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Sumitomo Pharma Co., Ltd.

Financial Results Briefing for FY2025

May 13, 2026

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
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[Date]	May 13, 2026
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[Venue]	Webcast
[Number of Speakers]	6

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Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Global Finance Administration External Affairs; Corporate Governance; Corporate Communications; IT Management & Data Analytics
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Yumi Sato	Managing Executive Officer Research and Development Division Senior Vice President, Head of Research and Development Division Chief Development Officer, Sumitomo Pharma America, Inc.
Yutaka Wakemi	Executive Officer Global Corporate Strategy; Global Finance
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	Kazuaki Hashiguchi	Daiwa Securities

Presentation

Maruyama: Now it is time to begin the Q4 financial results briefing for FY2025 for Sumitomo Pharma Co., Ltd. Thank you very much for joining us today despite your busy schedules.

I am Maruyama from the Corporate Communications and I will be the moderator.

Today's session will be held in a hybrid format from our Tokyo head office and via Zoom webinar for analysts, investors, and members of the press. Analysts and investors are participating online and members of the press are participating either in person or online.

To ensure smooth progress within the limited time, we have a request for those participating via Zoom. Please change your participant information displayed on your Zoom screen to your company name and your name.

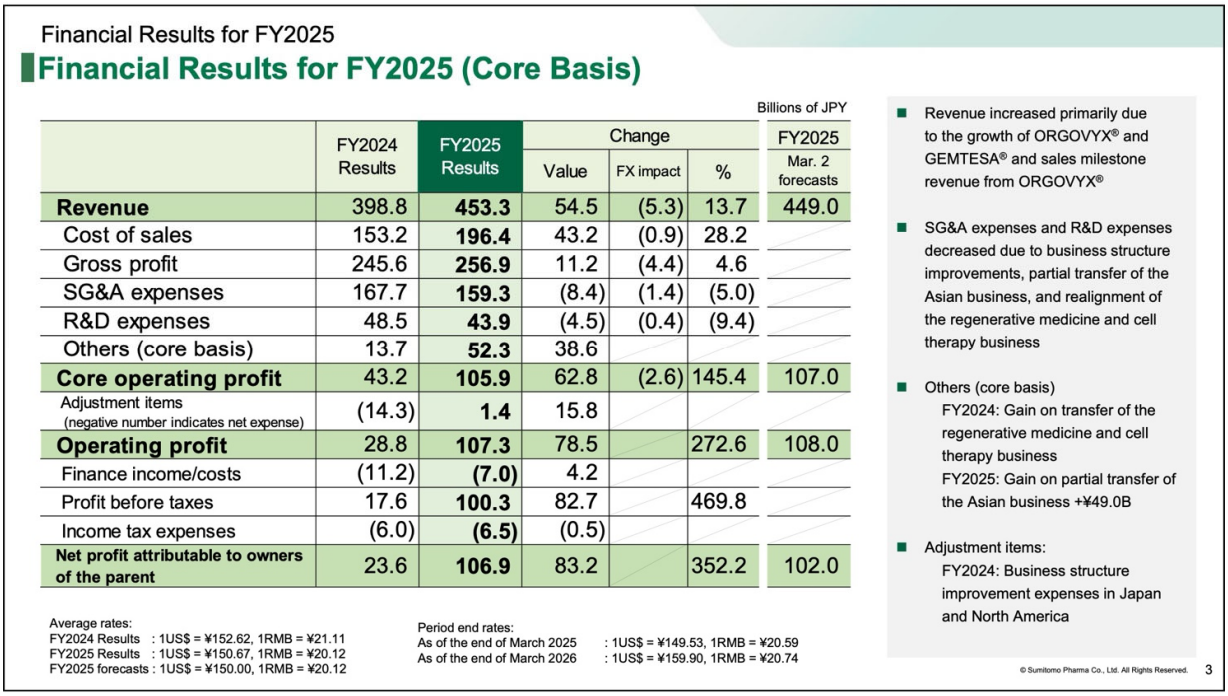
Also, I would like to inform you about the survey. For those attending at the venue, we have distributed survey forms along with the briefing materials. For those participating via Zoom, a survey screen will automatically appear after the briefing ends. We would appreciate it if you could share your impressions and opinions regarding this briefing. We will use your feedback for future operations so please cooperate with us.

Today, we will first provide an explanation based on the briefing materials posted on our website, and then we will have time for a Q&A session. The briefing is scheduled to end at 4:30 PM.

Now, let me introduce today's attendees. Representative Director, President and CEO, Kimura; Representative Director, Executive Vice President, Sakai; Board Member, Managing Executive Officer, Nakagawa; Managing Executive Officer, Sato; and Executive Officer, Wakemi. That is all.

Now we will move on to today's presentation. First, Dr. Kimura will explain the results for FY2025 and the status of clinical development. Dr. Kimura, please go ahead.

Kimura: Thank you for participating in the financial results briefing for FY2025 of Sumitomo Pharma today. I am Kimura, Representative Director, President and CEO.



Financial Results for FY2025

Financial Results for FY2025 (Core Basis)

Billions of JPY

	FY2024 Results	FY2025 Results	Change			FY2025 Mar. 2 forecasts
			Value	FX impact	%	
Revenue	398.8	**453.3**	54.5	(5.3)	13.7	449.0
Cost of sales	153.2	**196.4**	43.2	(0.9)	28.2	
Gross profit	245.6	**256.9**	11.2	(4.4)	4.6	
SG&A expenses	167.7	**159.3**	(8.4)	(1.4)	(5.0)	
R&D expenses	48.5	**43.9**	(4.5)	(0.4)	(9.4)	
Others (core basis)	13.7	**52.3**	38.6			
Core operating profit	43.2	**105.9**	62.8	(2.6)	145.4	107.0
Adjustment items (negative number indicates net expense)	(14.3)	**1.4**	15.8			
Operating profit	28.8	**107.3**	78.5		272.6	108.0
Finance income/costs	(11.2)	**(7.0)**	4.2			
Profit before taxes	17.6	**100.3**	82.7		469.8	
Income tax expenses	(6.0)	**(6.5)**	(0.5)			
Net profit attributable to owners of the parent	23.6	**106.9**	83.2		352.2	102.0

Average rates:
FY2024 Results : 1US$ = ¥152.62, 1RMB = ¥21.11
FY2025 Results : 1US$ = ¥150.67, 1RMB = ¥20.12
FY2025 forecasts : 1US$ = ¥150.00, 1RMB = ¥20.12

Period end rates:
As of the end of March 2025 : 1US$ = ¥149.53, 1RMB = ¥20.59
As of the end of March 2026 : 1US$ = ¥159.90, 1RMB = ¥20.74

- Revenue increased primarily due to the growth of ORGOVYX® and GEMTESA® and sales milestone revenue from ORGOVYX®
- SG&A expenses and R&D expenses decreased due to business structure improvements, partial transfer of the Asian business, and realignment of the regenerative medicine and cell therapy business
- Others (core basis)
  FY2024: Gain on transfer of the regenerative medicine and cell therapy business
  FY2025: Gain on partial transfer of the Asian business +¥49.0B
- Adjustment items:
  FY2024: Business structure improvement expenses in Japan and North America

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I will explain the summary of the FY2025 financial results.

As announced at 1:00 PM, we are showing the business results for FY2025 on a core basis. As shown here, revenue was JPY453.3 billion, an increase of JPY54.5 billion or 13.7% YoY. On the other hand, gross profit was JPY256.9 billion, an increase of JPY11.2 billion YoY.

Regarding SG&A expenses, we are controlling them well through structural reforms, so they were JPY159.3 billion, down JPY8.4 billion YoY, and R&D expenses were also controlled, decreasing by JPY4.5 billion to JPY43.9 billion.

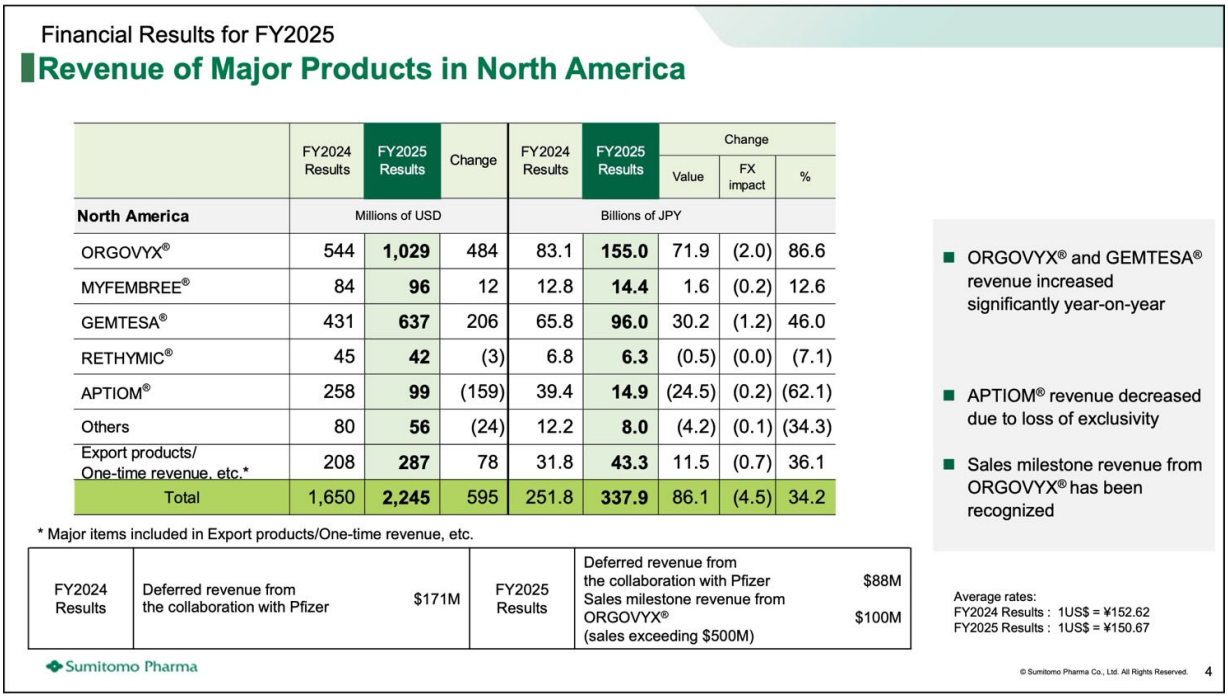
Although this was almost according to the budget, there was more than 30% of the budget remaining at the time of the Q3 results, so we on the management side expected that we would have some unused budget.

On the other hand, as we have introduced for some time, we have made the Research, Development, and Technology Research Headquarters, R&D, into one department and are operating it efficiently. Cooperation in that area went well, and we were able to proceed with R&D by using the budget properly. As a result, the budget spent was slightly more than expected at the time of the Q3 results announcement at the end of January.

Also, as you know, last year there was a gain on the transfer of the China and Asia business of JPY49 billion, so including that, core operating profit was JPY105.9 billion, an increase of JPY62.8 billion YoY.

On the other hand, net profit attributable to owners of the parent came in at JPY106.9 billion, an increase of JPY83.2 billion YoY.

In addition, although I skipped the explanation just now, both operating profit and net profit attributable to owners of the parent were the highest ever for the Company. Next slide please.



Financial Results for FY2025

Revenue of Major Products in North America

	FY2024 Results	FY2025 Results	Change	FY2024 Results	FY2025 Results	Change		
						Value	FX impact	%
North America	Millions of USD			Billions of JPY				
ORGOVYX®	544	**1,029**	484	83.1	**155.0**	71.9	(2.0)	86.6
MYFEMBREE®	84	**96**	12	12.8	**14.4**	1.6	(0.2)	12.6
GEMTESA®	431	**637**	206	65.8	**96.0**	30.2	(1.2)	46.0
RETHYMIC®	45	**42**	(3)	6.8	**6.3**	(0.5)	(0.0)	(7.1)
APTIOM®	258	**99**	(159)	39.4	**14.9**	(24.5)	(0.2)	(62.1)
Others	80	**56**	(24)	12.2	**8.0**	(4.2)	(0.1)	(34.3)
Export products/ One-time revenue, etc.*	208	**287**	78	31.8	**43.3**	11.5	(0.7)	36.1
Total	1,650	**2,245**	595	251.8	**337.9**	86.1	(4.5)	34.2

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

FY2024 Results	Deferred revenue from the collaboration with Pfizer	$171M	FY2025 Results	Deferred revenue from the collaboration with Pfizer	$88M
				Sales milestone revenue from ORGOVYX® (sales exceeding $500M)	$100M

- ORGOVYX® and GEMTESA® revenue increased significantly year-on-year
- APTIOM® revenue decreased due to loss of exclusivity
- Sales milestone revenue from ORGOVYX® has been recognized

Average rates:
FY2024 Results : 1US$ = ¥152.62
FY2025 Results : 1US$ = ¥150.67

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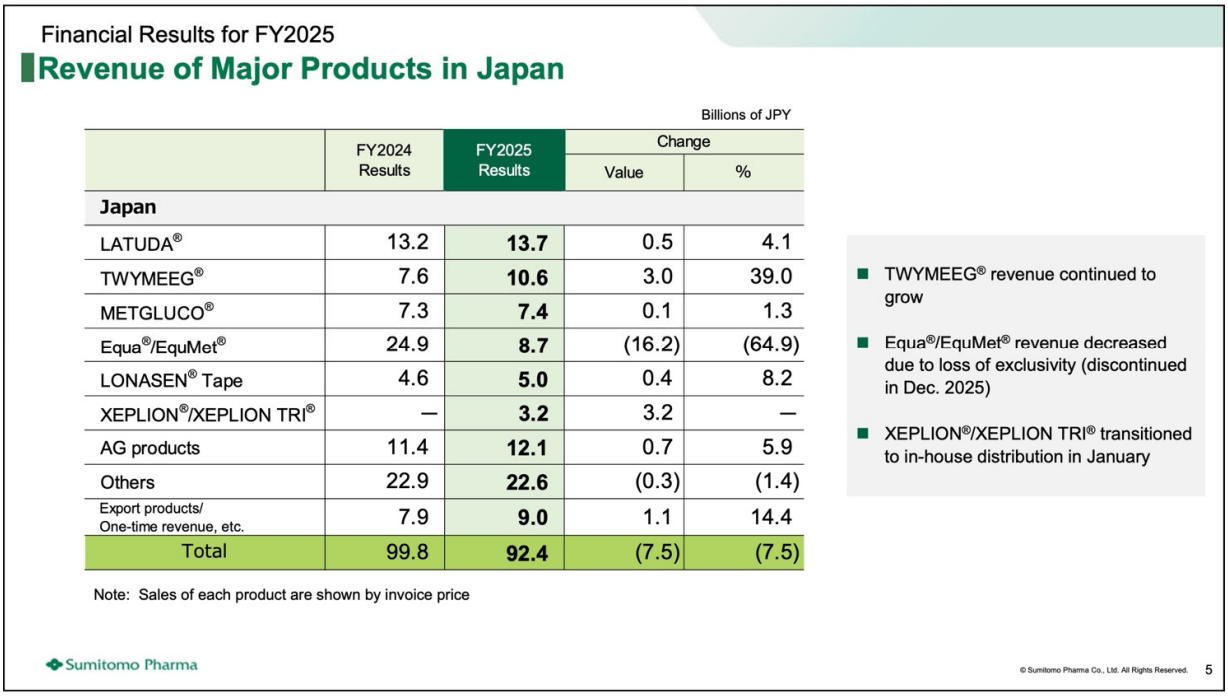
Regarding the revenue of major products, I will explain for both the US and Japan.

Please look at the center. In the US, revenue was JPY337.9 billion in FY2025. This is an increase of JPY86.1 billion, or 34.2% YoY.

Last year, there was the LOE, or the end of the exclusivity period for APTIOM, so sales of the main product APTIOM decreased significantly, but ORGOVYX more than made up for that, increasing by JPY71.9 billion to JPY155 billion, and GEMTESA increased by JPY30.2 billion to JPY96 billion. Furthermore, in the area of one-time payment income written in small letters, a sales milestone for ORGOVYX was received, with USD100 million for achieving the USD500 million milestone, and in total, revenue was JPY337.9 billion, which was a result well above expectations. Next slide please.



Financial Results for FY2025

Revenue of Major Products in Japan

Billions of JPY

	FY2024 Results	FY2025 Results	Change	
			Value	%
Japan				
LATUDA®	13.2	**13.7**	0.5	4.1
TWYMEEG®	7.6	**10.6**	3.0	39.0
METGLUCO®	7.3	**7.4**	0.1	1.3
Equa®/EquMet®	24.9	**8.7**	(16.2)	(64.9)
LONASEN® Tape	4.6	**5.0**	0.4	8.2
XEPLION®/XEPLION TRI®	—	**3.2**	3.2	—
AG products	11.4	**12.1**	0.7	5.9
Others	22.9	**22.6**	(0.3)	(1.4)
Export products/ One-time revenue, etc.	7.9	**9.0**	1.1	14.4
Total	99.8	**92.4**	(7.5)	(7.5)

Note: Sales of each product are shown by invoice price

- TWYMEEG® revenue continued to grow
- Equa®/EquMet® revenue decreased due to loss of exclusivity (discontinued in Dec. 2025)
- XEPLION®/XEPLION TRI® transitioned to in-house distribution in January

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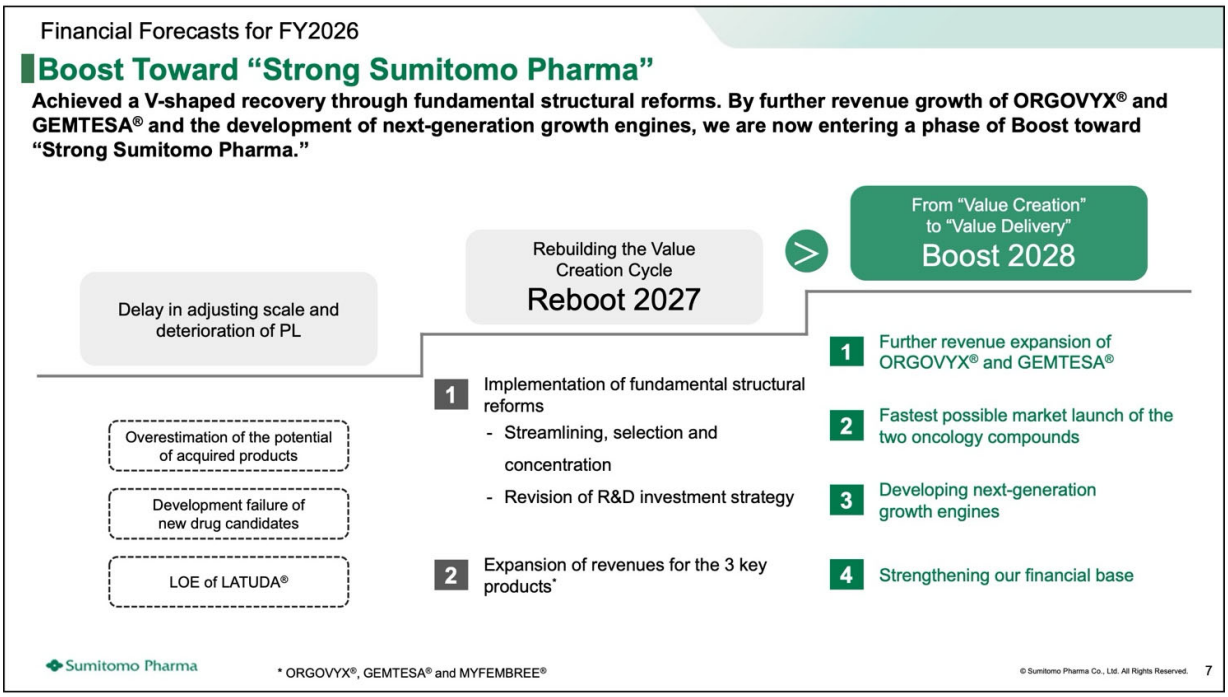
On the other hand, the revenue in Japan is shown here.

It was JPY92.4 billion, a decrease of JPY7.5 billion YoY.

In Japan as well, during this fiscal year, the exclusive sales period for the main product EquMet ended, leading to a significant decrease in sales. In response to this, sales growth of TWYMEEG, the introduction of XEPLION/XEPLION TRI, as well as the sales of LATUDA and LONASEN Tape, which we are focusing on, progressed steadily. However, due in part to the JPY1.4 billion impact of drug price revisions, we did not reach the previous year's level. Next slide please.

This is an explanation of the results for FY2025.



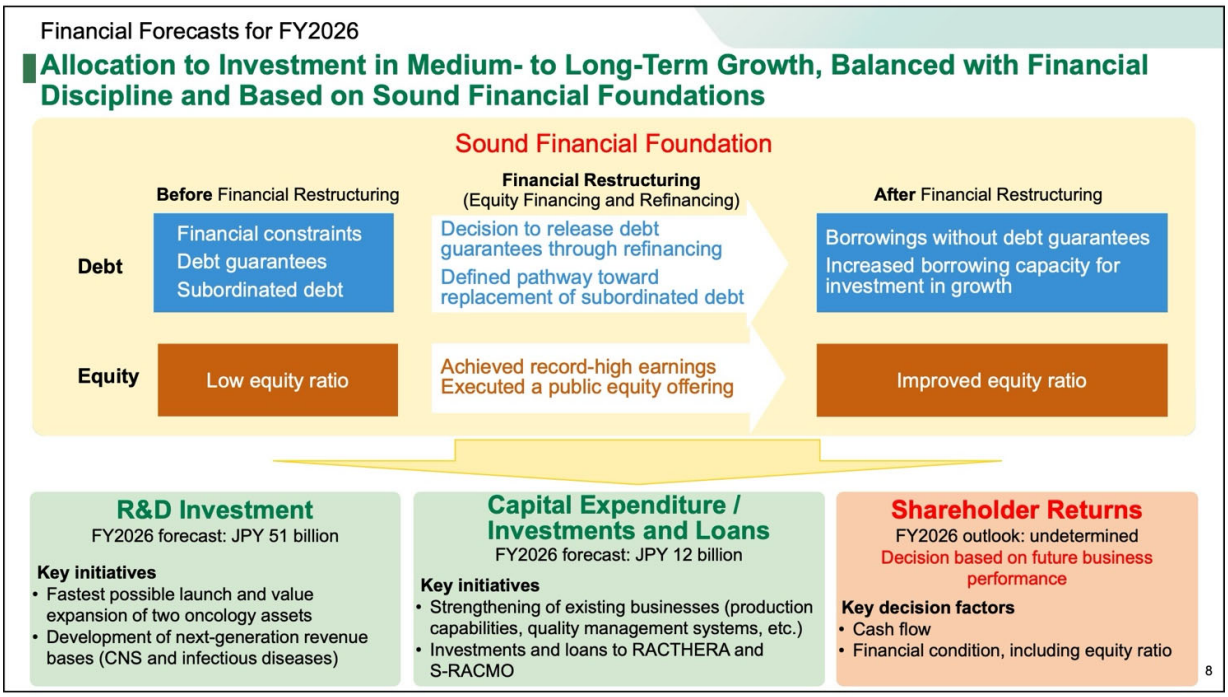
Next, I will explain the business forecast for FY2026.

As you know, our company had very harsh results in the fiscal year ended March 2024. Since then, we have implemented fundamental structural reforms, specifically proceeding with rationalization, selection and concentration of businesses, and reviewing R&D investment strategies.

Then, exactly one year ago, as a pharmaceutical company rooted in research and development, we announced a three year plan with several management goals to rebuild our value creation cycle.

Fortunately, we achieved that plan in one year. In response to that, in early March of this year, we announced a new three year management policy, Boost 2028, to become a company that can provide value from that new value creation.

In this, we aim for sales growth of the main products ORGOVYX and GEMTESA, the fastest launch of two oncology products, the cultivation of next generation growth engines, and since our financial base had significantly deteriorated after the very difficult fiscal year ended March 2024, we conducted a public offering last month to strengthen our financial base. Next slide please.



Following the very challenging results in the fiscal year ended March 2024, our equity ratio temporarily dropped to the 10% range. There were also financial constraints, and we had to have the parent company provide debt guarantees for our loans, and for subordinated bonds, we had to replace them with capital like funds. These issues and tasks remained.

By conducting the aforementioned public offering and achieving the record high profit explained at the beginning, our equity ratio has returned to a very healthy level of around 45% at present. At the same time, we implemented refinancing for loans and have refinanced into loans without debt guarantees.

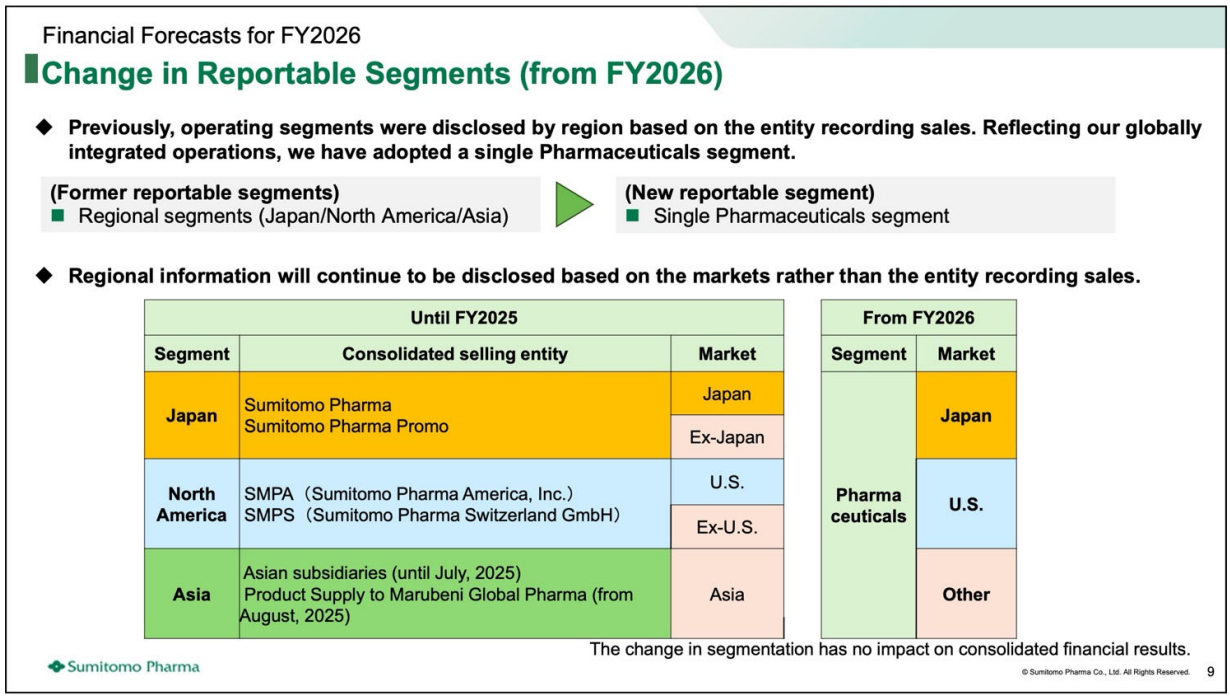
In addition, regarding the subordinated bonds, through this capital increase, the capital like funding for the replacement has been recognized, so the previous tasks have disappeared. With this financial reorganization, we believe we have moved from the reconstruction phase to the growth phase.

Our future investment policy is shown below. We controlled R&D investment at JPY44 billion in FY2025, but as research and development are progressing smoothly, we plan to increase it by JPY7 billion to JPY51 billion this year. We have a plan to invest JPY180 billion over three years including FY2026.

Regarding regenerative medicine, since RACTHERA and S-RACMO are in the form of joint ventures, funds will be in the form of investment and loans, but including capital investment and investment and loans, we plan JPY12 billion in FY2026.

Another point is that for the past three years, we have continued to pay no dividends. We aim to resume dividends as soon as possible. At this point, partly because the capital increase was just recently conducted,

the amount and timing of the dividend resumption are undecided. However, we intend to proceed so as to meet the expectations of our shareholders as soon as possible. Next slide please.

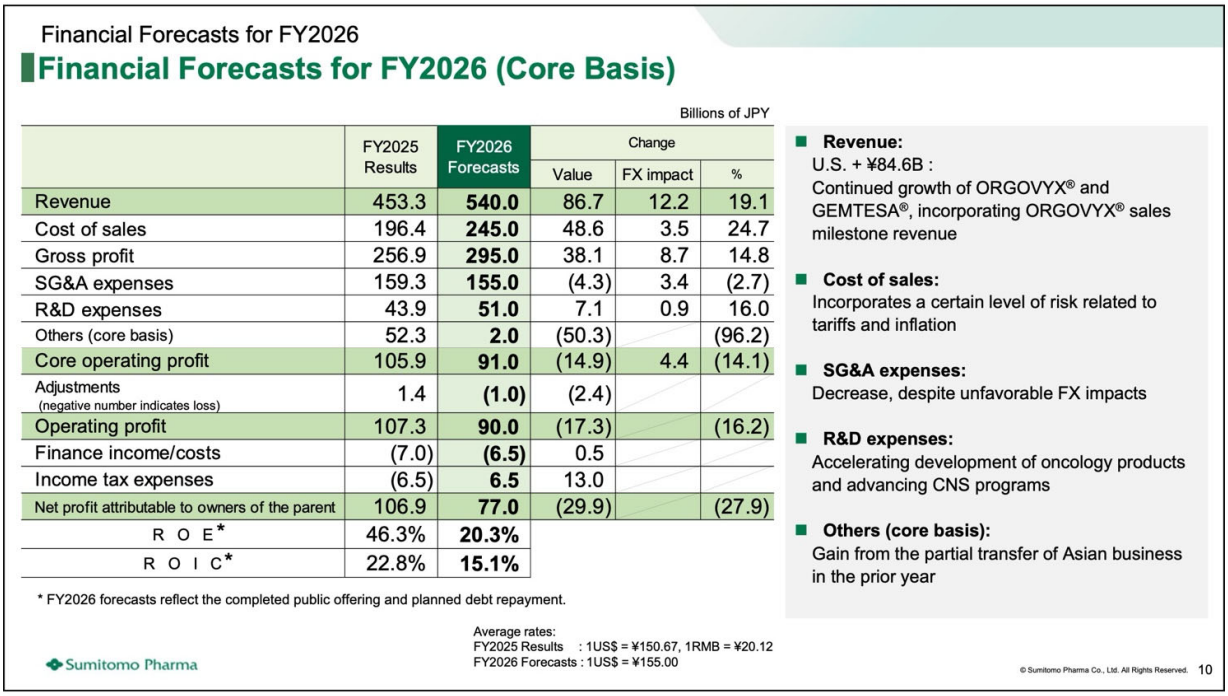


Another point in our structural reform is that revenue recognition was previously disclosed by regional segment, such as Japan, the US, or China and Asia, according to the respective legal entity in charge.

On the other hand, at present, all IP for main products is transferred to Japan, and we have shifted to a form where the global business is controlled from within Japan, and the business operation itself is conducted globally. Based on this, we have reorganized into a single segment for the pharmaceutical business.

At the same time, we will disclose and explain the business for each market where our sales are generated, such as Japan, the US, Asia, or Europe. We intend to change from this year to inform every one of the business situation by region.

For example, in the case of Japan, there are naturally sales in the Japanese market, but there are also exports from Japan to overseas, specifically to the Asian region, or to North America and Europe. Similar things happen in North America as well. We decided to change the format to aggregate such areas into a market called others. Next slide please.



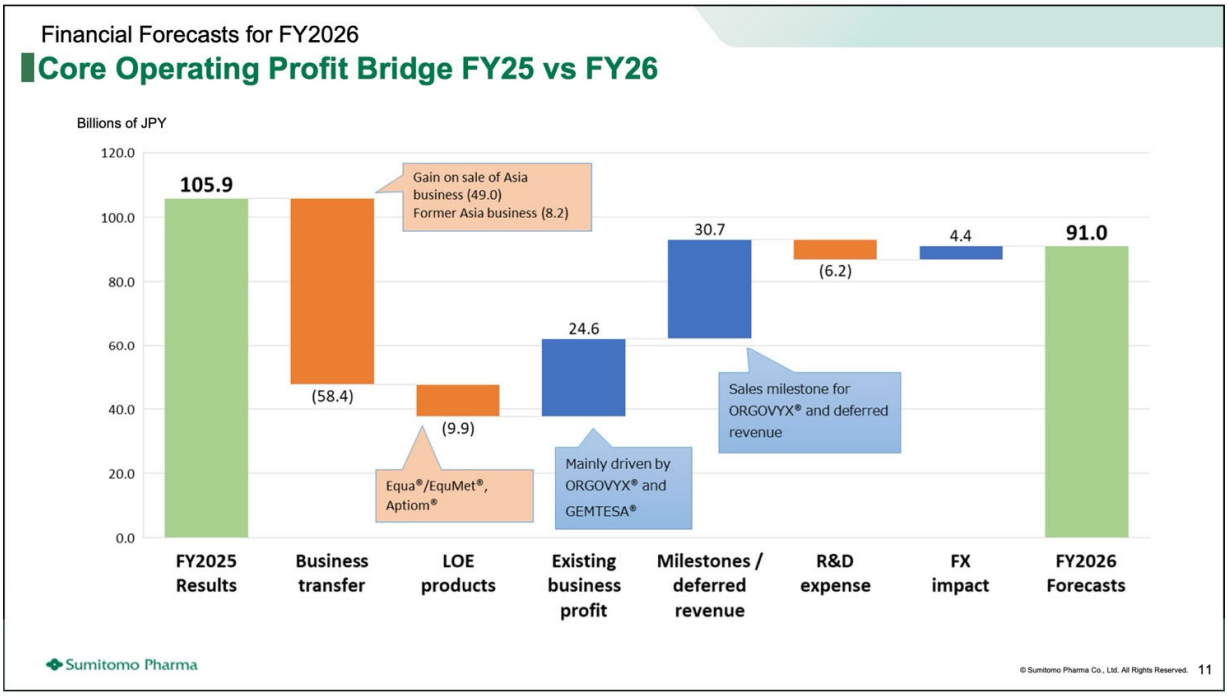
This shows the business forecast for FY2026 on a core basis.

Revenue is expected to be JPY540 billion, an increase of JPY86.7 billion compared to FY2025.

Gross profit is expected to be JPY295 billion, an increase of JPY38.1 billion. While continuing to firmly control SG&A expenses, we plan to increase R&D expenses by JPY71 billion to JPY51 billion.

As a result, it will be JPY91 billion, a decrease of JPY14.9 billion compared to the previous year, FY2025. At first glance, this looks like a decrease in profit, but in reality, as I mentioned last year, we recorded JPY49 billion from the transfer of the China and Asia business, so excluding that, it will be an increase in profit. I will explain a little more on the next slide.

Operating profit is forecast at JPY90 billion, and net profit attributable to owners of the parent is forecast at JPY77 billion. Next slide please.



This diagram explains the core operating profit in more detail.

I think you remember that in the fiscal year ended March 2024, there was a deficit of JPY130 billion at the core operating profit level.

On the other hand, as I explained, in the results for FY2025, we recorded a record high of JPY105.9 billion. I am sorry to repeat this many times but excluding the JPY49 billion gain from the transfer of the Asia business and JPY8.2 billion in profit obtained from the Asia business, as well as the contribution of main products whose exclusive sales periods ended in FY2025, as the product mix changed in both Japan and the US, this part is our current strength as of the end of FY2025.

In contrast, profits from existing businesses such as ORGOVYX and GEMTESA will grow, so our strength will improve to this level in the fiscal year ending March 2027. Three years ago, it was minus JPY130 billion, and I would like you to understand that our business structure reform is progressing very rapidly.

On the other hand, there is JPY30.7 billion for sales milestones and deferred revenue for ORGOVYX, and with pluses and minuses in R&D expenses and others, it comes to JPY91 billion. I would like you to understand that we are not simply comparing this and that. Next slide please.

Financial Forecasts for FY2026

Revenue of Major Products in U.S.

	FY2025 Results	FY2026 Forecasts	Change	FY2025 Results	FY2026 Forecasts	Change		
						Value	FX impact	%
U.S.	Millions of USD			Billions of JPY				
ORGOVYX®	1,029	**1,354**	325	155.0	**209.9**	54.9	5.9	35.4
MYFEMBREE®	96	**100**	4	14.4	**15.4**	1.0	0.4	7.3
GEMTESA®	637	**686**	49	96.0	**106.3**	10.3	3.0	10.7
RETHYMIC®	42	**35**	(7)	6.3	**5.4**	(0.9)	0.1	(14.2)
APTIOM®	99	**35**	(64)	14.9	**5.4**	(9.5)	0.2	(63.6)
Others*	234	**412**	178	35.2	**63.9**	28.7	2.2	81.7
Total	2,137	**2,622**	485	321.8	**406.4**	84.6	11.8	26.3

- ORGOVYX® and GEMTESA® revenue are expected to increase significantly
- APTIOM® revenue is expected to decline due to the impact of generic products
- Sales milestone for ORGOVYX® is expected in FY2026

* Major items included in Others

FY2025 Results	Deferred revenue from the collaboration with Pfizer	$88M	FY2026 Forecasts	Deferred revenue from the collaboration with Pfizer	$65M
	Sales milestone revenue from ORGOVYX® (sales exceeding $500M)	$100M		Sales milestone revenue from ORGOVYX® (sales exceeding $1.0B)	$325M

FX rates:
FY2025 Results : 1US$ = ¥150.67
FY2026 Forecasts : 1US$ = ¥155.00

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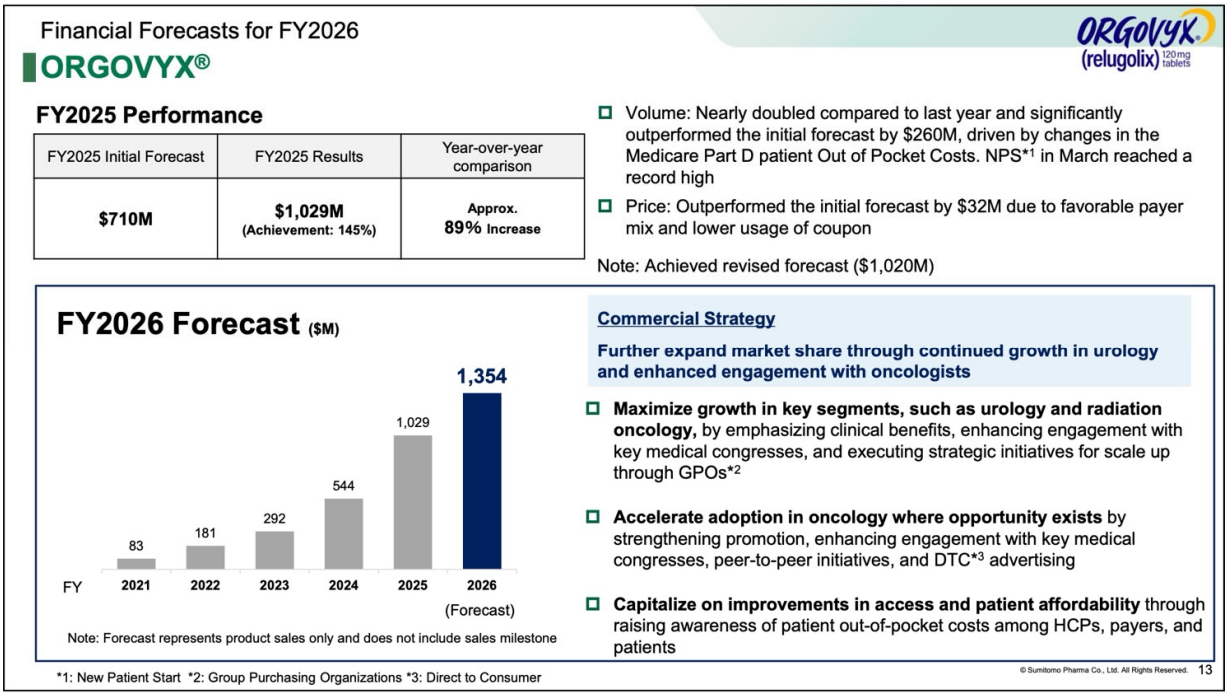
I will explain the revenue of major products in the US and Japan.

We forecast that ORGOVYX will exceed JPY200 billion and reach JPY209.9 billion. This is an increase of JPY54.9 billion compared to the previous year.

Also, GEMTESA is expected to exceed JPY100 billion, with an increase of JPY10.3 billion YoY.

On the other hand, there is a large increase of JPY28.7 billion in the others section. This is because there is a contract where a sales milestone of USD325 million will be received if ORGOVYX sales reach USD1 billion in a calendar year. In our sales forecast, we expect to hit this in the autumn, probably Q3, so a large figure appears in the others section.

With that, we forecast revenue of JPY406.4 billion, an increase of JPY84.6 billion YoY. Next slide please.



I will explain the status of the main products in more detail. First is ORGOVYX.

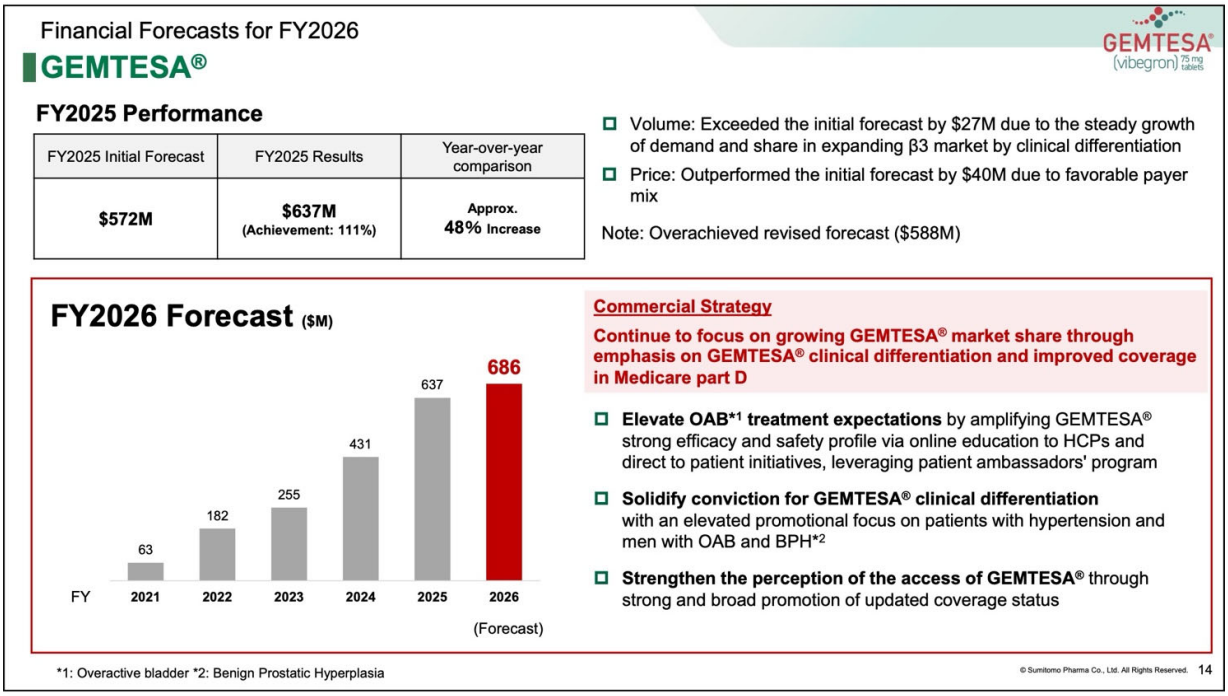
It is a treatment for prostate cancer. For the FY2025 results, the initial budget forecast was USD710 million, but the actual result significantly exceeded that at USD1,029 million. Also, compared to the previous year, very strong sales were achieved, almost doubling.

Even now, the number of new patients in this March reached a record high, and it continues to trend strongly.

We forecast sales of USD1,350 million. Currently, urology is our main battlefield, and it is being adopted by many urologists.

On the other hand, for oncology doctors or specialized hospitals, there is a drug with a similar efficacy called leuprolide, which is an injectable, and that is still mainly used. We know that the overall market for that is larger. Our ORGOVYX is an oral drug, and its features are that it is very easy to use and has few side effects. We want to proceed with promotion to tell doctors and patients that they do not need injections.

However, Medicare, the US insurance system, has been revised, and the out of pocket costs for patients have decreased significantly. But this is not necessarily well known, so we plan to continue promotion for that as well. Next slide please.

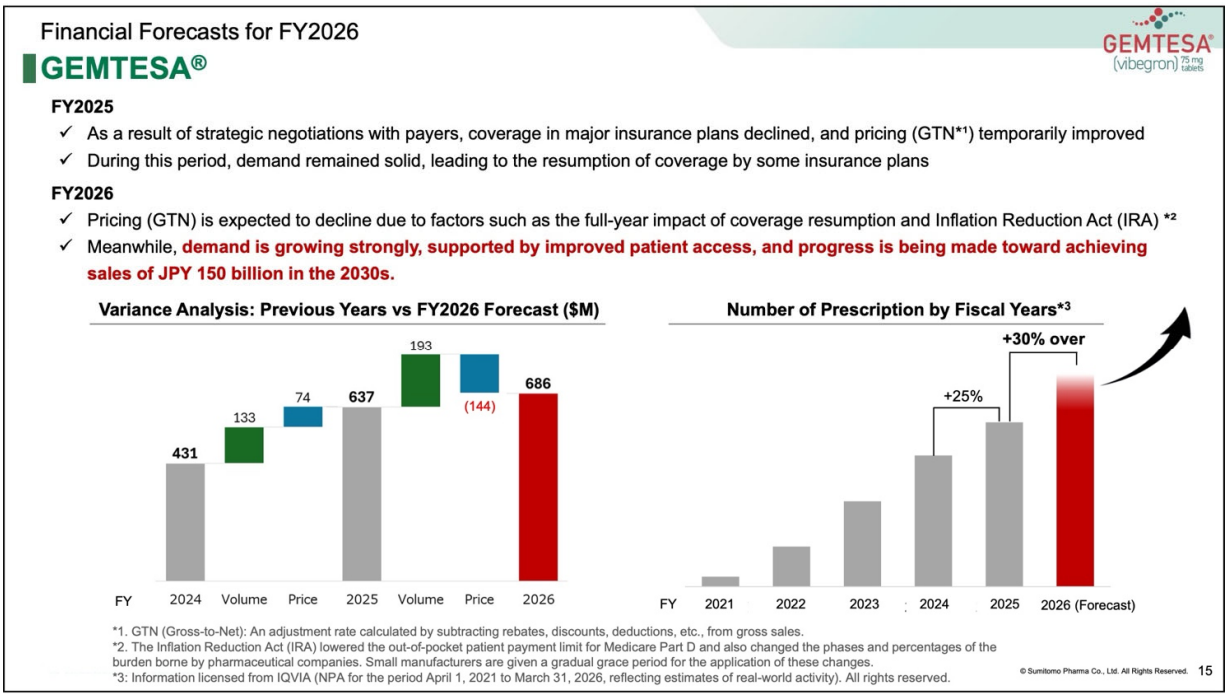


Moving on, we have GEMTESA. This is a drug for overactive bladder. The initial forecast was USD572 million, but the actual result was USD637 million, exceeding the estimated budget by 11%. Compared to the previous year, it grew by 48%, which was also very strong.

We believe this is because the ease of use and excellence of our GEMTESA in the beta 3 market for overactive bladder is becoming well known.

On the other hand, as I will explain on the next slide, because there were some temporary factors last year, the increase for this year FY2025 compared to FY2026 will be in the single digits.

In this context, we want to promote clinical differentiation and also firmly promote the indication for overactive bladder associated with benign prostatic hyperplasia, which is for male patients, as an indication that only this drug has. Next slide please.



I mentioned that there were some temporary factors. Last year, as I mentioned several times in financial results announcements, we continued business and sales by deciding to maintain prices firmly, even if it meant temporarily reducing insurance coverage.

Usually, this would lead to a decrease in usage. However, there were many patients and doctors who strongly wanted to use GEMTESA even without coverage. As a result, we were able to ship large quantities and at very high prices, which combined to achieve high growth from USD431 million to USD637 million.

This year, insurance coverage has returned, so the volume will increase sufficiently, but there will be negative factors in revenue due to rebates and other issues. If you compare both, it looks like the growth rate has slowed down, but if you look at the overall trend, I think you can see the whole picture.

One way to show this is the trend of prescriptions by year, and we expect that prescription shipments will increase by more than 30% from FY2025 to FY2026.

In the 2030s, we want to grow it to a scale of JPY150 billion in revenue. Next slide please.

Financial Forecasts for FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
FY2026 Forecast	Revenue	87.6	406.4	46.0	540.0
	Cost of sales	52.1	152.7	40.2	245.0
	Gross profit	35.5	253.7	5.8	295.0
FY2025 Results	Revenue	83.4	321.8	48.1	453.3
	Cost of sales	43.7	123.2	29.5	196.4
	Gross profit	39.6	198.7	18.6	256.9
Change	Revenue	4.2	84.6	(2.1)	86.7
	Cost of sales	8.4	29.5	10.7	48.6
	Gross profit	(4.1)	55.0	(12.8)	38.1

Japan
- XEPLION®/XEPLION TRI® contribute to increasing revenue, but gross profit decreases due to the product mix.

U.S.
- Gross profit increases due to increased revenue.

Other
- Profit decreases due to the partial transfer of the Asian business.

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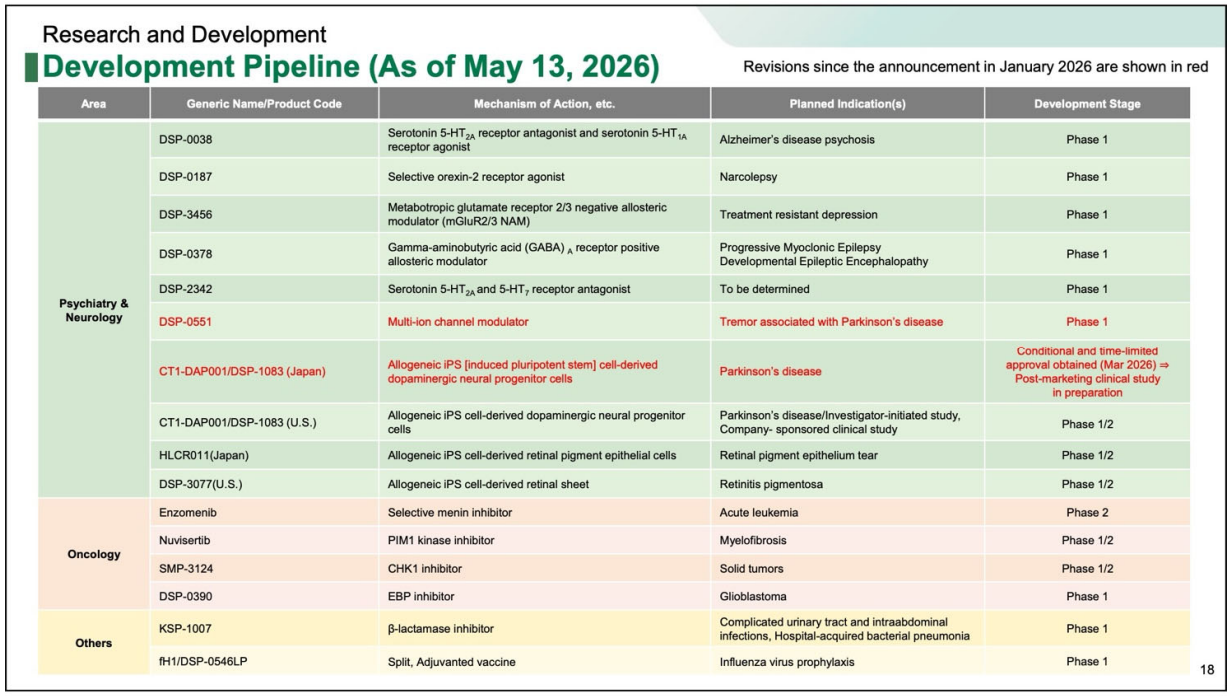
As I mentioned earlier, this shows the revenue and gross profit by segment.

Japan has revenue of JPY87.6 billion and gross profit of JPY35.5 billion. North America has JPY406.4 billion and JPY253.7 billion. Others have JPY46 billion and JPY5.8 billion. The total is JPY540 billion as explained in the FY2026 budget.

On the other hand, comparing with FY2025, North America is performing very well, but for the Japan business, although revenue will grow, gross profit will decrease slightly due to the product mix.

In addition, the China and Asia business is affected by the transformation of the business structure. Next slide please.



Research and Development

Development Pipeline (As of May 13, 2026)

Revisions since the announcement in January 2026 are shown in red

Area	Generic Name/Product Code	Mechanism of Action, etc.	Planned Indication(s)	Development Stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT_{2A} receptor antagonist and serotonin 5-HT_{1A} receptor agonist	Alzheimer's disease psychosis	Phase 1
	DSP-0187	Selective orexin-2 receptor agonist	Narcolepsy	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment resistant depression	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) $_A$ receptor positive allosteric modulator	Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy	Phase 1
	DSP-2342	Serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist	To be determined	Phase 1
	DSP-0551	Multi-ion channel modulator	Tremor associated with Parkinson's disease	Phase 1
	CT1-DAP001/DSP-1083 (Japan)	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease	Conditional and time-limited approval obtained (Mar 2026) ⇒ Post-marketing clinical study in preparation
	CT1-DAP001/DSP-1083 (U.S.)	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company- sponsored clinical study	Phase 1/2
	HLCR011(Japan)	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077(U.S.)	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	Phase 1/2
Oncology	Enzomenib	Selective menin inhibitor	Acute leukemia	Phase 2
	Nuvisertib	PIM1 kinase inhibitor	Myelofibrosis	Phase 1/2
	SMP-3124	CHK1 inhibitor	Solid tumors	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	Phase 1
Others	KSP-1007	β-lactamase inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Phase 1

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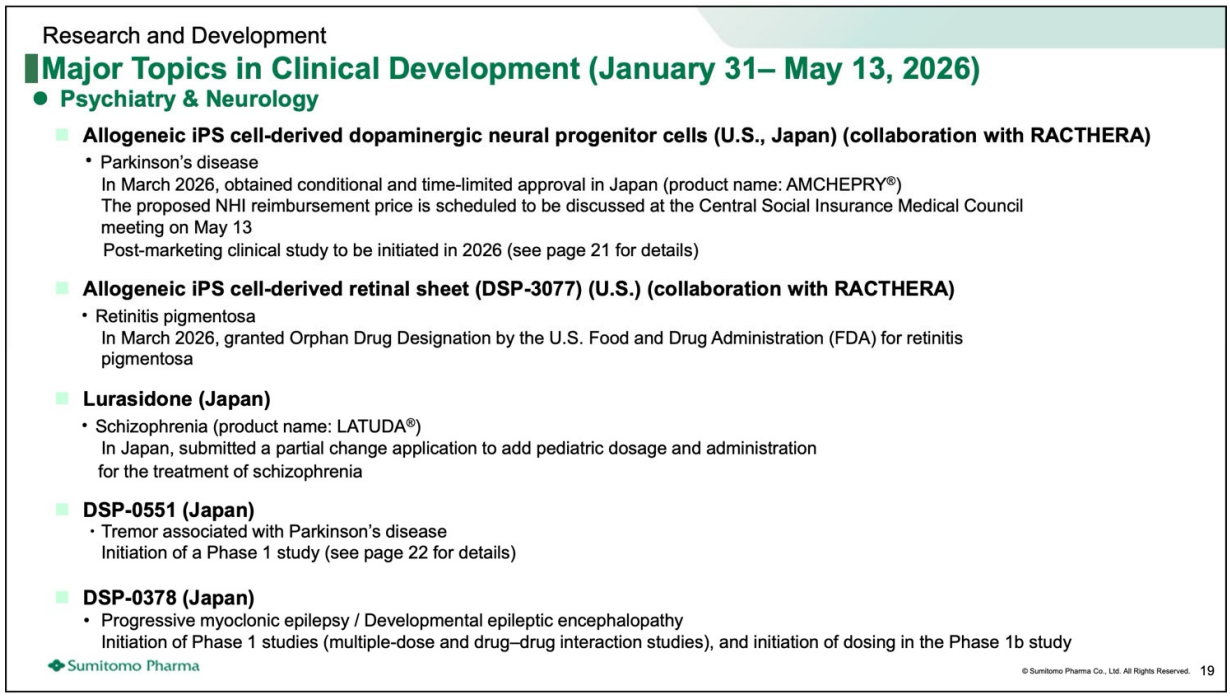
I'll move on to R&D.

The entire picture is shown here, and I will explain each topic. Next slide please.



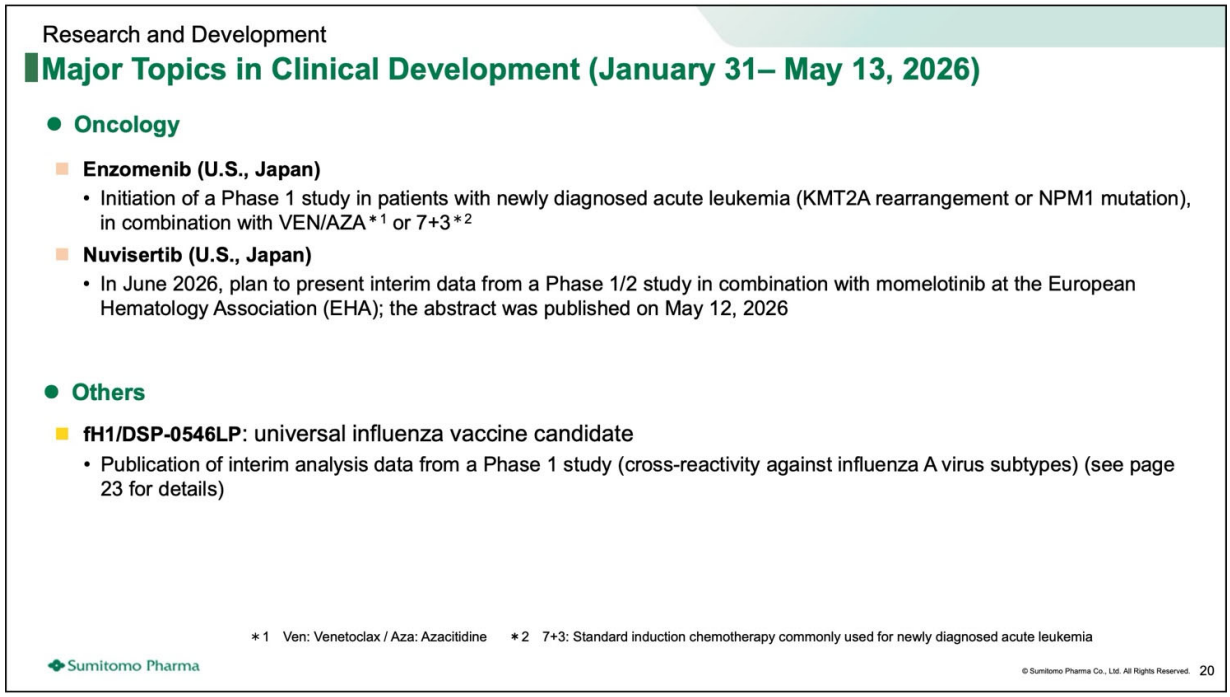
The main R&D topics from January to May of this year are summarized here.

First, in the psychiatry and neurology area, AMCHEPRY, an allogeneic iPS cell derived dopamine neural progenitor cell, received approval for manufacture and marketing on March 6. Also, the drug price was decided today by the Central Social Insurance Medical Council, and insurance reimbursement has been approved.

Regarding the iPS cell derived retinal sheet 3077, it received orphan drug designation in March. Clinical trials are progressing in the US.

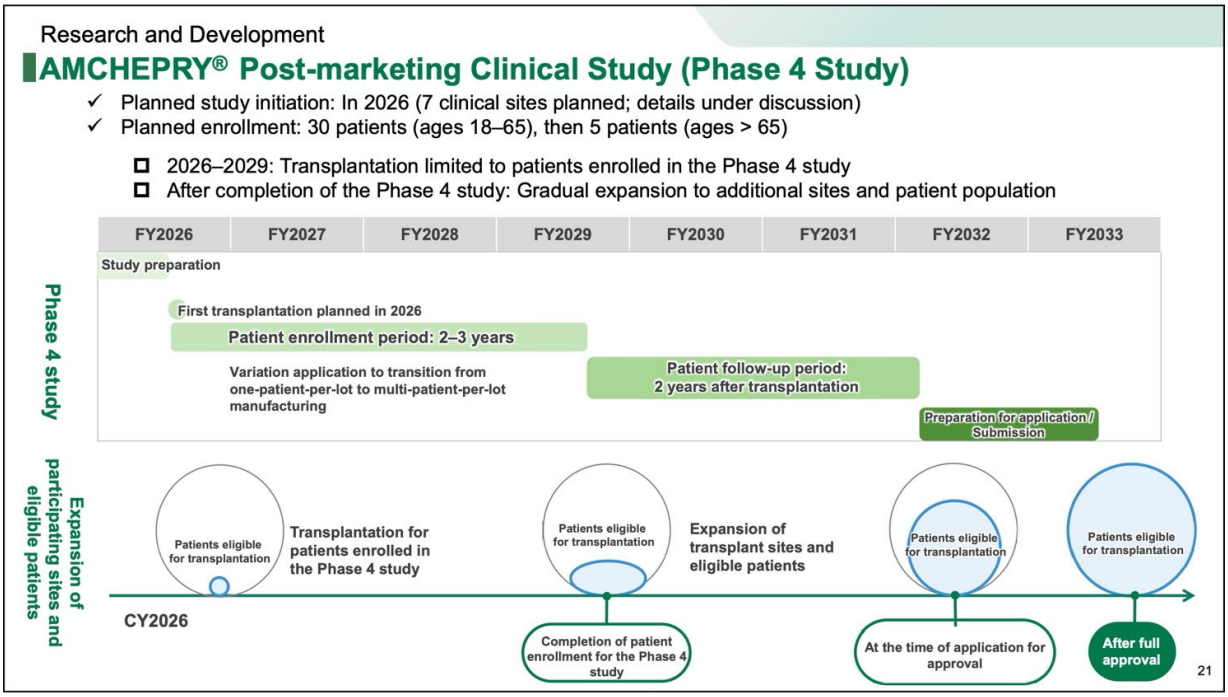
For lurasidone, an application for a partial change was made for the addition of pediatric dosage and administration. If this is approved, the drug price will increase and will not decrease in the future, which we are looking forward to.

As for new items, the administration for the Phase Ib trial of 0051 for tremor due to Parkinson disease and DSP 0378 has also started. Next slide please.



In the oncology area, for enzomenib, a Phase I trial of combination therapy with venetoclax and azacitidine for newly diagnosed acute leukemia has started. For nuvisertib, interim analysis data of combination therapy with momelotinib will be announced at the EHA to be held in June, and the abstract was released on May 12.

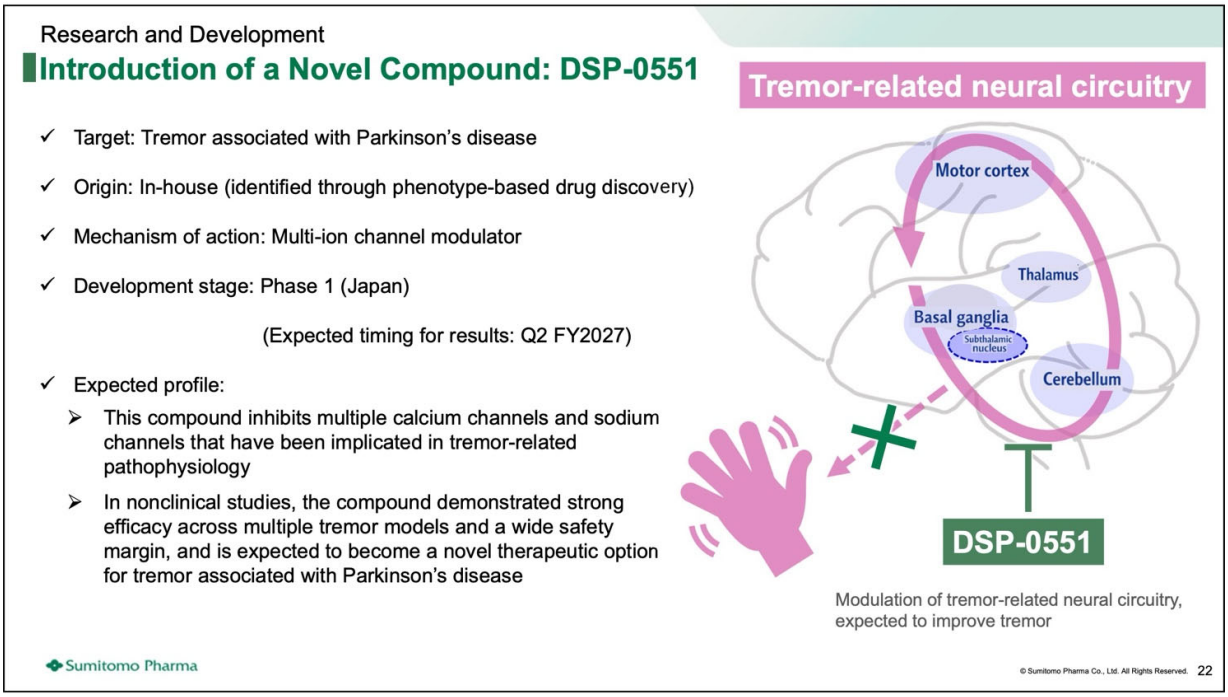
Another point, which I will explain later, is that very good data is coming out for the universal influenza vaccine. Next slide please.



Regarding AMCHEPRY, which is a topic for drug price listing today, since it is a conditional and time limited approval, we will now conduct post marketing clinical trials, commonly known as Phase IV.

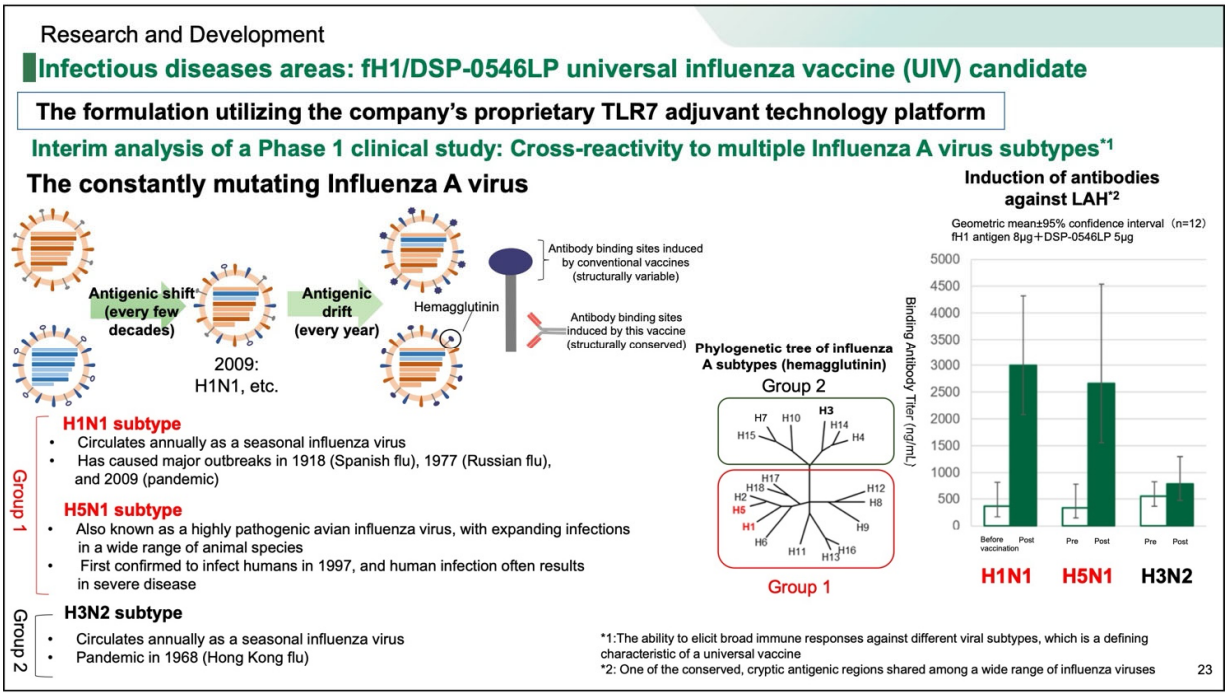
Preparations for the trial are currently underway. We have promised to transplant a total of 35 patients, follow up with each patient for two years, and apply for full approval within seven years.

Since the follow up period alone is two years, it is a very tight schedule, but we want to do our best to reach the application even one year earlier. Next slide please.



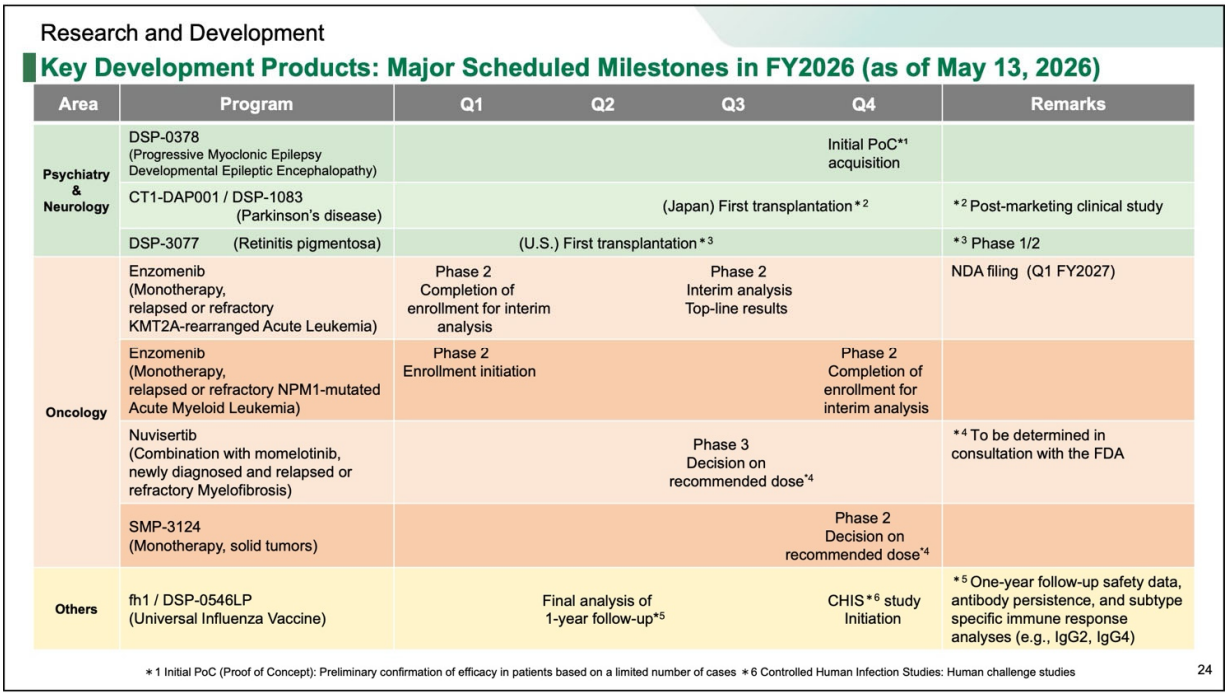
Another new drug is 0551, which is also for Parkinson disease. In the case of Parkinson disease, along with motor dysfunction, there is what is called tremor, where the patient handshakes when they try to stop their body.

We are considering a mechanism to adjust the neural circuits in the brain that cause tremor by acting on multiple ion channels, and we have started a clinical trial of 0551 for such tremor in Parkinson disease. Next slide please.



The other is the universal influenza vaccine. As you know, the influenza virus changes constantly, so the vaccine from last year might not work this year. Influenza viruses are broadly divided into groups one and two. For example, there are several types within H5. Our study showed that when immunized with a certain H1 antigen and our adjuvant, antibodies against H5 were produced along with antibodies against H1, demonstrating high universality in clinical data.

By the way, this H5 is avian influenza. If an avian influenza pandemic were to occur, using our vaccine would mean we could prepare the vaccine before the virus appears. Next slide please.



Research and Development

Key Development Products: Major Scheduled Milestones in FY2026 (as of May 13, 2026)

Area	Program	Q1	Q2	Q3	Q4	Remarks
Psychiatry & Neurology	DSP-0378 (Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy)				Initial PoC*1 acquisition	
	CT1-DAP001 / DSP-1083 (Parkinson's disease)			(Japan) First transplantation*2		*2 Post-marketing clinical study
	DSP-3077 (Retinitis pigmentosa)		(U.S.) First transplantation*3			*3 Phase 1/2
Oncology	Enzomenib (Monotherapy, relapsed or refractory KMT2A-rearranged Acute Leukemia)	Phase 2 Completion of enrollment for interim analysis		Phase 2 Interim analysis Top-line results		NDA filing (Q1 FY2027)
	Enzomenib (Monotherapy, relapsed or refractory NPM1-mutated Acute Myeloid Leukemia)	Phase 2 Enrollment initiation			Phase 2 Completion of enrollment for interim analysis	
	Nuvisertib (Combination with momelotinib, newly diagnosed and relapsed or refractory Myelofibrosis)			Phase 3 Decision on recommended dose*4		*4 To be determined in consultation with the FDA
	SMP-3124 (Monotherapy, solid tumors)				Phase 2 Decision on recommended dose*4	
Others	fh1 / DSP-0546LP (Universal Influenza Vaccine)		Final analysis of 1-year follow-up*5		CHIS*6 study Initiation	*5 One-year follow-up safety data, antibody persistence, and subtype specific immune response analyses (e.g., IgG2, IgG4)

＊1 Initial PoC (Proof of Concept): Preliminary confirmation of efficacy in patients based on a limited number of cases ＊6 Controlled Human Infection Studies: Human challenge studies

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Main events scheduled for FY2026 are shown here.

As an R&D oriented pharmaceutical company, we are about to start a new journey. That said, in terms of approvals, there are not that many for a company of our size, so this is a new way we have devised to show what milestones exist in each fiscal year.

Especially this year, in addition to AMCHEPRY, for the two oncology products, enzomenib and nuvisertib, we intend to restart activities to find new partners, using the achievement of milestones shown here as a trigger.

Then, that concludes my explanation.

Question & Answer

Maruyama [M]: Dr. Kimura, thank you. We would now like to move on to the Q&A session with analysts and investors. The Q&A session will last until 4:00 PM.

I will call names in order and we will unmute the microphone, so please ask your question after stating your affiliation and name.

First, Mr. Stephen Barker from Jefferies.

Barker [Q]: I am Stephen Barker from Jefferies. Thank you.

I would like to ask about the outlook for the gross profit margin for this fiscal year. In the fiscal year that ended, 56.7% was achieved, but I believe the outlook for this fiscal year is 54.6%, a 2.1 percentage point deterioration. However, looking at the product mix, especially with the milestone revenues for ORGOVYX, I think the product mix is rather improving. Why is it expected to deteriorate so much?

Kimura [A]: Yes, thank you for the question. I will give a brief explanation and Dr. Nakagawa, who is in charge of North America Business, is here, so he will also explain in detail.

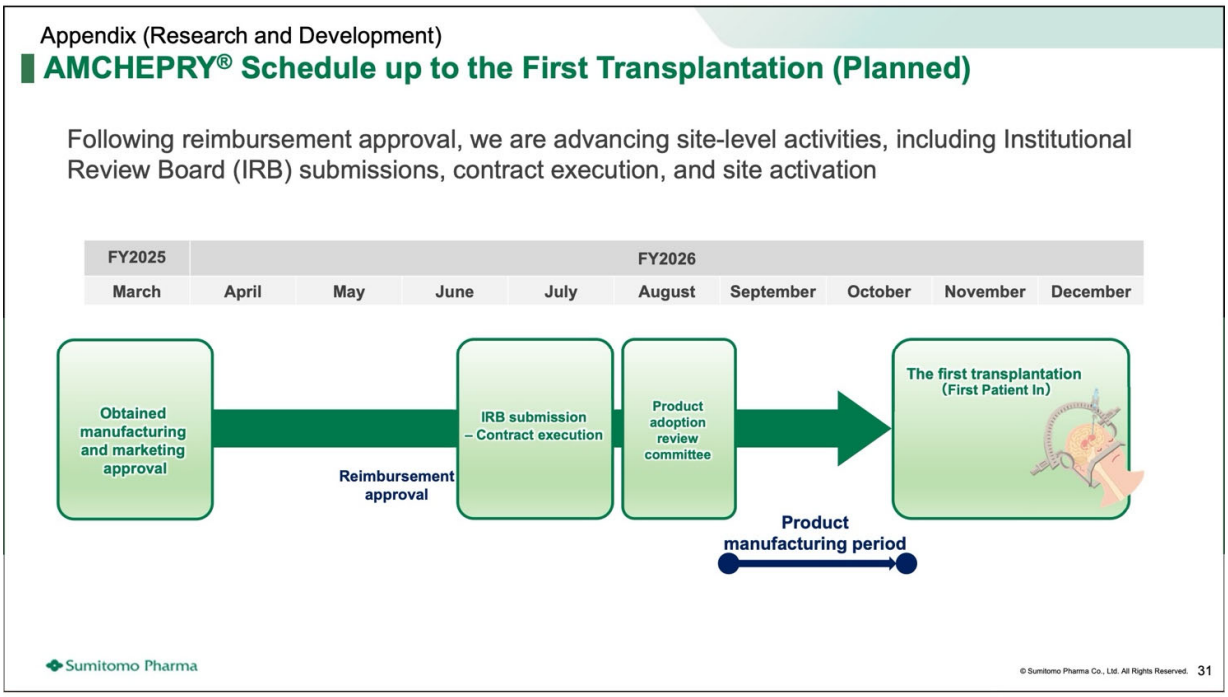
As you mentioned, our main products ORGOVYX and GEMTESA are growing steadily. However, as explained, while the main products grow this year, or rather last fiscal year, there were products that reached LOE in the middle of the year. Especially APTIOM was a product with a very high profit margin, so moving from such items to products with relatively lower profit margins is one factor.

In response to the current situation in Iran, although nothing has happened yet, there are signs that costs will increase in the future. We have factored in JPY4 billion for Japan and the US, JPY4 billion in total, into the cost of sales.

I recognize that it looks as if the gross profit margin has decreased more than it actually has. Dr. Nakagawa, do you have anything to add?

Nakagawa [A]: Yes, I will add a little. In addition to what Dr. Kimura said, we are factoring in the sales increase of ORGOVYX significantly. However, as we have explained before, this is in a copromotion with Pfizer, and regarding profits and costs, they are split 50 to 50. The cost of sales for ORGOVYX is not necessarily low, so since the cost of sales is high, it is one factor that relatively moves the gross profit margin in a lower direction.

Barker [Q]: Thank you. The second question. In addition to the attractive JPY55 million drug price for the Parkinson treatment AMCHEPRY, how much is it expected to contribute to revenue this fiscal year?



Kimura [A]: Yes, thank you for the question. Can you show page 31 of the supplementary materials? Today, a price of JPY55 million, including consumption tax, so over JPY50 million, was assigned, and it was decided around noon today that the drug price listing will be on May 20.

The future procedures are shown here. The drug price has finally been listed. From now on, we will conduct Phase IV using this. At each hospital, there will be an IRB hospital ethics application and product contracts, as well as deliberations for the adoption of the product at each hospital and university.

We think it will be this autumn when it actually becomes available for sale, and late autumn at that. We think that for this calendar year, doing one transplant case would be the most we can do.

This will be conducted strictly as Phase IV, so it will not be at all hospitals. We want to conduct it where the system of doctors and hospitals is firmly in place. We are currently making preparations with seven facilities in mind.

Barker [M]: I understand. Thank you very much. That is all from me.

Maruyama [M]: Mr. Barker, thank you for your questions. Next, Mr. Yamaguchi from Citigroup Global Markets.

Yamaguchi [Q]: Thank you. I am Yamaguchi from Citigroup Global Markets. I would like to ask a follow up to the question from Mr. Stephen.

Regarding the JPY4 billion for costs including the situation in Iran for Japan and the US, I thought I heard you say it was for Japan and the US. Is this JPY4 billion in total for Japan and the US, or JPY4 billion each? I could not hear that part well. I am sorry, but please confirm.

Kimura [A]: I am sorry for the ambiguous way of speaking. We have JPY2 billion each for Japan and the US, for a total of JPY4 billion in the budget. There is not much basis for this figure itself, but I hope you understand that it is a figure we included thinking it would be sufficient to handle the situation**.**

Yamaguchi [Q]: Thank you. This is a repeat, but you said it was an estimate. Do you mean that you will look at that much for this period if various things come up, such as rising oil prices or logistics costs?

Kimura [A]: Yes, exactly as you said.

Yamaguchi [Q]: I understand, thank you. The second point is about enzomenib. I think it was written that the interim analysis for Phase II would be in Q3. Regarding negotiations with partners, you said you started once and then stopped. What is the current status? For example, are you moving with the aim of completing it within the fiscal year? Or will you take a little more time to decide on a partner? Could you tell us the current status of these activities?

Kimura [A]: We believe that by showing the data from this interim analysis, the value of enzomenib will be understood. So, we intend to resume introductory activities once there is a prospect for this data.

In that sense, please understand that apart from general information exchange, activities to partner for enzomenib are currently suspended.

Yamaguchi [Q]: Thank you. Is the other one still stopped, nuvisertib?

Kimura [A]: Nuvisertib, yes. The clinical trial itself for this is progressing smoothly. However, we are waiting for the N number to accumulate for the combination trial with momelotinib so that everyone can understand the efficacy and safety. We expect such data to come out at almost the same timing, so activities will start moving again from around Q3 as shown here.

Regarding the timing of the contract conclusion, we are not thinking rigidly of it being within FY2026, and we have factored in the possibility that it might slide into the beginning of FY2027.

Yamaguchi [M]: Thank you. That is all from me.

Maruyama [M]: Yamaguchi, thank you very much. Next, Mr. Wakao from JPMorgan Securities.

Wakao [Q]: Yes, I am Wakao from JPMorgan. First, regarding the question about the partnership for Yamaguchi just now. Can I understand that your explanation, Dr. Kimura, has not changed particularly from the previous timing? Previously, there was talk that it would be at the end of this fiscal year, from January to March of next year, or in some cases, it might slide to April to June. Is the thinking unchanged?

Kimura [A]: That is right. It is as planned. This time we have made a table of future R&D events on page 24, and I explained based on this, but the plan itself has not changed.

Wakao [Q]: Thank you. Second, I apologize as it is something I always ask, but please tell us your evaluation of the one-three month figures for ORGOVYX that just ended and the assumptions for this fiscal year's plan. For this one-three month that ended, as you said, it landed roughly as planned I think, but basically I want to know whether these figures had, for example, inventory buildup in 10 to 12 of 2025 and a reaction from that, and also please tell us about your assumptions for this fiscal year.

Prescription trends continue to progress steadily I believe, and regarding gross to net too, you told us there is no major change this fiscal year, so volume increase should connect directly to revenue, so I think it could come out a bit higher, so I would appreciate your explanation.

Kimura [A]: Thank you. On whether it might go a bit higher, we too hope it goes higher, but as we have been saying for these two years or so, regarding budgets or performance forecasts, rather than putting out numbers we wish for, we have a policy of putting out numbers that we can take responsibility for properly, which might be influencing the difference in recognition with Mr. Wakao perhaps, but we are absolutely not lowering them intentionally.

In terms of assumptions, last fiscal year and the year before last, due to IRA impact, patient burden changed significantly, so there was a qualitative difference, but FY2025 and FY2026 have continuity, so I think it will become numbers very much in line with our forecasts.

On the other hand, since it doubled from FY2024 to FY2025, and the insurance situation is quite different. If you read that aggressively, it becomes a bit tough for us too in the current situation. Dr. Nakagawa, anything to add?

Nakagawa [A]: Yes, what Dr. Kimura just said covers it almost entirely, but we too strongly want to leverage the steady momentum so far and stretch further, but forecasts remain realistic, and we intend to tackle exceeding them by as much as possible.

Wakao [Q]: Yes, thank you. I do not think double but felt it a bit low. The second point is GEMTESA. As you explained, the volume will grow but the price will decrease, so the revenue for this period is USD686 million. On the other hand, you are aiming for about USD1 billion. To reach that, you would need to grow revenue to some extent. For example, since the price has decreased, will you not take aggressive strategies such as raising the price or increasing the volume a little more?

With this plan for this period, if you simply increase it by USD50 million each year, you will eventually reach USD1 billion. However, as it is one of the main products, I thought you should work on it more aggressively, so I would like to know about the plan for this period.

Kimura [A]: Yes, thank you. This is a matter of strategic thinking. As I have explained repeatedly, we are currently managing SG&A expenses very strictly. In the case of GEMTESA, we have learned from experience that it is promotion sensitive. In other words, we know that sales will grow if we put effort into promotion.

On the other hand, the financial base has been significantly strengthened by this capital increase. So although we have not decided yet, as Mr. Wakao just mentioned, we want to consider strategically strengthening promotion to increase sales as one option in our future medium term plan. We intend to take measures after doing a more detailed market forecast.

Nakagawa [A]: I am sorry, let me add a little from Nakagawa regarding the question just now. Regarding the first point, the price, you mentioned that we could raise it a little more. As you know, with the IRA, the discount rate will increase every year from now on. Also, considering that generic mirabegron will likely become full scale from now on, I think it will be difficult to bring the price up. As Dr. Kimura said, we want to rack our brains to think about how to increase volume. That is all from me.

Wakao [Q]: Thank you. Regarding the generic of mirabegron, Astellas has settled with generic manufacturers, so I think the number will increase. Am I correct in understanding that the assumption of volume increase is after factoring that in?

Nakagawa [A]: The scale of JPY150 billion in the 2030s that we presented in Boost 2028 is a figure that includes all of what you just pointed out.

Wakao [Q]: Yes, thank you. Finally, please tell us about shareholder returns on the eighth slide. I think the expectation of the stock market is a resumption of dividends after this capital increase. In that context, cash flow and equity ratio are written as judgment factors here. Could you be more specific about what conditions would lead to a dividend resumption? Could you tell us including the timing? That is all from me.

Kimura [A]: Yes, I am Kimura. Regarding this, we are considering it by thinking about these things comprehensively. We believe it is already time to specifically consider resuming dividends. However, if the current assumptions were to collapse significantly, we cannot just resume once and then stop again. So, we want to take a little more time to think. Please understand our intention from the fact that we wrote undecided where we had always said no dividend.

Wakao [Q]: I understand. So, I can understand that the possibility during this period is also constantly being considered, right?

Kimura [A]: That is right. We also want to consider resuming dividends at an appropriate timing. Since it is just after the capital increase, it is undecided.

Wakao [M]: I understand. Thank you very much. That is all from me.

Maruyama [M]: Mr. Wakao, thank you very much. Next, Mr. Wada from SMBC Nikko Securities.

Wada [Q]: Thank you. I am Wada from SMBC Nikko Securities. I would like to ask about the impact of the segment change on page nine. My understanding is that cost control has been conducted by region so far. I want to ask if the thinking behind cost control will change.

Kimura [M]: Sakai is here, so he will explain.

Sakai [A]: I am Sakai. Thank you for your question. The thinking behind cost control remains the same as before. Changing the segment does not mean we will change anything significantly. However, the cooperation between Japan and the US has become very close, so in that sense, we are presenting this segment in a form where we control costs as a whole.

Wada [Q]: I understand well. Thank you. Next is about enzomenib and nuvisertib. Regarding enzomenib, looking at page 24, I think we can see a certain trigger with the Top-line results of this Phase II interim analysis. For nuvisertib, will there be any data disclosed to us at the timing of around Q3?

Kimura [A]: Yes. There is a large academic conference in Q3, so we will present it there. Regarding the partnering I mentioned earlier, we intend to talk with the latest information, including information that can be disclosed under a CDA, in more detail.

Wada [Q]: Thank you. Finally, at the top of this diagram, Initial POC is written for 0378, so I think patient data will come out, although it might be a very small number of cases. Similarly, for 0551 on page 22, the result determination timing for Phase I is written Q2. Is this data from patients? Or will it be safety or PK data for healthy individuals?

Kimura [M]: Ms. Sato will explain this. Ms. Sato, please explain.

Sato [A]: I am Sato. As you asked, Q2 of FY2027 is written in the middle. We have just started single and multiple dose administration to healthy adults, and this is the timing for those results.

In addition to pharmacokinetics and safety, I think we will also obtain data to confirm brain penetration.

Wada [M]: Thank you. I understand well. That's all. Thank you very much.

Maruyama [M]: Mr. Wada, thank you very much. Now, with nine minutes remaining, we have two people waiting, so I would like to provide quick answers.

Next, Lee from Morgan Stanley MUFG Securities. Thank you for your patience. Please go ahead.

Lee [Q]: Yes. This is Lee from Morgan Stanley. This is a bit of an extension of Mr. Wakao's question on shareholder returns. Regarding the resumption of dividends, it changed from no dividend to undecided. Reading page eight, there are equity ratio and cash flow, and in my mind, I think the outlook for cash flow is important for your company.

The trigger would be that after the partnership for two new drugs, the outlook for cash flow and R&D spending will become much easier to formulate. Does this thinking seem wrong? Do you think it will not take that much time? Please let me follow up on this one point.

Kimura [A]: It is difficult, but we have not factored in any fees for partnerships into this year budget at all. I hope you understand that it means whether cash flow will come out as we expect in areas other than that.

Lee [Q]: I understand. Thank you. Please tell us one point about the new drugs. For SMP 3124, a checkpoint kinase 1 inhibitor, Phase I/II data for ovarian cancer or solid tumors will be released at ASCO in late May or early June. Regarding this development strategy, are you thinking of it on the premise of a partnership, or will you do it yourself to the end? Please tell us about the development strategy here.

Kimura [A]: Yes. We have not decided on a development strategy yet, but if 3124 comes along smoothly while enzomenib is running, we think our own resources might be a bit insufficient to maximize it. We will decide separately based on the situation at that time.

Lee [Q]: I understand. You plan to decide the Phase II dose by Q4, so can I understand that it is progressing smoothly at this point?

Kimura [A]: Yes. In terms of data coming out now and the enrollment situation, you can understand that it is progressing very smoothly.

Lee [Q]: I understand, thank you. Finally, regarding ORGOVYX. The composition of matter patent is scheduled to expire in January 2029, and in some parts of the market, there are some concerns about generic entry amid the current high growth of ORGOVYX. There is a view that generics could enter as early as FY2029.

On the other hand, your company is in ANDA litigation with other companies, and recently in Boost 2028 in March, you set a goal of JPY250 billion for ORGOVYX sales in the 2030s.

Therefore, it seems to me that your company does not see generic entry in 2029 or 2030 as a concern. Could you tell us about your thinking on this again? Thank you.

Kimura [A]: Yes, thank you. Just as you mentioned, in the US, after five years, ANDA litigation occurs for everything, and we fight in litigation with generics over how much exclusivity we can secure. Both ORGOVYX and GEMTESA have entered that phase.

As you said, the composition of matter patent is January 2029, but besides that, our group of patents is listed in the FDA Orange Book. The results of analysis involving experts show that our patents are very strong, and we do not expect at all to reach LOE after January 2029.

Lee [M]: Dr. Kimura, thank you very much. That is all from me.

Maruyama [M]: Mr. Lee, thank you for rushing. Now, sorry to have kept you waiting. Mr. Hashiguchi from Daiwa Securities, please go ahead.

Hashiguchi [Q]: I am Hashiguchi. Thank you. I have two questions.

First, you mentioned that you would strengthen promotion to oncologists, whereas it had been focused on urologists. Could you tell us the difficulty in achieving penetration among oncologists that was not there with urologists?

I think one point is that they have no resistance to injectables, but is there any difference in terms of economic benefits for medical institutions?

Kimura [A]: Yes, I will explain briefly and then ask Dr. Nakagawa to add more.

Exactly as you said, competing drugs are injectables, so there is a difference in what you call medical fees in Japan compared to oral drugs where you just issue a prescription. Oncology doctors consider a series of operations or treatments such as shrinking the cancer with ADT hormone ablation therapy using ORGOVYX and then surgically removing it. In that context, injectables are not so much of a problem.

On the other hand, for patients, they prefer oral drugs that have fewer side effects and work well. Our policy is to appeal to the latter. If there is a more detailed supplement, please provide it.

Nakagawa [A]: Yes. First, as a major trend, many patients seen by urologists are those with relatively early stage prostate cancer. On the other hand, the segment you call oncologists sees patients at a relatively more advanced stage.

Therefore, ADT is used basically, but for patients with more advanced disease, they also use various additional anticancer drugs. For oncologists, the choice of such other drugs is rather their interest, the center of their focus.

Naturally, there was talk of economic incentives, but even with those drugs, they have such rewards. Relatively, the positioning of ADT, ORGOVYX, and leuprorelin is low, which is a bit of a weak point in our explanation.

Dr. Kimura also mentioned that we believe ORGOVYX has superiority over leuprorelin, which is used as a base. So, we are working hard to develop that area now.

Hashiguchi [Q]: Thank you. The second question is the thinking on the number of target patients for AMCHEPRY in the future.

On the slide on page 21, you show an image of the blue circle becoming larger. In today Central Social Insurance Medical Council materials, the expected number of patients for administration in the 10th year is written as 133. My understanding is that this peak forecast at the time of drug price calculation is predicted from the current approval content and does not consider future indications expansion or changes in approval content.

However, in this case, does this 133 people assume the expansion to the far right of page 21, or is it an intermediate stage? Could you tell us about this relationship?

Kimura [A]: Yes, I will explain. The blue area shown in the material on page 21 assumes the period from the application for conditional and time limited approval to the approval. We are also thinking that the number of patients we will administer during the conditional and time limited approval will be around 100.

Then after approval is obtained, it will be 10 years later, so three years later, the current drug price is calculated on the premise of 133 people as you mentioned. However, if safety or efficacy can be firmly demonstrated during this period, the target patients will expand, and it will become a treatment method used by more patients. We aim for that.

However, based on current data, please understand that it will be around this level.

Hashiguchi [M]: Yes, thank you very much. That's all from me.

Maruyama [M]: Mr. Hashiguchi, thank you very much. As those are all the questions, we will end the Q&A session with analysts and investors. Thank you very much.

Now, the following will be a Q&A session for the press, so analysts and investors may leave. Thank you.

Thank you for your patience. We would like to move on to the Q&A session for the press. The Q&A session will end at around 4:30 PM.

First, if those participating at the Tokyo head office have any questions, please raise your hand. A staff member will bring a microphone.

Then, let’s start with the person in front who was the fastest.

Innami [Q]: I am Innami from Toyo Keizai. Thank you for today. I have two questions to confirm regarding the figures.

On page 11 of the materials, there is the increase or decrease in core operating profit. It says that the sales milestone for ORGOVYX for this period will be about JPY51 billion when converted to JPY. Combined with that, the figure for the increase or decrease in deferred revenue is 307. What does this refer to? It might have already come out, but please explain again.

Kimura [A]: Regarding deferred revenue, for example, if you look at page 12, it says deferred revenue at the bottom. When we contracted with Pfizer, we received about JPY50 billion as a one-time payment. In terms of accounting, we have the cash, but it is to be recorded little by little over the contract period. So, we were recording about JPY8.8 billion annually.

The period for deferred recording ends this December, so JPY8.8 billion last year will decrease to JPY6.5 billion this year, and it will become zero from next year onwards. Please understand that this decreased amount is included as the increase or decrease in deferred revenue.

Nakagawa [A]: Also, since we received a USD100 million milestone in FY2025, compared with FY2025, the current figure of 300 is after subtracting that amount.

Innami [Q]: Thank you. Also, it might be a bit early, but for this period, in comparison with the previous period, there is the disappearance of the gain on the transfer of the Asia business and this milestone part. When considering the results for FY2027, if there is any thinking that serves as a premise for your forecast, please introduce or guide us within the range of what is known.

Kimura [A]: Yes. What can be said now is that first, the basis will be the further growth of ORGOVYX, GEMTESA, and existing products. If we have a partnership in oncology, which was discussed in several questions earlier, if that enters in 2027, there is a possibility that a figure like some kind of upfront will come in.

Also, for ORGOVYX, I cannot mention the amount or timing, but such sales milestones are still set. We are thinking of increasing sales so that those will also come in some year. Those are the major points.

Innami [M]: Thank you. That is all from me.

Maruyama [M]: Ms. Innami, thank you very much. Then, the person next to you who was fast, please.

Yoshimizu [Q]: I am Yoshimizu from Iyakukeizai. I have two questions. First, since you have some financial leeway now, I think you might be considering introductions. Please tell us about your thinking on that.

Kimura [A]: Yes. It is as you said, that compared to before, things have become much more solid, or rather, the situation has become normal. Currently, products in oncology and regenerative medicine are close to being launched or are facing a temporary launch under conditional and time limited approval. We want to concentrate on finishing those firmly.

Eventually, like any pharmaceutical company, we will consider reinforcing our pipeline through introductions or partnerships. But for now, we want to concentrate on finishing our own products firmly.

Yoshimizu [Q]: I understand. If you were to reinforce the pipeline, would it be in the same field, or would it be something completely unrelated? What would be your thinking for introductions?

Kimura [A]: At present, we are not thinking specifically at all, but the most logical partner for introduction would be one where there is some kind of synergy, such as being able to utilize our development capabilities or sales capabilities and system. Again, we are not thinking specifically now, and I just stated our basic thinking.

Yoshimizu [Q]: I understand. Second, you mentioned JPY2 billion and JPY2 billion for Iran related costs earlier. For example, Kyorin this morning mentioned that packaging would become more expensive and talked about various things. What areas do you expect will increase the most?

Kimura [A]: We have received requests from various suppliers to raise prices, including for fuel costs. But we do not think it will be anything major, so we included it just in case. We do not expect it to exceed that at all now.

Yoshimizu [M]: I understand. That is all from me.

Maruyama [M]: Yoshimizu, thank you very much. Then, the man in the jacket in the first row, please go ahead.

Hagiwara [Q]: I am Hagiwara from MBS. Questions have come out several times earlier, but regarding AMCHEPRY, I believe it was approved at the meeting of the advisory body of the Ministry of Health, Labour and Welfare today. Could you give us your frank reaction to AMCHEPRY being the first product using iPS cells to be covered by insurance in the world? Also, how do you expect it to be used by patients and society in the future?

Kimura [A]: Thank you. Regarding AMCHEPRY, in the sense that it has now become possible to sell it in earnest with the drug price and insurance listing, as you know, iPS cell technology is a unique Japanese technology discovered by Professor Yamanaka of Kyoto University.

With government subsidies, and in reaching this point, we have consulted with university professors, various companies, and government officials. I feel that we have finally reached this point. However, as was discussed

at the Central Social Insurance Medical Council today, there has not yet been an example of moving from conditional and time limited approval to full approval.

So, we believe it is our responsibility to firmly conduct this Phase IV and move to full approval, while at the same time demonstrating efficacy and safety more firmly. We are happy, but to be honest, we are also tightening our resolve.

Maruyama [M]: Mr. Hagiwara, thank you very much. Then, the person with glasses in the first row of the back row, please go ahead.

Goto [Q]: I am Goto from Asahi Shimbun. It is about AMCHEPRY. In your past press conferences, Dr. Kimura, you have also said that you hope for a high drug price, given that it is a breakthrough treatment.

Considering recent US drug price policies, what did you frankly think about this drug price? Also, since you use existing iPS cells that have been stockpiled and the clinical trials were physician led, I have an image that the burden on the Company for development costs is quite small. Despite that, it is quite expensive. Could you tell us again the reason why it is expensive?

Kimura [A]: Yes. Regarding the drug price itself, we are actually incurring very high costs. Along with recovering past investments, running costs are very high. In that context, we had been asking for a higher drug price.

However, due to various circumstances, the drug price announced today has been set. In that sense, it is a bit regrettable for us. But as a manufacturer, once a target value is decided, it is our strength and responsibility to finish it in a form that generates profit. With this target value decided, we intend to finish it into a business that can generate profit firmly.

On the other hand, there were various discussions, including whether to set a drug price during a conditional and time limited approval. We are relieved that a drug price was clearly presented and that it will be listed for insurance.

Regarding the US and other countries in the future, I think the Japanese drug price will become a kind of standard or a sense of the market. We want to make efforts so that we can sufficiently get by with that.

I am very grateful that a drug price was set today.

I am sorry, I forgot one thing. Although it was a physician led clinical trial conducted at Kyoto University, for the clinical trial conducted at Kyoto University, we provided what is now AMCHEPRY at our own cost. I cannot say in detail, but we pay for the Kyoto University clinical trial costs as consideration for using the data.

Please understand that development costs were by no means zero because public funds were used, and at the corporate level, development costs were firmly incurred.

Goto [Q]: Thank you. When you say it is a bit regrettable, do you mean that if you were to be greedy, you wanted an even higher drug price?

Kimura [A]: It is not about being greedy, but based on the current cost structure, it is clearly a deficit. We tried to explain that and get understanding, but the Ministry of Health, Labour and Welfare was strict, and it became the current price.

Maruyama [M]: Mr. Goto, thank you very much. Then, the person right at the back, please go ahead.

Sakata [Q]: Thank you. I am Sakata from Yakuji Nippo.

I would also like to ask about AMCHEPRY. Regarding the post marketing clinical trial, Phase IV, there has indeed been no case that reached full approval. Regarding the implementation plan for this trial, the facilities, the number, the number of cases, evaluation items, and so on, you have made a plan. Is this a plan that you have discussed with the PMDA and reached an agreement that if you produce results with this, efficacy can be firmly confirmed rather than just estimated?

Kimura [A]: Yes. We believe that if we implement the current plan, we can firmly explain the efficacy and safety. The Ministry of Health, Labour and Welfare and PMDA have said that if such data comes out, they will grant full approval. However, in an environment where the number of facilities and patients increase, whether we can actually produce such data is something we are confident about, but if there is any laxity, a clinical trial will not go well. So, we want to proceed firmly. Ms. Sato, do you have anything to add?

Sato [A]: Thank you. As Dr. Kimura said, in the screening process, we spent a lot of time consulting with the PMDA about what kind of efficacy would be needed to confirm it, and we formulated the plan. We will work hard to obtain the planned trial results.

Sakata [M]: Thank you.

Maruyama [M]: Mr. Sakata, thank you very much. Then, the person in front, please go ahead.

Kozaki [Q]: I am Kozaki from Kokusai Iyakuhin Joho. Thank you. Some results for the universal influenza vaccine have been reported. I would like President Kimura to explain the feeling and future development, or the schedule.

Kimura [A]: Thank you. First, the results are as I explained, and the data I showed earlier demonstrated the possibility of a vaccine that works against a very wide range of influenza viruses, even mutant viruses that do not exist in the world yet.

As the next step, as shown on page 24, we can conduct Human Infection Studies. This is a study where healthy people are injected with the influenza virus and are infected with influenza. This is difficult to do in Japan, but in Europe, such studies can be conducted under a firm protocol.

We want to conduct that and prove that it can actually prevent infection or reduce severity, as currently we only have data that the antibody titer increased. We want to enter that trial as soon as possible. At the same time, since it is a vaccine, and as you know, vaccines are different from regular medicines, and there are only a limited number of companies that are good at vaccines. We would like to make it widely available through partnership or out licensing.

We have received interest, inquiries, and requests for lectures from specialized institutions overseas, or rather in the US.

Kozaki [Q]: In terms of the schedule, is it still as soon as possible?

Kimura [A]: Yes. As written on page 24, during this fiscal year, we will start the trial I mentioned, which will likely be in Europe. The results will come out relatively quickly. With those results, or if it is a specialist, they can understand the significance just by looking at the data, so we will talk to those who can understand.

We think the results of this Human Infection Studies will be the biggest trigger data.

Kozaki [M]: Thank you very much.

Maruyama [M]: Kozaki, thank you very much. Then, the person at the front, please go ahead.

Takeuchi [Q]: I am Takeuchi from Nikkei. I have two questions. First, regarding the judgment on resuming dividends this fiscal year, you said it was undecided and that you would especially emphasize cash flow. In that context, while there are ORGOVYX milestones and growth of two US products this period, I think there are also increases in R&D expenses and repayment of loans.

In forecasting cash flow for this period, what are the major factors that could cause upside or downside risks?

Kimura [A]: I do not think there are many major factors. Regarding loans, we have reached a level where we will be practically debt free within this fiscal year. Naturally, if revenue drops more than expected due to something we cannot predict now, it will affect cash flow. But currently, the cash flow is very good, and I think operating cash flow will likely exceed JPY100 billion.

Takeuchi [Q]: Was that cash flow including milestones and such?

Kimura [A]: Yes. The milestone for achieving USD1 billion that I explained today is included in that cash flow.

Takeuchi [Q]: Regarding being debt free, does that mean after adding and subtracting including the possession of cash?

Kimura [A]: It is the operating cash flow for this fiscal year. We have already received nearly JPY100 billion in cash through the public offering, but that is separate.

Takeuchi [M]: Thank you.

Sakai [A]: The question was about whether debt will practically become zero, right? That is a concept where it is netted with deposits.

Takeuchi [Q]: Thank you. Second.

Regarding the US MFN policy, at present, I think there is no major impact on your company from the US government design. However, could you tell us what kind of risks you are considering for the future?

Kimura [A]: Yes. We are monitoring and constantly considering this very closely. Dr. Nakagawa is the lead, so he will explain.

Nakagawa [A]: Yes, thank you. Currently, what is coming from the government is about imposing tariffs on pharmaceuticals. I think this is for reasons of US national security. As someone doing business in the US, providing pharmaceuticals stably to US patients is naturally our first objective. In that sense, the intention is the same.

To achieve this, it is not just a matter of making things in the US. We believe we must also stabilize the business by securing stable profits and provide pharmaceuticals to patients stably. In that sense, we are also considering the optimal supply chain.

Regarding tariffs, based on the information out now, considering our current supply chain and the import and export situation this year, we think it will be within a manageable range.

It is impossible to read at this point what further policy changes there might be, so those are not necessarily fully factored into today's figures.

Takeuchi [M]: Thank you.

Maruyama [M]: Ms. Takeuchi, thank you very much. Now, we have two people participating at the venue and online. Let's have questions in order starting from the person in front.

Abe [Q]: I am Abe from Kyodo News. Thank you for today.

I would like to ask about the table on page 21 for AMCHEPRY. Earlier, you mentioned about 100 people until the application for full approval. As shown here, is it the case that until 2029 it will only be patients for the Phase IV trial, and after that you expect to do about 65? Please tell us if you have a range of years.

Kimura [A]: Yes, it is exactly as you said. First, for the 35 transplant administrations until 2029, we want to prioritize the Phase IV patients Since completing those administrations will be the trigger for approval , our first goal is to achieve that as soon as possible.

Once that is over, it will be possible to administer to a slightly wider range of patients outside of clinical trials since it is already approved, so the circle has become a little larger.

Abe [Q]: Thank you. Regarding the number of facilities, is the image that it will be seven facilities until FY2029, and then you will increase them sequentially?

Kimura [A]: That is right. We will definitely proceed with clinical trials at seven facilities until FY2029. After that, the capacity within those seven facilities will naturally increase, and if there are other good facilities besides those, we want to increase them sequentially. But as there is still time until full approval, we want to place more emphasis on proceeding firmly.

Abe [M]: Thank you very much.

Maruyama [M]: Ms. Abe, thank you very much. Then, to the person on the window side of the front row, please go ahead.

Ando [Q]: I am Ando from Nikkei. I would like to ask about AMCHEPRY.

Earlier, you mentioned in your remarks that, at the current NHI price, it is clearly a deficit based on the current cost structure. If the hope was close to 100 million, the price becomes almost half. I cannot quite see how you will cover that by reducing development costs. For example, will you delay capital investment for the future, or is there some clever way?

Kimura [A]: It is not clever, but we have an intended way, which is to proceed with more mechanization and various other things. We have already started work on those, so we want to finish it in a form where we can firmly make a profit and recover investment with the JPY55 million we received under the conditional and time limited approval.

Ando [Q]: I understand. Do you have Plan B prepared for such a possibility, and are you proceeding with that?

Kimura [A]: Well, yes. As a manufacturer, reducing costs was a basic task we had from the beginning. We are constantly making efforts to reduce costs and at the same time reduce lot to lot variation, so we are thinking of achieving it as an extension of that.

Ando [Q]: Thank you. Another point is, in the same regenerative medicine area, could you tell us the progress of the corporate trial for retinal pigment epithelial tears?

Kimura [A]: We have transplanted into the first patient and are firmly observing that patient. Since it is originally a very rare disease and we have set strict entry criteria, we are currently looking for the next suitable patient.

Ando [Q]: About when would that be, the next one?

Kimura [A]: I don't know when it will be, but we have built a network of several large hospitals in Japan and are ready to do it as soon as a patient is found.

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

Maruyama [M]: Ando, thank you very much. Sorry to have kept you waiting. Please go ahead.

Iwase [Q]: Thank you. I am Iwase from the Science Department of Yomiuri Shimbun. Thank you for today. I have two major points.

First, I would like to ask about AMCHEPRY. The drug price for AMCHEPRY was decided today at the Central Social Insurance Medical Council. I would like to ask about future quality control and manufacturing improvements and measures as a product.

If it is iPS derived cells, I think the risk of tumorigenesis is an issue. How will you take measures against the risk of tumorigenesis? I believe there were points in the screening report about looking at tumorigenesis using immunodeficient mice, but how are you taking measures for safety as a product in the future?

Kimura [A]: Yes. The risk of tumorigenesis has been talked about ever since iPS cells were first created. However, one reason that was said was because originally, in the process of making iPS cells, what are commonly called oncogenes were introduced, and it was said that this might lead to new mutations. Currently, they are not made that way, and based on the accumulation of various data, I personally recognize that the risk of canceration remains in people's minds because such words circulated from the beginning.

No such situation has emerged from non-clinical safety trials or from clinical trials so far. We understand that this approval was granted because it is safe.

However, once such an idea has spread widely, it remains a reality. So, we think evidence that such things do not happen will increase as it is used widely in the future We do not expect it at all, but we will monitor patients firmly so that we can take action if anything happens.

Iwase [Q]: Even in the Central Social Insurance Medical Council, in the optimization of use promotion guidelines, there was a point about observing patients for a long time with MRI. Will you conduct patient surveys or inspections to see if there is any canceration in the product itself?

Kimura [A]: Of course, that includes monitoring the entire health condition. To repeat, the risk of canceration was mentioned by some doctors 10 years ago, but now there are almost no people in this field who think about it.

However, it is also true that such ideas remain here and there. In any case, we will monitor the health condition of patients firmly.

Iwase [Q]: Thank you. one last question. Within the range you can answer, could you tell us which the seven medical institutions are?

Kimura [A]: Patient expectations are very high, and the seven facilities are already preparing in various ways. But I would like to refrain from stating which facilities they are. It is at the discretion of each medical institution, and some might announce it when it actually starts. That will be the judgment of the other party.

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

Maruyama [M]: Ms. Iwase, thank you very much. It is the scheduled time, but if time permits, three reporters are waiting online, so I would like to call them in order.

Mr. Ishii from Iyaku Tsushinsha, sorry to have kept you waiting. Please go ahead.

Ishii [Q]: I am Ishii from Iyaku Tsushinsha. I would like to ask in which part you intend to utilize the benefits of strengthening the financial base.

Kimura [A]: Yes, thank you. First, if I were to describe our situation until last month, as a pharmaceutical company, equity was very low. At the same time, for loans, there were loans remaining that banks would not have lent unless Sumitomo Chemical, the parent company, provided debt guarantees. Also, we had issued JPY120 billion in subordinated bonds, but for redeeming subordinated bonds, there was a restriction that it must be done with capital like funds.

Capital like funds meant that even if we earned money through business activities, we could not pay them back. But by the public offering and the refinancing, those two were completely resolved. Also, nearly JPY100 billion in cash has come in. So, in that sense, we were able to significantly strengthen our financial base, and I hope you understand that the situation is completely different from a month ago.

Ishii [Q]: I understand. What is the current amount of interest bearing debt?

Kimura [A]: In terms of the amount of loan debt now, I think the net would be about JPY80 billion, on hand, after the capital increase. Mr. Sakai is looking into it right now.

Ishii [Q]: Is it JPY80 billion?

Sakai [A]: The balance of loans at the end of the period is JPY217.2 billion, but there is a fair amount of cash and deposits, so practically it is about JPY170 billion in net interest bearing debt. Since we raised JPY98 billion, I think you can consider the current net loan balance as that portion subtracted.

Ishii [Q]: Thank you. Can I understand that this will practically become zero debt within this fiscal year?

Kimura [A]: Yes. It does not mean that the loans will practically disappear, but I hope you understand that net cash will practically become positive.

Ishii [M]: Yes, thank you very much.

Maruyama [M]: Mr. Ishii, thank you very much. Now I will call the remaining two people.

Ms. Tsubokura from The Chemical Daily. Thank you for your patience.

Tsubokura [Q]: I am Tsubokura from The Chemical Daily. I have two questions. First, you have factored in JPY12 billion for capital investment and investment and loans this period. What kind of investment is needed for the production quality control system and such described in the materials?

Also, you mentioned that you have started working on the automation of AMCHEPRY manufacturing. Will investments related to the development of manufacturing methods for multiple patients per lot scheduled for the next three years or so also be included in this JPY12 billion?

Kimura [A]: Yes. As you know, our regenerative medicine is in the form of a joint venture with Sumitomo Chemical. Production is handled by S-RACMO and R&D by RACTHERA, both joint ventures. They use money for various capital investments and to proceed with R&D. Sumitomo Pharma, SMP, invests in or lends money to them. We show this in the form of capital investment and investment and loans.

Within this JPY12 billion for this fiscal year, improvements to the AMCHEPRY production method and reinforcement of production facilities that I mentioned earlier are included.

On the other hand, for existing pharmaceutical factories, we also have things like promoting digitization and updating equipment. For this fiscal year, we plan for a little over JPY6 billion in capital investment for SMP itself.

Tsubokura [Q]: I understand. So, you are thinking about half and half for Sumitomo Pharma and the regenerative cell medicine business?

Kimura [A]: Roughly speaking, the current plan is half for investment and loans to S-RACMO and RACTHERA, and half for capital investment for Pharma itself.

Tsubokura [Q]: I understand, thank you. One more point. Could you give us any comments on the progress of the US clinical trial for dopamine neural progenitor cells, or the plan for FY2026?

Kimura [A]: In the US, which has the most patients and is a market for pharmaceuticals almost 10 times that of Japan, we are proceeding with clinical trials aiming for early launch.

There is no major milestone this year, so we are proceeding. How about that?

Tsubokura [Q]: I understand. So, I can understand that patient enrollment and such are progressing smoothly?

Kimura [A]: Personally, I want to accelerate it further, and with that desire to accelerate, I think it is still insufficient.

Tsubokura [M]: I understand. Thank you very much. That is all from me.

Maruyama [M]: Ms. Tsubokura, thank you very much. Now, Ms. Nakata from Yomiuri Shimbun, thank you for your patience. Please go ahead.

Nakata [Q]: I am Nakata from Yomiuri Shimbun. This might be related to the previous question. I think AMCHEPRY manufacturing will be handled at the regenerative cell medicine manufacturing plant in Suita City, Osaka. Also, shares were issued in April and JPY10 billion is to be allocated to RACTHERA and S-RACMO by the end of March 2029. Is this with a view to reinforcing the cell production line at the facility? Also, if you have specific plans for what kind of manufacturing system you aim for and by when, please tell us.

Kimura [A]: Regarding the second question, as shown in the diagram earlier, we received approval this time on the basis of moving to full approval within the seven year period. During that period, we will enroll patients very strictly. But at the same time, we expect approval in the US at almost the same timing. So, we are proceeding with reinforcing the production scale around 2027 to 2028 so that more patients can receive transplants at that time. We are also thinking of further increasing the production scale in the early 2030s.

The JPY10 billion plus we are thinking of now will be allocated to both R&D expenses and equipment investment. Sumitomo Chemical is also now putting even more money than us into the regenerative cell medicine business. So as a group, we will proceed together. Please understand that we are not proceeding with just this amount.

Nakata [M]: Thank you.

Maruyama [M]: Ms. Nakata, thank you very much. We have exceeded the scheduled time by 10 minutes but thank you very much to all of you for participating. Since there are no other questions, we will end the Q&A session.

With that, we will end the Sumitomo Pharma FY2025 financial results briefing.

Thank you very much for participating today.

[END]