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Sumitomo Pharma Co., Ltd.

Q3 Financial Results Briefing for FY2025

January 30, 2026

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
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[Participants]	
[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; 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 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;

	Koichi Kino	Global Finance Vice President, Head of Corporate Governance
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	Seiji Wakao	JPMorgan Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Hiroshi Wada	SMBC Nikko Securities

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

Presentation

Kino: As it is now time, we would like to begin the Sumitomo Pharma Co., Ltd., Q3 financial results briefing for FY2025. Thank you very much for joining us today despite your busy schedules.

My name is Koichi Kino from the Corporate Governance Department, and I will be serving as moderator today.

This briefing will be conducted via live Zoom webinar streaming from our Tokyo head office. Before we begin, we have a brief announcement and request. We kindly ask that you change the participant information displayed on your Zoom screen to show your company name and your name.

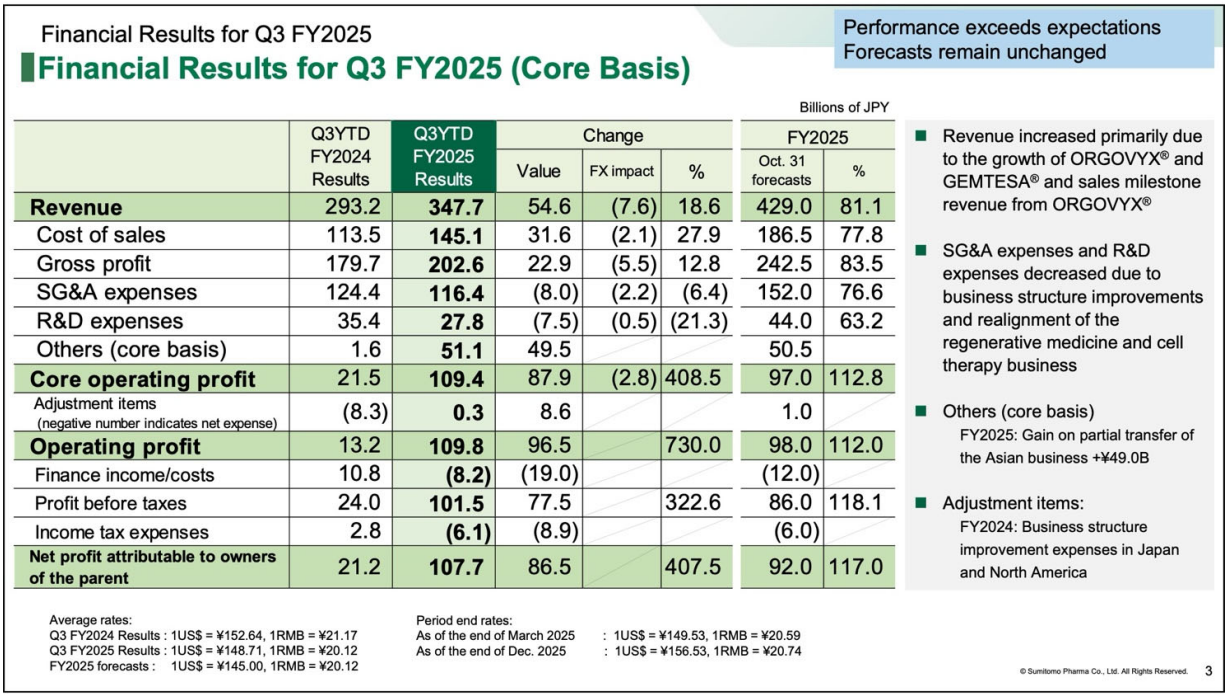
As for today's agenda, after we provide explanations based on the presentation materials posted on our website, we will move on to a Q&A session, first with analysts and investors, followed by members of the press. The scheduled end time is 6:15 PM.

Now, allow me to introduce today's participants. We are joined by Representative Director, President and CEO, Mr. Kimura; Representative Director and Executive Vice President, Mr. Sakai; Member of the Board and Managing Executive Officer, Mr. Nakagawa; Managing Executive Officer, Ms. Sato; and Executive Officer, Mr. Wakemi. Thank you all for joining us.

We will now begin with an explanation of our Q3 FY2025 performance and the current status of clinical development, presented by Mr. Kimura.

Mr. Kimura, please go ahead.

Kimura: I am Toru Kimura, Representative Director, President and CEO. I would like to explain our Q3 FY2025 financial results.



Financial Results for Q3 FY2025

Financial Results for Q3 FY2025 (Core Basis)

Performance exceeds expectations
Forecasts remain unchanged

Billions of JPY

	Q3YTD FY2024 Results	Q3YTD FY2025 Results	Change			FY2025	
			Value	FX impact	%	Oct. 31 forecasts	%
Revenue	293.2	**347.7**	54.6	(7.6)	18.6	429.0	81.1
Cost of sales	113.5	**145.1**	31.6	(2.1)	27.9	186.5	77.8
Gross profit	179.7	**202.6**	22.9	(5.5)	12.8	242.5	83.5
SG&A expenses	124.4	**116.4**	(8.0)	(2.2)	(6.4)	152.0	76.6
R&D expenses	35.4	**27.8**	(7.5)	(0.5)	(21.3)	44.0	63.2
Others (core basis)	1.6	**51.1**	49.5			50.5	
Core operating profit	21.5	**109.4**	87.9	(2.8)	408.5	97.0	112.8
Adjustment items (negative number indicates net expense)	(8.3)	**0.3**	8.6			1.0	
Operating profit	13.2	**109.8**	96.5		730.0	98.0	112.0
Finance income/costs	10.8	**(8.2)**	(19.0)			(12.0)	
Profit before taxes	24.0	**101.5**	77.5		322.6	86.0	118.1
Income tax expenses	2.8	**(6.1)**	(8.9)			(6.0)	
Net profit attributable to owners of the parent	21.2	**107.7**	86.5		407.5	92.0	117.0

- 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 and realignment of the regenerative medicine and cell therapy business
- Others (core basis)
  FY2025: Gain on partial transfer of the Asian business +¥49.0B
- Adjustment items:
  FY2024: Business structure improvement expenses in Japan and North America

Average rates:
Q3 FY2024 Results : 1US$ = ¥152.64, 1RMB = ¥21.17
Q3 FY2025 Results : 1US$ = ¥148.71, 1RMB = ¥20.12
FY2025 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.12

Period end rates:
As of the end of March 2025 : 1US$ = ¥149.53, 1RMB = ¥20.59
As of the end of Dec. 2025 : 1US$ = ¥156.53, 1RMB = ¥20.74

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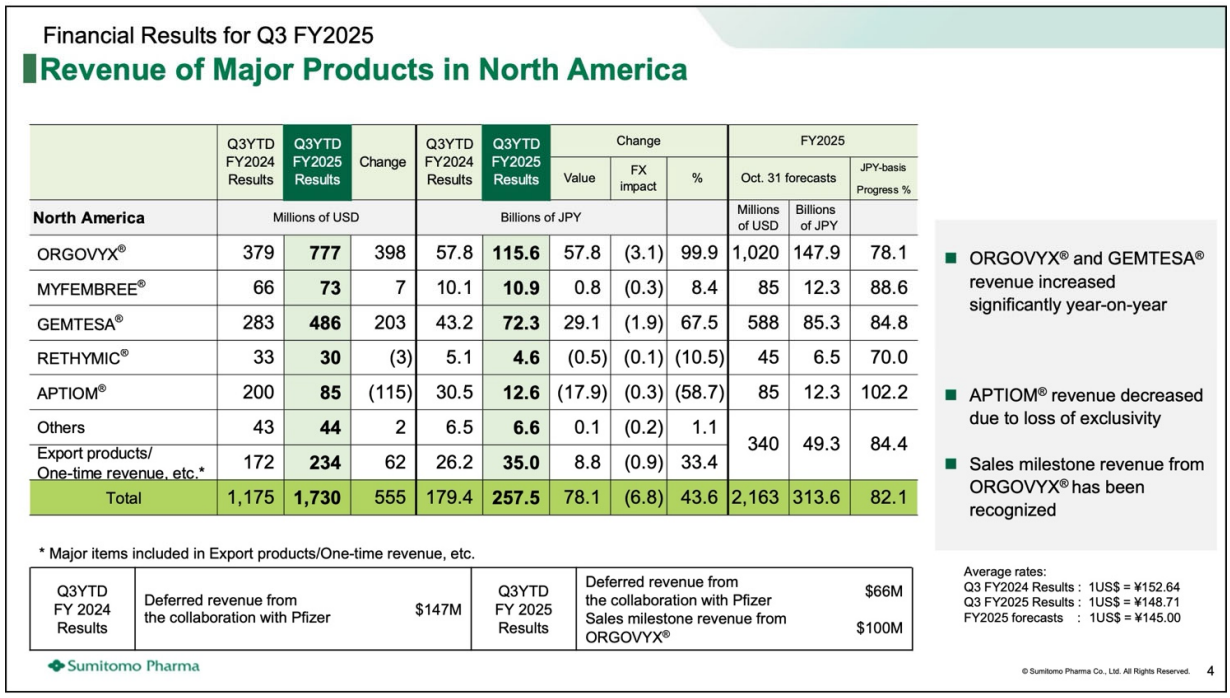
First, please turn to page three. Here we present our business performance for Q3 FY2025 on a core basis.

As you can see, revenue amounted to JPY347.7 billion, gross profit was JPY202.6 billion, core operating profit was JPY109.4 billion, and net profit attributable to owners of the parent was JPY107.7 billion. Compared with the same period last year, revenue increased by JPY54.6 billion, while core operating profit increased by JPY87.9 billion YoY.

On the cost side, selling, general and administrative expenses were restrained by JPY8 billion, and R&D expenses by JPY7.5 billion. As a result, profit attributable to owners of the parent increased by JPY86.5 billion to JPY107.7 billion.

At our Q2 financial results announcement on October 31, we revised our full-year performance forecast. Even relative to that revised forecast, we achieved an overperformance, with core operating profit reaching an achievement rate of 112.8%. We had previously believed that H2 of the fiscal year would represent the bottom of our profit and loss profile, but the Q3 results exceeded our expectations, and we interpret this as steady progress in profit improvement.

At the same time, we believe that foreign exchange effects and inventory buildup beyond our initial assumptions also contributed in part to these results. Traditionally, for our company, Q4 tends to see insurance resets in North America and a concentration of expenses. For that reason, we have left our full-year performance forecast unchanged. While we expect the final full-year results to exceed the October forecast by a comfortable margin, we also believe there is a possibility that operating profit in Q4 may come in slightly below the Q3 level.



Financial Results for Q3 FY2025

Revenue of Major Products in North America

North America	Q3YTD FY2024 Results (Millions of USD)	Q3YTD FY2025 Results (Millions of USD)	Change (Millions of USD)	Q3YTD FY2024 Results (Billions of JPY)	Q3YTD FY2025 Results (Billions of JPY)	Change Value (Billions of JPY)	Change FX impact (Billions of JPY)	Change %	FY2025 Oct. 31 forecasts Millions of USD	FY2025 Oct. 31 forecasts Billions of JPY	JPY-basis Progress %
ORGOVYX®	379	**777**	398	57.8	**115.6**	57.8	(3.1)	99.9	1,020	147.9	78.1
MYFEMBREE®	66	**73**	7	10.1	**10.9**	0.8	(0.3)	8.4	85	12.3	88.6
GEMTESA®	283	**486**	203	43.2	**72.3**	29.1	(1.9)	67.5	588	85.3	84.8
RETHYMIC®	33	**30**	(3)	5.1	**4.6**	(0.5)	(0.1)	(10.5)	45	6.5	70.0
APTIOM®	200	**85**	(115)	30.5	**12.6**	(17.9)	(0.3)	(58.7)	85	12.3	102.2
Others	43	**44**	2	6.5	**6.6**	0.1	(0.2)	1.1	340	49.3	84.4
Export products/ One-time revenue, etc.*	172	**234**	62	26.2	**35.0**	8.8	(0.9)	33.4			
Total	1,175	**1,730**	555	179.4	**257.5**	78.1	(6.8)	43.6	2,163	313.6	82.1

- 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

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

Q3YTD FY 2024 Results	Deferred revenue from the collaboration with Pfizer	$147M	Q3YTD FY 2025 Results	Deferred revenue from the collaboration with Pfizer $66M Sales milestone revenue from ORGOVYX® $100M

Average rates:
Q3 FY2024 Results : 1US$ = ¥152.64
Q3 FY2025 Results : 1US$ = ¥148.71
FY2025 forecasts : 1US$ = ¥145.00

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We are now showing revenue from our major products in North America.

If you look at the center of the slide, ORGOVYX recorded JPY115.6 billion, MYFEMBREE JPY10.9 billion, and GEMTESA JPY72.3 billion, for a total of JPY257.5 billion, representing an increase of JPY78.1 billion YoY.

As indicated by the YoY changes shown for each of the major products, ORGOVYX was nearly double, and GEMTESA increased by 67.5%, meaning that performance has been very strong. Compared with the full-year forecast we announced on October 31, although three quarters of the fiscal year has already passed, progress remains extremely strong.

FY2025 Q3 Financial Results Summary

ORGOVYX®

Plan for Q3 YTD FY2025	Actual for Q3 YTD FY2025	Year-over-year comparison
$742M	**$777M (Achievement 105%)**	**205%**

- Volume: Exceeded plan for Q3 YTD FY2025 due to higher-than- expected prescriptions and WHS inventory
- Price: In line with expectations

<Topics>

- Significant increase in New Patient Starts since Jan. 2025
  - Growth in Medicare patients due to the reduction of out-of-pocket caps
  - Increase in patients in Uro IOD and Academic/IDN channels by promoting product attributes
  - All-time-high New Patient Starts and volume in December

* *Source:* Internal calculation

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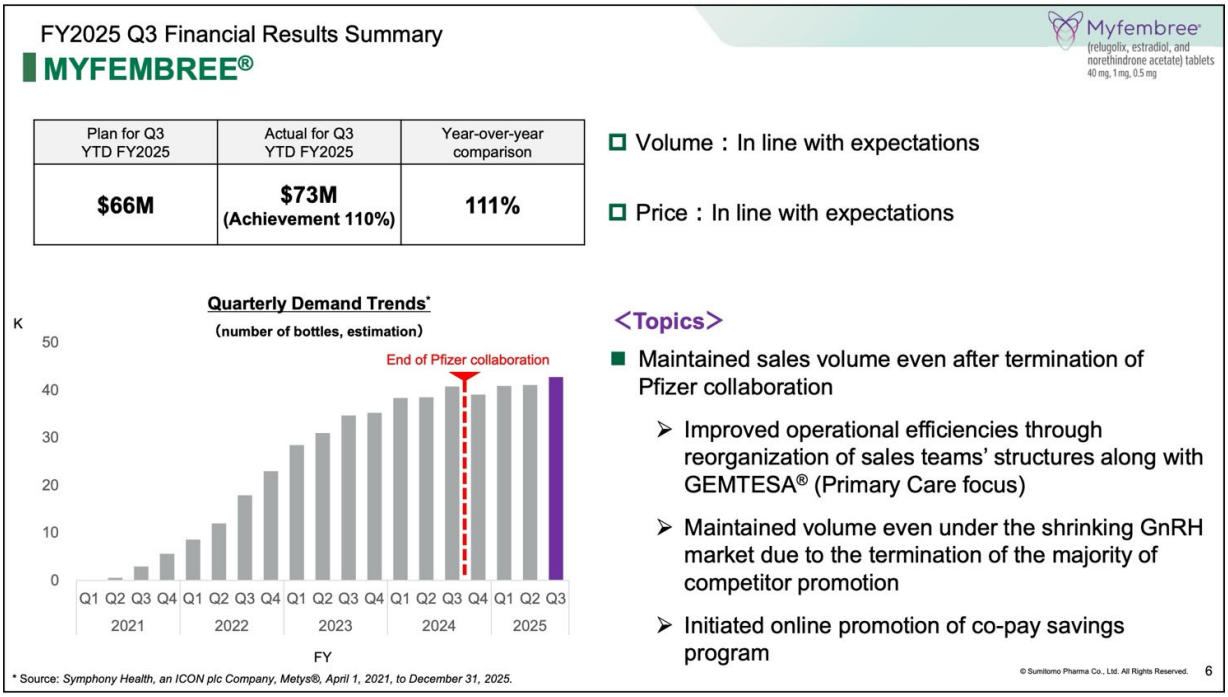
From here, I will explain each of the three major products one by one.

For ORGOVYX, compared with our internal plan for Q3, the actual results I have just described represent an achievement rate of 105%, exceeding the plan by USD35 million, and amounting to 205% compared with the same period last year. Both volume and price are progressing smoothly. At the same time, we recognize that there was a modest inventory buildup during Q3.

As shown in the topics below, since January of last year, the number of new patients has increased significantly in 2025. Contributing factors include the lowering of the out-of-pocket maximum, which has made it easier for Medicare patients to use the drug, as well as the fact that in this therapeutic area treatment had previously relied on injectable drugs, whereas our ORGOVYX is an oral formulation. In addition, the appeal of product value, such as the rapid onset of efficacy, has increasingly gained traction.

In December, both the number of new patients and volumes reached record highs.



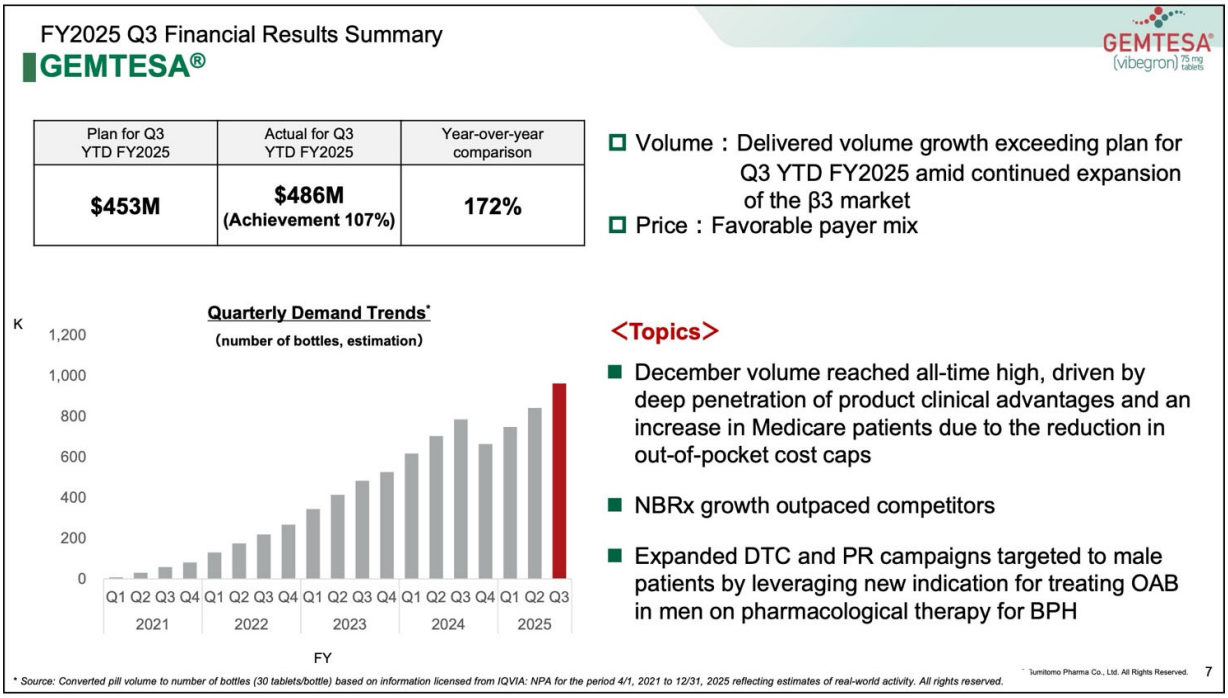
Next is MYFEMBREE.

Q3 performance came in at USD73 million, exceeding our plan by USD7 million and resulting in an achievement rate of 110%. Both volume and price trended largely in line with our expectations.

We ended our sales partnership with Pfizer in January of last year and transitioned to in-house sales. Under those circumstances, we have implemented measures to improve sales efficiency in combination with GEMTESA.

At the same time, while promotion by competing products has been scaled back and the GnRH market has softened, we were still able to firmly maintain volumes.

In addition, through online promotion and the use of co-pay cards, that is, discount cards for patients, we are encouraging patients to continue using the product for several months, during which they can clearly experience its benefits. As a result, beginning this fiscal year, the product on a standalone basis is contributing to profits. This qualitative change represents one of the key topics for this year.



Next is GEMTESA.

Against a Q3 plan of USD453 million, actual performance reached USD486 million, exceeding the plan by USD33 million for an achievement rate of 107%. This represents an increase of roughly 70% YoY.

As the β3 market within overactive bladder treatments continues to expand, we have steadily increased volumes and achieved our plan. In addition, the proportion of payer channels with higher discount rates was lower than expected, which served as a positive factor for pricing.

Here as well, the clinical superiority of our product has become more widely recognized, and with the reduction in patients' out-of-pocket maximums under the IRA system, which were lowered starting in calendar year 2025, the number of Medicare patients has increased. As a result, December volumes also reached a record high for this product.

New prescriptions are growing faster than those of competing products, and we are also gradually advancing awareness activities for a new indication, overactive bladder associated with benign prostatic hyperplasia.

Financial Results for Q3 FY2025

Revenue of Major Products in Japan

Billions of JPY

	Q3YTD FY2024 Results	Q3YTD FY2025 Results	Change		FY2025	
			Value	%	Oct. 31 forecasts	Progress %
Japan						
LATUDA®	10.2	**10.7**	0.4	4.2	13.5	78.9
TWYMEEG®	5.7	**7.9**	2.2	39.4	11.2	70.7
METGLUCO®	5.7	**5.7**	0.0	0.2	7.5	75.8
Equa®/EquMet®	20.9	**8.7**	(12.2)	(58.3)	9.0	97.1
LONASEN® Tape	3.6	**3.9**	0.3	8.2	5.0	77.4
AG products	8.8	**9.4**	0.6	6.6	11.6	80.6
Others	18.2	**17.7**	(0.5)	(2.8)	34.7	66.2
Export products/ One-time revenue, etc.	5.4	**5.3**	(0.1)	(2.0)		
Total	78.5	**69.2**	(9.3)	(11.8)	92.5	74.8

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)

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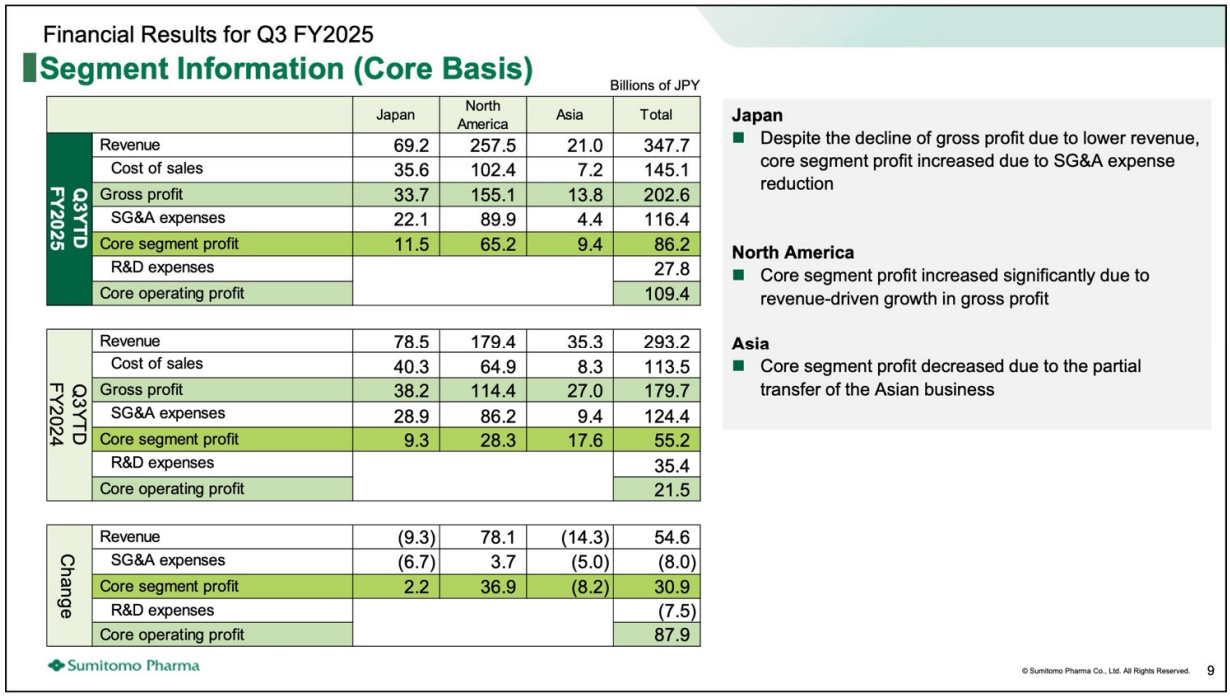
Next, we present revenue from our major products in Japan.

The total came to JPY69.2 billion, representing a decrease of JPY9.3 billion YoY. This is largely attributable to the expiration of the exclusive sales period for Equa and EquMet shown in the center of the slide, and the fact that sales of these products themselves ended in December.

On the other hand, compared with the forecast we presented on October 31, the achievement rate stands at 74.8%, and we believe you can understand that overall performance has been solid and is progressing in line with our plan.



On this page, we show business performance by segment on a core basis, compared with the previous year.

In Japan, as I have just explained, revenue declined, but selling, general and administrative expenses also decreased, and as a result, core segment profit increased by JPY2.2 billion.

In North America, as mentioned earlier, revenue has been very strong, resulting in an increase of JPY36.9 billion in core segment profit.

Including the shortfall in R&D expenses, at the core operating profit level, this translates into an increase of JPY87.9 billion YoY.

Research and Development

Development Pipeline (as of January 30, 2026)

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
	CT1-DAP001/DSP-1083 (Japan)	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study	MAA submitted in August 2025
	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/DSP-5336	Selective menin inhibitor	Acute leukemia	Phase 2
	nuvisertib/TP-3654	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

*Development rights: Japan, China, and certain Asian countries

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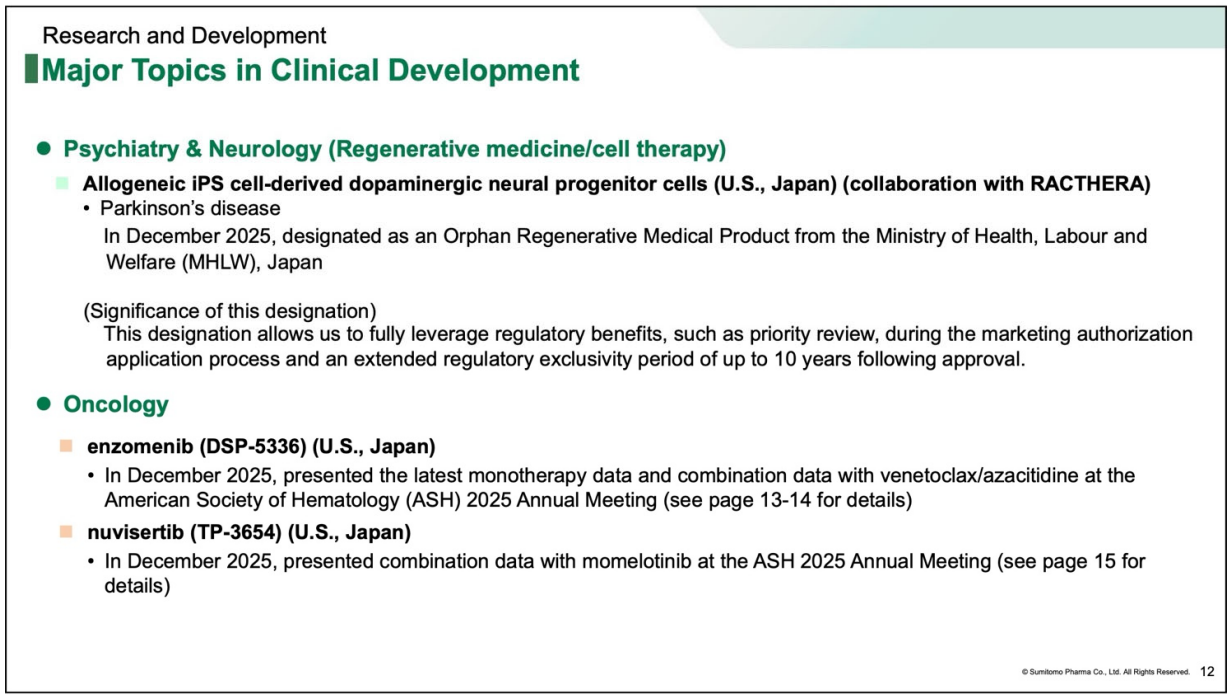
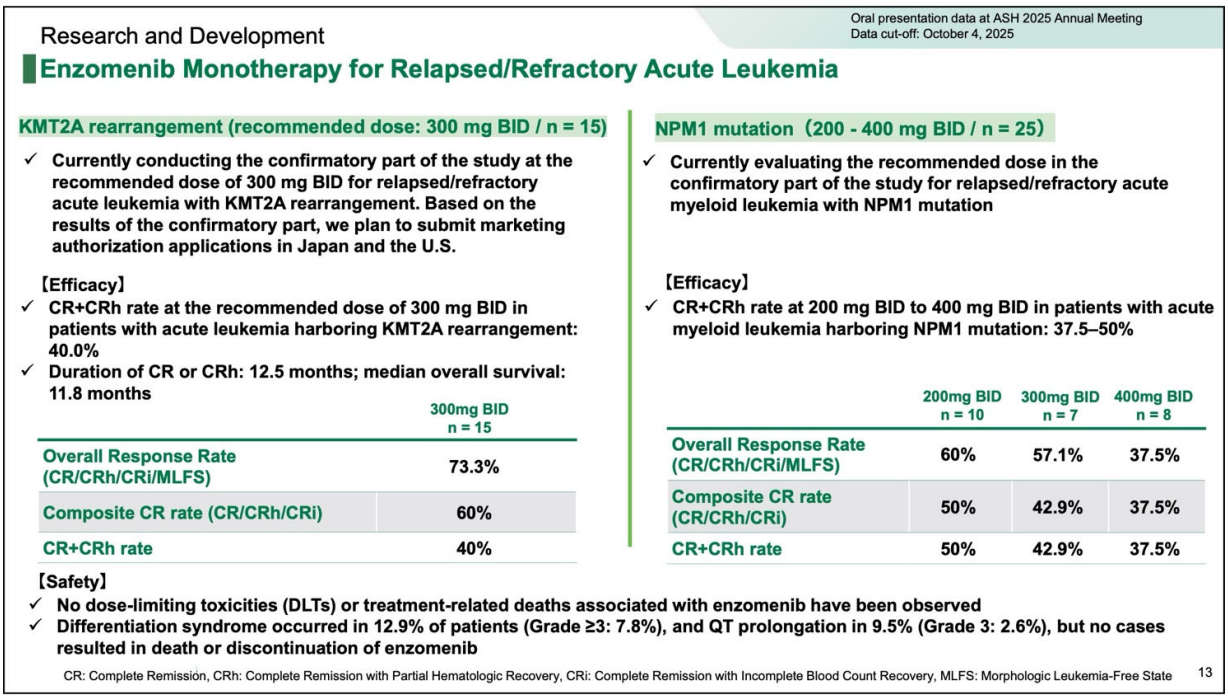
Next, I would like to explain the R&D highlights.

This slide shows the overall picture, and as there have been no changes here, the next page presents the main topics for Q3.



In the neuropsychiatric field, within regenerative and cell therapies, iPS cell–derived dopaminergic neural precursor cells received designation in Japan from the Ministry of Health, Labour and Welfare as a regenerative medical product for rare diseases. We submitted the application for approval on August 5 last year, and we recognize that discussions with the PMDA have been proceeding smoothly and that the review process is advancing.

In oncology, for both enzomenib and nuvisertib, the American Society of Hematology (ASH) meeting was held in December, and we have presented some of the latest data there. I will explain the details on the next slide.



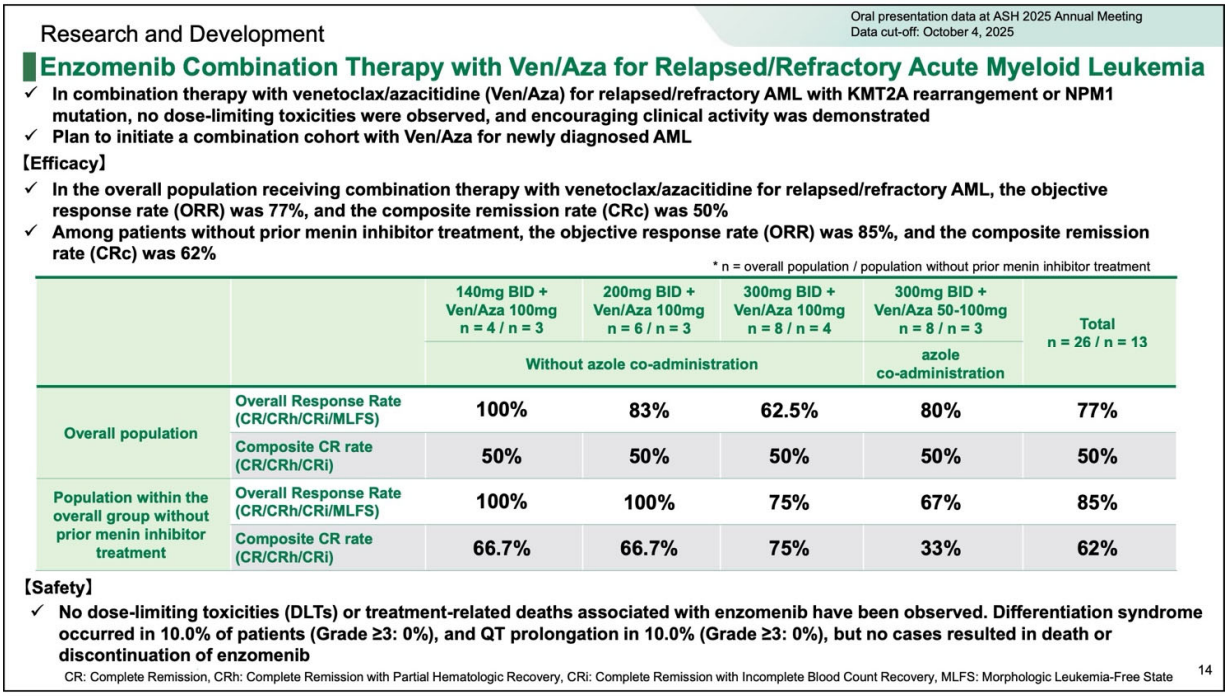
First, with regard to enzomenib, we are presenting data on monotherapy for relapsed/refractory acute leukemia, focusing separately on KMT2A rearrangements and NPM1 mutations.

For KMT2A, while a pivotal trial is currently underway, as indicated by the term confirmatory part, the results from the preceding study are summarized here. The CR plus CRh rate was 40%, the duration of CR or CRh was 12.5 months, and the median overall survival was 11.8 months, all of which represent very strong data.

In addition, with respect to safety, which is a key characteristic of enzomenib, as shown below, there were no treatment-related deaths, and both differentiation syndrome and QT prolongation occurred at very low rates. Furthermore, there have been no cases leading to treatment discontinuation, and this trend has been maintained.

For NPM1 mutations, we are currently conducting dose-finding to determine the recommended dose in the confirmatory part for patients with relapsed/refractory acute myeloid leukemia harboring NPM1 mutations. As shown below, data are available for 200 mg BID, 300 mg BID, and 400 mg BID. As indicated here, the CR plus CRh rate ranges from 37.5% to 50%, representing a very high response rate.

To reiterate, and as we have stated previously, the accumulation of safety data continues to demonstrate that this is a menin inhibitor with a very high safety profile.



Research and Development

Oral presentation data at ASH 2025 Annual Meeting
Data cut-off: October 4, 2025

Enzomenib Combination Therapy with Ven/Aza for Relapsed/Refractory Acute Myeloid Leukemia

- ✓ In combination therapy with venetoclax/azacitidine (Ven/Aza) for relapsed/refractory AML with KMT2A rearrangement or NPM1 mutation, no dose-limiting toxicities were observed, and encouraging clinical activity was demonstrated
- ✓ Plan to initiate a combination cohort with Ven/Aza for newly diagnosed AML

【Efficacy】

- ✓ In the overall population receiving combination therapy with venetoclax/azacitidine for relapsed/refractory AML, the objective response rate (ORR) was 77%, and the composite remission rate (CRc) was 50%
- ✓ Among patients without prior menin inhibitor treatment, the objective response rate (ORR) was 85%, and the composite remission rate (CRc) was 62%

* n = overall population / population without prior menin inhibitor treatment

		140mg BID + Ven/Aza 100mg n = 4 / n = 3	200mg BID + Ven/Aza 100mg n = 6 / n = 3	300mg BID + Ven/Aza 100mg n = 8 / n = 4	300mg BID + Ven/Aza 50-100mg n = 8 / n = 3	Total n = 26 / n = 13
		Without azole co-administration			azole co-administration	
Overall population	Overall Response Rate (CR/CRh/CRi/MLFS)	100%	83%	62.5%	80%	77%
	Composite CR rate (CR/CRh/CRi)	50%	50%	50%	50%	50%
Population within the overall group without prior menin inhibitor treatment	Overall Response Rate (CR/CRh/CRi/MLFS)	100%	100%	75%	67%	85%
	Composite CR rate (CR/CRh/CRi)	66.7%	66.7%	75%	33%	62%

【Safety】

- ✓ No dose-limiting toxicities (DLTs) or treatment-related deaths associated with enzomenib have been observed. Differentiation syndrome occurred in 10.0% of patients (Grade ≥3: 0%), and QT prolongation in 10.0% (Grade ≥3: 0%), but no cases resulted in death or discontinuation of enzomenib

CR: Complete Remission, CRh: Complete Remission with Partial Hematologic Recovery, CRi: Complete Remission with Incomplete Blood Count Recovery, MLFS: Morphologic Leukemia-Free State

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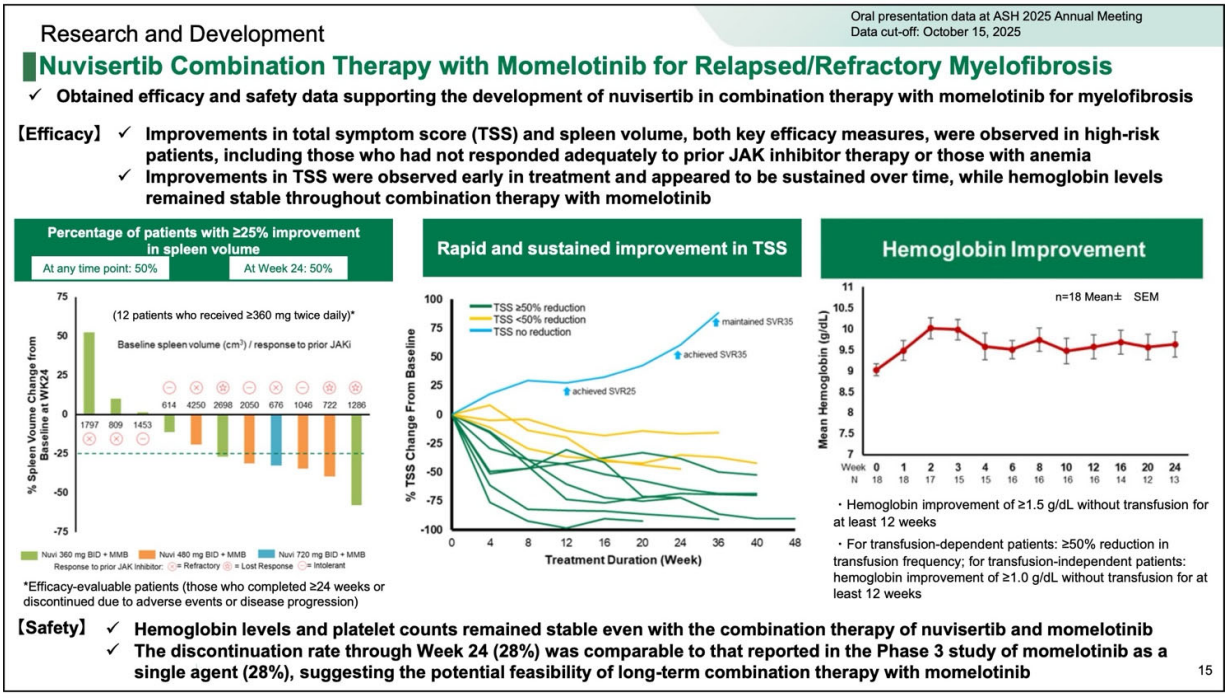
Next, still with enzomenib, we are also presenting data on combination therapy for relapsed/refractory acute myeloid leukemia.

Here, data have been compiled for relapsed/refractory patients with KMT2A rearrangements or NPM1 mutations treated in combination with venetoclax and azacitidine. No dose-limiting toxicities have been observed, and a combination effect is suggested.

As you can see on the far right, the overall response rate in the total population was 77%, with a composite complete remission rate of 50%. Among patients who had not previously received a menin inhibitor, the results were even stronger, with a response rate of 85% and a composite complete remission rate of 62%.

Here again, to reiterate, data continue to show that the safety profile is very favorable.



Finally, turning to nuvisertib, we have also begun to generate data on its use in combination with the weak inhibitor momelotinib for relapsed/refractory myelofibrosis, and these data have been presented at academic conferences. We hope you will understand that efficacy and safety data supporting the development of nuvisertib in combination with momelotinib have been accumulating.

First, on the far left of the graph, we show the proportion of patients achieving a reduction in spleen size of 25% or more, referred to as SVR25, which stands at 50% at week 24.

On the other hand, improvements in TSS, the total symptom score, are also shown, including the time course. A strong effect is observed immediately after initiation of dosing. Each line represents an individual patient, and at week 24, TSS50 is 45%, indicating that a large number of patients are experiencing substantial benefits.

Alongside this, we also show improvements in hemoglobin levels. One of the drawbacks often cited for weak inhibitors is bone marrow toxicity. Momelotinib, however, is characterized by a very low incidence of such toxicity, and even when combined with nuvisertib, improvements in bone marrow hemoglobin levels have been sustained. From this, we believe you can see that bone marrow toxicity is not emerging.

That concludes the information I wished to present today, and I would appreciate your questions.

Kino: Thank you very much, Mr. Kimura.

Question & Answer

Kino [M]: We will now move on to the Q&A session with analysts and investors. The Q&A session will run until 5:45 PM.

First, we would like to invite Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka [Q]: Thank you. This is Muraoka from Morgan Stanley.

I'd like to reconfirm President Kimura's interview that appeared in the media. Regarding oncology partnering, enzomenib and nuvisertib, you're not fixated on completing this by March. Given that the ASH data felt strong, and if you're thinking in terms of value enhancement first, you're not necessarily committed to doing it within the next fiscal year either, or maybe even the year after that, once a bit more data are in, would be fine. Is that roughly the time frame you're now thinking about? I'd appreciate your thoughts on that.

Kimura [A]: Mr. Muraoka, thank you for the question.

As you summarized, originally we were anticipating that R&D expenses would become quite tight, so we were thinking we needed to make something happen within this fiscal year. However, as I've just shown, we are starting to see good data emerge, and at the same time we now have a bit more financial leeway. Under these circumstances, we believe that having a proper discussion after accumulating solid data would allow us to partner under better terms. We very much want to pursue partnering, but our current goal is to delay it by about one year and aim to move forward with partnering in the next fiscal year, FY2026.

Muraoka [Q]: If we're talking about next fiscal year, and considering that negotiations themselves take time, will there be further data for value enhancement coming out over the next six to nine months or so?

Kimura [A]: We have studies underway that have not yet been disclosed, and as you can see from the currently published figures, the patient numbers in each study are still quite small. So we would like to properly accumulate that data before entering into discussions.

Up to now, with the data we have, we've already been introduced to and have generated interest from a number of companies. However, in order to arrive at what we consider the best possible partnership, we believe it would be better to proceed after accumulating more data. That is why we have changed our policy at this point.

Muraoka [Q]: Let me reframe the question slightly. The performance is extremely strong, clearly impressive. If this level of performance continues, should we think there's a possibility that, say six months from now, you might shift your stance and say, "We'll do one asset on our own and partner just one," or something along those lines?

Kimura [A]: I wouldn't say that there is absolutely no possibility, but at this point, we are thinking of partnering both assets.

That said, our clinical trials are progressing smoothly. We had been somewhat concerned about conducting them on our own, but at least at this stage, things are moving forward without issue. So we want to think carefully about this. Fundamentally, our intention is to pursue partnering for both assets. On the other hand, we are not currently considering a pure license-out approach.

Muraoka [Q]: Understood. Thank you. One more question.

Regarding the Japan business, on slide eight, the other category shows actual results of JPY17.7 billion, down JPY0.5 billion YoY. I believe co-promotion of Ozempic started in July and Wegovy in November, but based on what we see here, the impact doesn't appear to be showing up yet. Should we expect this to grow into something visible in terms of scale going forward, or is it likely to remain limited for a while? How should we think about this?

Kimura [A]: The figures are actually already included here, but due to considerations involving our partner, we have decided not to disclose the fee income.

On the other hand, Xeplion has been sold by us since January, so from here on, the figures themselves will start to be booked as sales.

Muraoka [Q]: So with GLP-1 drugs for diabetes and obesity, is it simply that they're not visible because there are also declining items offsetting them, or are they genuinely small in scale?

Kimura [A]: You can think of it as not being visible because there are also items that are declining. At the same time, we haven't been at it very long yet, so in terms of absolute amount, the impact is not that large. Basically, it is fee income.

Muraoka [Q]: By the way, overseas, Wegovy in pill form has already been launched. If possible, and depending on the partner, would it be fair to think that your company would like to participate in co-promotion for that as well?

Kimura [A]: That really depends on the partner, but for now, please understand that we are not considering that as a company.

Muraoka [M]: So for the time being, it's injection products only.

Understood. Thank you. That's all from me.

Kino [M]: Thank you very much.

Next, we will move on to Mr. Wakao from JPMorgan Securities.

Wakao [Q]: This is Wakao from JPMorgan. Thank you. I have a few questions.

First, I'd like to ask about ORGOVYX. You explained the recent trend through December, but I'd like to confirm whether there have been any changes in the very near-term trend. Also, my understanding is that the data for ORGOVYX are fundamentally better than for leuprorelin, so patients are steadily switching over, or rather, you're capturing new patients.

If this situation continues, then essentially everything other than ORGOVYX would be leuprorelin, so it wouldn't be surprising if ORGOVYX's share continued to rise further. One could even imagine a scenario where all patients end up using ORGOVYX. In that context, what kind of peak share are you currently envisioning? I feel it may be time to start having this kind of discussion, so I'd appreciate your thoughts.

Kimura [A]: Thank you for the question.

Regarding whether the current trend will continue, over the long term, we do believe the present trend will persist. That said, as I mentioned earlier, in this fiscal year we saw a significant jump due to the impact of the IRA. There was a sharp jump in calendar year 2025, but from calendar year 2026 onward, growth should normalize. Even so, we understand that growth will remain robust.

As for peak share, we have, of course, considered various possibilities, but we do not believe that ORGOVYX will take all of leuprorelin's share. For that reason, we would like to refrain from commenting on peak share at this point.

Wakao [Q]: Then who are the patients who are still using leuprorelin now? The data seem better for ORGOVYX, and in terms of price, especially from the patient burden perspective, that burden also seems to have become smaller. How should we think about that?

Kimura [M]: Since Mr. Nakagawa, who is responsible for North America, is here, I'll ask him to step in and explain.

Nakagawa [A]: This is Nakagawa, in charge of the North America business. I'll respond.

As Kimura just mentioned, we are not disclosing peak share. As you pointed out, of course, if we could achieve a 100% share, that would be welcome. However, in reality, there are patients who prefer injectable formulations, or in particular, long-acting injections with longer dosing intervals, such as once every three months. Taking those preferences into account, it is probably not very realistic to expect everyone to switch over.

Regarding your initial question about the near-term situation, the US business does have a bit of seasonality. What would correspond to Q4 in the Japanese fiscal year tends to be somewhat weaker. However, there has been absolutely no change in the broader trend. As Kimura said, while we do not expect another jump like the one seen around 2025, we do expect prescriptions to continue increasing steadily going forward.

Wakao [Q]: Understood.

Also, regarding ORGOVYX and GEMTESA, I assume it is your premise that they will eventually become subject to price negotiations under the IRA. In that case, since ORGOVYX is growing within Medicare, I think there is a fairly high possibility that at some point revenues could drop sharply. Are there any strategies you are currently considering to offset that kind of decline?

Kimura [A]: We recognize that IRA-related negotiations are still several years away. On the other hand, for both products, we believe that we have already built a sufficiently solid commercial base. We have just started thinking about how to carry that forward effectively. We would like to find a way to somehow connect this current momentum to what comes next.

Wakao [Q]: Would that be through in-house products, or through in-licensing?

Kimura [A]: At this point, we are beginning to think in terms of our own R&D. We are not concretely considering in-licensing right now, although depending on circumstances, it could be something we consider in the future. But at present, we are not considering it at all.

Wakao [Q]: Understood.

My second question is about the partnerships for nuvisertib and enzomenib, which we discussed earlier. With the ASH data updates for nuvisertib and enzomenib, how have potential license-out partners been evaluating them? Are things moving in a more positive direction, or has there been no real change?

Kimura [A]: Fundamentally, I think the response has been positive. That said, for enzomenib, we had already shared some monotherapy data previously, so what was new this time was the combination with venetoclax and azacitidine. For nuvisertib, the combination with momelotinib was new. Even so, the impression from potential partners is that they would like to see somewhat more robust patient numbers. Overall, I would say

the impression is very good, but they want to see things a bit more clearly, if I were to summarize it broadly, that would be the sense.

Wakao [Q]: I see. So in the end, while extending the timing of the partnership can be framed in a positive way, on the other hand, it also feels like there's a somewhat negative nuance, that the data are still insufficient. My understanding is that this interpretation isn't wrong, is it?

Kimura [A]: I think that depends on the terms. If we were willing to compromise, we could probably enter into a partnership now because the assets are viewed as very interesting. However, as you know, these are products that will support our future, so we want to maximize the value we can obtain. In that sense, we are accepting the risk of delaying things by close to a year and continuing development on our own. By doing so, we believe we can generate better data and connect that to a partnership on better terms.

Wakao [Q]: As for development speed, is it fair to understand that, at least at the current pace, even if you proceed independently, there will be no delay?

Kimura [A]: Yes. As you know, in oncology there comes a phase where many clinical trials need to be run in parallel. At that stage, we may be somewhat constrained if we are on our own. However, at the current stage, we are able to move forward with sufficient speed, and we believe that will carry us through to around next fiscal year.

Wakao [M]: Understood. Thank you very much. That's all from me.

Kino [M]: Thank you very much.

Next, we will move on to Mr. Wada from SMBC Nikko Securities.

Wada [Q]: This is Wada from SMBC Nikko Securities. Thank you.

First, I'd like to ask about performance. You've already touched on this, but there was a comment that operating profit in Q4 might dip slightly. Could you help us organize the factors that could lead to a decline when looking at Q4 on a standalone basis?

Kimura [A]: This will overlap with what I said earlier, but first, based on our analysis of Q3, we believe that there was an inventory buildup of around USD20 million included in the results.

Second, since our business is centered on North America, in North America there is an insurance reset at the start of the new year, in January. When that happens, patient out-of-pocket costs temporarily increase again, which tends to suppress the emergence of new patients.

Third, and this may be somewhat specific to our company, but historically we have seen a tendency for expenses, SG&A and R&D expenses in particular, to be concentrated in Q4. Taking all of that into account is what underlies the analysis I mentioned earlier. Sakai-san, do you have anything to add?

Sakai [A]: Thank you for the question. This is Sakai.

As Kimura explained at the beginning, we have not changed our revised forecast, so I will speak based on that premise. As Kimura also noted, if you run the numbers, you can see that the burden of R&D expenses in Q4 is currently being assumed to be quite heavy.

So, as Kimura explained, broadly speaking, one factor is that distribution inventories increased in Q3, sales exceeded underlying demand. In Q4, while demand itself remains solid, shipments may decline as a kind of pullback from that. The other factor is that, under our current assumptions, a certain level of R&D expenses

will be incurred in Q4. In broad terms, those are the two main reasons why we are not viewing Q4 overly optimistically.

Wada [Q]: Thank you.

My other question is about the pipeline, specifically enzomenib. On January 6, Amgen acquired Dark Blue Therapeutics. Dark Blue Therapeutics is developing an MLL protein degrader, and it seems likely that this was the main focus of the acquisition, which was for around JPY120 billion.

So, while I understand that there is strong interest in your menin inhibitor as well, how do you view the difference between a degrader and an inhibitor? Does the difference in mechanism of action broaden the patient population? Do safety or efficacy profiles change? How should we think about that?

Kimura [A]: I'm sorry, but at this point, we have not been able to conduct a scientific comparison within our own research, so it's difficult for us to analyze this in detail. On the other hand, since the mechanisms of action are completely different, we do think there may be some kind of differentiation or segmentation possible. Degraders are a very new concept, so as they are used more broadly, certain issues may also emerge. But that is simply a general observation.

Wada [M]: Thank you. That's all from me.

Kino [M]: Thank you very much.

Next, we will move on to Mr. Hashiguchi from Daiwa Securities.

Hashiguchi [Q]: This is Hashiguchi. Thank you.

I have a question based on the content of a media article from about two weeks ago, which said it was based on comments from President Kimura. It stated that you have a policy of increasing R&D expenses in stages, and in quotation marks it said that you are first considering an increase of around 10%. I'd like to ask whether that is something you actually said, and also, when you say 10%, the amount changes quite a bit depending on whether that's 10% off the expected full-year landing for this fiscal year, or 10% off the currently disclosed forecast. Earlier you mentioned that you are now in a position to spend more money, so could you comment a bit more on how much you think you can spend next fiscal year at this point?

Kimura [A]: Thank you.

I would appreciate it if you could understand that my true intent was not necessarily captured perfectly in the wording. As for R&D expenses, we are still in the process of preparing the budget, so I cannot provide precise or strict figures. However, in terms of sensitivity, we are currently working on a budget that assumes an increase of around 10%, or slightly more than 10%, compared with this year's budget base.

Hashiguchi [Q]: Thank you.

In that sense, I'd like to ask about your true intent, specifically regarding the resumption of dividends. The article states that you plan to formulate a medium-term management plan next fiscal year and, within that, present to the market a target timeline for resuming dividends. If the medium-term plan is developed next fiscal year, I imagine the actual announcement would be around next spring, roughly a year from now. If the timing for dividend resumption is only clarified at that point, then it seems that in the near term, say, at the end of this fiscal year or the start of next fiscal year, you would not yet be in a position to express such a view. Is that understanding incorrect?

Kimura [A]: That is actually the point where the article deviated the most from my true intent. What I wanted to convey was that, while we are fully aware of expectations for dividend resumption given that we have been non-dividend-paying for some time, considering our current situation, we also have challenges such as growth investment and strengthening our financial base. Within that balance, we want to carefully consider the amount and timing of dividend resumption. Separately, since we have largely achieved the numerical targets of our Reboot plan, we are thinking of formulating a new medium-term management plan with new targets next fiscal year. Those two points were combined, which resulted in the wording you saw.

Hashiguchi [Q]: Given that, when it comes to the timing of showing your thinking on dividend resumption, would you say that such a moment is likely to come relatively soon, or not likely in the near term?

Kimura [A]: I will say that we do not intend to link it directly to the formulation of the medium-term plan.

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

Kino [M]: Thank you very much.

Mr. Wakao from JPMorgan Securities has raised his hand again, so please go ahead.

Wakao [M]: Sorry, this is my second time. Is that all right?

Kino [M]: That's fine.

Wakao [Q]: This is more of a confirmation, and since it hasn't come up yet, I wanted to ask. Regarding the Parkinson's iPS program, is it reasonable to view the likelihood of approval within the fiscal year as fairly high?

Kimura [A]: As for that, the approval itself is, of course, subject to review by the PMDA, including external experts. From our perspective, however, we believe communication with the PMDA has been proceeding very smoothly. We don't know the exact timing of approval, but internally, we are making preparations so that, starting in April next fiscal year, we will be ready to respond immediately if approval is granted. At this point, all we can really do is leave it to them.

Wakao [Q]: Understood. So in terms of your sense of how things are going, there's been no change from before, and it still feels like approval by the end of March is reasonably achievable.

Kimura [A]: Yes. Unfortunately, it's not that the sense of confidence has increased compared with before, but it is also true that no major issues have emerged either.

Wakao [Q]: And there's nothing in particular being requested from the authorities at this stage?

Kimura [A]: Naturally, various requests come up in the course of communication, but we believe we have been able to respond adequately. We believe we have responded.

Wakao [M]: That's very clear. Thank you. That's all from me.

Kino [M]: Thank you very much. As there are no further questions, we will conclude the Q&A session for analysts and investors.

From this point on, we will move to the Q&A session with members of the press, so analysts and investors are free to leave.

Thank you for waiting. We will now begin the Q&A session with members of the press. This session will run until 6:15 PM.

First, we would like to invite Mr. Okada from Yakuji Nippo. Please go ahead.

Okada [Q]: Thank you for your time. This is Okada from Yakuji Nippo.

I have a question about enzomenib and nuvisertib. Earlier, you mentioned that you might push back the timing of partnering somewhat. I believe there was also discussion of approval application timing, with FY2026 or FY2027 being mentioned. Have there been any changes around that timing?

Kimura [A]: Thank you for the question.

Since this is oncology, we will be filing approval applications for various indications. For the very first one, enzomenib as monotherapy, we are proceeding with the aim of obtaining approval in 2027. This is a few months later than our original plan, but fundamentally, we are operating on schedule. There may be some slight instances where things cross fiscal years, but from where we stand, progress is smooth.

Okada [Q]: And how about nuvisertib?

Kimura [A]: For nuvisertib as well, at this point, it is progressing according to plan.

Okada [Q]: Understood. Thank you.

Regarding the content of partnering, my understanding is that you are essentially envisioning partnerships closer to the final stages of development, including manufacturing and sales. Could you elaborate a bit more on what kind of partnership structure you have in mind?

Kimura [A]: Naturally, this depends on the counterparty, but from our perspective, we would like to look for a partner within a framework of joint development and joint commercialization.

Okada [Q]: So rather than an out-license, it would be limited to joint sales, with your company remaining the marketing authorization holder?

Kimura [A]: That's correct.

Okada [M]: Understood. Thank you.

Kino [M]: Thank you very much.

Next, we will move on to Mr. Ishii from Iyaku Tsushinsha.

Ishii [Q]: This is Ishii from Iyaku Tsushinsha.

I'd like to ask about your sales strategy for diabetes drugs in Japan and your outlook for the Japan business going forward.

Kimura [A]: From our perspective, we are working to expand sales of TWYMEEG, and we are also proceeding with the partnership for Ozempic, and we have METGLUCO as well. So we want to steadily grow sales in those areas.

That said, the fact that we do not currently have a major new product is one source of concern, and we are now thinking about what to do with the Japan pipeline going forward.

Ishii [Q]: Given that, what kind of shape do you see the future outlook for the Japan business taking?

Kimura [A]: Speaking in general terms, including the drug price revisions at the end of last year, costs are rising significantly amid inflation, while drug prices are being reduced. In addition, there is the MFN, most-favored-nation, policy that the Trump administration frequently refers to, where if there is a drug price lower than that in the US, they seek to align US prices to that lower price. If that happens, the attractiveness of the Japanese market, where drug prices are low, will decline even further. That is something we are very concerned about.

Ishii [Q]: Understood. Also, could you tell us the current balance of interest-bearing debt?

Kimura [A]: Strictly speaking, Sakai will confirm the exact figure, but I believe it was JPY260 billion.

Sakai [A]: The balance sheet balance is JPY259 billion. However, since we also have a certain level of cash and cash equivalents, if you take net debt into account, the level is roughly JPY200 billion.

Ishii [M]: Understood. Thank you very much.

Kino [M]: Thank you.

Next, we will move on to Mr. Yoshimizu from Iyaku Keizaisha.

Yoshimizu [Q]: Thank you. President Kimura, Mr. Sakai, Mr. Nakagawa, Ms. Sato, Mr. Wakemi, thank you in advance for your continued cooperation this year. I have two questions. I'll ask them one by one.

First, regarding the Japan business that has just been discussed, what areas do you think should be strengthened as the next core pillar? I'd like to hear your thoughts on that first.

Kimura [A]: For us, our primary goal is to firmly build up areas where we have our own products. First of all, if the iPS Parkinson's therapy is approved, we would like to expand that. We also intend to launch the two oncology products in Japan, so we would like to strengthen those areas. At the same time, we also want to continue selling well in our existing areas and enhance our presence.

Yoshimizu [Q]: Understood. So rather than, say, something like diabetes area as some other companies do, you're thinking primarily along product lines?

Kimura [A]: Yes, basically it would be product-driven. That said, as someone asked earlier, we do have a presence in diabetes. We have strong sales capabilities and have built very good relationships with physicians, so we also want to value and leverage that.

However, we do not have an in-house diabetes pipeline, so how to address that will be an important strategic point going forward.

Yoshimizu [Q]: Understood. Thank you.

My second question is that after Hisamitsu conducted an MBO on January 3, a certain foreign news agency listed Sumitomo Pharma as a company that might pursue an MBO in the future. With issues such as parent–subsidiary listings being discussed more and more, could you share your view on whether the current capital structure is appropriate?

Kimura [M]: I assume you're referring to an MBO or delisting.

Yoshimizu [M]: Yes.

Kimura [A]: Given that our share price has been kept at a high level, I don't think delisting is a very realistic option at this point, and we ourselves are happy with the current situation.

Yoshimizu [Q]: You're happy with the current situation. As the issue of parent–subsidiary listings is likely to be discussed even more strictly this year, how would you comment on that?

Kimura [A]: That is more an issue for Sumitomo Chemical, but as I mentioned earlier, we do not feel that our management freedom is being constrained by the fact that Sumitomo Chemical holds more than 50% of our shares. On the other hand, in regenerative medicine, our collaboration with Sumitomo Chemical has been working very well, so we believe we are benefiting from those advantages. That is our current view.

Yoshimizu [M]: I understand very well. Thank you. That's all from me.

Kino [M]: Thank you very much.

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

This concludes Sumitomo Pharma's Q3 financial results briefing for FY2025. Thank you very much for joining us today.

[END]