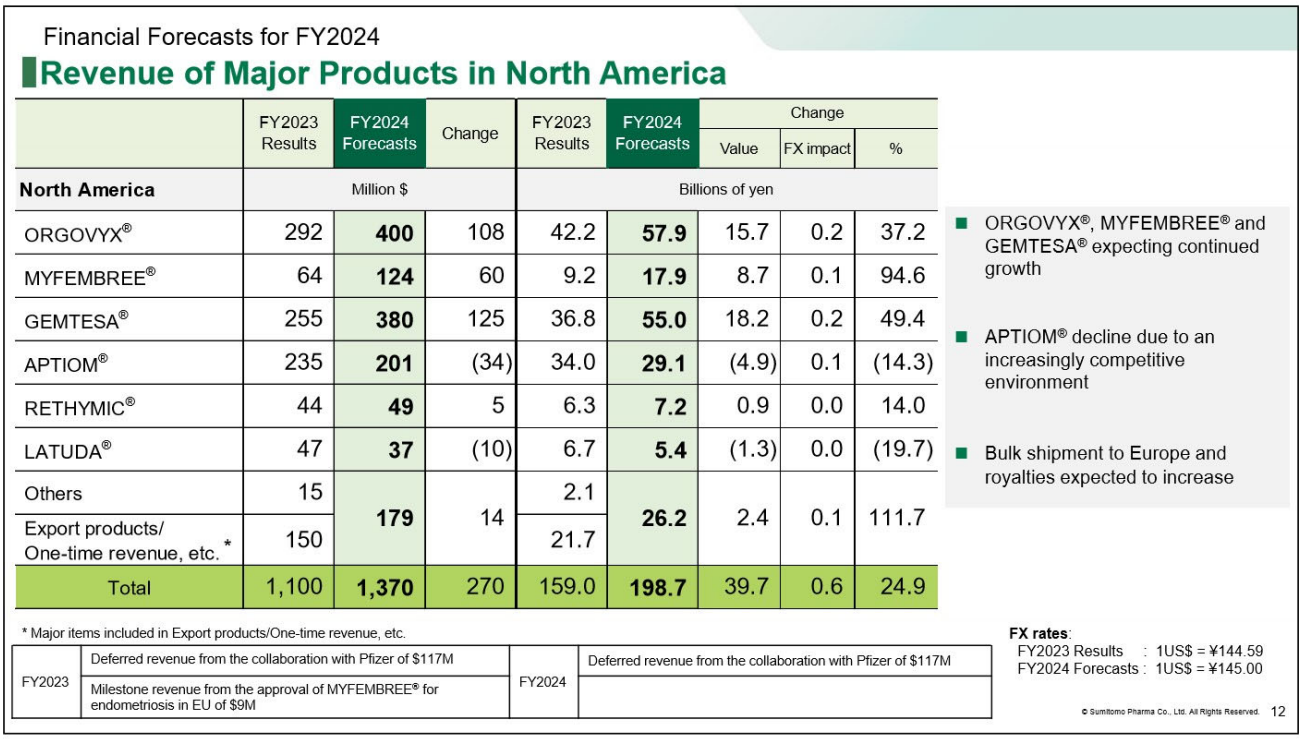
This is a comparison between FY2023 and the forecast.

The major initiatives are to reduce SG&A expenses by JPY67 billion and to decrease R&D expenses from JPY90.9 billion to JPY50 billion.



Financial Forecasts for FY2024

Revenue of Major Products in North America

	FY2023 Results	FY2024 Forecasts	Change	FY2023 Results	FY2024 Forecasts	Change		
						Value	FX impact	%
North America	Million $			Billions of yen				
ORGOVYX®	292	**400**	108	42.2	**57.9**	15.7	0.2	37.2
MYFEMBREE®	64	**124**	60	9.2	**17.9**	8.7	0.1	94.6
GEMTESA®	255	**380**	125	36.8	**55.0**	18.2	0.2	49.4
APTIOM®	235	**201**	(34)	34.0	**29.1**	(4.9)	0.1	(14.3)
RETHYMIC®	44	**49**	5	6.3	**7.2**	0.9	0.0	14.0
LATUDA®	47	**37**	(10)	6.7	**5.4**	(1.3)	0.0	(19.7)
Others	15	**179**	14	2.1	**26.2**	2.4	0.1	111.7
Export products/ One-time revenue, etc. *	150			21.7				
Total	1,100	**1,370**	270	159.0	**198.7**	39.7	0.6	24.9

- ORGOVYX®, MYFEMBREE® and GEMTESA® expecting continued growth
- APTIOM® decline due to an increasingly competitive environment
- Bulk shipment to Europe and royalties expected to increase

* Major items included in Export products/One-time revenue, etc.

FY2023	Deferred revenue from the collaboration with Pfizer of $117M	FY2024	Deferred revenue from the collaboration with Pfizer of $117M
	Milestone revenue from the approval of MYFEMBREE® for endometriosis in EU of $9M		

FX rates:
FY2023 Results : 1US$ = ¥144.59
FY2024 Forecasts : 1US$ = ¥145.00

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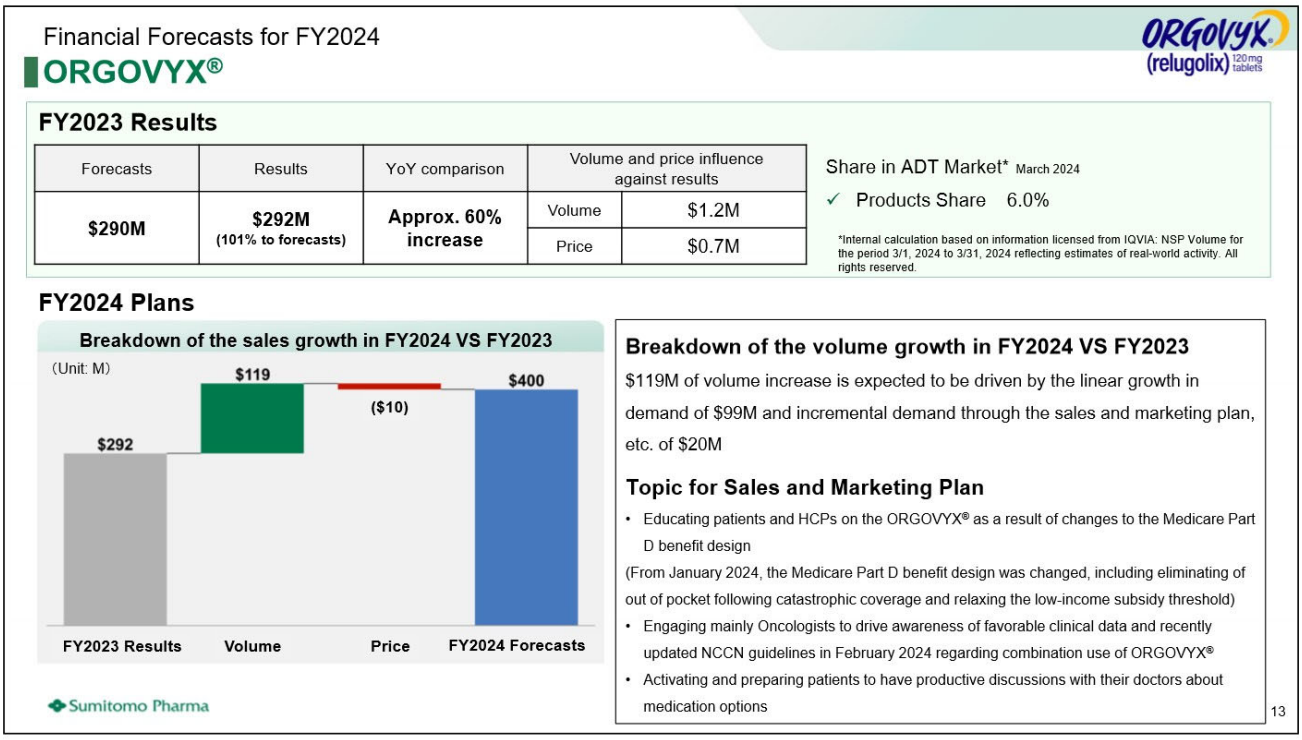
This is the revenue forecast by product.

If you look at our forecast in yen terms, you will see that our foreign exchange assumptions remain largely unchanged and we continue to grow.

You may have doubts about whether this target value in dollar terms can really be achieved. As I explained on May 1, we are running various simulations for impairment.

We also incorporate third-party views. This projected value is little different from the views of such third parties. We are not making this judgment on our own, but rather based on the fact that third parties are making similar observations, and therefore, we believe those revenues are achievable. Details will be explained later.



The above section is about the term that ended.

For the current fiscal year, we are targeting revenue of USD400 million. The volume difference from the previous year is USD119 million, while the price difference will have a slightly negative impact. As noted here, we intend to achieve this figure by adding USD20 million through our efforts to the USD119 million increase due to the linear growth in demand.

In particular, insurance coverage is changing, and some of treatments in the catastrophic coverage do not incur an individual copayment, making it easier to use ORGOVYX. Another significant factor, as will be reiterated later, is that ORGOVYX has become a recommended position in the NCCN guidelines.

We also help patients have meaningful discussions with their physicians about drug selection. This may sound very strange, but as you all know, in the US, what kind of treatment options patients want is a very powerful force in their treatment. We are committed to creating an environment that encourages patients to use our ORGOVYX by educating them about their treatment options with oral medications and insurance coverage. We will strive to increase the volume by doing so.

Financial Forecasts for FY2024

NCCN (National Comprehensive Cancer Network) Guidelines Update

ORGOVYX® (relugolix) 120mg tablets

NCCN Guidelines

- Standardized clinical practice guidelines for the diagnosis, treatment, and management of cancer, and highly valued by oncologists
- Language on combination use may impact prescriptions since combined treatments are common in advanced prostate cancer

Guidelines Revision

- Under previous guidelines, ORGOVYX® (generic name: relugolix) in combination therapy in some conditions were not recommended in the guidelines
- In Feb. 2024, however, guidelines included ORGOVYX® as a recommended option for some combination therapies*
- We anticipate increasing utilization, particularly in Academic Centers & Integrated Delivery Networks

Change in combination therapy

Before February 27, 2024	→	After February 27, 2024
Degarelix + Combinational Drugs**		LHRH antagonist (Degarelix & Relugolix) + Combinational Drugs**

*Regional (N1,M0) disease, Metastatic Castration-sensitive disease, and Secondary hormone therapy for M0/M1 Castration-resistant prostate cancer
**abiraterone acetate, apalutamide, darolutamide, enzalutamide, docetaxel, cabazitaxel

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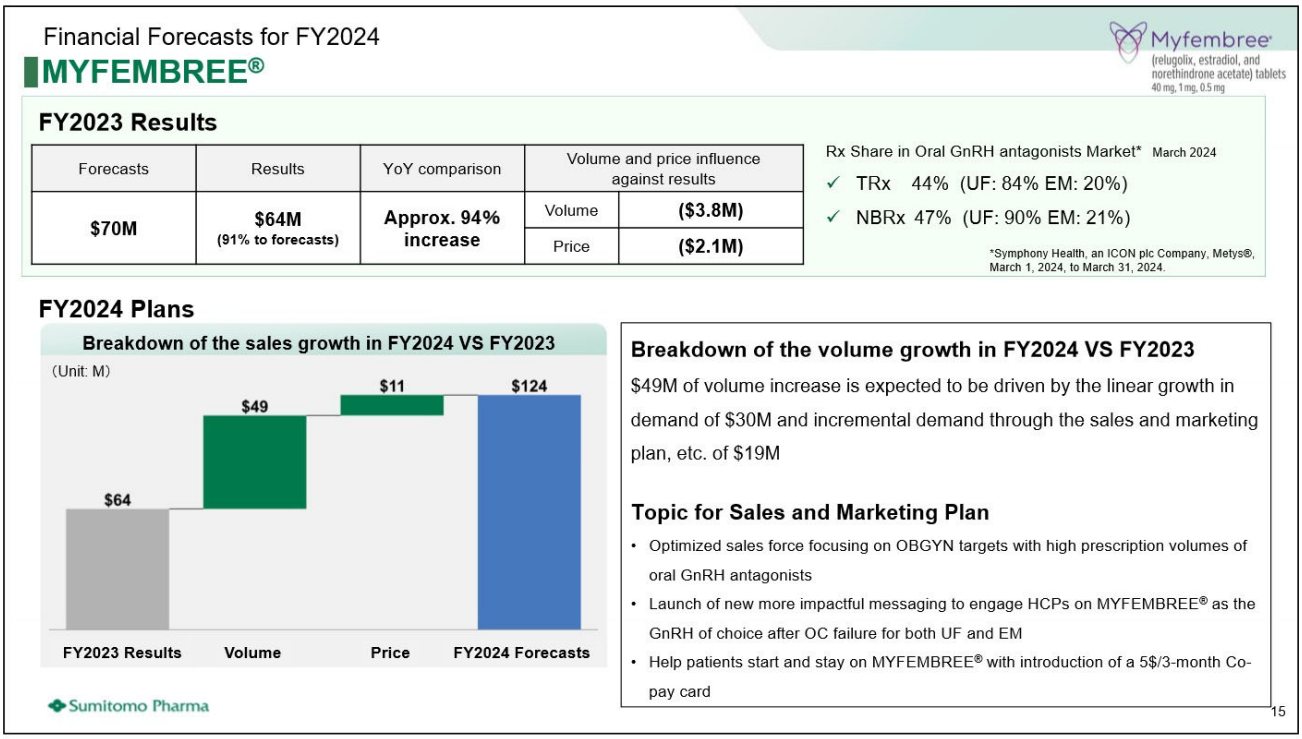
As a result of our combination data, the NCCN guidelines now recommend Relugolix as a combination drug, whereas previously only Degarelix was recommended.



This page describes MYFEMBREE.

As for MYFEMBREE, a significant impairment loss was recorded in the previous fiscal year. In that context, we hope to achieve a revenue of USD124 million in this fiscal year, with an increase of USD49 million from volume and USD11 million from price.

Of the USD49 million due to volume, USD30 million is an increase due to demand trends. A trend, of course, does not mean that it will increase if left alone. We are planning to add USD19 million to the USD30 million by conducting various marketing activities as we have done so far.

Until now, informational activities have been somewhat scattered. We will optimize sales force focusing on obstetrics and gynecology with a high volume of prescriptions for oral GnRH antagonists. We have optimized our sales team for this purpose. We are shrinking the number of people slightly, but by focusing more on high side of obstetrics and gynecology, we will increase the efficiency of our sales activities.

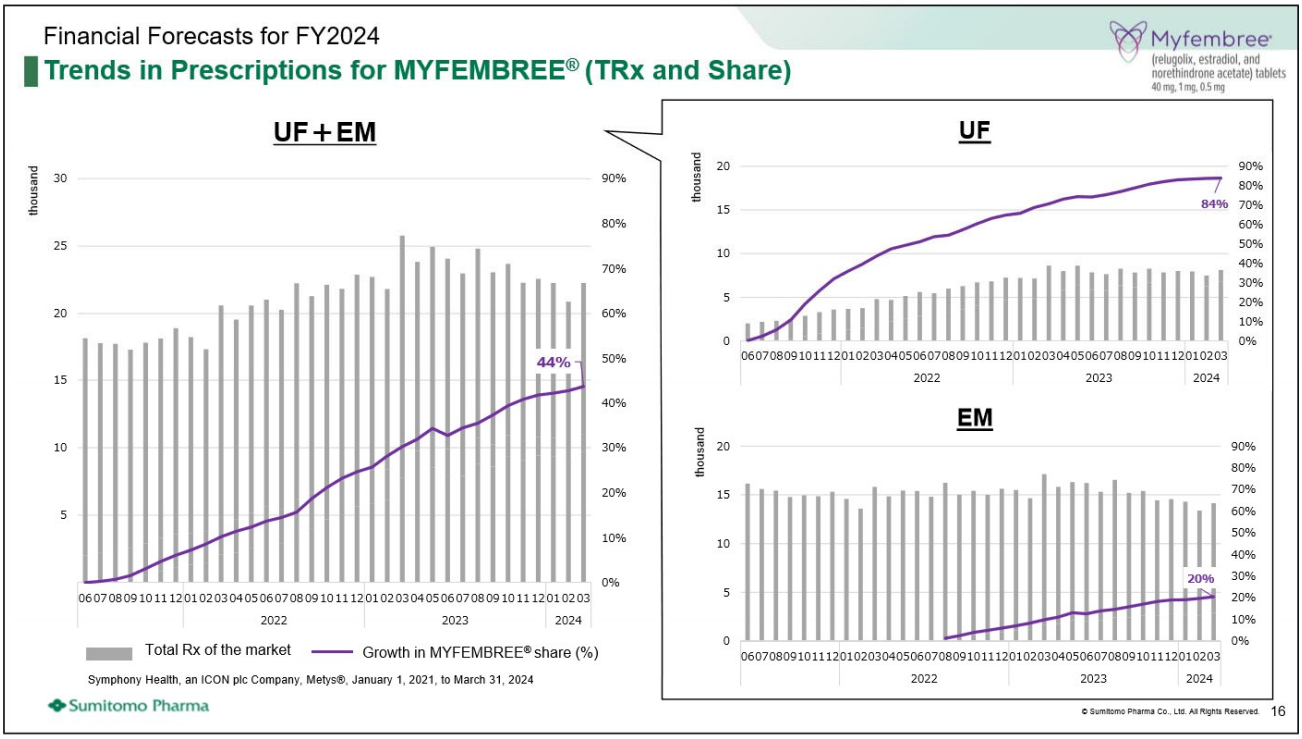
For the most part, oral contraceptives are used first for uterine fibroids and endometriosis, but there is some question as to whether oral contraceptives are effective enough for uterine fibroids and endometriosis. We will make sure to inform medical professionals to use MYFEMBREE for such invalid cases first.

We will also make every effort to convey such a message not only to medical professionals but also to patients.

The other is a Co-pay card. Co-pay cards are designed to lower the burden on patients. After all, with MYFEMBREE, too, you can finally realize the benefits and effectiveness of the product after using it for a long

period of time. The period was extended to three months to allow patients to experience the benefits of MYFEMBREE as much as possible.

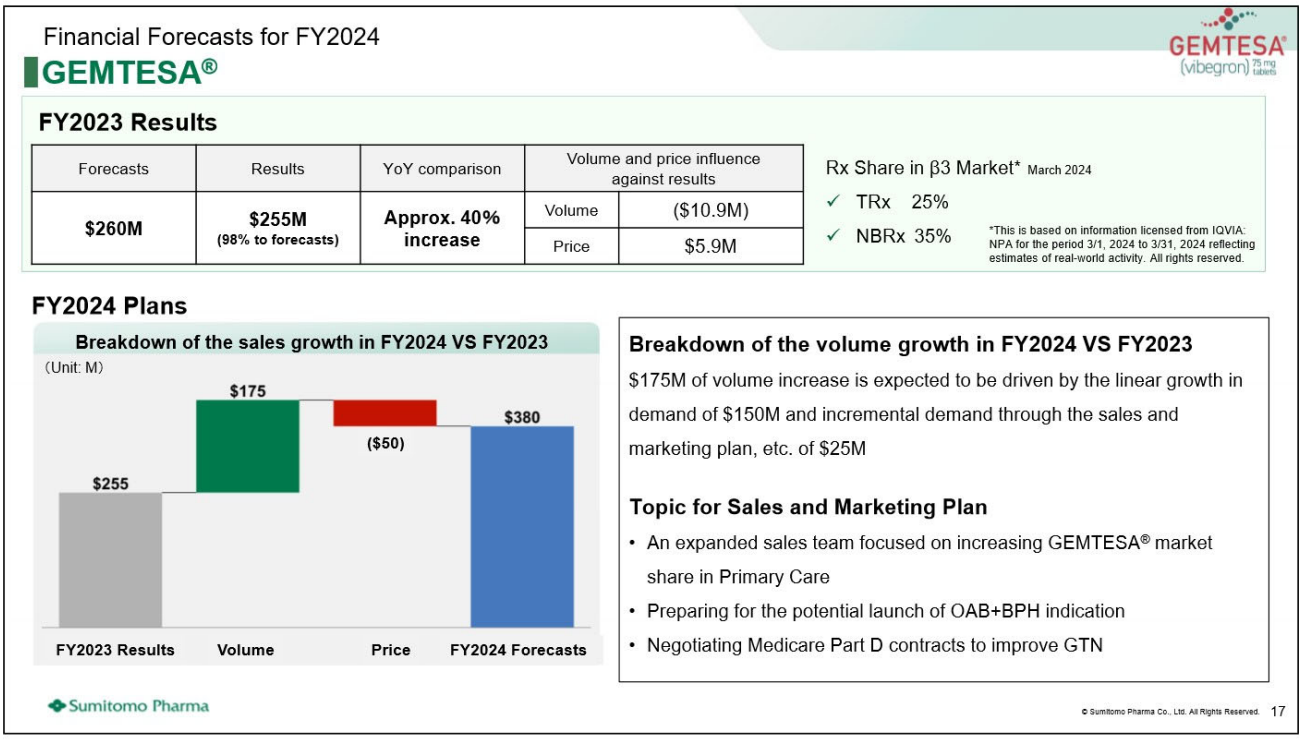
By doing so, we hope to increase loyalty to MYFEMBREE, or rather, to encourage patients to use it more.



Here are prescription trends.

Our share is 44% in total, but for uterine fibroids it is already a very large 84%. Unfortunately, the market share in endometriosis is still 20%, with AbbVie's Orilissa accounting for a very large share.

However, according to what we have heard, AbbVie's marketing focus on Orilissa has been declining since April. Therefore, we will first strive to take as much market share as possible from AbbVie in the area of endometriosis.



For GEMTESA, we expect revenue of USD380 million for the current fiscal year. The current estimate is that there will be a USD175 million positive impact from volume, while there will be a slight negative impact from price.

As a preliminary note, this is based on the assumption that the generic Myrbetriq will only come in from Q4. In a situation where temporary injunction has already been lifted, we are forced to look a little more closely at what the impact will be. Therefore, we would like you to understand that the impact of the projection has not yet been factored into this earnings forecast.

Of the USD175 million, USD150 million is from marketing efforts to date and USD25 million from additional efforts. We will also increase sales reps here, especially since primary care was not adequate.

We are also preparing for various promotional activities for the indication of overactive bladder with BPH, which is currently under sNDA.

We will also strive to reduce the slight negative impact of price and improve gross to net through contract negotiations regarding Medicare Part D.

Financial Forecasts for FY2024

Revenue of Major Products in Japan & Asia

Billions of yen

	FY2023 Results	FY2024 Forecasts	Change Value	Change %
Japan				
Equa®/EquMet®	30.6	**26.3**	(4.3)	(14.1)
LATUDA®	11.7	**13.0**	1.3	10.8
TWYMEEG®	4.6	**11.3**	6.7	147.7
METGLUCO®	7.3	**7.4**	0.1	1.4
LONASEN® Tape	3.8	**4.4**	0.6	15.2
TRERIEF®	15.5	**2.1**	(13.4)	(86.4)
AG products	9.7	**11.1**	1.4	14.6
Others	22.1			
Export products/ One-time revenue, etc.	8.0	**24.7**	(6.7)	(30.5)
Non-pharmaceutical operations	1.3			
Total	114.7	**100.3**	(14.4)	(12.5)
Asia				
MEROPEN® (China)	21.3	**21.2**	(0.1)	(0.3)
Others	19.6	**17.8**	(1.8)	(9.2)
Total	40.9	**39.0**	(1.9)	(4.6)

Japan

- Continue to focus on increasing revenue of LATUDA® and TWYMEEG®
- TRERIEF®'s sales are expected to decline significantly due to loss of exclusivity
- NHI drug price revision effect in FY2024 : (¥5.2B)

Asia

- In China, sales are expected to remain at the same level as FY2023, despite the impact of Volume-Based Procurement application
- The temporary expansion of MEROPEN® (Southeast Asia) shipments that occurred in FY2023 is expected to subside

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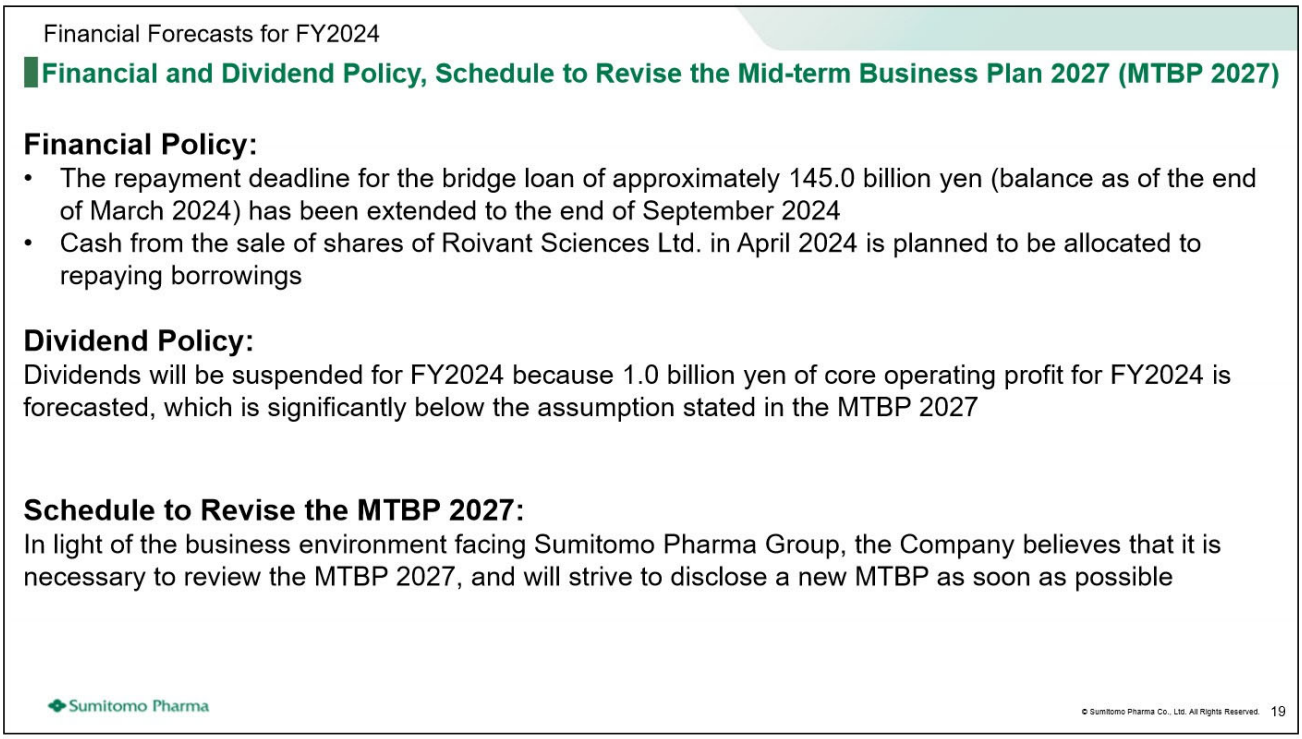
In Japan, unfortunately, revenue is expected to decrease by JPY14.4 billion.

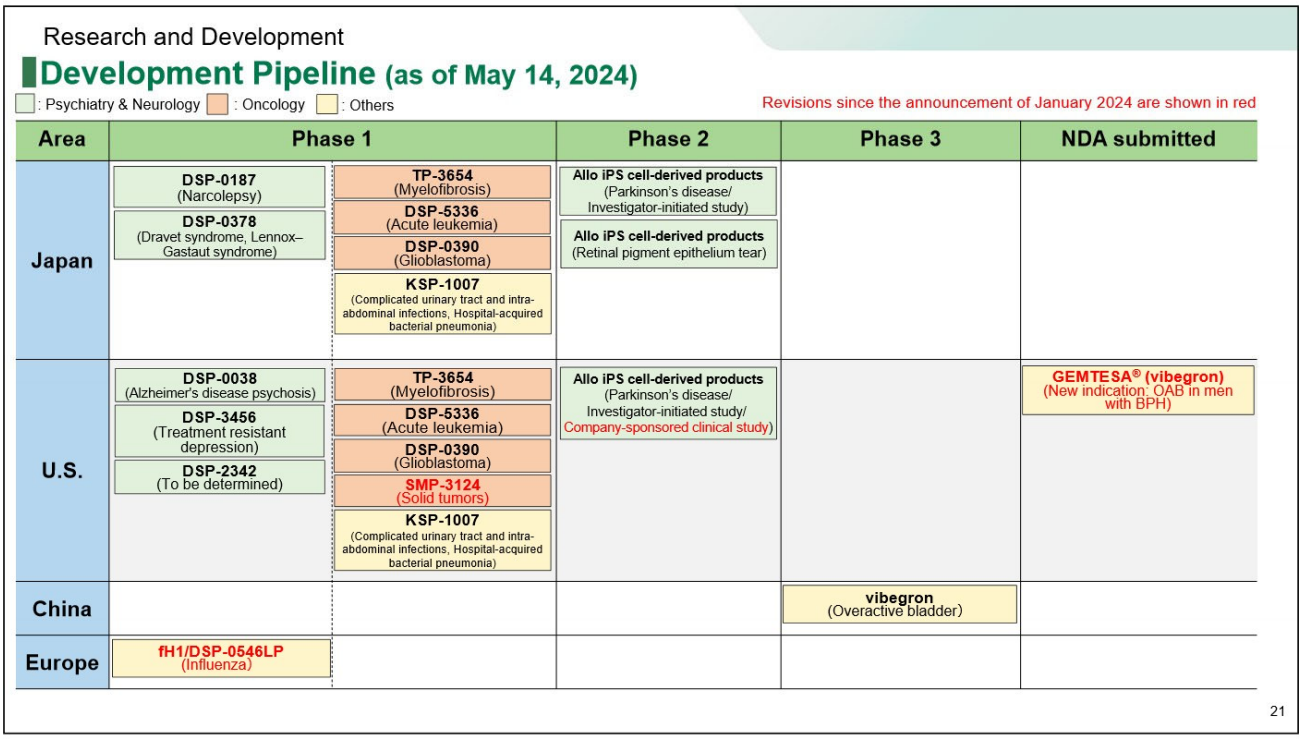
As for Equa/EquMet, revenue of Equa is expected to decrease due to the expectation that the generic will be launched in about December. TRERIEF revenue is expected to decrease due to the impact of generics. As a result of the above, we unfortunately expect a JPY14.4 billion decrease in Japan sales.



As we also mentioned on May 1, the deadline for repayment of the JPY145 billion bridge loan has been extended for now until the end of September. The money of about JPY98 billion from the sale of Roivant Science Ltd.'s shares will be used to repay loans.

At the briefing on the Mid-term Business Plan, we mentioned that we would like to resume dividend payments once core operating profit becomes profitable in FY2024. However, we plan to pay no dividend due to our current forecast of JPY1 billion, a very low level.

We intend to review and announce our Mid-term Business Plan 2027 as soon as possible in light of the significant changes in our assumptions.



Research and development will be explained.

Changes since the January Q3 financial results conference are shown in red.

An application was filed for GEMTESA for the treatment of overactive bladder with BPH.

For Allo iPS cell-derived products, we have started a company-sponsored clinical study for Parkinson's disease.

For SMP-3124, Phase I of the clinical study for solid tumors has started. This will be explained later.

In addition, Phase I of the influenza vaccine has begun.

This is supplemented in the reference material.

Research and Development

Major Progress in Clinical Development

- **Allo iPS cell-derived products (dopaminergic neural progenitor cells)**
  U.S.: Started Phase 1/2 study (Company-sponsored clinical study) for Parkinson's disease
- **ulotaront, SEP-380135**
  Granted Otsuka the exclusive worldwide rights to develop, manufacture, and commercialize ulotaront all indications and out-licensing
- **SMP-3124**
  U.S. : Started Phase 1/2 study for solid tumors
- **GEMTESA® (vibegron)**
  U.S.: Submitted sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in February 2024
- **fH1/DSP-0546LP (universal influenza vaccine)**
  Europe: Started Phase 1 study for influenza in Belgium

【Discontinuation of the development and the study】

- EPI-589 U.S.: Parkinson's disease (Phase 2), U.S. and Japan: Amyotrophic lateral sclerosis (ALS) (Phase 2)
- SEP-378614 U.S.: Indication undetermined (Phase 1)
- TP-1287 and TP-1454 U.S.: Solid tumors (Phase 1)

＊Decided to discontinue development of SEP-4199 and rodatristat ethyl, which were under consideration for development strategy

＊Deleted SP-101 from the table due to spin-out (U.S.: Phase 1/2 for cystic fibrosis)

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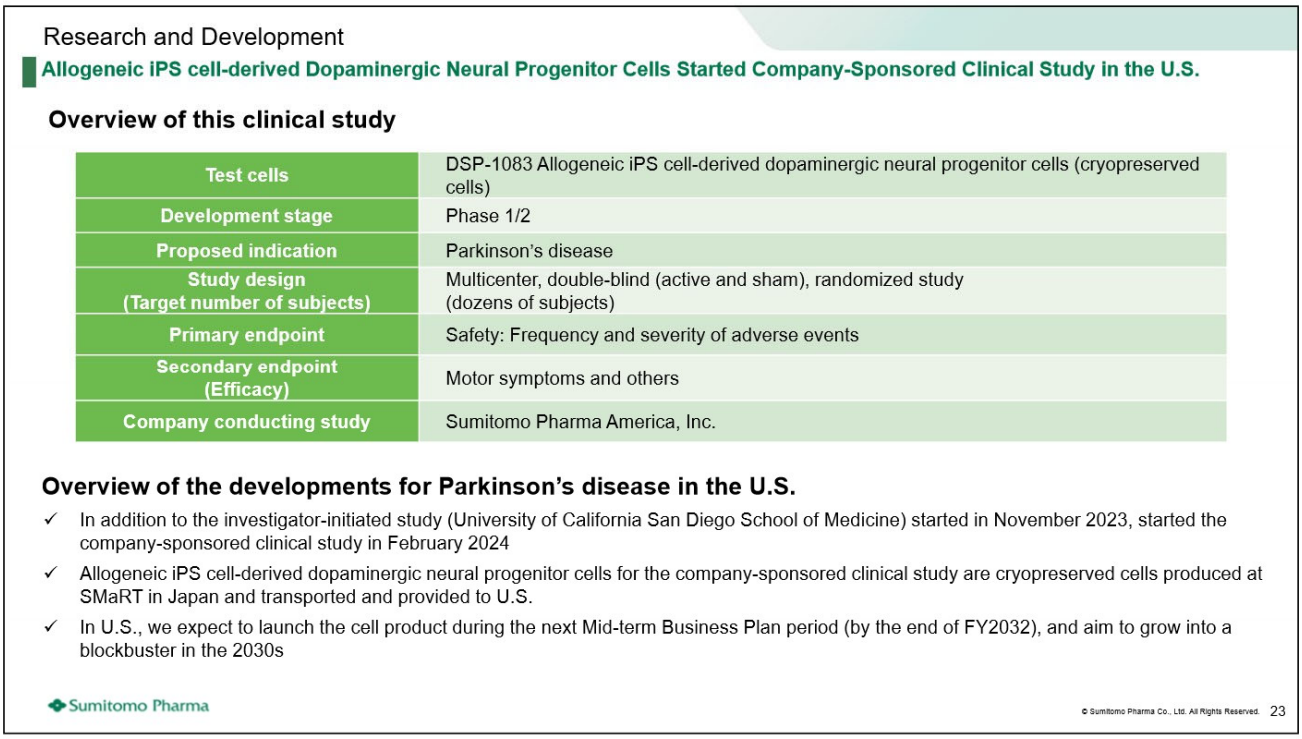
Here is what I just said in writing.



This is about a company-sponsored clinical study in the U.S. on allogeneic iPS cell-derived dopaminergic neural progenitor cells.

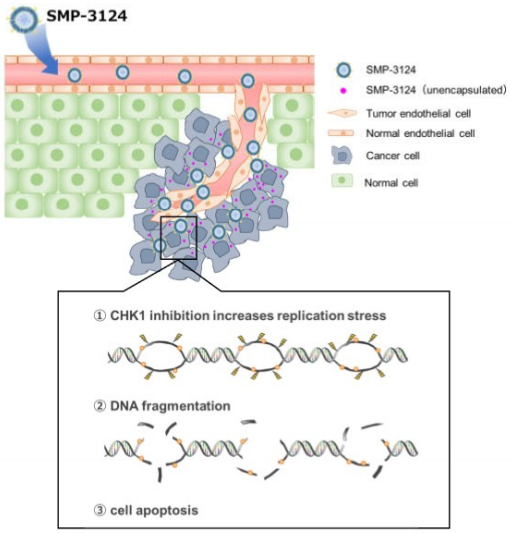
Like Kyoto University, we are conducting investigator-initiated study, but the major difference is that Kyoto University is using non-cryopreserved cells, while our company's clinical study is using cryopreserved cells.

Research and Development

New Chemical Entity: SMP-3124 (CHK1 inhibitor, Liposomal nanomedicine)

- ✓ Target indication: Solid tumors
- ✓ Origin: In-house
- ✓ Mechanism of action: Induce cell apoptosis by CHK1 (Checkpoint kinase 1) inhibition
- ✓ Stage: Phase 1/2 in the U.S.
- ✓ Expected profile:
  - ➢ CHK1 is activated by DNA damage response, then arrests the cell cycle, and induces DNA repair that is a serine-threonine kinase. CHK1 inhibition leads cancer cell with high replication stressed to apoptosis by inducing further DNA damages
  - ➢ SMP-3124 is expected to accomplish strengthen the anti-tumor activity and weaken side effects by changing pharmacokinetics of the compound with liposomal nanomedicinal encapsulation
- ✓ Japan will join the same Phase 1/2 study
- ✓ Pre-clinical study data was presented in a poster at AACR2024

Mode of action



Sumitomo Pharma

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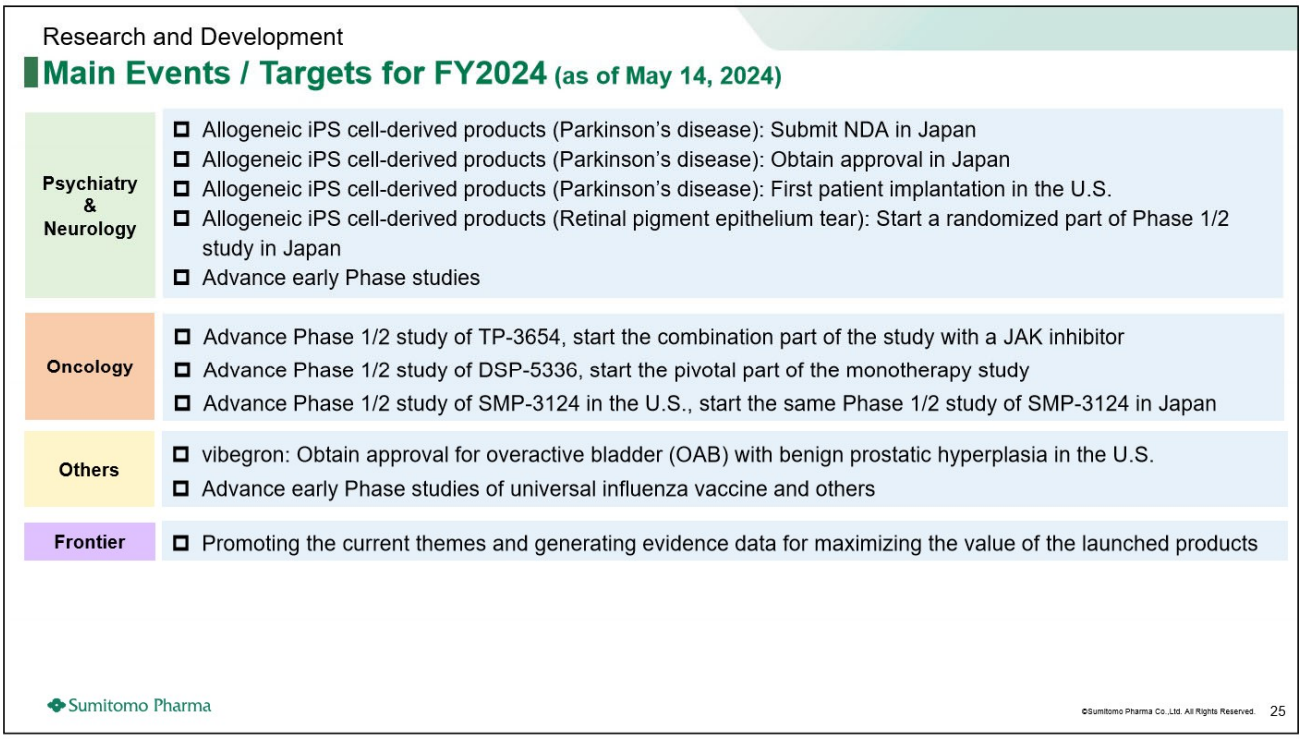
A new compound, SMP-3124, has newly come up to Phase I.

The pharmacological mechanism is induction of cell apoptosis by checkpoint kinase 1 inhibition. Liposomal nanomedicinal encapsulation is expected to accomplish strengthen the anti-tumor activity and weaken side effects by changing pharmacokinetics of the compound.

We are moving forward with this in the hopes that this will be a new treatment option. If you have any questions, we would be happy to answer them later.



Some of the milestones in this fiscal year's R&D are presented by area.

This time, there is nothing that has already been completed, and it is up to us to determine how much we can accomplish this fiscal year.

That is all I have to say. Thank you very much for your attention.

Question & Answer

Noguchi [M]: Thank you very much, Mr. Nomura. We would now like to move on to the question-and-answer session.

We will first take questions from analysts and institutional investors by 16:15, followed by questions from the media.

First of all, I would like to ask those analysts and institutional investors present at the Tokyo Head Office venue to raise their hands if they have any questions. After I call your name, an attendant will take the microphone. Please ask questions after mentioning your affiliation and name.

Mr. Hashiguchi, please ask your question.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities. I have a few questions. I would like to know about your plans for GEMTESA and MYFEMBREE, two of your three key products.

Regarding MYFEMBREE, you spoke about the introduction of Co-pay cards. On the other hand, your plan for this fiscal year assumes a positive price impact. How can we interpret this?

Nomura [A]: Last year we saw some inappropriate use of Co-pay cards, which significantly pushed down the real price. As that normalizes, we expect the price side to be positive compared to the previous year.

Hashiguchi [Q]: You have been talking about the normalization of it for some time. I believe you had such issues last year as well, but what kind of initiatives do you plan to take this year?

Nomura [A]: We are constantly monitoring the use of Co-pay cards. The results confirm, for now, that there will be little, if any, unusual Co-pay card use.

Hashiguchi [Q]: Thank you very much. Regarding GEMTESA's earnings forecast, you explained that the increase due to existing demand trends is USD150 million. I don't quite understand the USD150 million increase due to existing trends in the current quarter, since the previous quarter's actual increase was only USD73 million. How should this be understood?

Nomura [A]: Perhaps the term "linear growth" is not quite right. We estimate that it will increase by this amount.

As I mentioned earlier in my explanation, we did the impairment tests for ORGOVYX and MYFEMBREE, respectively. At that time, we also received a third-party opinion.

Basically, the impairment test is using that third-party view. In our tests, we tend to get slightly better results. Even in that situation, the results of GEMTESA, ORGOVYX, or MYFEMBREE have not made that much difference at the present time.

We expect to achieve this level of performance, and in addition to that, we have some additional targets to work toward.

Hashiguchi [Q]: I understand. Finally, you expect to pay no dividend this fiscal year, but what are your thoughts on the conditions for resumption of dividend payments? Could you also comment on when you expect to achieve this at this stage?

Nomura [A]: Thank you. In terms of resumption of dividends, we are currently in a situation where our financial condition, or rather the absolute value of our net assets, is very low. Therefore, we will consider resumption of dividends once our financial condition has recovered to a certain degree and we have a certain level of cash flow available to repay the current JPY400 billion in debt.

Therefore, rather than a temporary profit level, we will make a decision based on the overall financial condition, financial position, and debt repayment status, as well as future cash flow in a comprehensive manner.

Hashiguchi [Q]: Is it still difficult for you to answer when that might be?

Nomura [A]: Yes, that is still difficult. As I mentioned earlier, I think there is a process to review the Mid-term Business Plan one more time. In this context, we will once again consider resumption of dividend payments after reviewing the future development of cash flow and financial position.

Hashiguchi [M]: Thank you very much. That's all.

Noguchi [M]: Thank you very much. To other analysts, do you have any questions? Mr. Sakai, please ask your question.

Sakai [Q]: My name is Sakai from UBS. First, at the May 1 briefing, you, the president, also mentioned that you had taken in a third-party opinion in conducting the impairment test. By "third party" do you mean an auditing firm? Or did you take into account the opinions of the KOLs in creating the sales estimates?

What kind of person or organization is it? Of course, I think it is a reliable one. Moreover, since your company accepted it, I believe that these people have a certain amount of responsibility and that the figures are based on some degree of thought. Could you please explain this to us?

Nomura [A]: This is not an auditing firm. The auditing firm we have hired is KPMG AZSA, and KPMG AZSA determined whether the impairment test we have performed is appropriate. Therefore, we do not use the audit firm for creating the sales estimates.

The methodology is based on various parameters such as market growth, market share going forward, what happens if we increase sales reps, what happens if we change targets, etc. Based on those, our U.S. subsidiary made their forecasts.

The third party then made separate estimates, for example, of growth in demand or sales growth due to increased sales reps. They created their own forecasts based on the superimposition of such differences in their views.

In terms of which estimates we should trust more for impairment testing, we believe we should choose the more conservative one.

The Board of Directors also discussed at length what sales projections should be placed on the impairment test. As a result, it was decided that it would be appropriate to use an externally calculated, conservative view. Therefore, we use it.

Sakai [Q]: So, in layman's terms, the third party means consultants.

Nomura [A]: In layman's terms, it means consultants. We used experienced consultants for such sales projections.

Sakai [Q]: I understand. I have two more questions. Since the listing of ORGOVYX in the NCCN guidelines already took place in February, I would expect to see some changes in prescriptions in March, April, and May. However, the outside vendor data we see does not show much change.

I would like to know what is happening now in the field and any other information.

Kimura [A]: I think it will take some time for such data to be reflected. We are also in the process of monitoring the situation closely.

There was no significant change in the trend until March, but we have received information that there was a change in April, although it is only preliminary data. However, sales in the U.S. may rise or fall from month to month, but there is also a business custom to balance the books by quarter. I do not say something rash, but we have obtained such data.

We intend to strengthen our monitoring in this area in the coming year, checking whether our measures are progressing as we expect.

Sakai [Q]: It seems that recombination of reps has been done to some extent, but do you feel that you are getting a good response?

Kimura [A]: Yes. We are currently feeling a handful of positive results, but would like to continue to closely monitor the situation in the future. I believe it is a bit premature to judge whether the response is solid or not.

Sakai [Q]: I understand. Also, a new anti-cancer compound, SMP-3124, was introduced this time. I am not familiar with science and am not sure of the mechanism. Basically this is based on kinase, right?

You mentioned that you are going to decide on the type of cancer, but what organs are you currently targeting as suitable organs for this type of drug? You are currently in Phase I/II, so it may be too early to ask.

The fact that you are presenting it here means that this is probably a very promising addition to your company's portfolio. I also understand that this is the only novel mechanism in your oncology portfolio.

Can you tell us a little more about the future of this and how you will lead future development, including whether you will do this in-house or not?

Ikeda [A]: Thank you for your question. I, Ikeda, will explain.

First of all, regarding cancer types, we are trying various cancer types in the nonclinical phase. For example, very clear efficacy data have been confirmed for various major solid tumors such as ovarian cancer, breast cancer, and non-small cell lung cancer.

Based on those data, we are planning to select the most appropriate cancer type by having such patients participate in Phase I and exploring what that actually looks like in humans.

I think it would be a great deal of money to add it all up. In any case, we believe that this is an agent that can enter a large market for a reasonable amount of money.

As for how far we will go in-house, our current focus for the two compounds are on hematologic malignancy, and the scale of the clinical studies is relatively small, but we believe that the scale will be larger for solid tumors.

Naturally, depending on which diseases and cancer types we do in-house, we will be approached by other companies when good data become available. I hope we can discuss things again at that stage.

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

Kimura [A]: Thank you very much. Let me just add a little background on our expectations. This is a novel substance and the patent term is long enough. In creating liposome formulations, we convert substances that have already shown efficacy in clinical studies into a form that can be easily encapsulated in liposomes.

We are using something that has already been clinically confirmed to be effective for the major skeletal parts, but has been halted due to safety issues. In that sense, if the liposome formulation successfully acts as a delivery, I think we can expect anticancer activity. In fact, we are now starting clinicals, during which we will confirm that.

Noguchi [M]: Thank you very much. Do analysts and institutional investors present in the audience have any questions?

Since there do not appear to be any, please raise your hand if you are an analyst or institutional investor participating via Zoom and have a question. We will call your name and unmute the microphone. Please provide your affiliation and name followed by your question.

First, Mr. Muraoka of Morgan Stanley, please ask your question.

Muraoka [Q]: Thank you very much. I am Muraoka from Morgan Stanley.

Could you tell us a little more about your forecast of JPY1 billion in operating profit for the current fiscal year? There is a gain of JPY20 billion from the sale of assets, which is a significant improvement from the previous fiscal year. How does this improvement work quarterly? If possible, please tell us when the gains on asset sales will occur and how operating profit excluding those gains will improve from QtoQ.

For example, around Q4, would you see break even on a three-month basis, or not, and would the deficit continue until the final quarter, excluding asset sales? It would be helpful if you could share your assumptions in this area.

Kimura [A]: The assumption is that SG&A and R&D expenses will be significantly reduced, either through last year's measures or in this year's budget. We believe that this will be realized every quarter or every month, and I think you will feel it with each passing quarter.

However, although we closed the CNS R&D in March, some activities in collaboration with Otsuka Pharmaceutical remain, and we believe that there will be some increase or decrease due to this.

We have not yet decided on the timing for the sale of assets. However, given the circumstances, we hope to implement it as far ahead of the end of the fiscal year as possible. We expect sales to increase with each passing quarter, and we hope to see the effects of cost reductions with each passing quarter, bringing us into the black on a QtoQ basis in Q4. We hope to be able to explain this with clearer figures as we see future developments.

Muraoka [Q]: Thank you very much. The Mid-term Business Plan runs through FY2027, so that would mean four years, including the current term. When could you share it with us?

Kimura [A]: When I said that we would explain the QbyQ forecasts after careful examination, I meant that I assumed that we would explain them after creating a new Mid-term Business Plan and making clear forecasts.

As announced in today's press release, the management structure will undergo major changes from June onward, and we are considering formulating a new Mid-term Business Plan within this context.

In that sense, we believe that Q1 and Q2 are a bit early to introduce new plans. We have not set a specific timing, and will try to report as soon as it is decided.

Muraoka [Q]: By the way, I believe there will be a review of MYFEMBREE and ORGOVYX in the sixth year of the contract with Pfizer. Considering the major impairment of MYFEMBREE this time around, it seems difficult to see how the contract can really be extended around 2026. Do you anticipate such risks several years down the road?

Kimura [A]: I cannot explain the details of the contract, but we have a contract on a set of ORGOVYX and MYFEMBREE. ORGOVYX is progressing well, and we believe that Pfizer will be reasonably satisfied with the overall contract.

I think the situation is the same for Pfizer, with MYFEMBREE underperforming. We will consider this and other trends this fiscal year, especially since we are restarting in April with a new sales structure.

As for what happens after five years, it is for Pfizer to decide. However, I believe that a lot will depend on how well sales of ORGOVYX and MYFEMBREE go until then.

Muraoka [M]: I understand. Thank you, that's all.

Noguchi [M]: Thank you very much. Mr. Yamaguchi of Citigroup, please ask your question.

Yamaguchi [Q]: Thank you. I am Yamaguchi from Citi.

This question relates to the third party mentioned in the earlier discussion. It is clear that the assumptions have changed between the time the GEMTESA forecast was created and now. I think from the outside looking in, if the impact of this is quite a bit, you may be forced to make some revisions.

In that case, until now it was sales of Roivant, or Myovant, and therefore could not be corrected, but from now on it will be your company's product. Therefore, I believe your company will constantly review its forecasts. Assuming that you may consider incorporating third-party opinions, if the situation of the three key products changes in Q1 or Q2, at what timing, such as in H1 or H2 of the year, do you intend to make revisions?

Sorry for the question assuming a revision. Could there be a review on a quarterly basis? Or is it basically unchanged for the entire H1 of the year?

Kimura [A]: Thank you for your question. I think you are mainly saying this in anticipation of a change in the GEMTESA situation. The impact on sales will become apparent in Q2 at the earliest. Therefore, we expect to revise our sales forecast after that time.

One thing I would like to add is that last fiscal year we made Myovant a wholly owned subsidiary, and with the announcement of the Mid-term Business Plan, we issued a sales forecast, which was revised downward many times during the year. We have issued an internal projection based on figures since July, when we actually had control of sales, and we are only 2% to 3% off from those figures. Therefore, we believe that our current sales forecast is not that far off the mark.

However, when there are external factors such as those you just mentioned, I believe that we must make corrections, if necessary, accordingly.

Yamaguchi [Q]: I understand. I would like to ask one more question, especially about appointments, which you have no comment on at the moment. It says that the Company will work on various measures to turn around its performance and will receive human resources support to restore its performance as soon as possible. I wonder if you, the new president Kimura, and others could comment on the major differences

between the new structure and the previous structure. Can you comment on how the system will be structured?

Kimura [M]: You are asking about our company's structure?

Yamaguchi [M]: Yes, I am.

Kimura [A]: As stated in the press release, the first major change is the structure of the Board of Directors. I am the only one remaining among the current internal Members, Board of Directors. The CEO of the U.S. operations was replaced by a Japanese in April, and Dr. Nakagawa is in charge of the U.S. as a Member, Board of Directors. We would like to steer the U.S. business while maintaining a firm grip on the U.S. business and increasing its visibility.

Also, Sumitomo Chemical Co., Ltd., the parent company that has guaranteed our debt, will send one person to the Board of Directors as a Representative Director and Executive Vice President. One person from Sumitomo Chemical will also join the board as a non-executive Director. This will significantly change the structure of the Board of Directors.

Yamaguchi [M]: Thank you.

Noguchi [M]: Thank you very much. Mr. Wakao from JPMorgan, please ask your question.

Wakao [Q]: My name is Wakao from JPMorgan. My first question is about turning a profit, which has been touched on a bit in previous discussions. Although a Mid-term Business Plan is currently being formulated, do you still consider it uncertain for your company to become profitable?

You have narrowed down fixed costs considerably, and I believe you have narrowed them down to a level where your business could be profitable. As for the top line, a third party has been brought in this time to review it, so I think that to some extent, the timing for a turnaround is becoming clear.

I also wondered if adjustments would be made depending on the timing of penetration of generic of mirabegron for your products such as GEMTESA. How do you envision the timing of the return to profitability? Please tell us about the case considered without the gain on the sale of assets in the current period.

Kimura [A]: We expect to be profitable on the bottom line in the next fiscal year. In the next fiscal year, we intend to move forward so that both core operating profit and income excluding asset sales will be in the black.

Wakao [Q]: Thank you very much. However, while I believe that the sales milestone should also be considered as revenue, I think you mentioned last time that the sales milestone will be included in the next fiscal year.

Even without sales milestones, will the Company be profitable in the next fiscal year?

Kimura [A]: I think it is on the borderline whether we are able to make a profit without the sales milestone, but I do not think it is impossible. As you mentioned, we would like to release detailed figures while also looking at the figures for the current fiscal year.

Wakao [Q]: Okay, thank you very much. My second question is about finances. The repayment of the JPY145 billion bridge loan was extended until September, and the sale of Roivant is to be used for this purpose. It is my understanding that there is no problem for this JPY145 billion. If there are any loans that will mature and need to be repaid over the next few years, could you please tell us the timing and amount of those repayments, as well as what the funds will be allocated by, to the extent possible?

Kimura [A]: I cannot explain the specifics right now. While we have about JPY98 billion in cash from the sale of Roivant shares, we also have the challenge of a JPY145 billion long-term loan. In addition, there is a bridge loan for Roivant's deal, and other loans, which will be repaid as we move forward.

Last fiscal year was very difficult for us in terms of cash flow, but as I have already mentioned, cash flow will improve from the next fiscal year onward. Therefore, we would like to manage this area in consultation with the parent company and financial institutions. I think we will be taking very good care of those areas over the next few years.

Wakao [Q]: Let me just check. As I recall, there was a repayment of debt arranged at the time of the Roivant acquisition of about JPY60 billion each for the current and next fiscal years. Is this still there?

Kimura [A]: Yes. I believe that JPY60 billion is due for repayment this fiscal year and JPY65 billion next fiscal year.

Wakao [Q]: I understand. Finally, let me ask about cancer. You mentioned that you were going to concentrate on oncology and regenerative and cellular medicine, but I don't think you have a good track record in oncology. Please tell us about your company's capability in oncology.

As I recall, you mentioned at the last briefing that you are also looking into partnering, so I don't think you will be doing everything in-house. I think the track record is poor, so it is difficult to see how this can be accomplished.

I also think there is a possibility of partnering in TP-3654 for myelofibrosis. Please let me know the timing of this partnering, if possible.

Kimura [A]: In terms of our capability in oncology, we certainly don't have a large product. However, fortunately or unfortunately, the TP-3654 and DSP-5336 for which we have a high expectation are still in the early development stage. We would like to make the compounds more effective, increase its value, and consider how it can be combined with other products.

However, as you mentioned, oncology is a tough field, so I think it is necessary to consider some kind of partnership with other companies in order to maximize its value.

Ikeda [A]: As Dr. Kimura just answered, within the scope of our R&D capabilities, we are basically aiming to obtain approval and launch DSP-5336 in FY2026 and TP-3654 in FY2027.

When we present these two compounds at conferences, other companies show very strong interest. We would like to consider various possibilities, depending on the conditions, if such an offer is made, while keeping an eye on the status of our development.

Wakao [Q]: Regarding TP-3654, I think you mentioned last time that you were going to proceed with the next study, whether it was Phase III, Phase II, pivotal, or something else, to add on to the existing drug. Is there any update on that?

Ikeda [A]: For TP-3654, we are currently working on a study with two kinds of JAK kinase inhibitors.

Wakao [Q]: When will this begin?

Ikeda [A]: This will begin in FY2024.

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

Noguchi [M]: Thank you very much. Do you analysts or institutional investors have any other questions? Mr. Hashiguchi, please.

Hashiguchi [Q]: I'm sorry, I have an additional question since there seems to be some time left. I understand that you are planning to obtain conditional and time-limited approval for the development of dopaminergic progenitor cells for Parkinson's disease in Japan by the end of this fiscal year. Are these non-cryopreserved cells or cryopreserved cells?

Kimura [A]: These are non-cryopreserved cells.

Hashiguchi [Q]: If so, what is the assumed production and supply capacity?

Kimura [A]: Even if approval is obtained, we believe that it will be conditional and time-limited approval, and in that case, there will be a limit to the number of patients who can receive the transplant, or in the case of regenerative medicine, it will inevitably be a surgical transplant, which will limit the number of hospitals that can perform it.

Based on that assumption, we will have at most 20 to 30 patients per year. In fact, we expect the number to be less than that, especially in the first year. We have enough production capacity to do that.

Hashiguchi [M]: Thank you very much.

Noguchi [M]: Thank you very much. Mr. Wada of SMBC Nikko Securities, who is joining us in Zoom, please ask your question.

Wada [Q]: I am Wada from SMBC Nikko Securities. Thank you very much. I would like to ask you about one point regarding the results by region in the forecast by segment on page 11.

I believe you mentioned previously that you are trying to turn a profit in each region first. Looking at the core segment profits for the current fiscal year, they are all projected to be in the black. I would like to ask if that approach will continue for the foreseeable future.

As sales in Japan will decline, I suspect that the Company will be in the red in the next fiscal year or so. I know it is a little early to ask about the next fiscal year and beyond, but I would like to ask you about your thinking on this.

Kimura [A]: Thank you. As you mentioned, we are working to improve profitability in Japan, North America, and Asia.

In this context, we are taking steps to ensure that the performance of our U.S. business will improve significantly from the last fiscal year to the current fiscal year. Our Japan business has always been profitable, and we will manage to remain profitable this fiscal year as well. On the other hand, as you have just asked, we are considering that sales in Japan will drop at least once in the future. In response, we are currently putting a lot of effort into introducing products for sale, but it is difficult to do so in the Japanese market.

We believe that the Japanese business structure must be firmly restructured.

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

Noguchi [M]: Thank you very much. This concludes our Q&A session with analysts and institutional investors. Analysts and institutional investors are welcome to leave at their convenience.

From here, we would like to take questions from the media. First of all, I would like to ask you members of the media who are present at the Tokyo headquarters to raise your hands if you have any questions. Please state your affiliation and name followed by your question.

Yamamoto, the Asahi Shimbun [Q]: My name is Yamamoto from the Asahi Shimbun. Thank you for your cooperation.

First of all, I would like to ask Mr. Nomura and Dr. Kimura for a few words each about the fact that you had to forecast a loss for this fiscal year.

On another note, what should we think of the change of president at this time? I would like to ask you both about the aim of this.

Nomura [A]: I would like to express my sincere apologies to our shareholders for the loss forecast for this fiscal year. However, as I mentioned on May 1, we are making every possible effort to reduce costs by JPY108 billion, while at the same time working on the growth of our three key products, and we are still now forecasting a bottom-line loss for the current fiscal year. We would like you to understand that we are doing everything we can.

As President Iwata of Sumitomo Chemical said, the Company is in the midst of an unprecedented crisis, and in order to overcome this crisis, we need to work under a new structure with the support of human resources from Sumitomo Chemical.

It is not a new organization if the president is the same. For this reason, Dr. Kimura will be a president. Also, as Dr. Kimura mentioned earlier, the North American business is very important right now. So, Dr. Nakagawa, who is responsible for North America and president, will join the Board of Directors. And since our administrative division was a bit weak, we invited the Executive Vice President in charge of administration from Sumitomo Chemical to join us as a non-executive Director. The purpose of this change, including the change of president, is to establish a system to overcome future difficulties through this new structure.

We are really sorry that the bottom line will be in the red again this year. In any case, we are doing everything we can, and as Dr. Kimura mentioned earlier, we are now moving forward internally to achieve core operating profit and bottom-line profitability next year without having to sell any assets.

Kimura [A]: This is Kimura. My point is almost the same as what Mr. Nomura just said. We believe that a major path has already been created for how our company will address this LATUDA cliff under Nomura's regime.

In particular, the structure in North America was greatly improved last year, including two restructurings, and while SG&A expenses are being controlled, we are now in a position to incorporate two agents into three products and to increase sales of four products. We will make this a reality by firmly implementing it under the new structure from this fiscal year onward. At the same time, as you have already asked, unexpected things can happen in the business, and we would like to rebuild the business while dealing with such unexpected situations.

On the other hand, we were fortunate to have Sumitomo Chemical guarantee our debt. In this context, the basic situation is that we must further deepen our cooperation with Sumitomo Chemical. We would like to proceed together with the people from Sumitomo Chemical who will join our management team, while maintaining good communication with the parent company.

Yamamoto [M]: Thank you.

Noguchi [M]: Please ask your questions.

Hori, the Nikkanyakugyo [Q]: I am Hori from the Nikkanyakugyo. Let me first ask President Nomura: You will become Corporate Senior Executive Advisor in June of this year. I would like to ask you how you will be involved in management in the future as Corporate Senior Executive Advisor.

I would like to ask Dr. Kimura, the new president: At a recent press conference, you indicated a policy of further streamlining operations in Japan. How do you intend to address this in the future?

Nomura [A]: As Corporate Senior Executive Advisor, I am not involved in any decision making in the management of the Company. If I can help a little with in-house training, etc., I will do so. My position is that I am not involved in management at all.

Kimura [A]: You have asked another question regarding the streamlining of operations in Japan. Before that, we have received some questions about whether our Japan business will suffer in the future. As for North America, we were able to take very significant steps in the last fiscal year. Our challenge is to actually implement this in the current fiscal year and beyond. In Japan, the business is still operating under the existing concept and structure.

If the top line can be increased by introduction and other means, a bigger picture can be painted. If that becomes difficult in reality, there could be a phase in which the size itself is made more streamlined, or the way work is done is reformed to pursue greater efficiency. Under the new structure, we would like to make decisions in this area as necessary.

Hori [M]: Thank you very much.

Noguchi [M]: Next, please ask your question.

Ando, Nihon Keizai Shimbun [Q]: My name is Ando from Nihon Keizai Shimbun. I would like to ask you two questions. First, there was an explanation about the new management structure. It is true that a full management team from Sumitomo Chemical will be joining the Company, but I would like to ask if you are concerned that this will reduce the degree of freedom of the Company.

Second, I believe that as you streamline R&D, you will hold firm to your R&D into regenerative medicine/cell therapy. Although clinical studies are underway, as you mentioned earlier about Parkinson's disease, you are still making only incremental progress, and given the delays to date, I feel that expectations are somewhat too high.

When will products for Parkinson's disease, or eye disease, be firmly reflected in sales and become a reliable source of revenue?

This Regenerative Medicine/Cell Therapy business will also be cut out for the new company which you establish together with Sumitomo Chemical. Will there be any difficulties regarding the impact of this, such as the issue of the degree of freedom and who will control the production facilities depending on who will own them?

Kimura [A]: First of all, I would like to answer about the degree of management freedom. Our financial situation is already very bad, and Sumitomo Chemical has guaranteed our debt. Or the bank has given us a repayment deferment. Since management is conducted within this context, there are some restrictions, such as not being able to invest in R&D to the same extent as in the past, for example. In this context, I see the direct participation of members from the parent company in the management of the Company as a very positive development that will allow us to move forward under smoother cooperation.

We have already been in communication with the parent company, and President Iwata has repeatedly expressed to us that both the pharmaceutical business and the Regenerative Medicine/Cell Therapy business

are extremely important businesses and that he would like to somehow rebuild or grow them. So, we are aware that we can proceed with the restructuring together.

As you mentioned, Mr. Ando, the development of regenerative medicine/cell therapy has been delayed due to various external factors, such as the COVID pandemic, as you know. Especially for Parkinson's disease, the clinical study has been completed and the data have actually reached us.

We have very promising data, and we will make sure to obtain it approved first. The results will naturally be made public in some form by Kyoto University. We believe that this will change the situation and atmosphere as understanding of the power of iPS cell regenerative medicine spreads.

At a time when regenerative medicine is at a critical juncture, both Sumitomo Chemical and Sumitomo Pharma are in extremely severe business conditions. For this reason, we have recently explained our policy of using R&D expenses and making capital investments as a separate company so that we can expand without slowing down.

We are now at the stage where we need to start discussing who will actually be involved, and how pharmaceutical research, production, regulatory affairs, and sales will be divided between Sumitomo Pharma and the new company.

The thing that is understood by both sides as a consensus is that we do not want to negatively impact the progress of ongoing programs, especially the Parkinson's disease and retinal pigment epithelium tear programs, and that we will operate as separate companies in terms of budget.

Not delaying that division is also a prerequisite. In practice, it is quite difficult to do so, and we have to devise a way to do so. We hope you understand that our basic premise is to avoid any impact.

Ando [Q]: Will the new company be able to maintain the same level of R&D expenses related to Regenerative Medicine/Cell Therapy business, depending on the status of clinical studies?

Kimura [A]: If it wants to have expenses at the same level, it can stay at Sumitomo Pharma, but we have two Parkinson's disease studies running in the U.S. We are also planning to start a clinical study for 3D retinas during this fiscal year. The clinical study for retinal pigment epithelium tear is moving smoothly in Japan, and as you know, the budget scale will become very large once we enter the clinical development phase from the research phase.

In addition, regenerative medicine cannot be produced in a single large tank, so it is necessary to invest in expanding the scale of production. We are discussing with our parent company, Sumitomo Chemical, the need for a framework for such expansion, as I mentioned earlier.

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

Noguchi [M]: Thank you very much. Please ask your questions.

Idaka, Yakushin Plaza [Q]: My name is Idaka from Yakushin Plaza. I think there is a bit of overlap with the earlier question. You, President Nomura, have been replaced this time, but since you took office, you have taken various steps, including napabucasin, the patent extension for LATUDA, the alliance with Roivant, and the partnership with Otsuka Pharmaceutical.

However, your challenges were not fruitful. As you look back on your retirement at this juncture, I would be very interested to hear your thoughts on your efforts and your feelings about stepping down now.

Nomura [A]: Thank you for your question. My impression is that the results are all that matters. That is all.

Idaka [Q]: Thank you very much. New President Kimura will now work to restore the Company's performance. What is the mission given to you within the Sumitomo Chemical Group?

Also, in your earlier answer, you mentioned that the system is in place for a post-LATUDA era. I honestly wonder if that is really in place. I would appreciate it if you could be more specific.

Kimura [A]: Thank you very much. I believe that I have two missions. The first is to rebuild the pharmaceutical business. The second is I believe to firmly establish the Regenerative Medicine/Cell Therapy business as a new business.

One more thing, I understood your last question to be a question about whether a post-LATUDA system is in place. Products that would take up the post-LATUDA era are growing, and sales are up nearly 50% over the last fiscal year and the year before. We expect to increase by about 40-plus percent or 50% this year. The steady growth of such things will create a business of the size that will take over LATUDA.

In contrast, what we struggled with very much was our inability to produce a product from within the Company that would take over LATUDA. In contrast, we explained that the two oncology compounds, it will become three compounds in a short while. There are also other compounds that are still in the early stages of development but whose efficacy is being partially confirmed in clinical studies, although we have not introduced them to you in detail. Those seeds are also growing well.

We recognize that if sales recover firmly in our three key products, we will be able to get back on the growth track.

Idaka [Q]: Thank you very much. You plan to continue to reduce SG&A expenses. Please tell us which areas of SG&A expenses you intend to reduce and by what specific measures.

Kimura [A]: I understood your question to be about Japan. We are now closely examining SG&A expenses in Japan. There is room to cut back in many areas or rethink the way we work itself. We would like to make a firm commitment to such things by the end of this fiscal year.

Idaka [Q]: Thank you very much. Finally, I'm wondering if I need to ask you something because of my profession. With Sumitomo Chemical's management team joining the management of your company, is there a possibility that your company will eventually become a wholly owned subsidiary of Sumitomo Chemical, or that Sumitomo Chemical will spin off Sumitomo Pharma? This may be a harsh question, but I would like to ask you about it.

Kimura [A]: I believe that this is a matter for Sumitomo Chemical to decide. For my part, I would like to focus first of all on firmly rebuilding the pharma business or putting it back on a growth path. I also think this will change Sumitomo Chemical's decisions.

Idaka [M]: Thank you very much.

Noguchi [M]: Thank you very much. The person at the front of the line, please ask your question.

Sakata, Yakuji Nippo, Limited. [Q]: Thank you. My name is Sakata from Yakuji Nippo, Limited. First, I would like to ask Dr. Kimura. You assumed the position of president during a very difficult period. First of all, I would like to ask you about your impressions and preparedness.

You mentioned earlier that you have yet to see any change in the past approach Japan business. What is the bottleneck in this regard, and how do you hope to change it?

Also, this may be too early, but do you have any message for your employees?

Kimura [A]: As you mentioned, I became president at a very difficult time, and I am very aware that I have to lead SMP.

On the other hand, up to now, I have been working with Nomura on various measures for the post-LATUDA era under his direction, either in corporate planning or in charge of accounting. Therefore, I understand that our mission for the time being is not to think of ways to do things from scratch, but to realize one by one what we have already found the way to do.

Over the past several years, we have repeatedly told our employees that we will achieve the ambitious goals, both in North America and in our Chinese operations. We have said that we should create such a culture.

We, the management team, are determined to carry out the plan, which will lead to a turnaround in our business performance and renewed growth. In this sense, we naturally feel that we have a very heavy responsibility to our shareholders and other stakeholders. We also believe that we now must demonstrate to our employees what we have said many times in the past as a management team.

As a message to our employees, I would like to say that we will proceed firmly from now on, so please believe in us and follow us. I also believe that although the situation is difficult at the moment, we are growing something that has great potential for the future, and I want to make sure that I communicate this to the public.

In addition, as we have repeated several times today, our financial situation is very difficult due to our very poor performance in the last fiscal year. In contrast, I would like to convey to our employees in Japan that we want them to be fully aware that the Company exists thanks to the parent company's guarantee and the postponement of repayment from financial institutions.

Nothing has changed in our workplace environment , and I am aware that some employees may not be aware of this. So, I am thinking of sending out such a message as soon as possible.

Sakata [Q]: Thank you. I would like to ask President Nomura: You mentioned earlier that results are everything. If so, can I take the change in the president as a sign that you are taking responsibility for the Company's performance?

Nomura [A]: As I have said before, we need a new structure to get us through this difficulty. By changing the people who lead, new paths will open up. New reforms will also be promoted as new personnel come in.

If the president were not replaced, it would be difficult to do some new things. Earlier, Dr. Kimura remarked that we have been working together, however, this may be a way to negate what we have been doing. Maybe we can do those things as well. I think it will be necessary to replace the leader for this purpose.

Therefore, I am positive that a new leader is needed to take the helm in order to revitalize and grow the Company.

Sakata [Q]: I understand. Did you make such a decision yourself in stepping down as president this time? Or was it the parent company's intention?

Nomura [A]: That is difficult to answer. Regarding the replacement of the president, we have always believed that one of the major tasks of the president is to first select a candidate for the next president, and we have a Nomination and Compensation Committee, although it is voluntary.

In fact, we have started more than a year in advance to consider what kind of person we would like to see as the next president and what the candidate pool looks like. In addition, an outside consultant interviewed those in the candidate pool to identify all of their strengths and weaknesses. The Nomination and

Compensation Committee, which includes all outside directors, conducted a number of individual interviews. It is in this context that we are deciding on the next president.

I hope you understand that such a thing did not happen suddenly, but that we were originally ready to replace the president.

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

Noguchi [M]: Please ask your question.

Kamio, MIX [Q]: I'm Kamio from MIX. I would like to ask Dr. Kimura, the new president: At the recent Sumitomo Chemical press conference, in relation to the investment ratio, there was a comment that if sustainable growth can be achieved, Sumitomo Chemical will consider the most appropriate partner. Do you have any thoughts on this optimal partner? How would you consider this area?

Kimura [A]: It seems to me that this is something that should be considered primarily by Sumitomo Chemical. For my part, I believe that there is great potential for growth in our pharmaceutical business, as well as in Regenerative Medicine/Cell Therapy business, which will be separated from our company. We hope to be a positive partner in that growth.

We understand that Sumitomo Chemical probably thinks the same way.

Kamio [Q]: I think they had a general policy on Regenerative Medicine/Cell Therapy business, but I think they also had some pretty clear comments about Sumitomo Pharma. What did the President of Sumitomo Chemical say to Sumitomo Pharma?

Kimura [A]: I know that is also something that is perceived differently depending on who is hearing, but I don't think that what you said was at all about selling the pharma business.

Not only Sumitomo Pharma but also Sumitomo Chemical is struggling, and I repeat, a certain amount of upfront investment is necessary in this industry for growth. I believe they meant it could be possible if that would be positive for it.

Kamio [Q]: I have one more question. This time, a director from the parent company, Sumitomo Chemical, has joined the board. In this regard, it is understood that the cost side of the business will be managed and SG&A expenses will be closely supervised. On the other hand, is there a significant change from the past in terms of introduction and discernment, which has been a challenge?

Kimura [A]: Currently, I don't think we are in a position to make a major introduction, so we will proceed with what we have at hand first. In the case of pharmaceuticals, the success rate or evaluation will be determined as we proceed, so we will concentrate on that.

In that sense, we have already replaced one of our R&D systems since last fiscal year, so I believe that we are now in a position to move forward firmly.

Noguchi [M]: Thank you very much. Please ask your questions.

Yasukawa, the Nikkan Kogyo Shimbun [Q]: This is Yasukawa from the Nikkan Kogyo Shimbun. I would like to ask President Nomura and Dr. Kimura, respectively.

First of all, from President Nomura's point of view, please tell us about the personality of Dr. Kimura and what kind of skills you are looking forward to seeing in him.

Dr. Kimura, how do you intend to make the most of your extensive experience in research and development? What is your management philosophy and your motto?

Nomura [A]: I will answer first. I believe that Dr. Kimura is fully capable of fulfilling the role of leader, and he has a science background that I do not have. I think he is probably the leader in Japan in the commercialization of regenerative medicine related to iPS, which we are going to work on in the future. I think he is very well suited to change our company in the future.

Kimura [A]: I would like to ask the person from Sumitomo Chemical to take charge of the administrative and planning divisions and lead our new SMP. In addition, as long as we are a pharmaceutical company, our major challenge is how to launch new products.

On the other hand, with R&D expenses drastically reduced from JPY90.9 billion in the previous fiscal year to JPY50 billion this year, and with a renewed structure underway, I think it is important to have a good understanding of R&D and to be a good judge of what is going on. I also have a lot of experience in research and development, so although I am the president, I believe that I can use my intuition in various ways and contribute to the Company's performance.

As for management styles, I know there are many different leaders. I would like to ask each board member to express a variety of opinions, and I hope that we can manage our company in a way that allows us to set our direction and move forward based on the free and open opinions of our board members.

I did not catch the last question.

Yasukawa [Q]: What is your motto?

Kimura [A]: I have always been fond of dreams and hopes, and I always believe that those without dreams cannot succeed, but I don't think it is appropriate to say such things under these circumstances.

I will steadily take the necessary measures to advance the project, based on the idea that a journey of a thousand miles begins with a single step.

Yasukawa [M]: Thank you very much.

Noguchi [M]: Thank you very much. The next question will be the last.

Sakaguchi, Iyakukeizai [Q]: Thank you very much. My name is Sakaguchi from Iyakukeizai. I would like to ask one question to Dr. Kimura, the new president.

You recently announced the company split of the frontier business, but how will it be positioned in the future?

Kimura [A]: I recognize that the frontier business was a very small group of businesses that looked for or nurtured many interesting seeds. On the other hand, the necessary business infrastructure is quite different from that of pharmaceuticals, and I felt that there would be significant limitations on our platform in terms of actual development in the future.

We have had many small decisions in the past, but we were not familiar with the area and felt that it took a lot of extra time. We thought that as our investment grows in the future, that will become more and more of a hindrance to their growth in the face of our poor situation.

Rather, I hope they can develop their business with those who have more expertise or flexibility through the company split.

We believe that Sumitomo Pharma's platform, which has contributed to human health, can very much be utilized in frontier businesses. We would like to contribute to the new company, FrontAct, in this area.

Sakaguchi [Q]: So, at this point, you have no intention of handing over it to a third party?

Kimura [A]: The words “handing over” conjures up all sorts of images, but we remain firmly involved and hope to see FrontAct grow even larger with new input and power. We want to support them in finding their own way.

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

Noguchi [M]: Thank you very much. Continuing on, if you are a member of the media participating via Zoom and have a question, please raise your hand using the raise your hand button. We will call your name and unmute the microphone. We would appreciate your affiliation and name followed by your question.

First of all, Mr. Ishii of the Iyaku Tsushinsha, please ask your question.

Ishii, the Iyaku Tsushinsha [Q]: I am Ishii from the Iyaku Tsushinsha. First, I would like to know if there is anything that President Nomura would like to convey to the new President Kimura. We would also like to know the advantages of outsourcing ulotaront to Otsuka Pharmaceutical.

Nomura [A]: Thank you. As I have said before, what we need to do now is to recover our business performance. This is something that must be accomplished.

I hope that, by maintaining a firm grip on the North American business and by managing costs properly, he will be able to achieve figures that will demonstrate to everyone that our business is recovering as quickly as possible.

By firmly developing the seeds of Regenerative Medicine/Cell Therapy and oncology area, which will be the seeds of future growth, I hope that he will firmly create the pillars of our growth toward the latter half of the 2030s.

Do you ask about the benefit of submitting ulotaront to Otsuka Pharmaceutical? Our R&D expenses have always been very limited. Thus, for example, it is difficult to do cancer if we are going to continue to do ulotaront. These were, so to speak, trade-offs.

Therefore, one of the advantages of having Otsuka Pharmaceutical do all the development of ulotaront is that we can now focus on oncology area and Regenerative Medicine/Cell Therapy. I believe that such things have become possible as a result of the contract with Otsuka Pharmaceutical.

Ishii [M]: Thank you very much.

Noguchi [M]: It is time to end the session, but since there are several people waiting for questioning, we would like to extend the time a little bit to take your question.

Mr. Sugiyama of Yomiuri Shimbun, please ask your question.

Sugiyama, Yomiuri Shimbun [Q]: I am Sugiyama of the Yomiuri Shimbun. I would like to ask Senior Managing Executive Director Kimura: When and by what words and by whom were you approached about becoming the next president? Also, how did you frankly feel when you were approached to be entrusted with the management of a business in unprecedented crisis?

Kimura [A]: I don't remember when I was told, but Mr. Nomura told me that he will depart and that I would be next. At the time, I thought my mission was to move forward together under Mr. Nomura, so I was honestly surprised.

Under these circumstances, I actually have to take over and do it under very difficult circumstances, causing inconvenience to all parties. I must proceed with your firm understanding of what we have presented, as well as a firm implementation of what we have presented. I am concerned about the heavy responsibility I bear, but I will do my best to fulfill it.

Fortunately, I have very capable members of management and subordinates, and if I work together with them, I am confident that I will be able to rebuild the Company.

Sugiyama [Q]: I would like to ask Senior Managing Executive Director Kimura one more question. Please tell us about your most memorable job to date and how you would like to apply that job to your future as president of the Company.

Kimura [A]: I have had many experiences so far, but what impresses me the most is that we have finally reached the point where we can apply for approval for regenerative medicine, which is what we have been concentrating on recently in particular. One of our goals is to grow it into a solid new business. I believe that the fact that we have been able to nurture a completely new initiative to such a degree will be put to good use in getting the entire company back on its feet again from a very difficult situation.

I have been involved in the Global Corporate Strategy for the past several years, and last year I was also in charge of the Global Finance, so I have learned a lot. I hope to demonstrate all of those things and move forward successfully.

Sugiyama [Q]: I would like to ask one last point. What assets will you be selling this year? Also, regarding future structural reforms in Japan, please tell us if you are considering any reductions in employee headcount.

Kimura [A]: Regarding the sale of assets, as Mr. Nomura has explained several times in these forums, there are companies that handle products that we handle and whose exclusivity period has expired. We could sell our assets to such a place.

I will refrain from discussing what other individual ideas we have in mind.

With regard to personnel reductions in Japan, I believe that, as sales decline, there will inevitably be a phase in which there is an excess of personnel in Japan. However, in terms of management commensurate with size, for example, we can reduce the number of employees by about 100 per year by narrowing down recruitment. So, either that form or some kind of restructuring.

Or if we can increase the top line, we can avoid such things. As such, we believe that there are many options.

We will make a decision on this at some stage and decide what path to take in the new structure.

Sugiyama [M]: That's all. Thank you very much.

Noguchi [M]: Thank you very much. Mr. Mochizuki of MIX, please ask your question.

Mochizuki, MIX [Q]: This is Mochizuki from MIX. I would like to ask Dr. Kimura: You mentioned that you are on the road to achieving profitability, but what exactly do you think is the path you are going to take? If you have any specific expectations, I would like to know them.

Kimura [A]: If we proceed firmly, we will definitely be able to achieve profitability in core operating profit in the current fiscal year and in net profit in the next fiscal year, and even more so in the year after next with a comfortable margin. As a basis for this, I believe that we will strive for steady growth of our three key products in North America at all costs.

Mochizuki [Q]: Thank you. Second, the board will also be significantly revamped this time around. I listened to your talk, thinking that there have been both good and bad points, but that there are also some new things that need to be changed.

I would like to ask for your opinion on the areas that you will take over, the areas that you will change, and the kind of company you would like to grow again.

Kimura [A]: Until now, all of our internal directors were from Sumitomo Pharma and we had discussions with those who knew a lot about pharmaceuticals and with outside directors who have very broad knowledge. In the future, we will have people from Sumitomo Chemical who are not necessarily familiar with the pharmaceutical business joining us as internal directors, while at the same time we will have excellent people who have experience in completely different businesses.

We have always been a board that allows very free discussion, but we would like to make it a board that allows us to take a new direction by exchanging opinions and ideas even more than before. Even at the executive level below the Board, I would like to encourage each executive officer to express their views more clearly than ever before.

Until now, there have been times when they think carefully about their own areas of responsibility, but leave other areas to others.

Mochizuki [Q]: Thank you. One last point, regarding Japan business, you mentioned earlier about personnel. Do you intend to review the sales structure, including MRs, in the future?

Kimura [A]: We would like to discuss everything. Rather than simply reducing the number of people, we would like to make the work process itself speedier, so that decisions can be made and everyone can move more quickly.

I believe the difference will lead to organizational strength. I hope you understand that reforming the business, or making it more muscular or slimmer, does not simply mean reducing the workforce.

Mochizuki [M]: Thank you.

Noguchi [M]: Thank you very much. The next question will be the last. Mr. Matsuda of the Yomiuri Shimbun, please ask your question.

Matsuda, Yomiuri Shimbun [Q]: I am Matsuda of the Yomiuri Shimbun. I would like to ask briefly about new vaccines. Am I correct in understanding that the universal influenza vaccine is intended for type A? Also, can you tell us the number of subjects for the clinical study, how to proceed, the development of Phase II and Phase III after Phase I, and the target date for commercialization?

Kimura [A]: We are targeting the seasonal influenza vaccine, so it is Type A. Occasional pandemics, or bird flu is another example, are characterized by the annual mutation of the virus. The main reason why people get the flu once and then get it again, or why the vaccine does not work at all, is that the type of virus changes every year.

The universal influenza vaccine we have begun to develop will function properly as a vaccine even if the virus mutates. If such a thing is actually put to practical use, it may greatly reduce the number of vaccines that miss or do not work every year.

The problem with a pandemic is that the conventional immune system does not work because of the new virus. We are hopeful that a universal influenza vaccine administered or prepared could be very revolutionary because it can respond to any virus that comes along. However, it is still in the early stages. Pre-clinical studies have provided data to support this, and we have just started a clinical study.

We would like to start with a clinical study of 100 or so subjects to see if antibodies can be produced to react to a virus that is different from the actual antigen virus.

Matsuda [Q]: Thank you very much. Since the study will be conducted on a scale of more than 100 subjects, is there a plan to have a placebo group?

Kimura [A]: Yes. The control group is inevitably needed, so we will be looking at changes in the control group and those who are administered by injection.

Matsuda [Q]: Is it correct to understand that basically you will confirm the efficacy and safety of the product?

Kimura [A]: Yes. Since this is a first-in-human test, we will first check the safety of the product. One of the characteristics of vaccines is that antibody production will always occur in those who are vaccinated, so the efficacy and safety, or dose, can be checked at once.

Matsuda [Q]: I understand. I believe you will be starting a clinical study in Belgium this time. When do you expect to put this technology to practical use in the future, and when exactly do you expect to put it to practical use in Japan?

Kimura [A]: I think we are still more than a few years away from putting it to practical use. The main reason for starting in Belgium is that after the vaccine is administered in the form I just mentioned and the person has developed antibodies, we need the person to actually be infected with the influenza virus in order to confirm the effectiveness of the vaccine. There is environment in Europe where we can test for infection.

The next step will be to actually expose the vaccinated person to the influenza virus. That would be a true POC. The next step would be to test the vaccine on-field on hundreds of people, or even more, to see how many people actually get the flu.

After that, it will be put to practical use. Since it is seasonal, we inevitably need to see results for a year. So, it will still take more than a few years.

Matsuda [M]: Understood, thank you very much.

Noguchi [M]: Thank you very much.

This concludes the conference regarding Sumitomo Pharma's financial results for FY2023 and the change of President and CEO.

Thank you very much for your participation today.

[END]