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Sumitomo Pharma Co., Ltd.

Q2 Financial Results Briefing for FY2026

October 30, 2026

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
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[Event Type]	Earnings Announcement
[Event Name]	Q2 Financial Results Briefing for FY2026
[Date]	October 30, 2026
[Time]	16:00 – 17:33 (Total: 93 minutes, Presentation: 29 minutes, Q&A: 64 minutes)
[Venue]	Webcast
[Number of Speakers]	6

Toru Kimura	Representative Director, President and CEO
Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Global Finance Administration External Affairs; Corporate Governance; Corporate Communications; IT Management & Data Analytics
Tsutomu Nakagawa	Member, Board of Directors, Managing Executive Officer North America Business President and CEO, Sumitomo Pharma America, Inc.
Yumi Sato	Managing Executive Officer Vaccines and Adjuvants Business Development, 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
Megumi Maruyama	Vice President, Head of Corporate

		Communications
[Analyst Names]	Kazuaki Hashiguchi	Daiwa Securities
	Seiji Wakao	JPMorgan Securities
	Jaeheon Lee	Morgan Stanley MUFG Securities
	Hiroshi Wada	SMBC Nikko Securities

Presentation

Maruyama: It's now time to begin Sumitomo Pharma Co., Ltd.’s Q2 financial results briefing for FY2026. Thank you very much for your participation in our meeting today.

I am Maruyama from Corporate Communications Department, and I will be your moderator.

Today’s event will be held in a hybrid format, at our Tokyo headquarters and via Zoom webinar, for analysts, investors, and members of the media. Analysts and investors are participating online, while members of the media are participating either in person or online.

We will begin with an explanation of the Company in accordance with the presentation materials posted on our website, followed by a question-and-answer session. The event is scheduled to end at 17:40.

First, let me introduce today's attendees.

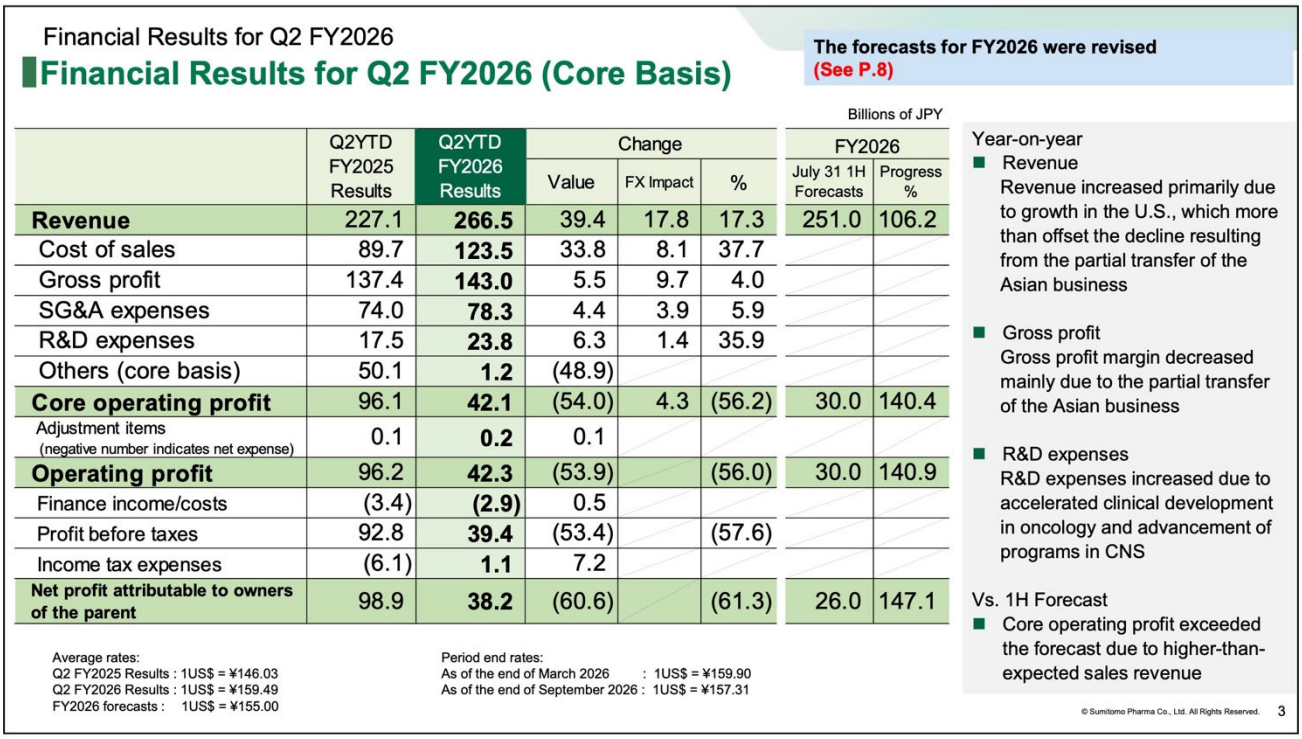
Kimura, Representative Director, President and CEO; Sakai, Representative Director, Executive Vice President; Nakagawa, Member, Board of Directors, Managing Executive Officer; Sato, Managing Executive Officer; and Wakemi, Executive Officer, and that is all. Thank you very much.

Kimura will begin his presentation on the financial results for Q2 of FY2026 and the current status of the clinical development.

Dr. Kimura, please go ahead.

Kimura: Thank you very much for your participation in our Q2 financial results meeting today.

Let me begin my presentation on the financial results for Q2 of FY2026.



Financial Results for Q2 FY2026

Financial Results for Q2 FY2026 (Core Basis)

The forecasts for FY2026 were revised
(See P.8)

Billions of JPY

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change			FY2026	
			Value	FX Impact	%	July 31 1H Forecasts	Progress %
Revenue	227.1	**266.5**	39.4	17.8	17.3	251.0	106.2
Cost of sales	89.7	**123.5**	33.8	8.1	37.7		
Gross profit	137.4	**143.0**	5.5	9.7	4.0		
SG&A expenses	74.0	**78.3**	4.4	3.9	5.9		
R&D expenses	17.5	**23.8**	6.3	1.4	35.9		
Others (core basis)	50.1	**1.2**	(48.9)				
Core operating profit	96.1	**42.1**	(54.0)	4.3	(56.2)	30.0	140.4
Adjustment items (negative number indicates net expense)	0.1	**0.2**	0.1				
Operating profit	96.2	**42.3**	(53.9)		(56.0)	30.0	140.9
Finance income/costs	(3.4)	**(2.9)**	0.5				
Profit before taxes	92.8	**39.4**	(53.4)		(57.6)		
Income tax expenses	(6.1)	**1.1**	7.2				
Net profit attributable to owners of the parent	98.9	**38.2**	(60.6)		(61.3)	26.0	147.1

Year-on-year
- Revenue
  Revenue increased primarily due to growth in the U.S., which more than offset the decline resulting from the partial transfer of the Asian business
- Gross profit
  Gross profit margin decreased mainly due to the partial transfer of the Asian business
- R&D expenses
  R&D expenses increased due to accelerated clinical development in oncology and advancement of programs in CNS

Vs. 1H Forecast
- Core operating profit exceeded the forecast due to higher-than-expected sales revenue

Average rates:
Q2 FY2025 Results : 1US$ = ¥146.03
Q2 FY2026 Results : 1US$ = ¥159.49
FY2026 forecasts : 1US$ = ¥155.00

Period end rates:
As of the end of March 2026 : 1US$ = ¥159.90
As of the end of September 2026 : 1US$ = ¥157.31

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This is the overview of our financial results.

Here are our Q2 financial results on a core basis.

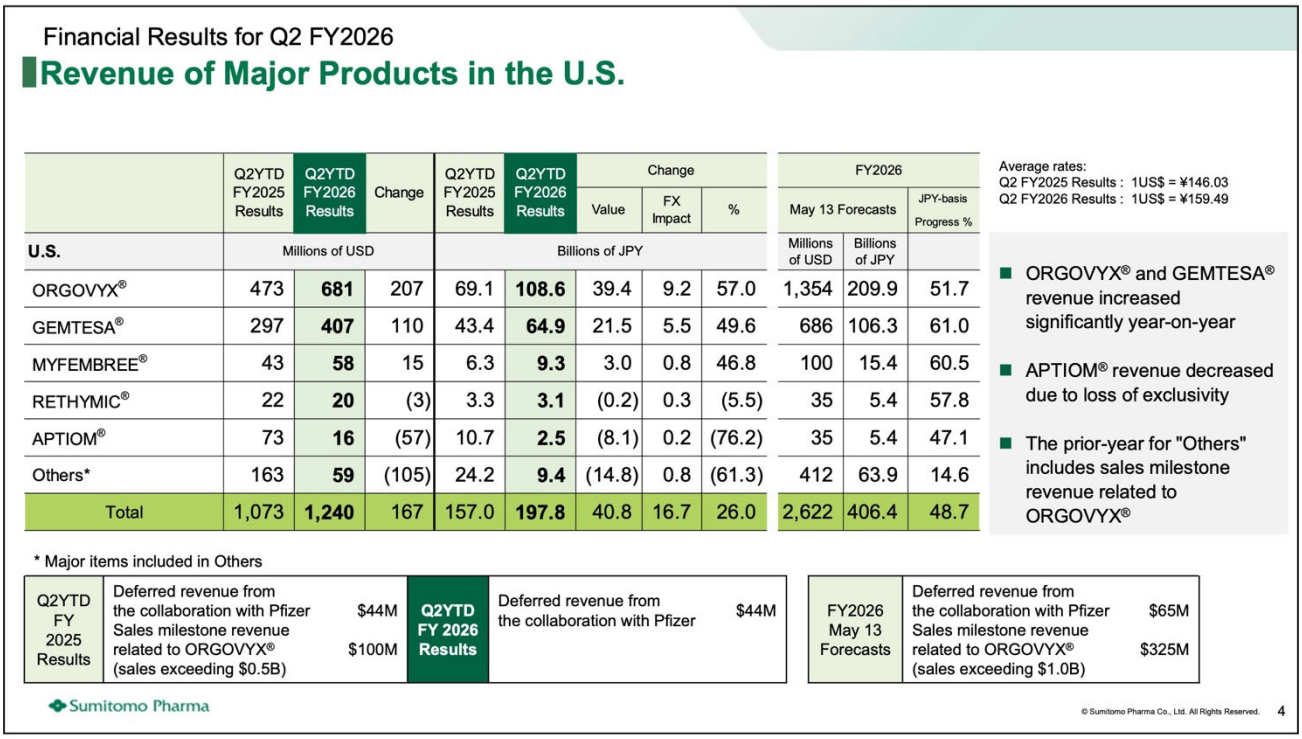
As you can see, revenue totaled JPY266.5 billion, and core operating profit was JPY42.1 billion.

Although we have shown the difference here compared to the previous fiscal year, as you know, our China and Asia operations were included in the first half of last year, which makes a direct comparison difficult. Therefore, I will not explain the figures directly in comparison to last year; instead, please consider this in terms of the difference from the forecast for Q2 of this fiscal year, which we announced on July 31.

We had forecast sales of JPY251 billion, but they actually came in at JPY266.5 billion. As for core operating profit, the actual figure was JPY42.1 billion, compared to a forecast of JPY30 billion, meaning it exceeded expectations by more than 40%. Similarly, operating profit and profit before taxes both exceeded our forecasts by more than 40%; we have already disclosed these results in our timely disclosure announcement.

One point of concern compared with last fiscal year is that Other core profits decreased by JPY48.9 billion. However, as I mentioned at the beginning, this is because we divested our China and Asia operations in August of last year. Since we had included that capital gain of JPY49 billion in last year's figure, the difference arose this year.

Let me explain more specifically in the next slide.



Financial Results for Q2 FY2026

Revenue of Major Products in the U.S.

U.S.	Q2YTD FY2025 Results (Millions of USD)	Q2YTD FY2026 Results (Millions of USD)	Change (Millions of USD)	Q2YTD FY2025 Results (Billions of JPY)	Q2YTD FY2026 Results (Billions of JPY)	Change Value (Billions of JPY)	Change FX Impact (Billions of JPY)	Change %	FY2026 May 13 Forecasts Millions of USD	FY2026 May 13 Forecasts Billions of JPY	JPY-basis Progress %
ORGOVYX®	473	**681**	207	69.1	**108.6**	39.4	9.2	57.0	1,354	209.9	51.7
GEMTESA®	297	**407**	110	43.4	**64.9**	21.5	5.5	49.6	686	106.3	61.0
MYFEMBREE®	43	**58**	15	6.3	**9.3**	3.0	0.8	46.8	100	15.4	60.5
RETHYMIC®	22	**20**	(3)	3.3	**3.1**	(0.2)	0.3	(5.5)	35	5.4	57.8
APTIOM®	73	**16**	(57)	10.7	**2.5**	(8.1)	0.2	(76.2)	35	5.4	47.1
Others*	163	**59**	(105)	24.2	**9.4**	(14.8)	0.8	(61.3)	412	63.9	14.6
Total	1,073	**1,240**	167	157.0	**197.8**	40.8	16.7	26.0	2,622	406.4	48.7

Average rates:
Q2 FY2025 Results : 1US$ = ¥146.03
Q2 FY2026 Results : 1US$ = ¥159.49

- ORGOVYX® and GEMTESA® revenue increased significantly year-on-year
- APTIOM® revenue decreased due to loss of exclusivity
- The prior-year for "Others" includes sales milestone revenue related to ORGOVYX®

* Major items included in Others

Q2YTD FY 2025 Results	Deferred revenue from the collaboration with Pfizer	$44M	**Q2YTD FY 2026 Results**	Deferred revenue from the collaboration with Pfizer	$44M
	Sales milestone revenue related to ORGOVYX® (sales exceeding $0.5B)	$100M			

FY2026 May 13 Forecasts	Deferred revenue from the collaboration with Pfizer	$65M
	Sales milestone revenue related to ORGOVYX® (sales exceeding $1.0B)	$325M

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First, here is a breakdown of our revenue of major products in the United States.

If you look at the section in the middle labeled yen, the total is JPY197.8 billion, which represents an increase of JPY40.8 billion compared to the previous fiscal year, though there is a slight impact from exchange rate fluctuations.

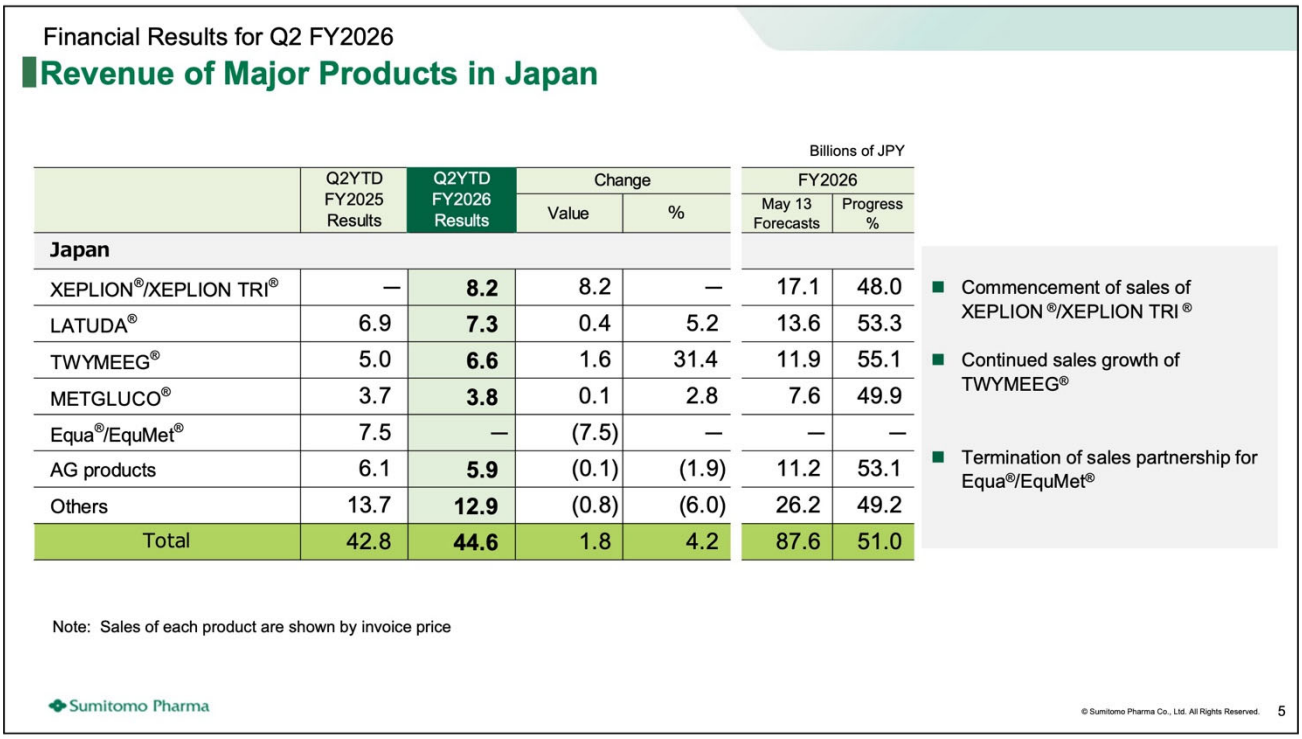
Looking at each product individually, ORGOVYX, GEMTESA, and MYFEMBREE, each has seen an increase of around 50% compared to the previous fiscal year.

On the other hand, while sales of the product APTIOM have declined significantly this year due to the LOE, the growth of the three products I mentioned earlier has offset that decline, resulting in an overall increase.

Here, too, there is a decrease of approximately JPY15 billion in the other category; this is because last fiscal year included a USD100 million sales milestone revenue related to ORGOVYX, whereas this year there is no such payment. However, even taking that into account, the result was a significant increase in sales.

Looking at our overall progress for this fiscal year, GEMTESA and MYFEMBREE have performed particularly well, with more than 60% of our annual revenue forecast having been achieved in H1. Details will be explained later.

In addition, while progress in other has been slow, we are projecting USD325 million for sales milestone revenue related to ORGOVYX this year upon exceeding the USD1 billion sales. Although we have not yet conducted a detailed analysis, we anticipate reaching this sales target shortly.



Financial Results for Q2 FY2026

Revenue of Major Products in Japan

Billions of JPY

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change		FY2026	
			Value	%	May 13 Forecasts	Progress %
Japan						
XEPLION®/XEPLION TRI®	—	**8.2**	8.2	—	17.1	48.0
LATUDA®	6.9	**7.3**	0.4	5.2	13.6	53.3
TWYMEEG®	5.0	**6.6**	1.6	31.4	11.9	55.1
METGLUCO®	3.7	**3.8**	0.1	2.8	7.6	49.9
Equa®/EquMet®	7.5	—	(7.5)	—	—	—
AG products	6.1	**5.9**	(0.1)	(1.9)	11.2	53.1
Others	13.7	**12.9**	(0.8)	(6.0)	26.2	49.2
Total	42.8	**44.6**	1.8	4.2	87.6	51.0

- Commencement of sales of XEPLION®/XEPLION TRI®
- Continued sales growth of TWYMEEG®
- Termination of sales partnership for Equa®/EquMet®

Note: Sales of each product are shown by invoice price

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The next slide shows the results in Japan, on the other hand. Japan's total is JPY44.6 billion, which represents an increase of JPY1.8 billion compared to the previous fiscal year.

In Japan, the product called Equa/EquMet is no longer available as of this year. We replaced them with new products such as XEPLION/XEPLION TRI, TWYMEEG, and other products.

As you know, in Japan, there are drug price revisions. In our case, while we are affected by this fiscal year's JPY2.8 billion drug price revision, assuming half of that amount occurred in H1 of the fiscal year, we believe that, even factoring that in, the JPY44.6 billion figure is sufficient to offset the impact.

Financial Results for Q2 FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
Q2YTD FY2026 Results	Revenue	44.6	197.8	24.1	266.5
	Cost of sales	25.0	78.1	20.4	123.5
	Gross profit	19.6	119.7	3.6	143.0
Q2YTD FY2025 Results	Revenue	42.8	157.0	27.3	227.1
	Cost of sales	21.9	56.9	10.9	89.7
	Gross profit	21.0	100.1	16.3	137.4
Change	Revenue	1.8	40.8	(3.2)	39.4
	Cost of sales	3.1	21.2	9.5	33.8
	Gross profit	(1.3)	19.5	(12.7)	5.5

Japan
- Gross profit decreased due to the change in product mix

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

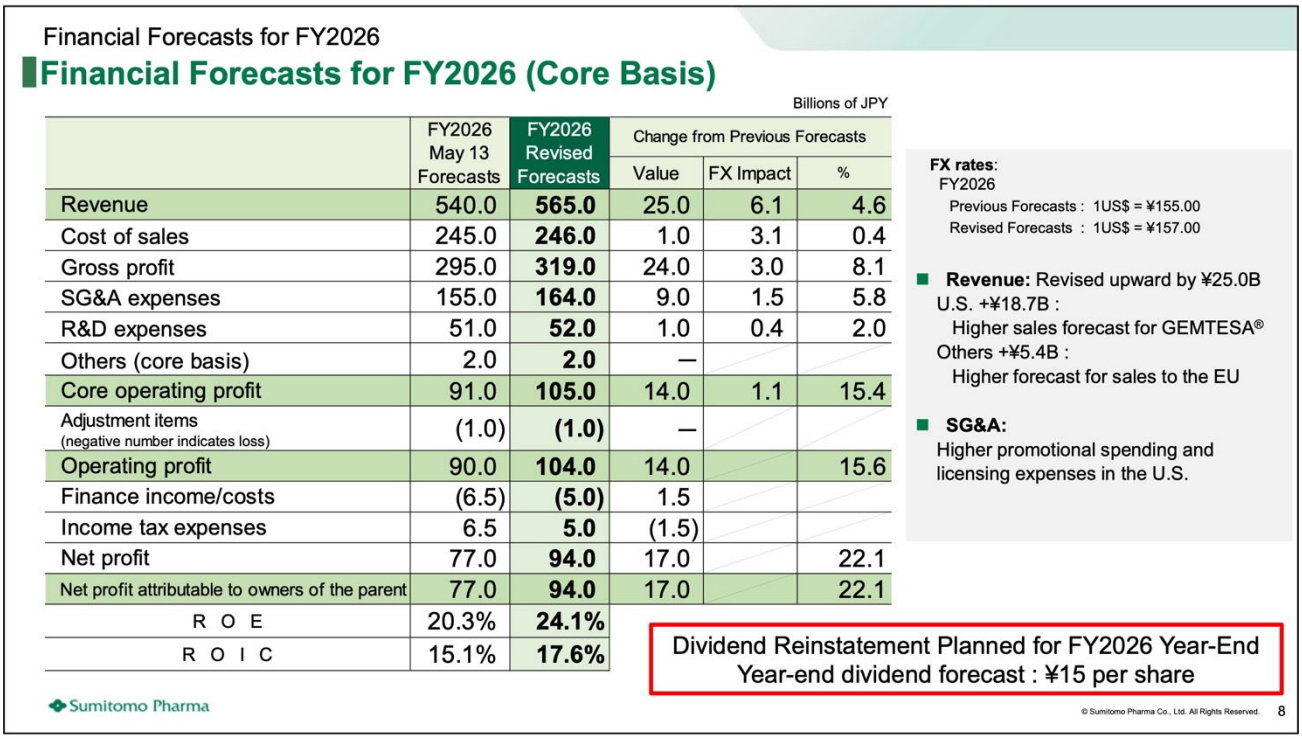
Other
- Gross profit decreased due to the partial transfer of the Asian business

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Although we have consolidated the segments into a single segment starting this fiscal year, we have presented the data in this format so that you can see our activities broken down by region.

In the US, revenue totaled JPY197.8 billion, with gross profit amounting to JPY119.7 billion. If you compare these figures with the overall picture, you'll see that more than 80% of sales and three-quarters of revenue come from the US, indicating that the shift toward the US market has accelerated further.



In light of our strong business performance, we have also revised our earnings forecast for the end of FY2026.

We forecast revenue of JPY565 billion, gross profit of JPY319 billion, core operating profit of JPY105 billion, and net profit of JPY94 billion.

While there is a discrepancy here compared to previous forecasts, we are revising our revenue upward by JPY25 billion and our core operating profit upward by JPY14 billion.

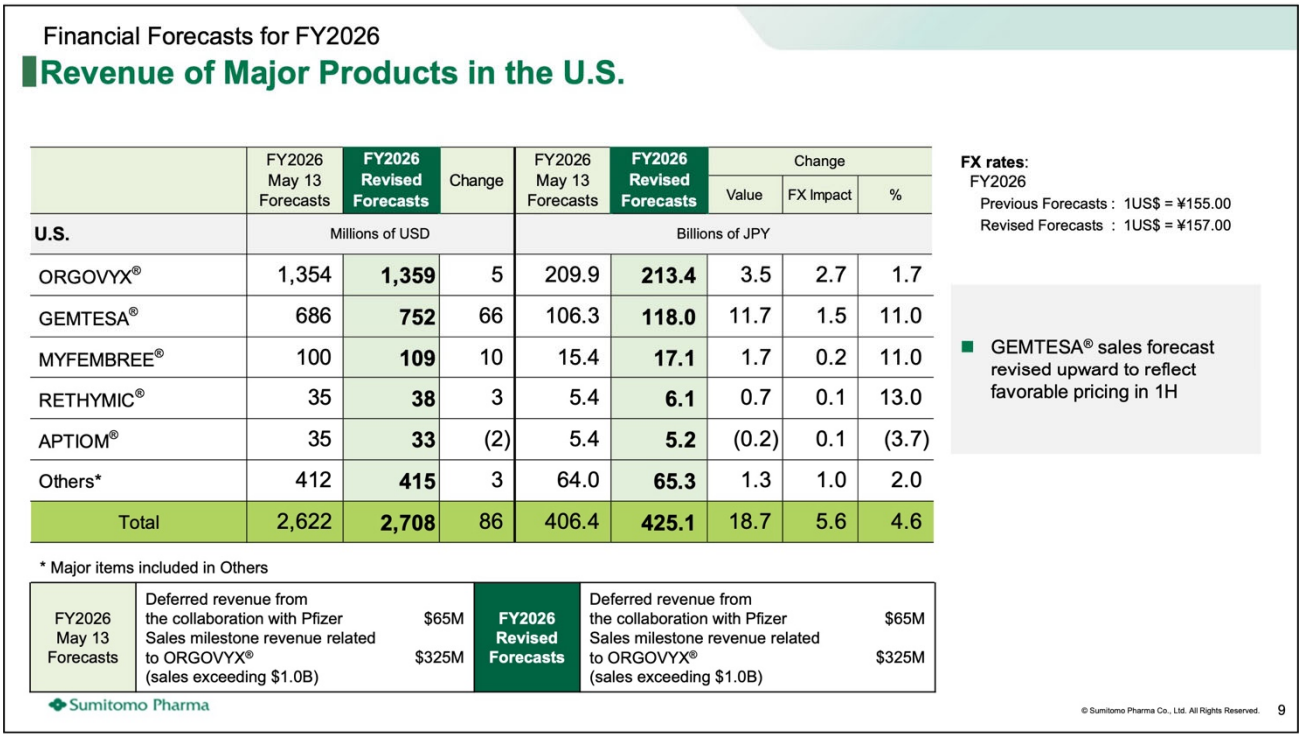
Specifically regarding sales, as I explained earlier, our three products in the US are performing exceptionally well. As for cost of sales, we had originally estimated that various costs would rise by approximately JPY4 billion due to tariffs and the situation in the Middle East. However, since various countermeasures are currently being implemented, we expect to limit this increase to JPY1 billion or less, which is another factor contributing to this upward revision.

One more point, in terms of the figure, JPY565 billion, although this is a forecast, if we can achieve this, it will mark our company's highest-ever revenue.

Core operating profit was JPY105 billion; last year, we reported that it had reached a record high of just over JPY105 billion, but that figure included JPY49 billion in gains from the sale of our China and Asia operations, the gain on sales of our own businesses. This year, we expect to generate profits at roughly the same level without those gains.

Finally, while we are sorry that we have been unable to pay dividends for some time now, we intend to resume dividend payments with the year-end dividend for FY2026.

We are projecting a dividend of JPY15 per share. In the past, when our company paid dividends, the highest annual dividend was JPY28. Taking that amount into account, we are projecting a dividend of JPY15 for this half-year.



Financial Forecasts for FY2026

Revenue of Major Products in the U.S.

	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change		
						Value	FX Impact	%
U.S.	Millions of USD			Billions of JPY				
ORGOVYX®	1,354	**1,359**	5	209.9	**213.4**	3.5	2.7	1.7
GEMTESA®	686	**752**	66	106.3	**118.0**	11.7	1.5	11.0
MYFEMBREE®	100	**109**	10	15.4	**17.1**	1.7	0.2	11.0
RETHYMIC®	35	**38**	3	5.4	**6.1**	0.7	0.1	13.0
APTIOM®	35	**33**	(2)	5.4	**5.2**	(0.2)	0.1	(3.7)
Others*	412	**415**	3	64.0	**65.3**	1.3	1.0	2.0
Total	2,622	**2,708**	86	406.4	**425.1**	18.7	5.6	4.6

FX rates:
FY2026
Previous Forecasts : 1US$ = ¥155.00
Revised Forecasts : 1US$ = ¥157.00

- GEMTESA® sales forecast revised upward to reflect favorable pricing in 1H

* Major items included in Others

FY2026 May 13 Forecasts	Deferred revenue from the collaboration with Pfizer	$65M	FY2026 Revised Forecasts	Deferred revenue from the collaboration with Pfizer	$65M
	Sales milestone revenue related to ORGOVYX® (sales exceeding $1.0B)	$325M		Sales milestone revenue related to ORGOVYX® (sales exceeding $1.0B)	$325M

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This slide shows the US revenue figures based on the new financial forecast here.

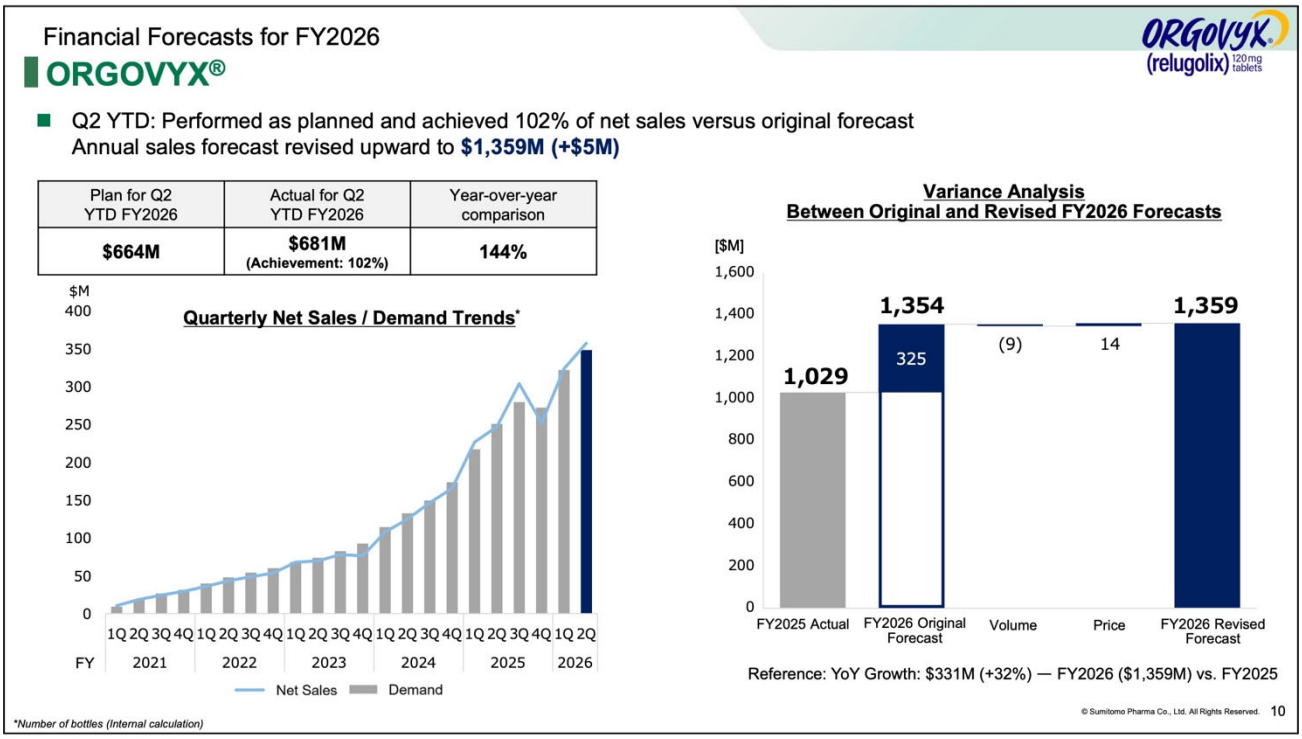
While our initial forecast was JPY406.4 billion, the revised forecast stands at JPY425.1 billion, representing an increase of nearly JPY19 billion.

On the other hand, while many products are seeing upward revisions, the most significant one is GEMTESA. GEMTESA performed exceptionally well in H1 of the fiscal year, and the full-year forecast has been revised accordingly.

Since we have already captured most of this in H1, we believe an increase of nearly JPY12 billion is certain; however, this does not mean that the current momentum will continue unchanged. In H1, prices were higher because many non-formulary patients used our products, and we also reversed the allowance for sales returns through a minor accounting adjustment, which contributed to the significant increase. As I'll explain later, things are generally going very well.

Another factor is the exchange rate trends; based on current exchange rates, our revised forecast anticipates a JPY2 depreciation of the yen, so that exchange rate impact is also factored in to some extent.

As I mentioned earlier, regarding the milestone of exceeding USD1 billion, USD325 million, we are confident that we will almost certainly achieve this milestone.

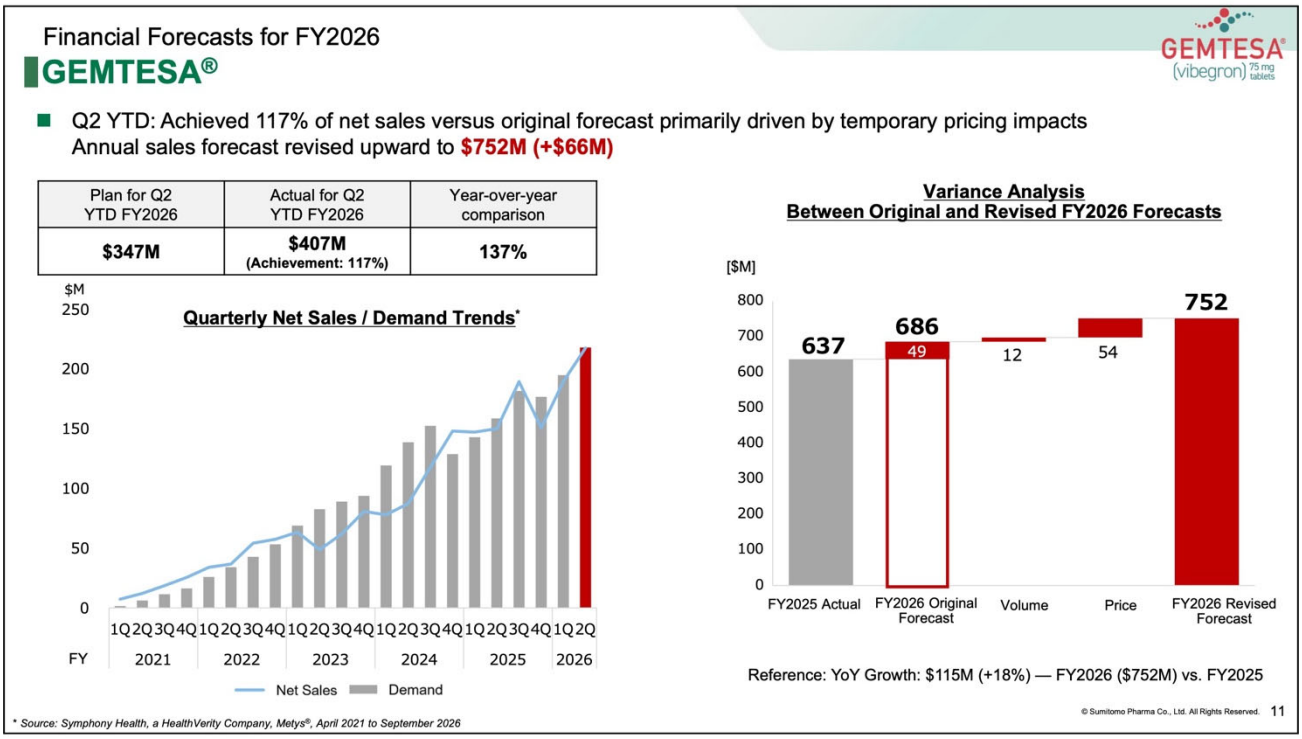


In the next two slides or so, I'll explain the status of ORGOVYX and GEMTESA in a little more detail.

First, in Q2 of this fiscal year, ORGOVYX achieved revenue of USD681 million, representing 102% of its budget. This represents a 44% increase compared to the same period last year, and a 44% increase in US dollar terms.

This graph shows both sales revenue and sales volume. As you can see, while there are slight fluctuations from period to period, overall, sales are performing very well, and an increasing number of patients are receiving treatment with ORGOVYX.

Looking at this in a bit more detail, there are separate effects from volume and price per unit, but both volume and price are trending as we expected. This means that the merits of ORGOVYX are gradually becoming more widely recognized.



Next, GEMTESA.

In Q2 of FY2026, we performed exceptionally well, with a 17% increase over budget, a 117% achievement rate, and a 137% increase compared to the previous fiscal year.

As you can see here, the overall trend shows that both volume and sales are growing at a very rapid pace.

However, if we look at this quarter in a little more detail, breaking it down into volume and price, we can see that much of this increase is due to price. Volume is growing as expected, but prices are rising more than we had anticipated.

The reason for this is, as I explained earlier, that there were more patients than expected who were either non-formulary patients or patients who, although they lacked insurance coverage, were willing to pay high prices for their medications, and thus required fewer rebates, and there are accounting-related factors. This was influenced by the reversal of the allowance for returns, as well as the fact that rebates were lower last fiscal year, which had a positive impact on prices.

However, as anticipated, more patients are beginning to use GEMTESA, and this positive trend contines.

Financial Forecasts for FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
FY2026 Revised Forecasts	Revenue	88.5	425.1	51.4	565.0
	Cost of sales	50.7	152.3	43.0	246.0
	Gross profit	37.8	272.8	8.4	319.0
FY2026 May 13 Forecasts	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
Change	Revenue	0.9	18.7	5.4	25.0
	Cost of sales	(1.4)	(0.4)	2.8	1.0
	Gross profit	2.3	19.1	2.6	24.0

Japan
- Higher gross profit driven by upward revisions to TWYMEEG® sales forecast, with a limited increase in cost of sales

U.S.
- Higher gross profit mainly driven by pricing-driven revenue upside in 1H

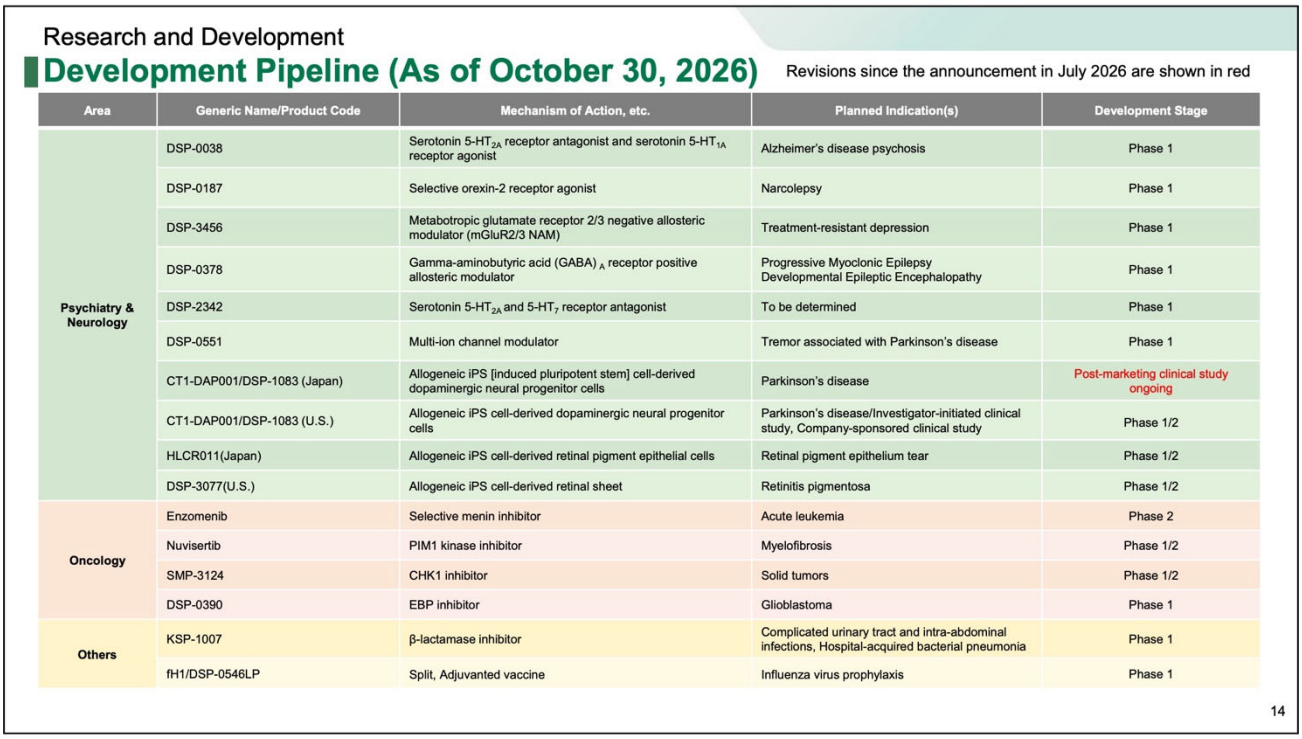
Other
- Higher gross profit reflecting stronger sales to Europe

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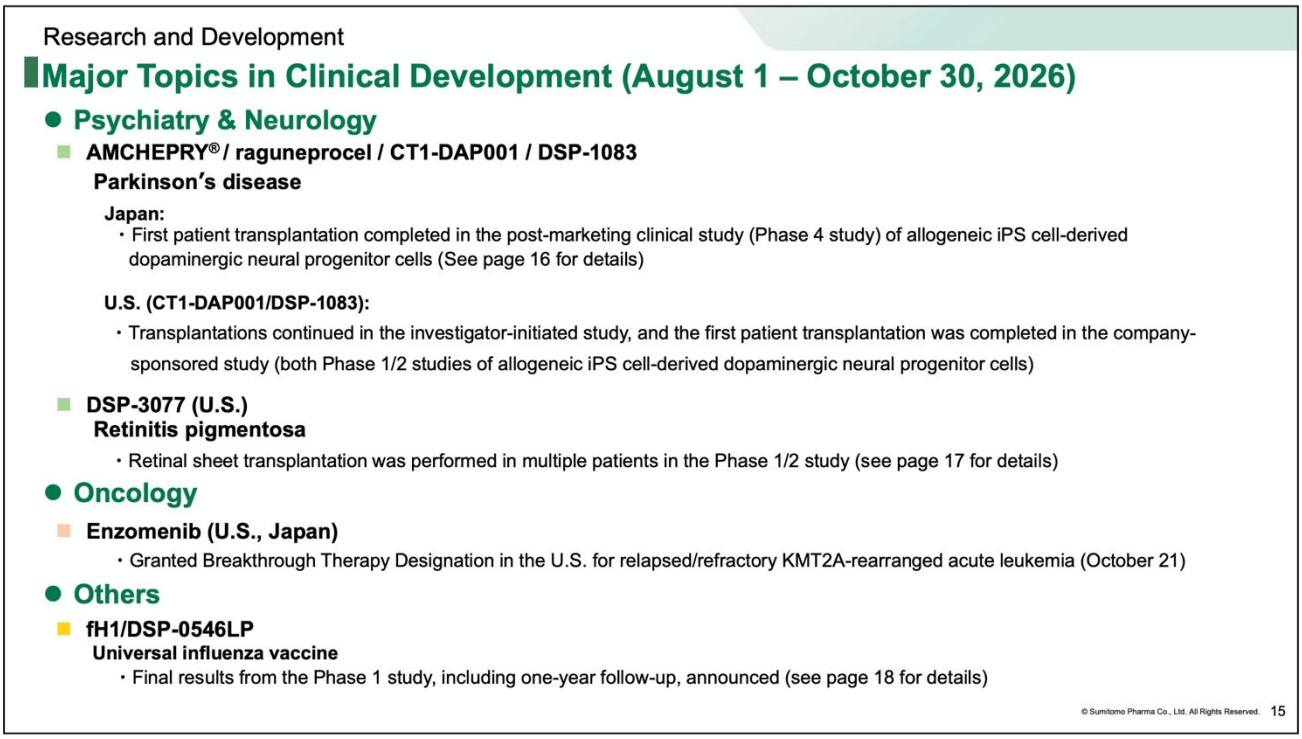
We have also revised our sales and gross profit forecasts by region.

As shown here, we have revised both revenue and gross profit upward compared to our initial forecasts.



Next, I would like to explain the current status of the research and development.

This is our development pipeline. The item marked in red has been updated to show that we are currently conducting post-marketing clinical trial for AMCHEPRY, an iPS cell-based product.



This shows the major topics in clinical development in text form.

I'll explain AMCHEPRY in a bit more detail in the next slide, but the transplantation for the first patient has been completed.

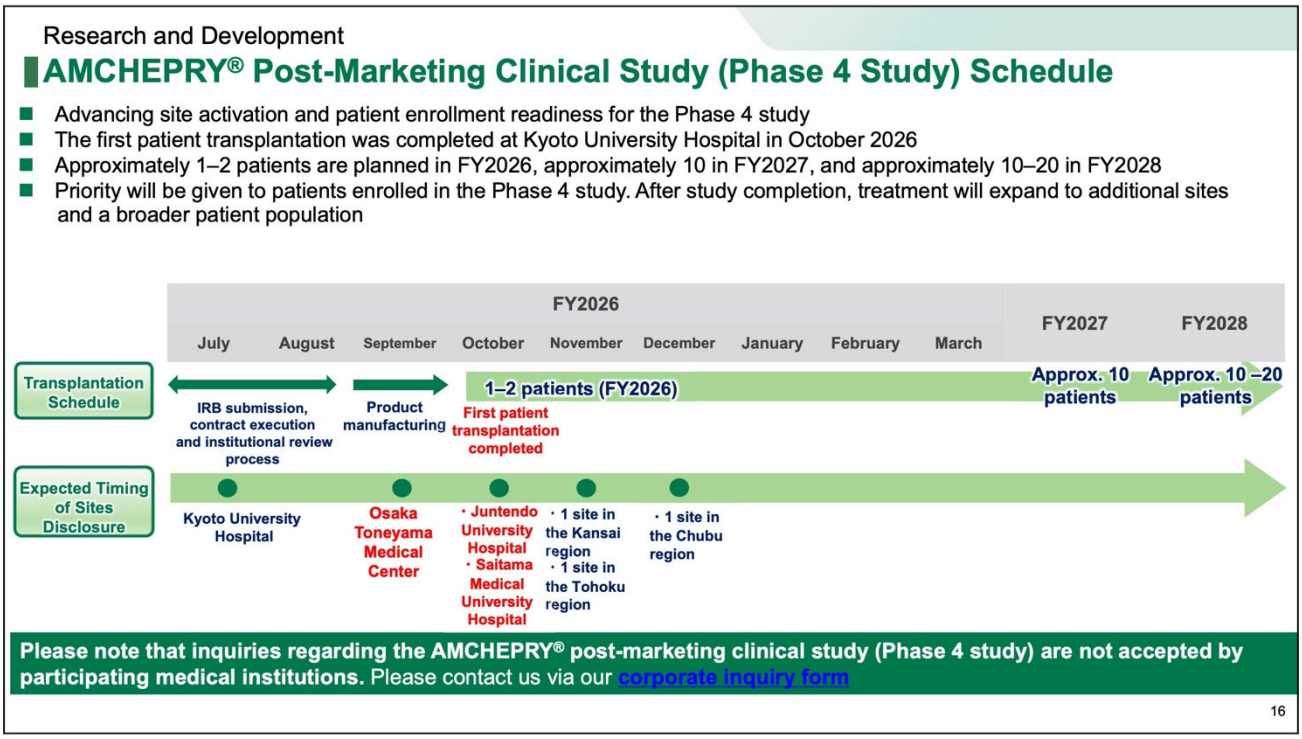
In addition, in the United States, transplants are proceeding in the investigator-initiated study, and the first transplantation in a company-sponsored study has also been completed.

In addition, regarding 3077, another iPS cell-based product intended for the treatment of retinitis pigmentosa, a clinical study is currently underway in the United States, and we are pleased to report that transplantations have already been completed in several participants.

Additionally, in the field of oncology an area where we are focusing our efforts, one notable development is that enzomenib has received Breakthrough Therapy Designation for patients with relapsed or refractory KMT2A-rearranged acute leukemia.

This means that we presented this information, including unpublished data, to US authorities, who recognized it as a breakthrough compared to existing treatments. Since information related to this topic is under embargo in advance of a major US medical conference scheduled for December, I am unable to disclose details at this time; however, I hope you will understand the significance of this from a qualitative perspective, given that the Breakthrough Therapy Designation has been granted. This means that we have been accumulating good data just as we had expected.

I will also explain the universal influenza vaccine on a separate slide.



This is about AMCHEPRY.

Following approval on March 6 and the completion of the drug pricing listing process, we have been proceeding with preparations for Phase IV post-marketing study. First, I would like to report that preparations have been completed at Kyoto University. Following that, four clinical trial sites have already opened: the Toneyama Medical Center in Osaka, and, just recently in the Kanto region, the Juntendo University Hospital and the Saitama Medical University Hospital. Progress is going smoothly, and if everything goes as planned, one additional facility each in the Kansai, Tohoku, and Chubu regions will open shortly, meaning that all of the study sites we plan to open this year will be up and running by the end of the year.

As I explained earlier, the transplantation for our first patient has been completed; the patient has been discharged from the hospital and has already returned to work. We have confirmed that clinical course is progressing very smoothly. It is a female patient in her 50s.

We have already launched numerous sites, and we are currently working toward performing one more transplantation before the end of the year. We plan to continue building up our case history over the next two fiscal years.

Also, regarding various inquiries, there is a link on our website; if you check it out, you'll find who the specialists are and what kinds of patients are eligible for treatment.

Research and Development

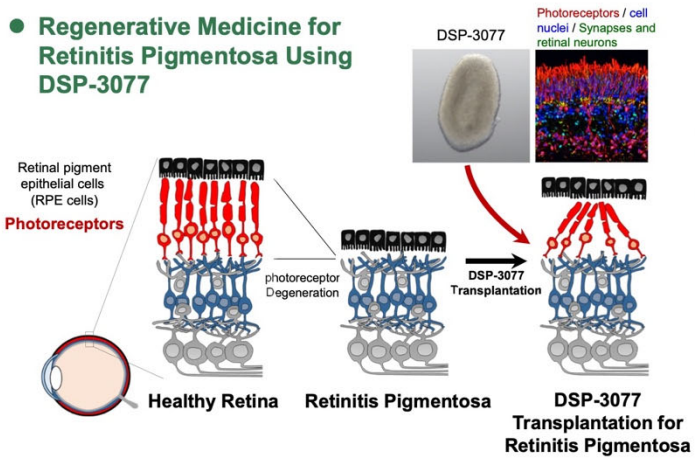
Psychiatry & Neurology: Allogeneic iPS Cell-Derived Retinal Sheet (DSP-3077) for Retinitis Pigmentosa

- ✓ **Retinal sheet transplantation was performed in multiple patients in the U.S. Phase 1/2 study**
- ✓ **The Q2 FY2026 milestone was achieved, and the clinical study is progressing as planned**

About DSP-3077

- ✓ A retinal sheet derived from allogeneic iPS cells **containing abundant photoreceptor precursor cells**
- ✓ Single subretinal transplantation into the eye with poorer visual acuity

Regenerative Medicine for Retinitis Pigmentosa Using DSP-3077



Overview of U.S. Phase 1/2 Study (NCT06891885)

Target disease	Retinitis pigmentosa
Study design (target enrollment)	Open-label, single-arm, dose-escalation study; untreated fellow eye as control (12 patients)
Primary endpoint	Safety and tolerability
Secondary endpoints	Engraftment, efficacy, and others

Cohort	Patients	Visual acuity**	Dose***
Cohort 1	4 patients	HM* to approx. 0.05	Low dose
Cohort 2	4 patients	HM* to approx. 0.05	High dose
Cohort 3	4 patients	Approx. 0.05 – 0.1	High dose

* HM(hand motion) : visual acuity sufficient to distinguish the direction of hand movement.
** Visual acuity: best-corrected visual acuity assessed using the ETDRS chart. Study-eye eligibility thresholds are hand motion, ETDRS 20 letters (approx. 0.05), and ETDRS 35 letters (approx. 0.1).
*** Low dose: 0.8–2.4 mm²; high dose: 2.4–6.4 mm²

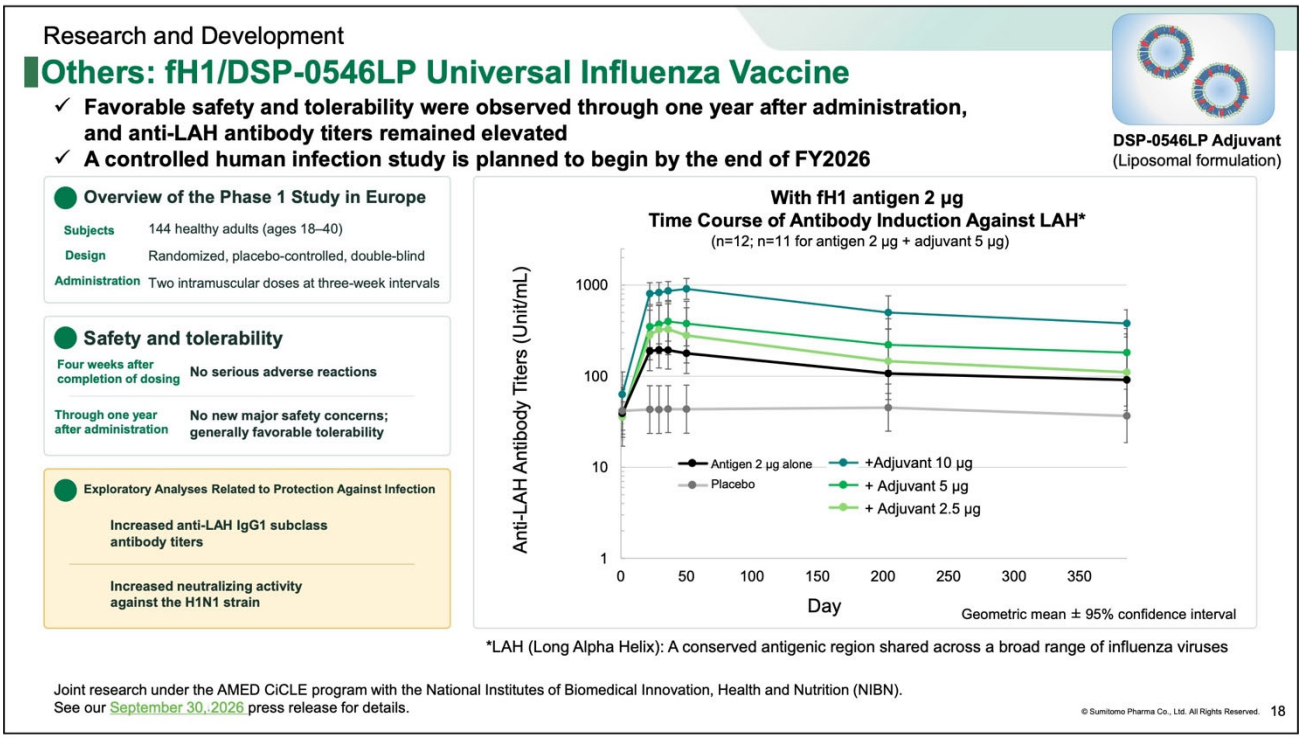
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The other product is 3077; a retinal sheet product also derived from iPS cells.

It might be a little hard to understand, but please think of this as a 3D cross-section of the eyeball, with the lens over here and the skull on this side. This is surrounded by a tissue called the retina. This diagram shows a slightly enlarged view of the retina, which contains photoreceptor cells, bipolar cells, and ganglion cells, through which the visual signals are transmitted to the brain. In the eye, this side is the inner surface and this side is the outer surface. Retinitis pigmentosa is a disease in which the photoreceptor cells that detect light in that area degenerate and die off, ultimately leading to blindness.

For this disease, clinical studies are currently underway based on the idea that transplanting three-dimensional retinal tissue created from iPS cells in a laboratory, this is an actual photograph, might restore vision.

There are three cohorts, and we have just begun conducting the clinical trial primarily with patients who have very severe vision loss, specifically, those classified as having “hand motion, or HM” which refers to a level where they can barely perceive the movement of a hand right in front of their eyes. To reiterate, we have already completed transplantations for several patients.

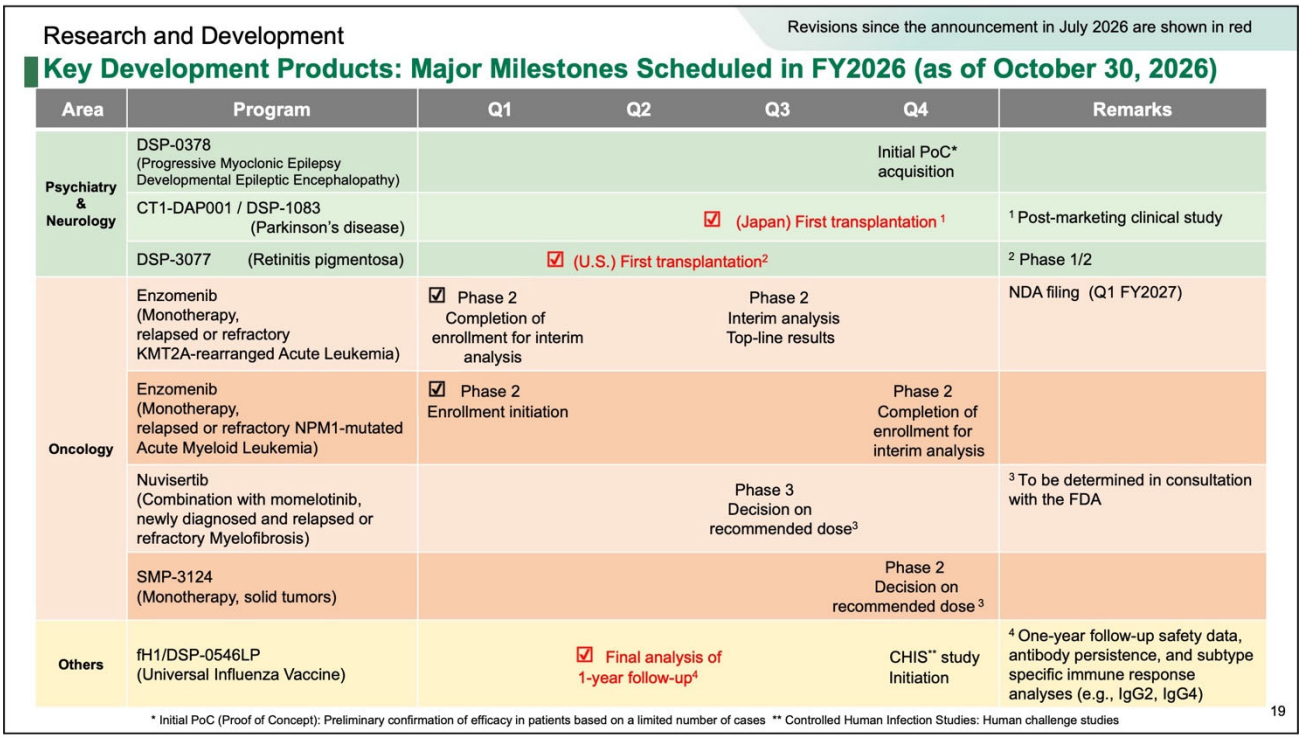


Next, I'd like to provide an update on the universal influenza vaccine, which we typically discuss at times like this.

It is well known that the influenza vaccine becomes ineffective whenever a new strain of the influenza virus emerges; however, since this is a universal vaccine, we are currently testing one that responds to a very wide range of viral strains.

In our previous financial results announcement, we demonstrated that vaccination using this method with an antigen from the H1 influenza virus also elicited a response against the H5 avian influenza virus. This time, we examined the extent to which the induced antigen was mimicked in the study participants. As you can see, this indicates that a significant amount of that antibody remained even after one year, and since no major side effects were observed even one year later, we were able to confirm good tolerability.

In addition, regarding new findings: while the type of antibodies produced is crucial in an immune response, we are very pleased to report that the antibodies produced were primarily of the IgG1 subclass, which is considered the most important for combating infections by viruses and bacteria like these. Furthermore, we have also confirmed that these antibodies possess strong neutralizing activity against the H1N1 virus. Therefore, we are currently making preparations to begin human infection trials, if possible, before the end of this fiscal year.



Research and Development

Revisions since the announcement in July 2026 are shown in red

Key Development Products: Major Milestones Scheduled in FY2026 (as of October 30, 2026)

Area	Program	Q1	Q2	Q3	Q4	Remarks
Psychiatry & Neurology	DSP-0378 (Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy)				Initial PoC* acquisition	
	CT1-DAP001 / DSP-1083 (Parkinson's disease)			☑ (Japan) First transplantation [1]		[1] Post-marketing clinical study
	DSP-3077 (Retinitis pigmentosa)		☑ (U.S.) First transplantation[2]			[2] 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[3]		[3] To be determined in consultation with the FDA
	SMP-3124 (Monotherapy, solid tumors)				Phase 2 Decision on recommended dose [3]	
Others	fH1/DSP-0546LP (Universal Influenza Vaccine)		☑ Final analysis of 1-year follow-up[4]		CHIS** study Initiation	[4] One-year follow-up safety data, antibody persistence, and subtype specific immune response analyses (e.g., IgG2, IgG4)

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

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I believe this will likely be the last one, but we have outlined the major R&D events and milestones we are planning for FY2026.

As planned, we have achieved all the milestones that were scheduled to be completed by this time. It seems we're running a little ahead of schedule.

This fiscal year, we plan to present the interim analysis of enzomenib and KMT2, as well as the results for NPM1 and the combination of nuvisertib with momelotinib, at academic conferences as soon as the data are compiled.

Thank you very much. That's all from me.

Maruyama: Thank you very much for your presentation.

Question & Answer

Maruyama [M]: We will now move to the question-and-answer period for analysts and investors.

Due to time constraints, we ask that each person limit their questions to two. We appreciate your cooperation. The question-and-answer session will end at 17:10.

Continuing on, Mr. Wakao of JPMorgan Securities, please go ahead.

Wakao [Q]: Thank you very much. I'm Wakao from JPMorgan. Thank you very much for your presentation.

First, please tell me about enzomenib. In President Kimura's explanation earlier, he mentioned that there's an embargo in place at an academic conference and that some promising data has been released, so I'd like you to clarify those points again. Also, I believe you were originally planning to present at ASH, and I think the abstracts for the general sessions will be posted online next week on November 4, I believe. In that case, will anything related to the results of this study come up there?

Kimura [A]: Thank you very much for your question.

Due to the embargo, we cannot provide any specific details at this time, including whether the findings will be presented orally or as a poster, but we are currently making preparations to announce the results of our latest clinical study. The abstract will be released next week, so I think you'll be able to learn a little more about the specifics then.

Ms. Sato, do you have anything else to add?

Sato [A]: No, I don't. Since ASH is in early December, I think the actual announcement will be made then. We hope you will wait until then.

Wakao [Q]: I see.

In that case, since there was originally the possibility of presenting the data at ASH once it was compiled, and if it wasn't ready in time for that, I believe there had also been talk of releasing one or two sets of data in the meantime, so am I correct in understanding that you're saying all the data might not be available by the time the abstracts are released?

Kimura [A]: I'm Kimura.

The follow-up period is six months, and while I believe it's still a bit too early to compile data covering the entire six months, we anticipate being able to summarize as much data as possible up to a certain number of months. However, since ASH requires a review process for presentations, and decisions regarding whether a presentation will be an oral or a poster presentation are generally made only after the embargo is lifted, we'll have to wait until then. Sorry for that. Please wait for a week.

Wakao [Q]: Yes.

Also, when you said that you are accumulating good data, does that mean, since it's an open-label study, you've been reviewing the data and have found that it's turning out to be good?

Kimura [A]: While I'm certainly not observing this myself, there are situations where it can be observed even under blind conditions, or where there is data that can be presented to the authorities; taking all of that into account, my understanding is that things are proceeding smoothly.

Wakao [Q]: I see. Sorry for being long.

As a second point, regarding enzomenib and nuvisertib, I believe there was talk of a partnership once the dosages were determined. Based on your explanation just now, it seems enzomenib is in a very good position, but is my understanding correct that, if things proceed smoothly with both drugs, discussions will move toward a partnership?

Kimura [A]: Yes, we're looking into opportunities for a partnership. However, as we have mentioned before, this does not mean we will simply outsource everything. As I just explained, we have built up our capacity, and we now have a system in place that allows us to conduct clinical studies very thoroughly. Therefore, we intend to carefully consider what approach would be best for us.

Wakao [Q]: Thank you very much.

While it's certainly very appealing to structure things so that you can secure 100% of the profits in the future, I do wonder, for example, whether it would actually be feasible for you to handle both in-house, given your current P&L situation. So, even if you were to choose an option other than a partnership, I've been wondering whether it would actually be possible to develop both in-house. What are your thoughts on that? Given the gap between what your company wants to do and your current resources, I think there may be some things you simply can't do.

Kimura [A]: I would like to consider this comprehensively, taking into account our resources, including personnel and budget. As you pointed out, it is true that we are not a company that sells major products related to cancer, so we will make our decision with that fact fully in mind. After all, this is a matter that involves another party. Thank you very much.

Wakao [Q]: Since the original plan was to aim for partnerships on both fronts by H1 of next year, is it correct to understand that these details will become clearer as you move through H1?

Kimura [A]: Yes. As for the KMT2A schedule, we expect the final results of the interim analysis to be available around the start of the new year. In that case, we'll need to proceed immediately with the application or establish the necessary sales infrastructure. As we move forward with full-scale development and commercialization, we'll need to take a comprehensive look at how much of our own resources, and those of our potential partners, we can allocate to this effort.

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

Maruyama [M]: Mr. Wakao, thank you very much.

Mr. Wada of SMBC Nikko Securities, please go ahead.

Wada [Q]: I'm Wada from SMBC Nikko Securities. Thank you very much.

I would like to ask about the revision to the earnings forecast. I have a question regarding the forecasts for your two flagship products, ORGOVYX and GEMTESA, if they are a bit too conservative? For example, regarding ORGOVYX, the Q2 results came in at USD681 million. If you double that figure for the full year, it would likely come to USD1,360 million. In other words, the forecast calls for a decline in one of the quarters of H2 of the fiscal year. Could you explain your thinking on this point and what assumptions you've made?

Kimura [A]: I'll explain the basic concept behind how these figures are calculated, and then Nakagawa, who handles US affairs, will provide some additional details.

Our basic policy is that when setting targets, we aim to set figures that are neither overly ambitious nor overly conservative, but rather, targets that we are confident we can achieve. As a result, we are often told that our targets are not ambitious enough, but we hope you will understand that this is our policy. Now, Dr. Nakagawa, please provide a brief supplement.

Nakagawa [A]: Regarding your question, from our perspective, while it's true that sales, or rather, sales volume, for both GEMTESA and ORGOVYX are gradually leveling off year over year, there's no change in the fact that we're still in a phase of steady growth.

However, when it comes to whether sales remain at the same pace throughout the year, there are some circumstances unique to the US. Specifically, from January through March, which is Q1 on the calendar but the last quarter of the fiscal year. Since this is when insurance policies are reset in the US, it tends to be the quarter with the slowest sales growth in our fiscal year; consequently, growth in H2 is inevitably weaker than in H1.

Also, regarding the specific situation for next year, as so-called IRA implementation began several years ago, since we are certified as a "small manufacturer," the discount rate is set to increase slightly each year. We're offering a certain discount this fiscal year as well, but starting in January, on the calendar, that is, starting next January, the discount rate will increase even further. For these reasons, sales tend to be a little slower from January through March.

Given that, as you just asked, H2 might be roughly on par with H1, but it does involve the factors I just mentioned.

Wada [Q]: Thank you very much.

Next question is about GEMTESA. You've increased SG&A expenses this time, raising the full-year earnings forecast by about JPY9 billion, and you've written it for expanded promotional investments in the US. However, I recall that during the previous meeting, you mentioned that GEMTESA's performance was marketing-sensitive, suggesting that sales might increase if you ramp up sales efforts. Could you please explain how you view this balance between GEMTESA's sales and costs?

Kimura [A]: This is Kimura. I'll give a basic overview of this, and I think Nakagawa will provide the specific details.

Just as you said, in the case of GEMTESA, we consider it a marketing-sensitive issue. We recognize that this is a product that can be improved if we invest the necessary resources. However, when it comes to determining the most efficient course of action, we're asking our field teams to develop sales strategies while carefully considering the specific measures and expected returns. Dr. Nakagawa, would you like to say something?

Nakagawa [A]: Thank you very much. Nakagawa will give you the follow-up comment.

Not all of the JPY9 billion you just asked about is allocated to GEMTESA's promotional activities, it's only a portion of that amount. However, as Kimura mentioned, overactive bladder, or OAB, is a condition that also affects the QOL, and there are patients who, even though they experience certain symptoms, may not realize they have the condition and simply put up with it.

Taking all of that into account, and of course, even for patients who are already undergoing treatment, I believe there is room for us to continue our educational efforts in various ways to highlight how our product differentiates itself from competitors' products and medications with different mechanisms of action.

However, we take a very critical look at what kind of return we can expect from that investment. We've actually been working on this since H1 of this year, but what we're focusing our efforts on right now is what we sometimes refer to as DTC, that is, television commercials. However, rather than airing on a very common, standard channel, what you might call DTC, we're running our GEMTESA ads on cable TV, where the viewership is more defined and targeted. We believe this approach holds great promise, so we've launched it as a trial.

Of course, there are various other initiatives we're working on as well, but as I just mentioned, we're proceeding in stages while carefully considering the return on investment and monitoring progress as needed.

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

Kimura [A]: This is Kimura.

First, as I thought Nakagawa would mention, there is a one-time factor in H2 of the fiscal year. We are scheduled to pay the originator as the sales milestone. That is included in SG&A expenses. Because business is going so well, those kinds of expenses are also coming up.

Wada [Q]: Regarding the increase in license-related costs, that's what's listed on page eight, isn't it**?**

Kimura [A]: Yes, that is included in there.

Wada [M]: I see. Thank you very much. That is all.

Maruyama [M]: Mr. Wada, thank you very much.

Continuing on, Mr. Lee of Morgan Stanley MUFG Securities, please go ahead.

Lee [Q]: I'm Lee of Morgan Stanley.

Regarding Mr. Wada's question just now, the part about the revised guidance. I understand the figures for Japan and the US quite well, but as for the others sales figures, which have been revised upward from JPY46 billion to JPY51.4 billion, I think this item has become somewhat of a black box since the disclosure policy changed this year. I understand that the factors behind this upward revision specifically include overseas exports of Meropen, as well as MYFEMBREE, GEMTESA, and ORGOVYX for the EU market. Could you please first explain the background behind this upward revision?

Kimura [A]: As you just mentioned, the others category includes the total sales figures for markets outside Japan. Sakai will provide a detailed explanation about 54.

Sakai [A]: Thank you very much for your question.

This others category includes sales from the US to Europe, and the strong performance of those sales is the main factor behind the upward revision.

Lee [Q]: Thank you very much.

You mentioned that things are going well, is it correct to understand that this is sustainable?

Sakai [A]: Yes. Since it has been gradually increasing recently, we currently believe this trend will continue.

Lee [Q]: Thank you very much.

Given that the Company has just announced the resumption of dividends, you may be asking us to wait until the mid-term plan is released to understand its future strategy; however, given that cash flow has improved and the equity ratio has reached 50%, I believe some market participants are expecting things like progressive dividends. While I certainly don't anticipate a dividend cut, could you, Dr. Kimura, please elaborate on the Company's dividend policy, including the timing of the mid-term plan announcement? Thank you very much.

Kimura [A]: Thank you very much.

While it goes without saying that avoiding a dividend cut is our top priority, as you just mentioned, we plan to explain the criteria we will use to determine future dividends when we announce our medium-term plan, as part of our dividend policy going forward.

As for the timing of the medium-term plan announcement, we are currently working toward releasing it within this fiscal year if possible, though there is a possibility it may be slightly delayed. However, our target is to achieve this within the current fiscal year, preferably by March; or rather, to be specific, we are working toward a March deadline.

Lee [Q]: Dr. Kimura, thank you very much.

My second point concerns the outlook for the next fiscal year. I fully understand that you haven't finalized the budget yet and therefore can't comment, but when looking ahead to the next fiscal year, I would appreciate it if you could share any positive or negative factors, even if only in qualitative terms.

For example, ORGOVYX was mentioned earlier in the context of "small manufacturers," and there is also talk that we can expect positive developments in the next fiscal year, such as the Company reaching the third sales milestone. When looking ahead to the next fiscal year, I would appreciate it if you could share any positive or negative factors, even if only in qualitative terms.

Kimura [A]: From my perspective, on the positive side, the current trend is a very good one, so I think it will continue.

On the other hand, the downside is that, as Mr. Wakao mentioned in his question at the beginning, clinical development for cancer, as well as for AMCHEPRY, will be ramping up in earnest. This will inevitably lead to increased costs, including R&D expenses and, once products are sold, SG&A expenses. While I believe this will be a negative factor for our profit and loss, we intend to manage the overall situation by maintaining a balanced approach.

Another milestone of USD325 million was reached this year, and while we're looking forward to the next one, as we've repeatedly stated, we're not yet authorized to disclose the specific trigger conditions or amounts agreed upon with Pfizer, so I'd like to refrain from commenting on that for now.

Lee [Q]: I see.

Finally, let me ask Ms. Sato a question about R&D. This is about enzomenib and nuvisertib. As for enzomenib, it's about the expansion of indications. Looking at ClinicalTrials.gov, it appears that the Phase I trial, which includes MDS and multiple myeloma, concluded at the end of September. Are there any updates on this? I believe there were hints about expanding the scope of indication at Boost 2028 in March, if I recall correctly, so I'd like you to follow up on that.

Sato [A]: Thank you for your question.

We are continuing to gather data on enzomenib, in what we might call a Phase I study, across multiple cancer types. While we're not yet at the stage where we can explain the results themselves, we're moving forward step by step as we explore various possibilities, including MDS.

Lee [Q]: I see. Thank you very much.

Finally, regarding nuvisertib, it was stated that the recommended Phase III dose would be determined in consultation with the FDA by the end of December. Is it correct to assume that this process is proceeding smoothly? Also, there's a major academic conference coming up in December, and I'm expecting we'll be able to review the interim data there as well. What do you think?

Sato [A]: Progress is proceeding as scheduled. While we don't have anything to report as of today, we have stated our goal of determining the dosage for the next phase in Q3, and we expect to proceed as planned.

Lee [Q]: How about ASH? Do you say that we should wait until next week for the next academic conference as well?

Sato [A]: Yes. As Kimura mentioned, the details regarding ASH are currently under review, so we are unable to provide an answer at this time.

Lee [M]: I see. Thank you very much. That is all.

Maruyama [M]: Mr. Lee, thank you very much.

Next, Mr. Hashiguchi of Daiwa Securities, please.

Hashiguchi [Q]: I'm Hashiguchi from Daiwa Securities. Thank you very much.

Regarding the relation between partnerships and the medium-term plan, I would appreciate it if you could summarize what you explained around spring and whether anything has changed since then.

As I understand it, your previous explanation was that you would proceed with formulating the medium-term plan based on the partnership framework once it had been largely finalized. However, if you are aiming for a March deadline, does that mean there is a possibility the plan could be drafted and announced based on a provisional business plan even before the framework has been fully finalized?

Or, as mentioned earlier in this discussion, is it the case that plans, which do not necessarily involve your company collaborating with other companies on both drugs, are now emerging as a strong option, allowing you to make decisions and take action more quickly without having to coordinate with other parties?

Kimura [A]: This is Kimura. Thank you for your question.

First, regarding the relation with the medium-term plan, as I have stated previously, I have not necessarily said that the medium-term plan will be finalized only after the contract with our partner expires. Rather, I have stated that once our partnership strategy becomes clear, we will announce a medium-term plan based on that strategy, and I do not believe this is in significant contradiction with what I explained today.

Also, regarding whether to work with a partner or go it alone, our policy remains unchanged. We will make that decision based on a comprehensive assessment of which option offers the most benefits and the least risk for us.

On the other hand, this means that our financial situation, among other things, has improved significantly compared to last year. With the latest milestone from ORGOVYX now in place, and as profits increase a bit more, I believe our company, which had JPY300 billion in debt two or three years ago, will likely transition to a net cash position, meaning we'll effectively be debt-free, sometime this fiscal year. While our situation has improved in that regard, we initially wondered whether we would even be able to conduct the clinical study itself within our own organizational framework. In the case of enzomenib in particular, there is a lot of competition, so we had been concerned; however, given that we are making very smooth progress with our global clinical studies, we have gained a bit more confidence on our end.

However, as a company that is, in a sense, a newcomer to the field of cancer, our basic policy is to carefully consider what approach is most reliable and will provide the greatest long-term benefits for our company, taking data into account, and to make decisions based on a thorough review of that data.

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

Maruyama [M]: Mr. Hashiguchi, thank you very much.

Now, I'd like to move on to the person who asked the second question.

Mr. Wakao of JPMorgan Securities, please go ahead.

Wakao [Q]: Thank you for the opportunity to ask another question.

Just to confirm, even though I asked the question myself, the interim analysis and top-line results for the Phase II trial of enzomenib are scheduled for Q3. However, according to your earlier explanation, while the six-month data won't be ready in time for ASH, some data will be presented. I believe you mentioned that the data for the six months would be available early next year.

So, since I get the impression that "Top Line Results" refers to data from the first six months, does that mean some kind of data will be presented at ASH, and the final "Top Line Results," whether it was successful or not, will be announced early next year?

Kimura [A]: Mr. Wakao, thank you very much.

Your understanding is right. After a six-month follow-up, the data analysis will be complete, and we expect to have the top-line results, indicating whether we met our targets or not, by the start of the new year.

I believe we previously issued a press release stating that we had reached the number of cases required for the interim analysis; the timeframe we are referring to now is six months from that point, and I hope you will understand that this also includes the analysis of that data.

At ASH, our specific plan is to collect data for a certain number of months, though not quite six months, and we intend to present those findings.

Wakao [M]: I see. Thank you very much. That is all.

Maruyama [M]: Mr. Wakao, thank you very much.

Is there any other question?

Since there are no further questions from analysts or investors, we will now conclude the Q&A session with our investors. The remainder of the session will consist of a question-and-answer period for members of the media, so analysts and investors are welcome to leave at this time.

Thank you for your patience. We will now move to the question-and-answer period for members of the media.

Due to time constraints, we ask that each person limit their questions to two. We appreciate your cooperation. The question-and-answer session will end at 17:40.

First, I would like to ask any members of the media attending at our Tokyo headquarters who have questions to raise their hands. The staff will bring you a microphone. Please state your affiliation and name before asking your question.

The person on the third row on the front wall side, please ask your question.

Maki [Q]: Thank you. I'm Maki from NHK.

I have a question about AMCHEPRY. I would like to ask for the specific date the surgery was performed, as well as whether the patient is a woman in her 50s and where she lives, even just the prefecture would be fine, if you know, and I would also appreciate your thoughts on the surgery having been performed.

Kimura [A]: Please understand that the surgery was performed early October. I'd prefer not to disclose where the patient lives.

We hope you will understand our mindset; our job is to carefully manufacture the product and deliver it to hospitals. However, with the Phase IV trials, the post-approval clinical trials that everyone has been anticipating, finally underway, we find ourselves feeling a renewed sense of determination. We are committed to making a company-wide effort to ensure that the Phase IV trial is completed as soon as possible and that we obtain full approval.

Maruyama [M]: Thank you very much, Ms. Maki.

Is there any other question?

The woman in the middle of the second row, please go ahead.

Takeuchi [Q]: My name is Takeuchi from the Nikkei.

Regarding the resumption of dividend payments, which I believe marks the first time in four fiscal years since the last one, I'd like to ask for your thoughts on how the Company has achieved a V-shaped recovery in its business performance and was able to announce the resumption of dividends at this particular time.

Kimura [A]: I believe this represents a very significant milestone for us as management. As I mentioned briefly, our FY2023 financial results began with a net loss of JPY300 billion.

Furthermore, not only that, but while the restructuring was carried out with support from our parent company and banks, as I mentioned earlier, we will effectively be able to become debt-free within this fiscal year, during that time, we carried out a public offering of nearly JPY100 billion. While our shareholders made significant investments during this period, we were unable to resume dividend payments as expected. However, having just announced very strong financial results, and with the confidence that we can continue to perform solidly going forward, despite some minor fluctuations, we have announced the resumption of dividends. Therefore, I truly feel that this marks a phase in our restructuring where we have, in a sense, finally reached our initial goal. Moving forward, we intend to steadily move forward, step by step, with the goal of developing a new Sumitomo Pharma.

Takeuchi [M]: Thank you very much.

Maruyama [M]: Ms. Takeuchi, thank you very much.

The person in the center of the front row, please go ahead.

Tsubokura [Q]: I'm Tsubokura from The Chemical Daily.

You mentioned that GEMTESA's price rose during this interim period. Could you explain what factors led to its widespread use among patients not covered by insurance, or how you analyze the background behind this trend? Also, could you tell me if this is the kind of situation that might continue in the future?

Kimura [M]: I think it would be best that Nakagawa answers this question, so Dr. Nakagawa, please go ahead.

Nakagawa [A]: Nakagawa will answer the question.

As you probably know, unlike in Japan, in the US, there are annual discussions between us and our insurance providers regarding whether our medications will be included in the formulary or not. Last fiscal year, some payers removed our drug from their formulary, but early this year, there was a major development in which our drug was added back to the formulary.

For that reason, among others, we had anticipated that the number of patients using our drugs through insurance payers would increase. However, contrary to our expectations, the situation where patients continue to use our drugs on a non-insurance basis has persisted. I believe this likely indicates that the unique selling points we have been emphasizing are having a certain degree of success.

However, as payers' coverages take effect, the number of people using these drugs outside of insurance coverage is gradually decreasing. While we aren't actively promoting this, we're simply tracking the results, the percentage has been gradually decreasing, so we expect the trend to level off rather than continue.

However, looking ahead, since negotiations with payers take place almost every year, the outcome will depend on those negotiations; but as far as this fiscal year is concerned, the situation is gradually stabilizing from where it was, as I just mentioned. Therefore, we predict that we will not see any significant price-related benefits in H2.

Tsubokura [Q]: I see. Thank you very much.

One more question. Regarding the cost of sales, you mentioned that while costs were originally projected to increase by about JPY4 billion, you were able to limit the increase to about JPY1 billion by implementing certain measures. Could you explain what specific steps you took to achieve this cost reduction? Could you tell me about it as much as you can?

Kimura [A]: I'm afraid we can't go into too much detail about the supply chain, so I hope you'll understand.

As a result of comprehensive measures, such as purchasing from low-cost sources or devising strategies to minimize such tariffs, the impact was limited to the extent I mentioned.

Also, there may be a few areas where we initially overestimated the impact, as well as a few where we were too conservative in our assessment.

Tsubokura [M]: I see. Thank you very much.

Maruyama [M]: Ms. Tsubokura, thank you very much.

The person in the front seat of the second row from the front, please go ahead.

Ando [Q]: My name is Ando from the Nikkei. There are two questions.

The first question is about AMCHEPRY. Regarding the treatment of Parkinson's disease, there have been reports, though not all of them have been published as scientific papers, that the use of iPS cells, particularly in autologous transplants, has yielded significant results in the United States over the past few months. I wonder if this type of autologous transplant, even though your company uses a different approach, will end up competing quite heavily with it. I think this is the direction things are likely to take, especially in the US, so I'd like to ask how you plan to succeed in this environment, or rather, how you plan to carve out your niche.

Kimura [A]: There is gene therapy, and there is also autologous cell therapy. So, in that sense, as several treatment options emerge that aim to increase dopamine production in the brain, as AMCHEPRY is doing, we will need to compete effectively. However, in the case of autologous transplants, there are inevitably issues with cost and time, as well as variability in efficacy from person to person. Therefore, I believe allogeneic transplants offer greater stability and will likely provide benefits, especially when used for a large number of patients.

On the other hand, while this does not pertain to Parkinson's disease, although it has been suggested that autologous transplants are less likely to cause rejection, there have also been some reports indicating that unique immune reactions specific to autologous transplants can occur. Therefore, as the number of patients increases, we believe that new challenges may arise with both autologous and allogeneic transplants.

Ando [Q]: I see. When you think about it that way, it means there's plenty of room for each to coexist. Thank you very much.

One more thing: while the major events scheduled for FY2026 do not mention retinal pigment epithelium tears, I would appreciate it if you could explain how this issue will develop from this fiscal year onward, given the current situation.

Kimura [A]: As you can see from the case of Parkinson's disease or DSP-3077, we want patients and hospitals to be able to proceed with clinical trials quietly, so we refrain from making announcements every time something happens, or rather, we try to avoid making announcements too frequently. While we expect we will be able to provide some explanation regarding retinal pigment epithelium tears within this fiscal year, I have nothing specific to report today.

Ando [Q]: So, basically, things are proceeding as planned, is that correct**?**

Kimura [A]: We hope you understand in that way. When the time comes, we'll explain something or other.

Ando [M]: Thank you very much.

Maruyama [M]: Mr. Ando, thank you very much.

Is there any other question?

The person in the window seat in the third row from the front, please go ahead.

Takehara [Q]: My name is Takehara from LSEG. I have two questions.

First question: The Company raised approximately JPY110 billion through a public offering in April. Is there a possibility that additional equity financing will be needed to support future growth investments?

Another point is that Sumitomo Chemical is moving toward a borrowing structure that does not rely on debt guarantees. Are you also considering options such as issuing straight corporate bonds or raising debt from the capital markets in the future?

Kimura [A]: I'll give a brief explanation, and then Sakai will go into more detail.

It wasn't JPY110 billion; since we didn't exercise the over-allotment option, we raised about JPY98 billion.

One more point I would like to make is that Sumitomo Chemical's debt guarantee has been completely withdrawn, and they have now switched to borrowing without a debt guarantee.

Sakai will explain the funding requirements and other matters.

Sakai [A]: Thank you very much for your question.

Were you referring to the possibility of a future capital increase and corporate bonds? Since we just completed a capital increase very recently, rather than asking whether or not we have such plans at this point, we do not have any plans at this time, if it becomes necessary to raise funds to meet the capital needs that will arise when a major business venture spins off in the future, it may be possible to do so, though that would, of course, depend on the circumstances at that time.

As for corporate bonds, while we do not currently have any specific plans in that regard, I believe there is a possibility we may consider such a move depending on market conditions or our funding needs.

Maruyama [M]: Mr. Takehara, thank you very much.

The person second from the front, please go ahead.

Osawa [Q]: My name is Osawa from the Yomiuri Shimbun.

Regarding AMCHEPRY, you mentioned earlier that it was "early October." I apologize for getting a bit nitpicky here, but when we say early, we're referring to the "early part of the month," which generally means up to around October 10. So, I just wanted to confirm whether it's okay to write it as "early part of the month" in that context.

Kimura [A]: Yes, you can just write "early part of the month." Since enough time has passed since the patient was discharged from the hospital and has already returned to work.

Osawa [Q]: Thank you very much.

One more thing, following the completion of this first case, may I ask you again what the significance of this treatment is for patients with Parkinson's disease?

Kimura [A]: There are many patients with Parkinson's disease, and while there have been many existing medications available for a long time, no matter which medication is used, the nerve cells that produce dopamine in the brain gradually die off, and eventually none of them work anymore, that has been the most challenging aspect of Parkinson's disease. However, by transplanting AMCHEPRY, the transplanted nerve cells begin to produce new dopamine in the brain, which we believe is the greatest benefit, as it allows patients to recover in a way that's different from anything we've seen before.

Based on this mechanism, as well as clinical trial data, the AMCHEPRY clinical trials have shown that when patients take it in the same way as commonly used treatments, such as L-dopa, it produces a stronger effect. Therefore, we believe it will be a new treatment option that is highly compatible with existing therapies.

Maruyama [M]: Ms. Osawa, thank you very much.

Is there any other question?

The lady in the second row from the front, sitting by the window, please go ahead.

Fukumiya [Q]: My name is Fukumiya from the Asahi Shimbun. Thank you very much.

I also have a question about AMCHEPRY. Regarding future plans, as stated on the website, the plan is to first enroll 30 cases aged 18 through 60, and then, once that phase is complete, enroll five cases over the age of 65, for a total of 35 cases by around 2029. Is it correct that this schedule remains unchanged? Also, I believe I heard that, during the seven-year period leading up to the approval deadline in 2033, transplants would be performed on a total of 90 to 130 patients. Could you please let me know if there have been any changes to those plans?

Kimura [A]: Since we have to reapply within at least seven years, we won't be able to meet the deadline unless we follow the schedule you just mentioned; however, we plan to increase our production capacity. Alternatively, we are currently working on getting the necessary preparations, such as setting up facilities at universities or hospitals, completed as soon as possible. As I mentioned at the beginning, the launch of the university's website is going very smoothly, so we hope to enroll our target of 35 patients as soon as possible.

From that point on, since we will be operating under conditional approval, we will be able to enroll patients outside of clinical trials, while continuing to collect safety data, so we are planning a two-phase approach with the goal of expanding use to a larger number of hospitals.

To reiterate, we are treating this condition as the most time-consuming one and are looking to move forward as quickly as possible.

Fukumiya [Q]: Thank you very much. Excuse me for asking more questions.

In that case, I believe you mentioned that another transplant is scheduled before the end of the year, is this also at Kyoto University Hospital, or is it at a different facility? Also, regarding the new facilities, such as Juntendo University, that have already been announced, has patient recruitment already begun there? One more point: I believe this is the second instance, following Cuorips' RiHeart, where an iPS-derived product is being transplanted in a clinical setting outside of a clinical trial. Could you please confirm whether that is your understanding as well?

Kimura [A]: First, regarding the hospitals where the transplants will be performed, we're deliberately refraining from naming them. However, Kyoto University and the other three hospitals you just mentioned are already capable of performing transplants, so we'll proceed with transplants at the hospitals where patients are present and where preparations are most thoroughly in place.

One more thing: I am well acquainted with RiHeart, Cuorips, and Professor Sawa, but we are by no means in competition with each other, and I am not concerned with which of us comes first.

Maruyama [M]: Ms. Fukumiya, thank you very much.

Is there any other question from the venue?

The person in the center, second from the front, please go ahead.

Yoshimizu [Q]: This is Yoshimizu from RISFAX, Iyaku-Keizai.

I'd like to ask Dr. Kimura, as of right now, which is more likely to happen with enzomenib, in-house sales or a partnership?

Kimura [A]: I'll just say that, for now, we are neutral.

Yoshimizu [Q]: I see.

If you were to form a partnership, what would be your top priority among the conditions? Key considerations when choosing a partner.

Kimura [A]: We intend to use this as a springboard to build a solid sales structure for cancer treatments, so I believe the most important or non-negotiable point is that the partner aligns with our goals.

Yoshimizu [Q]: So you're looking for a partner who can help ensure that your existing cancer-related products continue to sell well in the future.

Kimura [A]: Yes. At the same time, based on our past experience, we've learned that unless we handle sales ourselves, we can't maintain proper control over them. On the other hand, while Japan does engage in co-promotions like the one with ORGOVYX, as well as with products from the US and elsewhere, there are areas where we feel confident in our ability to manage them effectively. We'll give that, and everything else, careful thought going forward.

Yoshimizu [Q]: I see.

Second, while your financial situation has improved significantly, can we finally expect R&D expenses for the next fiscal year to reach the four-digit range?

Kimura [A]: Given the current situation, I don't think reaching four digits is impossible, but since we want to proceed with a solid balance, you can assume we won't exceed four digits.

Yoshimizu [M]: I see. That is all. Thank you very much.

Maruyama [M]: Mr. Yoshimizu, thank you very much.

Is there any other question from the venue?

The person in the middle of the third row from the front, please go ahead.

Ishigaki [Q]: My name is Ishigaki from the Nikkei Biotech.

Regarding the universal influenza vaccine, I refer to a minor point, but on slide 18, it states that human challenge trials are scheduled to begin at the end of FY2026. The same slide also includes an overview of the Phase I trial in Europe. Is it correct to understand that these are separate matters?

Kimura [A]: Yes, you're right. It's something else entirely. Phase I will consist solely of vaccination. Since some facilities in Europe allow participants who have been vaccinated to be exposed to the virus, specifically, the influenza virus, during the challenge trial, we would like to use this opportunity to verify their actual ability to prevent infection.

Ishigaki [Q]: So, rather than being part of Phase II or something like that, are these challenge tests being conducted as preliminary research**?**

Kimura [A]: While “preliminary” might not be the most accurate term, we’re proceeding in consultation with vaccine experts, and in terms of assessing the vaccine’s universality, thoroughly evaluating its ability to prevent infection will likely be a key benchmark. Next, as is usually the case, comes the field test, right?

Sato [A]: After the challenge trials come the field trials, which constitute what is known as Phase III. Since these are the types of treatments administered to healthy individuals, the concept of clinical phases doesn’t quite apply here; however, to give you an idea, a Phase II trial is equivalent to a “challenge trial,” it’s a trial designed to confirm the concept in practice.

Ishigaki [Q]: Is there a set number of cases or something like that**?**

Sato [A]: I’m not quite ready to discuss specifics like the number of cases yet, but I think we’ll be able to explain once we’ve actually started working on them.

Maruyama [M]: Mr. Ishigaki, thank you very much.

Is there any other question from the venue?

There seems to be no question here, so thank you for your patience. Members of the media participating in the live stream who have questions are asked to either click the raise your hand button in Zoom or enter the questions in the Q&A section.

First, Mr. Suwa from the Asahi Shimbun, please go ahead. Thank you for your patience.

Suwa [Q]: On page nine, regarding sales of ORGOVYX and GEMTESA in the US, the forecast for this fiscal year exceeds JPY300 billion. Could you tell me what you expect those sales to be in a few years, or, in other words, what you anticipate the peak sales will be**?**

Kimura [M]: Thank you very much for your explanation. Dr. Nakagawa, is there anything?

Nakagawa [A]: As we have explained so far, our target, for the 2030s, I believe, is a total of more than JPY350 billion for both.

Suwa [Q]: In that case, since the total will be around JPY330 billion this fiscal year, and there are still four years until 2030, would you say you’re on track to reach the threshold of a plateau much sooner than expected?

Nakagawa [A]: I think we can say that. As Kimura mentioned at the beginning, we are currently reviewing our medium-term plan, so I believe there is a possibility that we will make some updates to those goals as part of that process.

Suwa [Q]: I see. When you say “update,” are you referring to considering a figure slightly larger than the JPY350 billion you mentioned earlier, even though I realize there are exchange rate issues involved, or are you suggesting to think along those lines?

Nakagawa [A]: You’re absolutely right. While there are certainly aspects of the foreign exchange market that are difficult to predict, in terms of our actual performance, we’ve consistently exceeded our targets slightly. So, while I’d like to revise our targets upward if possible, I think we’ll need to wait and see how things develop.

Suwa [M]: I see. Thank you very much.

Maruyama [M]: Mr. Suwa, thank you very much.

Next, Mr. Nagao from the Yomiuri Shimbun, please go ahead.

Nagao [Q]: This is Nagao from the Yomiuri Shimbun. Thank you.

I have a question about the first case of AMCHEPRY. Regarding the patient who underwent surgery this time, what symptoms were observed or reported prior to the surgery that led to their decision to undergo the procedure? Also, based on what is known at this point, do you happen to know what kind of improvements were observed after the surgery?

Kimura [A]: While I would prefer not to discuss individual patients, generally speaking, the patients who will be enrolled in this post-approval trial are those with Parkinson's disease whose symptoms are primarily motor in nature, and who are beginning to experience "off" symptoms, that is, periods when the medication, L-dopa, is no longer effective.

In terms of the effects of the transplantation, there are naturally various factors at play immediately after the procedure due to the transplantation itself; however, based on our understanding of the underlying mechanisms, it takes a little more time for the cells themselves to take root and begin producing dopamine. This is by no means a reference to a patient's lab test results.

Nagao [Q]: Thank you very much.

Regarding AMCHEPRY that was administered, have you been able to confirm the extent of cell engraftment at this point?

Kimura [A]: Since PET scans aren't yet included in the protocol, I don't think there's any way to verify this at this point.

Nagao [M]: I see. Thank you very much.

Maruyama [M]: Mr. Nagao, thank you very much.

Mr. Ishii from Iyakutsushinsha, please go ahead.

Ishii [Q]: Before resuming dividend payments, were there any particular challenges you faced in getting to that point? I would like to ask President Kimura.

Kimura [A]: The hardships we faced on the road to resuming dividend payments, though they weren't specifically for the sake of resuming dividends, involved a great deal of effort to turn the Company's performance around and improve our financial situation. We also caused a great deal of inconvenience to all stakeholders, including our employees. I'm referring to structural reform here.

Given that our team size had shrunk, and everyone really gritted their teeth and gave it their all, I wouldn't exactly call it a struggle, but I do think it's fair to say it was a very challenging process.

Ishii [Q]: Also, aside from the two anticancer drugs currently in development and the iPS cells, are there any other in-house products that you have high hopes for?

Kimura [A]: Page 14 of the materials lists our development pipeline. Since we are moving forward with these projects while keeping R&D expenses to a minimum, we have a lineup of projects backed by very solid nonclinical data. We're all looking forward to all of the lineups.

Although you didn't mention it, vaccine adjuvants are somewhat outside the scope of our portfolio, but as I mentioned earlier, they are progressing smoothly as well.

Ishii [M]: Thank you very much.

Maruyama [M]: Mr. Ishii, thank you very much.

Next, Ms. Akita from Kansai Television, please go ahead.

Akita [M]: First, regarding the patients' conditions, could you please tell me about the condition of the patients who took this medication in early October who was indicated for AMCHEPRY?

Kimura [A]: This is not about the current condition of individual patients; rather, according to the clinical trial protocol, patients enrolled in this trial are those whose Parkinson's disease primarily manifests as motor symptoms, and whose condition has progressed to the point where they experience "off" periods, times when L-dopa, a medication commonly used to treat Parkinson's disease, is no longer effective.

Akita [Q]: That person underwent treatment in early October and has now recovered enough to return to work. Is it correct to understand that, until then, that patient was in a condition unable to return to work?

Kimura [A]: I think that needs to be confirmed, but I imagine the patient was working, the condition worsened and then underwent a transplant. I think it would be correct to understand that the patient was discharged from the hospital and returned to work then.

Akita [Q]: I see. Thank you very much.

Just one more final point. Once again, I apologize, I'm sorry to be asking the same question, but given that the patient has successfully returned to work, could you please share your thoughts on completing this first case of AMCHEPRY?

Kimura [A]: To avoid any misunderstanding, let me reiterate: while I understand that, based on AMCHEPRY's mechanism of action, it is not entirely accurate to say that the drug's effects led to a significant improvement in symptoms and a return to work, the fact remains that, since this is a transplant procedure, the patient was hospitalized and took immunosuppressants, then recovered to the point where the patient can be discharged and resume a normal, or rather, a completely normal, life.

In that sense, since we plan to conduct this as a post-approval trial involving 35 patients initially and then expand to more than 100 patients over the next few years, we can say we've gotten off to a solid start.

Akita [M]: Thank you very much.

Maruyama [M]:

Is there any other question from the participants to the webinar? Isn't there anyone else? Anything from the members of the media here at the venue as well?

Now, please pass the microphone to Mr. Ando.

Ando [Q]: My name is Ando from the Nikkei.

Just to clarify regarding your answer to the last question: when you say that the patient has completed surgery, been discharged from the hospital, and returned to work, does that mean that the effects of AMCHEPRY have

taken hold, leading to a recovery from Parkinson's disease symptoms and a return to work? Or are you simply stating that the patient underwent surgery, completed the postoperative recovery period, and has returned to work following the surgery?

Kimura [A]: Yes. In the case of AMCHEPRY, it takes a certain amount of time for it to take root and begin producing dopamine neurons, so it's not quite time for that yet. I believe someone just asked if we've been able to confirm engraftment. Based on the current clinical trial data, engraftment has occurred in all transplant recipients, but we haven't yet reached the point where we can confirm it. That means we'll have to wait a little longer before checking.

As I mentioned earlier, the surgery itself involves drilling a hole in the skull to perform a cell transplant. However, by the time the patient is discharged, the wound has healed, the blood levels of immunosuppressants have stabilized, and the patient is able to lead a normal life and has returned to work. From now on, while the patients go about their normal daily life, we'll be monitoring how the effects of AMCHEPRY gradually take hold, it might sound strange to put it that way, but that's essentially what we'll be doing as time goes on.

Ando [Q]: I see. By "normal life," you mean a normal life outside the hospital, right? It doesn't mean just living a normal life without symptoms.

Kimura [A]: Yes. I'm sorry, maybe I didn't phrase that very well, but what I mean is that the patient is now able to lead a normal life, commuting from home to work.

Ando [Q]: When you said earlier that it would take a little more time, did you mention exactly how much longer it would take?

Kimura [A]: While we cannot comment on individual patients, our clinical trial is designed to thoroughly collect follow-up data for up to one or two years. During that time, the clinical trial protocol stipulates that patients must visit the hospital to have their symptoms monitored, and at certain points, undergo a PET scan to confirm actual engraftment.

Therefore, for our patients, this places a considerable burden on them, as it requires them to visit the hospital more frequently than usual, and we are deeply grateful to those patients who have been so cooperative.

Ando [Q]: Thank you very much.

Another point, it's been a while now, but at the Central Social Insurance Medical Council, regarding the cost-effectiveness system and the cost-effectiveness of drug prices, the general consensus seems to be that the current approach to the cost-effectiveness system might need to be adjusted slightly. The government's tentative stance was that we should consider that matter, but by the end of September, the results turned out to be somewhat different from that. If you have any thoughts on this development, please share them.

Kimura [A]: When it comes to over-the-counter drugs, in terms of cost-effectiveness, I believe the original system was introduced to curb drug costs, and I agree that assessing that cost-effectiveness is, in principle, very important, but I understand there is still ongoing debate regarding the methodology, specifically, what approach should be taken to accurately estimate cost-effectiveness. What we are currently asking as pharmaceutical companies and the Pharmaceutical Manufacturers Association is to thoroughly address these issues.

Ando [M]: Thank you very much.

Maruyama [M]: Mr. Ando, thank you very much.

Is there any other question in the venue from the participants to the webinar? Thank you very much.

Since there are no further questions, we will now conclude the Q&A session.

This concludes the Q2 financial results briefing for FY2026 of Sumitomo Pharma.

Thank you very much for your participation today.

[END]