Sumitomo Pharma

Sumitomo Pharma Co., Ltd.

Q1 Financial Results Briefing for FY2026

July 31, 2026

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
[Company ID]	4506
[Event Language]	ENG
[Event Type]	Earnings Announcement
[Event Name]	Q1 Financial Results Briefing for FY2026
[Date]	July 31, 2026
[Time]	16:30 – 17:28 (Total: 58 minutes, Presentation: 19 minutes, Q&A: 39 minutes)
[Venue]	Webcast
[Number of Speakers]	5

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]	Seiji Wakao	JPMorgan Securities
	Hiroshi Wada	SMBC Nikko Securities
	Jaeheon Lee	Morgan Stanley MUFG Securities

Presentation

Maruyama: We will now begin Sumitomo Pharma's financial results briefing for Q1 FY2026.

Thank you very much for joining us today. I'm Maruyama, Head of Corporate Communications, and I'll be serving as the moderator.

This information session is being live-streamed via Zoom Webinar from our Tokyo headquarters. After we present the financial results based on the material posted on our website, we will hold a question-and-answer session first with analysts and investors, followed by one with members of the press. The information session is scheduled to end at 17:45.

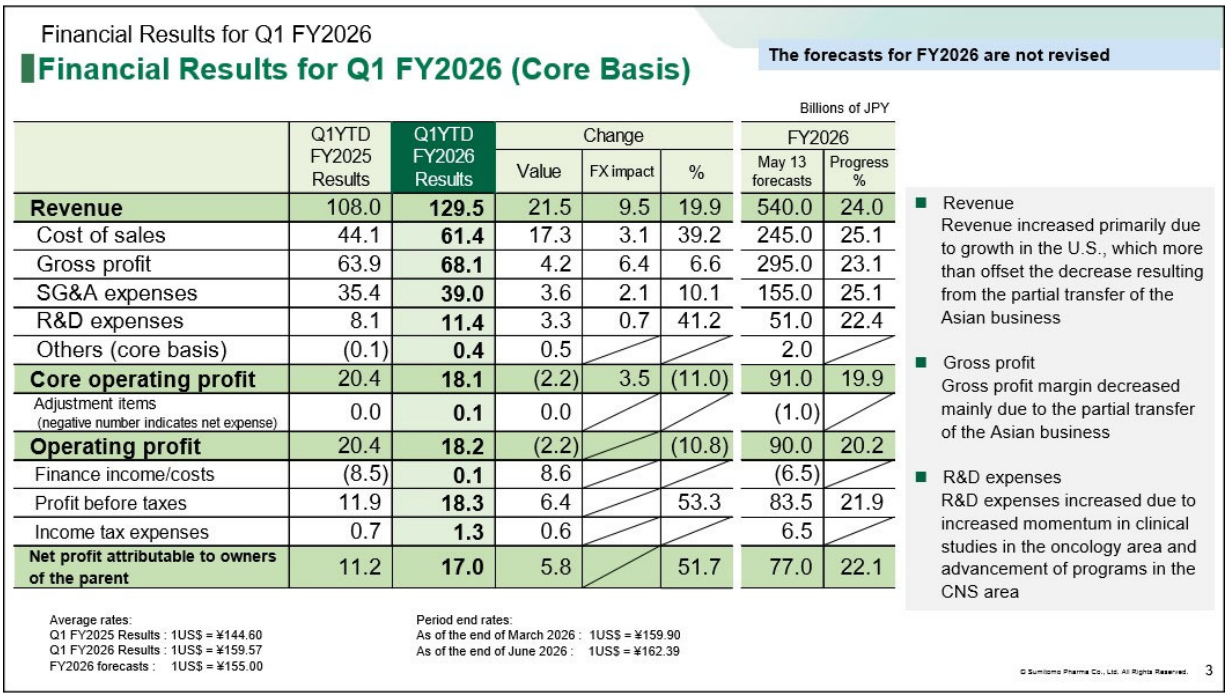
I would like to introduce today's speakers. Sakai, Representative Director and Executive Vice President. Nakagawa, Member, Board of Directors and Managing Executive Officer. Sato, Managing Executive Officer, and Wakemi, Executive Officer.

Sakai will now provide an overview of the financial results for Q1 FY2026 and the current status of clinical development.

Mr. Sakai, please proceed.

Sakai: This is Sakai from Sumitomo Pharma. Thank you for joining us today.

First, we would like to express our sincere sympathy to all those affected by the Reiwa 8 Kumamoto Earthquake that occurred on July 28, 2026, and we sincerely pray for the swiftest possible recovery of the affected areas.



Financial Results for Q1 FY2026

Financial Results for Q1 FY2026 (Core Basis)

The forecasts for FY2026 are not revised

Billions of JPY

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change			FY2026	
			Value	FX impact	%	May 13 forecasts	Progress %
Revenue	108.0	**129.5**	21.5	9.5	19.9	540.0	24.0
Cost of sales	44.1	**61.4**	17.3	3.1	39.2	245.0	25.1
Gross profit	63.9	**68.1**	4.2	6.4	6.6	295.0	23.1
SG&A expenses	35.4	**39.0**	3.6	2.1	10.1	155.0	25.1
R&D expenses	8.1	**11.4**	3.3	0.7	41.2	51.0	22.4
Others (core basis)	(0.1)	**0.4**	0.5			2.0	
Core operating profit	20.4	**18.1**	(2.2)	3.5	(11.0)	91.0	19.9
Adjustment items (negative number indicates net expense)	0.0	**0.1**	0.0			(1.0)	
Operating profit	20.4	**18.2**	(2.2)		(10.8)	90.0	20.2
Finance income/costs	(8.5)	**0.1**	8.6			(6.5)	
Profit before taxes	11.9	**18.3**	6.4		53.3	83.5	21.9
Income tax expenses	0.7	**1.3**	0.6			6.5	
Net profit attributable to owners of the parent	11.2	**17.0**	5.8		51.7	77.0	22.1

- Revenue
  Revenue increased primarily due to growth in the U.S., which more than offset the decrease 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 increased momentum in clinical studies in the oncology area and advancement of programs in the CNS area

Average rates:
Q1 FY2025 Results : 1US$ = ¥144.60
Q1 FY2026 Results : 1US$ = ¥159.57
FY2026 forecasts : 1US$ = ¥155.00

Period end rates:
As of the end of March 2026 : 1US$ = ¥159.90
As of the end of June 2026 : 1US$ = ¥162.39

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I will now begin my presentation on our financial results for Q1 FY2026.

For Q1 FY2026, revenue was JPY129.5 billion, core operating profit was JPY18.1 billion, and net profit for the quarter was JPY17.0 billion.

Revenue increased by JPY21.5 billion compared to the same period last year, including the impact of foreign exchange rate fluctuations. Although we were impacted by the sale of certain businesses in our Asian operations last year and the expiration of exclusive distribution agreements for some products, increased sales of ORGOVYX and GEMTESA in the US offset that decline, enabling us to achieve revenue growth.

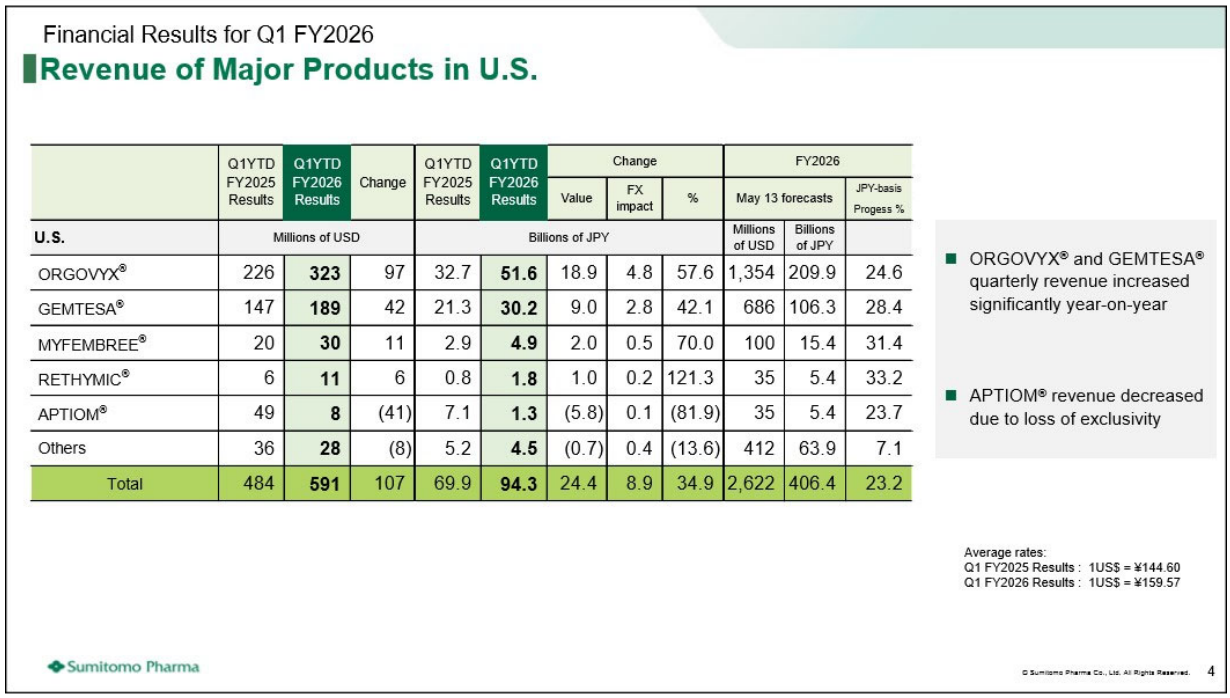
Despite this JPY21.5 billion increase, gross profit rose by only JPY4.2 billion, partly due to the impact of the decline in earnings resulting from the divestiture of our Asian operations, as mentioned earlier.

Selling, general, and administrative expenses increased YoY due to higher sales promotion expenses in North America, while research and development expenses rose due to the acceleration of clinical trials in the oncology field and the advancement of development in the neuropsychiatric field, among other factors.

As a result, as I mentioned earlier, core operating profit was JPY18.1 billion, a decrease of JPY2.2 billion compared to the same period last year.

Financial income/costs improved, primarily due to a favorable change in foreign exchange gains and losses, and net profit for the quarter increased by JPY5.8 billion to JPY17 billion.

Although core operating profit decreased compared to the same period last year, we believe we have gotten off to a solid start in relation to our plan for the current fiscal year.



Financial Results for Q1 FY2026

Revenue of Major Products in U.S.

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change			FY2026		
						Value	FX impact	%	May 13 forecasts		JPY-basis Progess %
U.S.	Millions of USD			Billions of JPY					Millions of USD	Billions of JPY	
ORGOVYX®	226	**323**	97	32.7	**51.6**	18.9	4.8	57.6	1,354	209.9	24.6
GEMTESA®	147	**189**	42	21.3	**30.2**	9.0	2.8	42.1	686	106.3	28.4
MYFEMBREE®	20	**30**	11	2.9	**4.9**	2.0	0.5	70.0	100	15.4	31.4
RETHYMIC®	6	**11**	6	0.8	**1.8**	1.0	0.2	121.3	35	5.4	33.2
APTIOM®	49	**8**	(41)	7.1	**1.3**	(5.8)	0.1	(81.9)	35	5.4	23.7
Others	36	**28**	(8)	5.2	**4.5**	(0.7)	0.4	(13.6)	412	63.9	7.1
Total	484	**591**	107	69.9	**94.3**	24.4	8.9	34.9	2,622	406.4	23.2

- ORGOVYX® and GEMTESA® quarterly revenue increased significantly year-on-year
- APTIOM® revenue decreased due to loss of exclusivity

Average rates:
Q1 FY2025 Results : 1US$ = ¥144.60
Q1 FY2026 Results : 1US$ = ¥159.57

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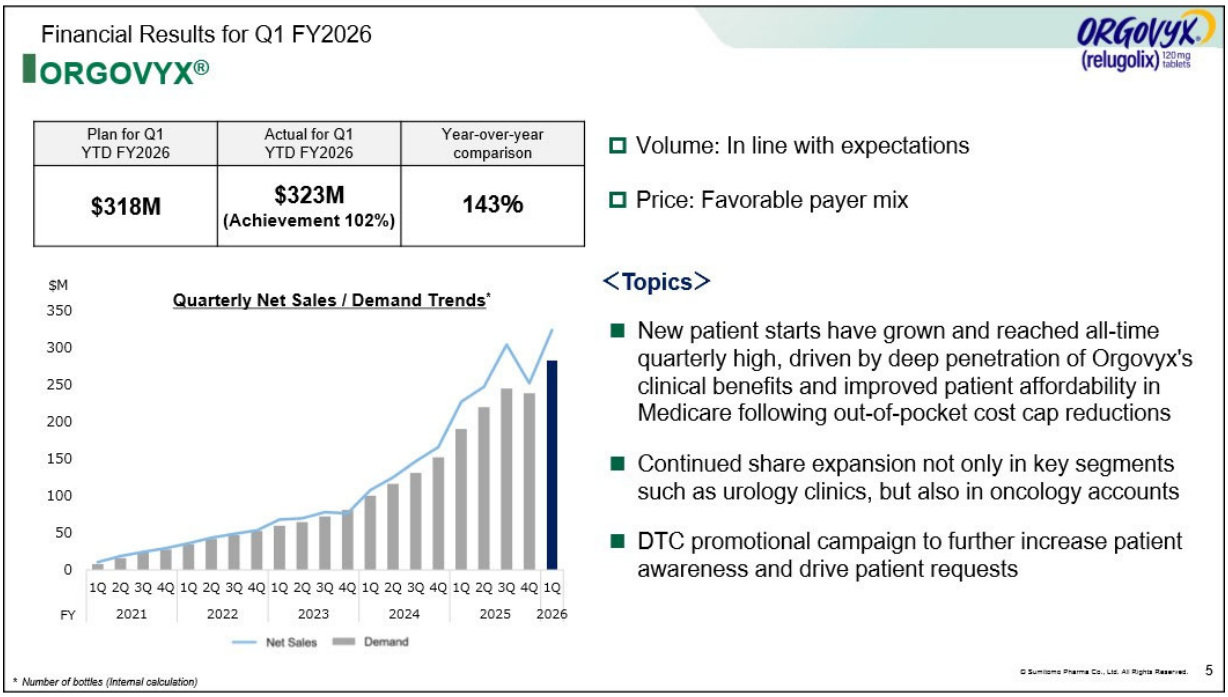
Next, I will explain the situation in North America.

Sales in the United States totaled JPY94.3 billion, representing an increase of JPY24.4 billion, including the impact of exchange rate fluctuations. As you can see, sales of ORGOVYX and GEMTESA have increased.

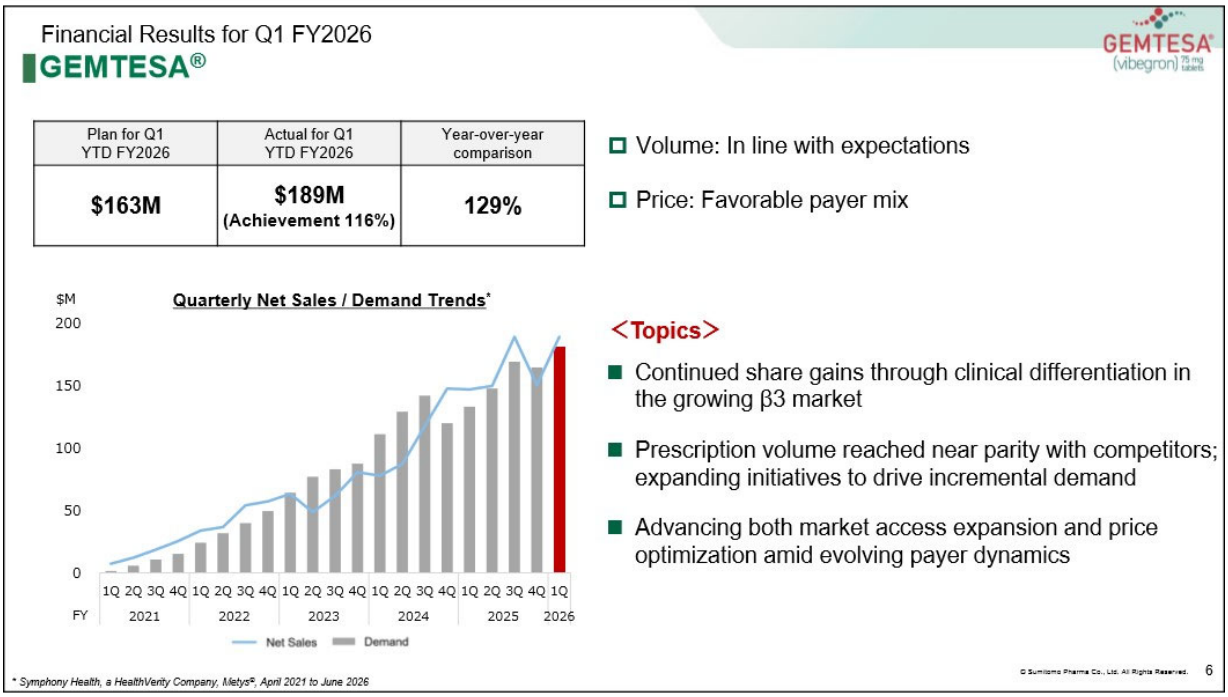


I would like to explain the current status of ORGOVYX and GEMTESA.

First, as shown by the figure in the upper right corner, ORGOVYX's performance was largely in line with the initial plan.

Please take a look at the bar chart. Although sales temporarily declined in Q4 FY2025 due to seasonal factors, they rebounded in Q1, with both sales and volume increasing compared to the previous year.

Also, although this is not mentioned here, on a calendar-year basis, we have already recorded approximately USD570 million in revenue through June, and we believe we are on track to reach the USD1 billion milestone.

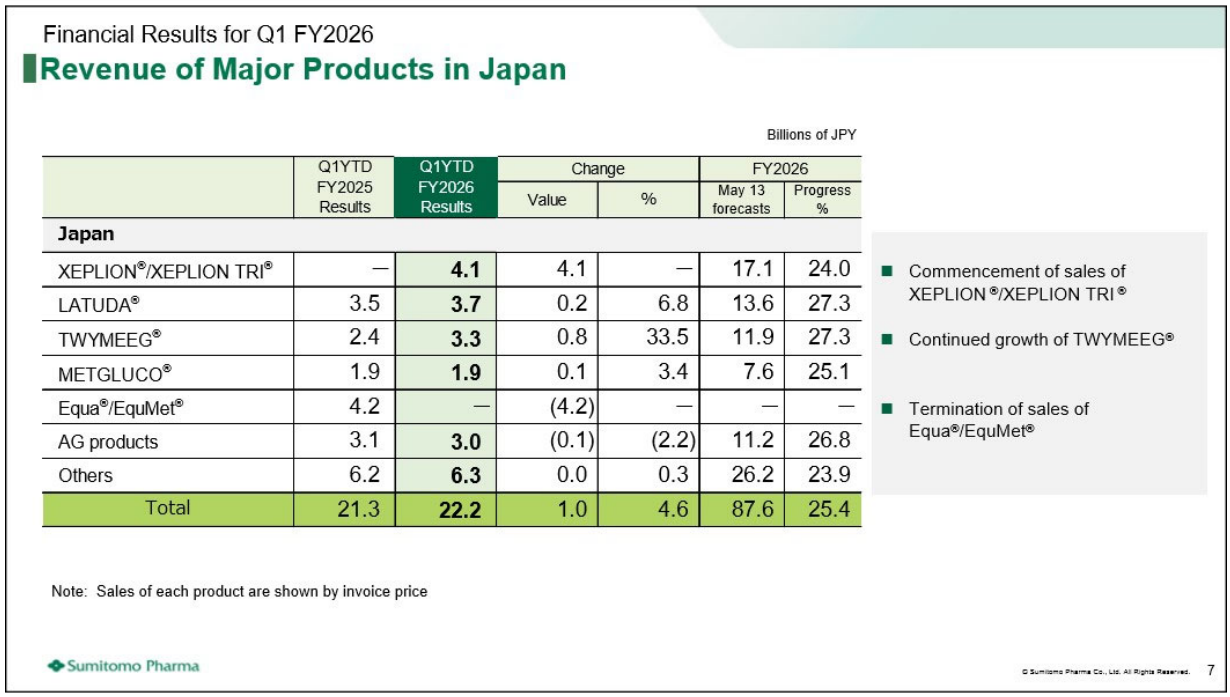


Next up is GEMTESA.

As shown in the upper right corner, the actual result exceeded the plan by 16%.

Although sales volume was generally in line with projections, the payer mix had a positive impact, and thanks to higher prices, we exceeded our plan.

As with ORGOVYX, sales declined temporarily in Q4 FY2025 due to seasonal factors, but recovered in Q1, resulting in a YoY increase of nearly 30 percent.



Financial Results for Q1 FY2026

Revenue of Major Products in Japan

Billions of JPY

	Q1YTD FY2025 Results	Q1YTD FY2026 Results	Change		FY2026	
			Value	%	May 13 forecasts	Progress %
Japan						
XEPLION®/XEPLION TRI®	—	**4.1**	4.1	—	17.1	24.0
LATUDA®	3.5	**3.7**	0.2	6.8	13.6	27.3
TWYMEEG®	2.4	**3.3**	0.8	33.5	11.9	27.3
METGLUCO®	1.9	**1.9**	0.1	3.4	7.6	25.1
Equa®/EquMet®	4.2	—	(4.2)	—	—	—
AG products	3.1	**3.0**	(0.1)	(2.2)	11.2	26.8
Others	6.2	**6.3**	0.0	0.3	26.2	23.9
Total	21.3	**22.2**	1.0	4.6	87.6	25.4

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

Note: Sales of each product are shown by invoice price

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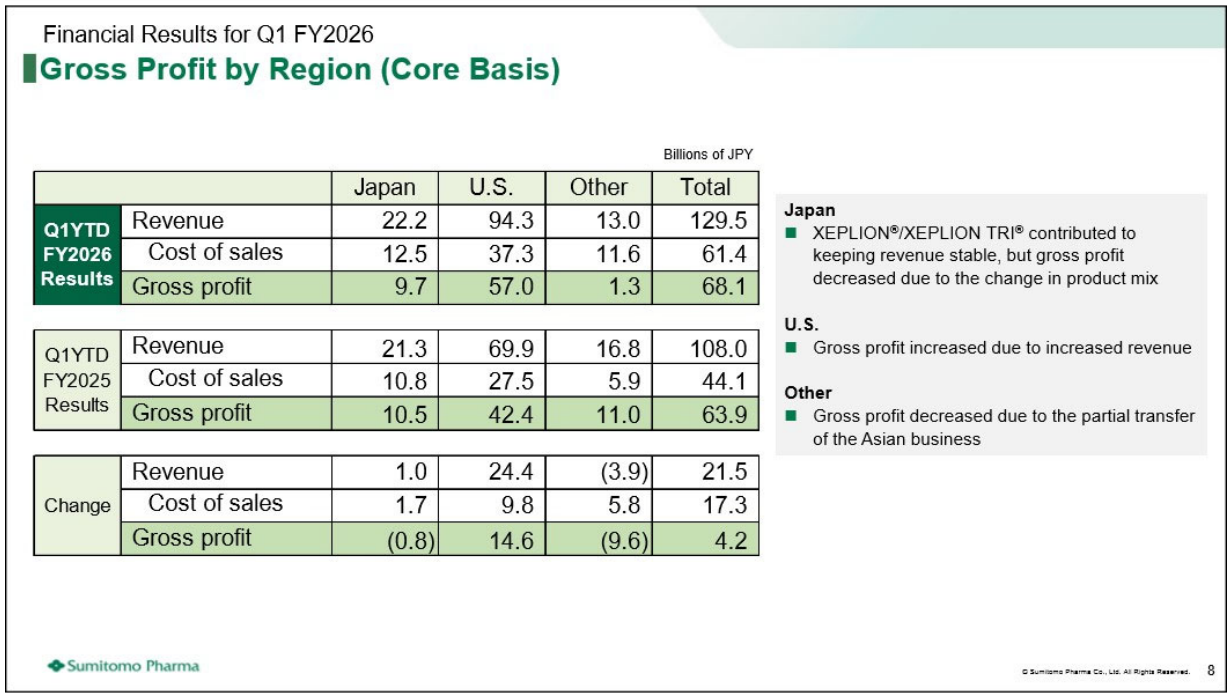
Next is the Japan segment.

Revenue for the Japan segment was JPY22.2 billion, an increase of JPY1 billion compared to the same period last year. As you can see, the main factor behind the revenue increase was the recognition of sales resulting from the launch of our in-house sales of XEPLION/XEPLION TRI.

On the other hand, revenue from Equa/EquMet decreased by JPY4.2 billion because its exclusive sales period expired last year and sales were discontinued in December.



Financial Results for Q1 FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
Q1YTD FY2026 Results	Revenue	22.2	94.3	13.0	129.5
	Cost of sales	12.5	37.3	11.6	61.4
	Gross profit	9.7	57.0	1.3	68.1
Q1YTD FY2025 Results	Revenue	21.3	69.9	16.8	108.0
	Cost of sales	10.8	27.5	5.9	44.1
	Gross profit	10.5	42.4	11.0	63.9
Change	Revenue	1.0	24.4	(3.9)	21.5
	Cost of sales	1.7	9.8	5.8	17.3
	Gross profit	(0.8)	14.6	(9.6)	4.2

Japan
- XEPLION®/XEPLION TRI® contributed to keeping revenue stable, but gross profit decreased due to the change in product mix

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

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

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Here is the gross profit by region.

In the US and Japan, changes in gross profit were in line with the sales figures explained earlier. In other regions, gross profit declined significantly due to the sale, at the end of July last year, of the Asia segment's operations, which had been included in this category until last year.

Marketing and Sales in Japan

Wegovy® Subcutaneous Injection Receives Additional Approval for Metabolic Dysfunction-Associated Steatohepatitis (MASH) Without Cirrhosis

- Wegovy® Subcutaneous Injection, co-promoted with Novo Nordisk Pharma for obesity disease, receives approval for an additional indication for MASH*1
- In accordance with the Package Insert and the Proper Use Promotion Guideline, Sumitomo Pharma and Novo Nordisk Pharma will work closely to provide information to healthcare professionals to support the appropriate use of the product

Wegovy®

Estimated MASH data in Japan*2,3

Number of patients	Approximately 3.7M (Approximately 3.0% of the population)
Direct medical costs	Approximately ¥180B
Productivity loss	Approximately ¥2.1T

*These estimates represent the total MASH patient population in Japan and are not indicative of the number of patients eligible for Wegovy® or future sales forecasts. Wegovy® is indicated for patients with MASH without cirrhosis who have moderate or advanced liver fibrosis

Providing the first approved treatment in Japan for MASH, an area with high unmet medical needs

Key products in the diabetes area, including obesity disease

TWYMEEG® METGLUCO®
Ozempic® Wegovy®

- The diabetes area (including obesity disease) is one of our key strengths and focus areas in Japan
- Leveraging our accumulated expertise and network with healthcare institutions

*1 MASH is a chronic progressive disease characterized by liver inflammation and fibrosis associated with metabolic dysfunction. This approval covers an additional indication for metabolic dysfunction-associated steatohepatitis (MASH) without cirrhosis in patients with moderate to advanced fibrosis.
*2 Based on a prevalence of 3% reported in Journal of Hepatology 69.4 (2013): 896–904, the number of patients was estimated using a Japanese population of 124 million
*3 The Japan Research Institute, Limited. Report on Improving Access to Diagnosis and Treatment for Patients with MASLD/MASH in Japan. April 24, 2026, p.8

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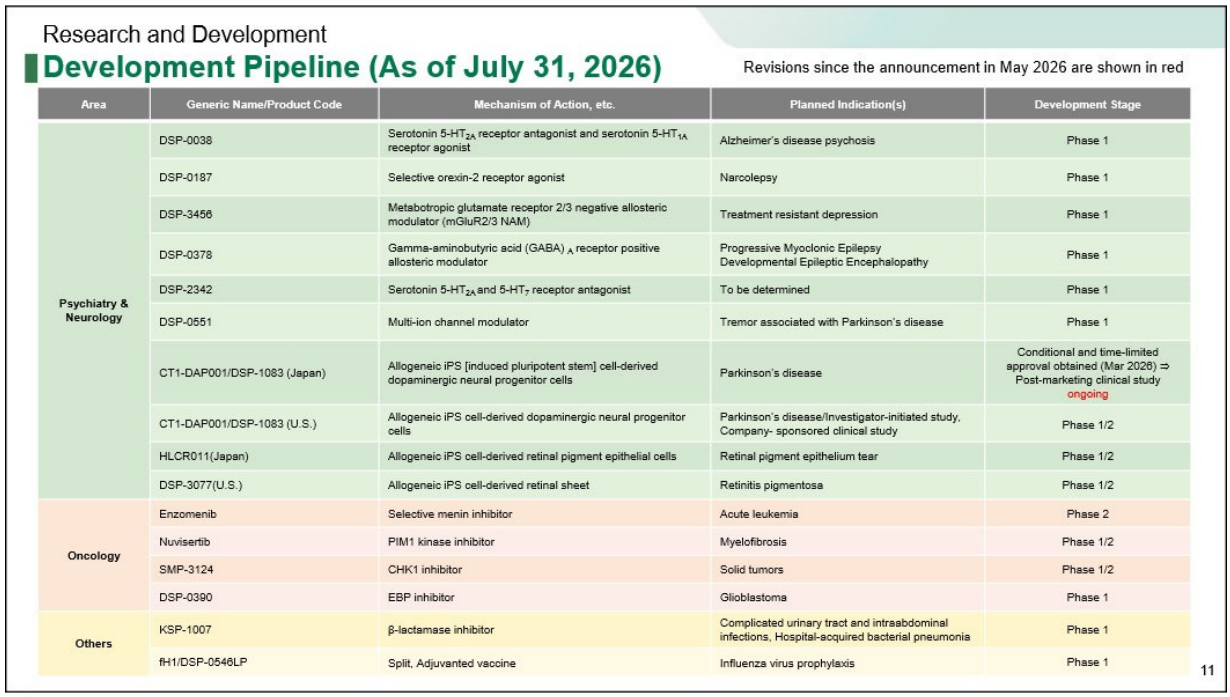
I'd like to discuss one topic related to domestic sales.

As announced in our press release on June 19, we have obtained additional approval for Wegovy subcutaneous injection—for which we have a promotional partnership with Novo Nordisk Pharma as a treatment for obesity—as a treatment for metabolic and dysfunction-associated steatohepatitis (MASH) without cirrhosis. In the field of MASH, we are now able to offer Japan's first treatment option.



Research and Development

Development Pipeline (As of July 31, 2026)

Revisions since the announcement in May 2026 are shown in red

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

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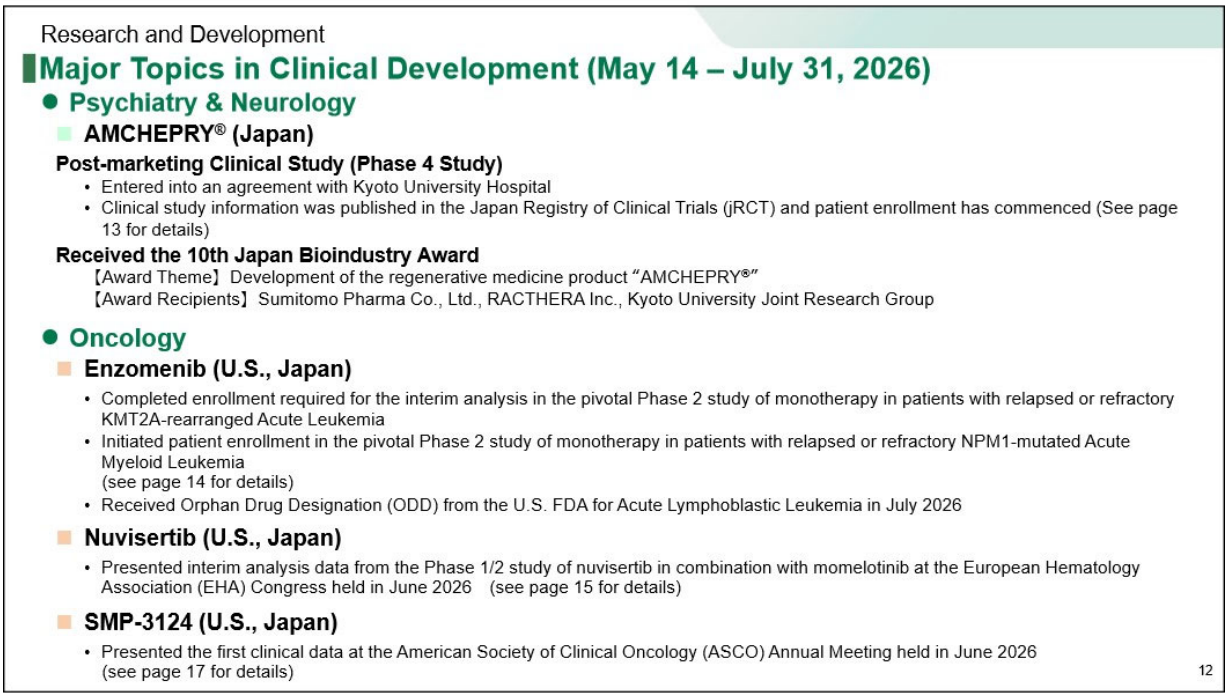
I would like to provide an update on the progress of our research and development.

You are currently viewing a list of our main product lines. As for changes made since the announcement of our financial results in May, we have updated the development status of DSP-1083, which is intended for the treatment of Parkinson's disease and is listed in the middle of the page, from "in preparation" to "ongoing."



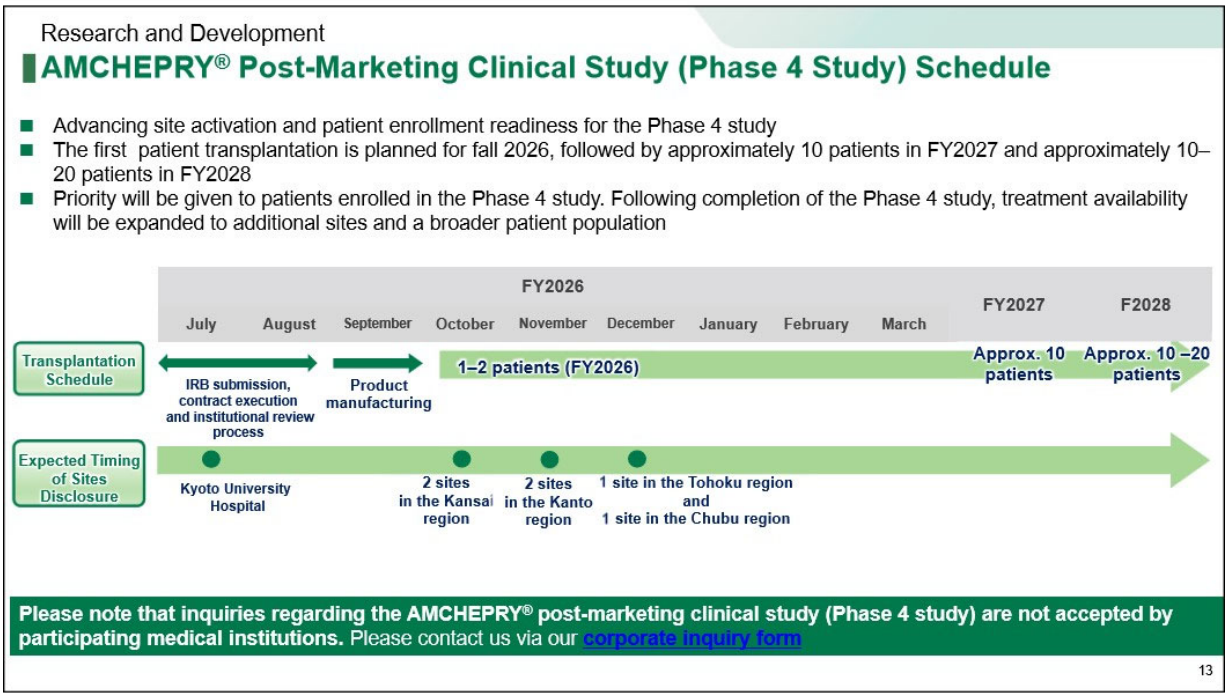
I will now explain the main topics in clinical development starting in May.

Clinical development is generally proceeding as planned.

For AMCHEPRY, we have completed the necessary procedures, including the signing of a contract with Kyoto University Hospital, regarding our Phase IV trial and have begun enrolling participants. In addition, AMCHEPRY was recognized for its achievements in drug discovery and received the 10th Bioindustry Grand Prize.

Regarding enzomenib in the oncology field, we have completed enrollment of the cases required for the interim analysis of the pivotal Phase II trial for acute leukemia with KMT2A rearrangements. We have begun enrolling patients with NPM1-mutated acute myeloid leukemia.

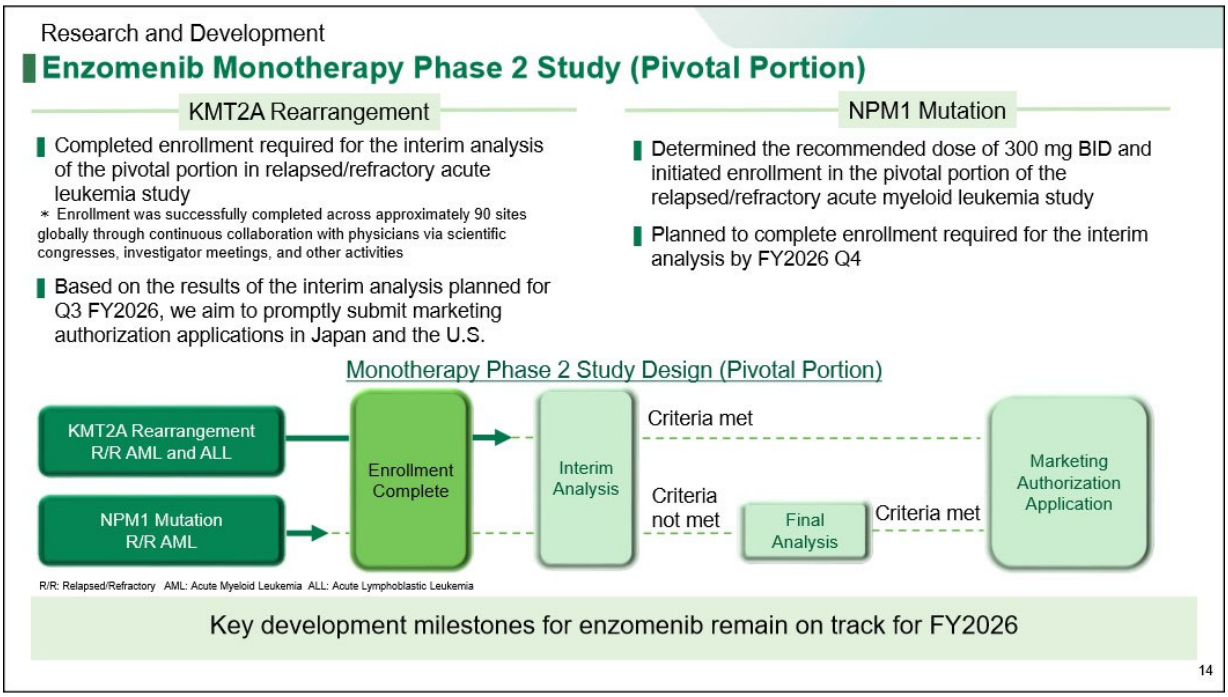
We presented data from a combination therapy trial for nuvisertib at the European Hematology Association (EHA) Congress and the first clinical data for SMP-3124 at the American Society of Clinical Oncology (ASCO) Annual Meeting. I'll explain the details on the next page.



First, AMCHEPRY. Preparations for the Phase IV trial of AMCHEPRY are proceeding smoothly, and following the completion of various procedures and manufacturing, we plan to perform the first transplant this fall. We also plan to perform approximately 10 transplants in FY2027 and approximately 10 to 20 transplants in FY2028.

Kyoto University Hospital began enrolling participants this July. Going forward, we will continue to prepare the necessary infrastructure at the facilities scheduled to host the program in the Kanto, Kansai, Chubu, and Tohoku regions.

On our website, we provide information tailored to both patients and healthcare professionals. Today's presentation material is also available on our website in PDF format. You can view various information by clicking the "here" link.

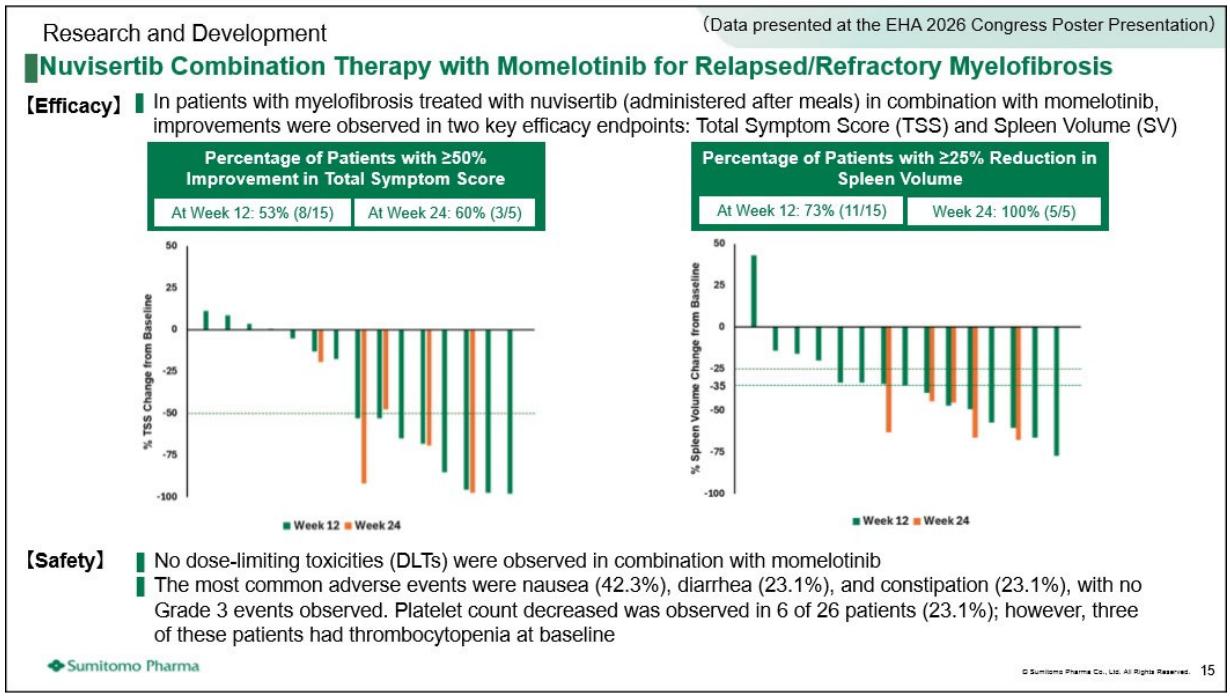


Let's move on to the topic of cancer.

The pivotal portion of the Phase II monotherapy trial of enzomenib is proceeding as planned in the two patient populations—those with KMT2A rearrangements and those with NPM1 mutations—as described.

For the KMT2A rearrangements, we have completed patient enrollment for the interim analysis, and we aim to submit regulatory applications in Japan and the United States around Q3 FY2026, based on the results of the interim analysis.

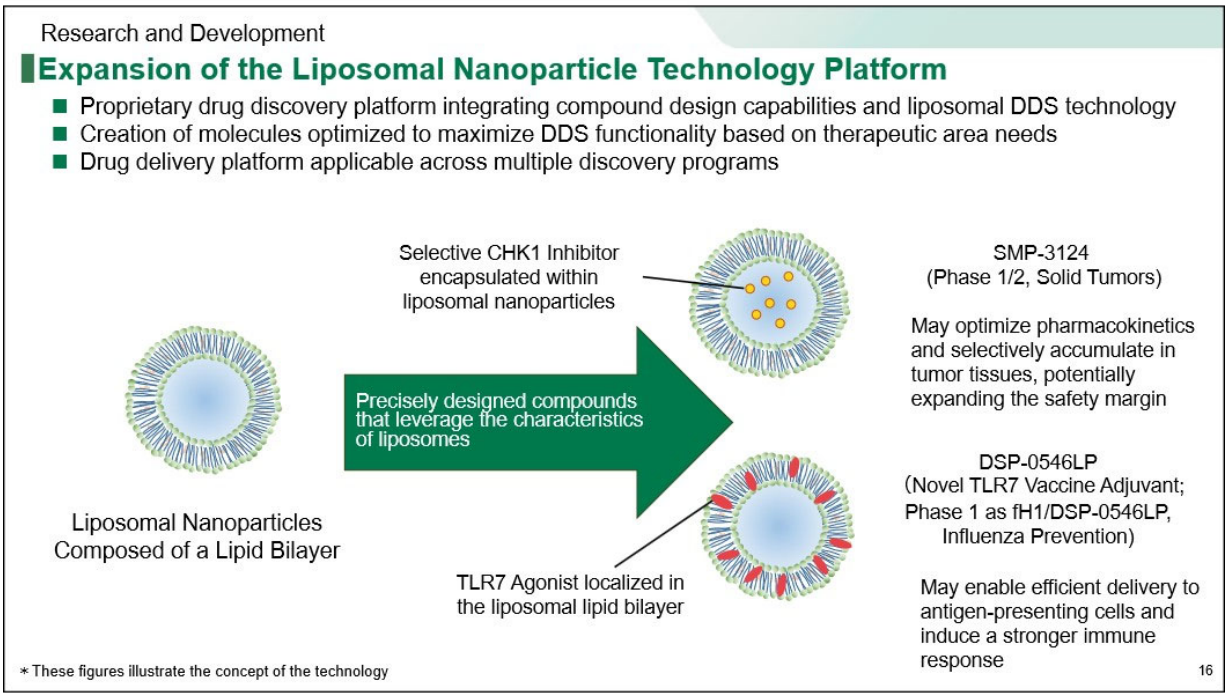
With regard to the NPM1 mutation, we plan to complete patient enrollment for the interim analysis by Q4 FY2026.



The next topic is nuvisertib.

In the nuvisertib and momelotinib combination trial presented at the European Hematology Association Congress, we obtained favorable data demonstrating efficacy and safety.

The combination therapy was shown to improve systemic symptom scores and spleen volume, indicating a signal of efficacy in myelofibrosis. In terms of safety, no dose-limiting toxicity was observed, and the treatment was found to be well tolerated.

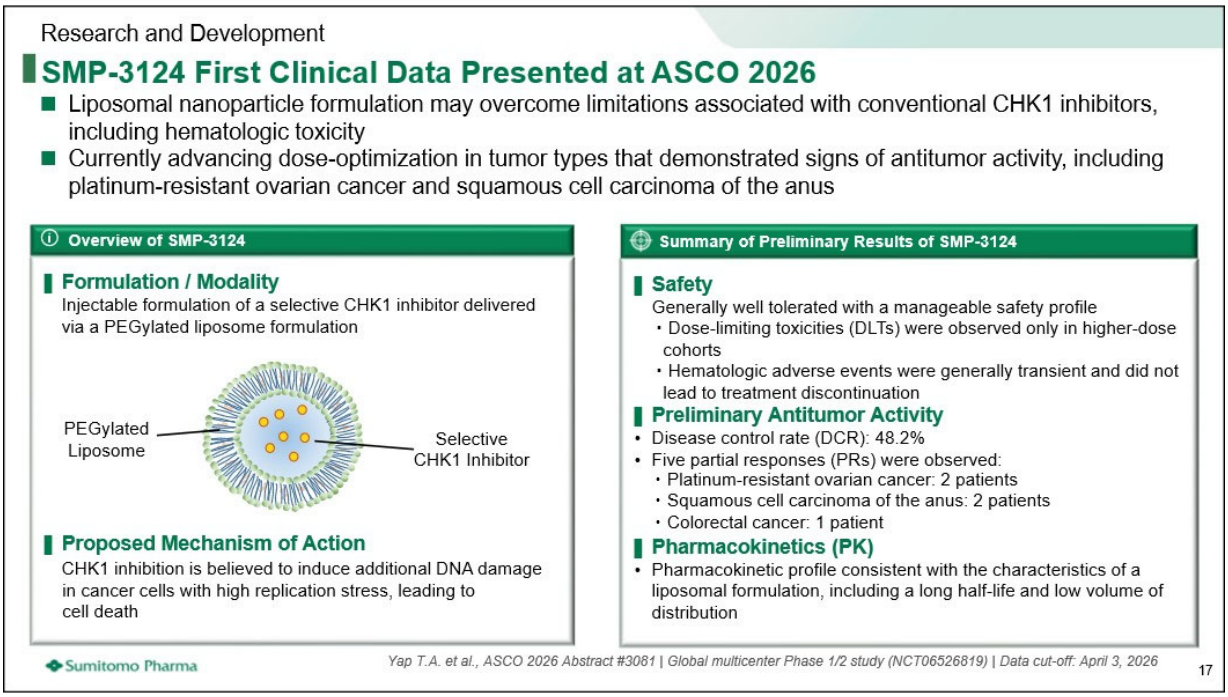


Next, I'd like to move on to the topic of liposomes.

Our company's strength lies in our unique drug discovery platform, which integrates compound design with liposome-based drug delivery system (DDS) technology.

For liposomes composed of a lipid bilayer, as shown on the left, there are implementation examples such as SMP-3124 (shown in the upper right), in which a compound is encapsulated within the membrane, and DSP-0546 (shown by the image below), in which a compound is localized within the membrane.

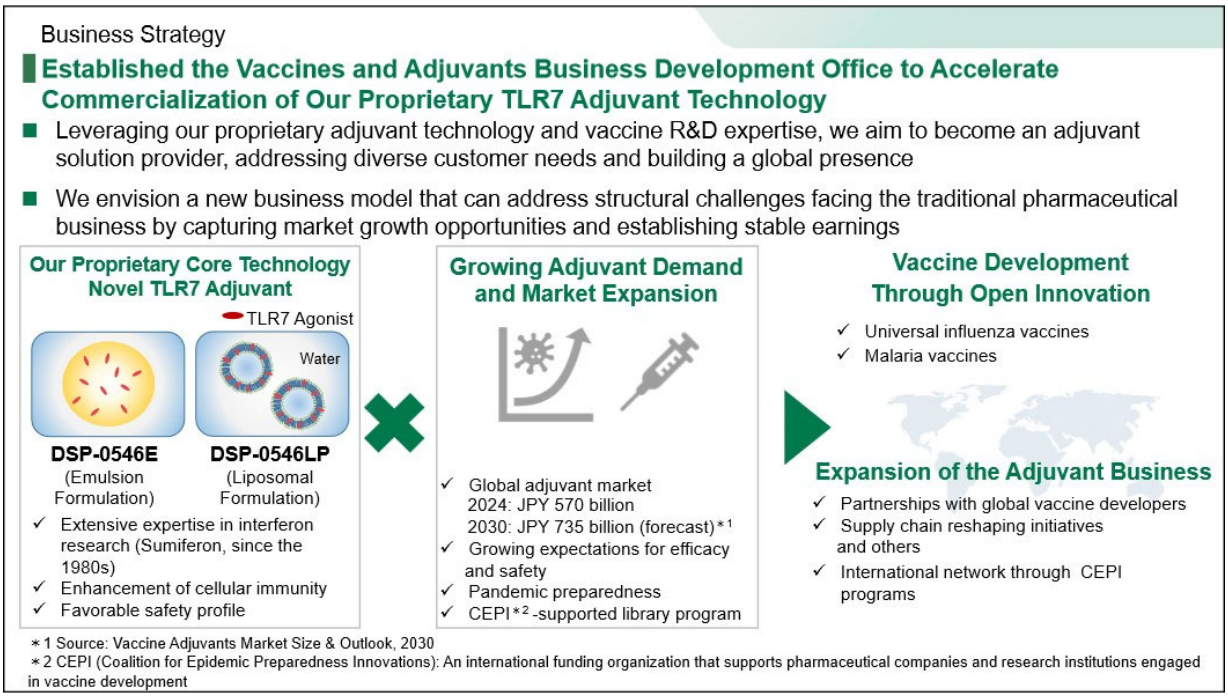
Liposome formulation makes it possible to control drug efficacy and pharmacokinetics; specifically, SMP-3124 is expected to widen the safety margin, while DSP-0546 is expected to induce a strong immune response.



Next up is the SMP-3124.

At the American Society of Clinical Oncology (ASCO) 2026 conference held in June, we presented our first-ever clinical data.

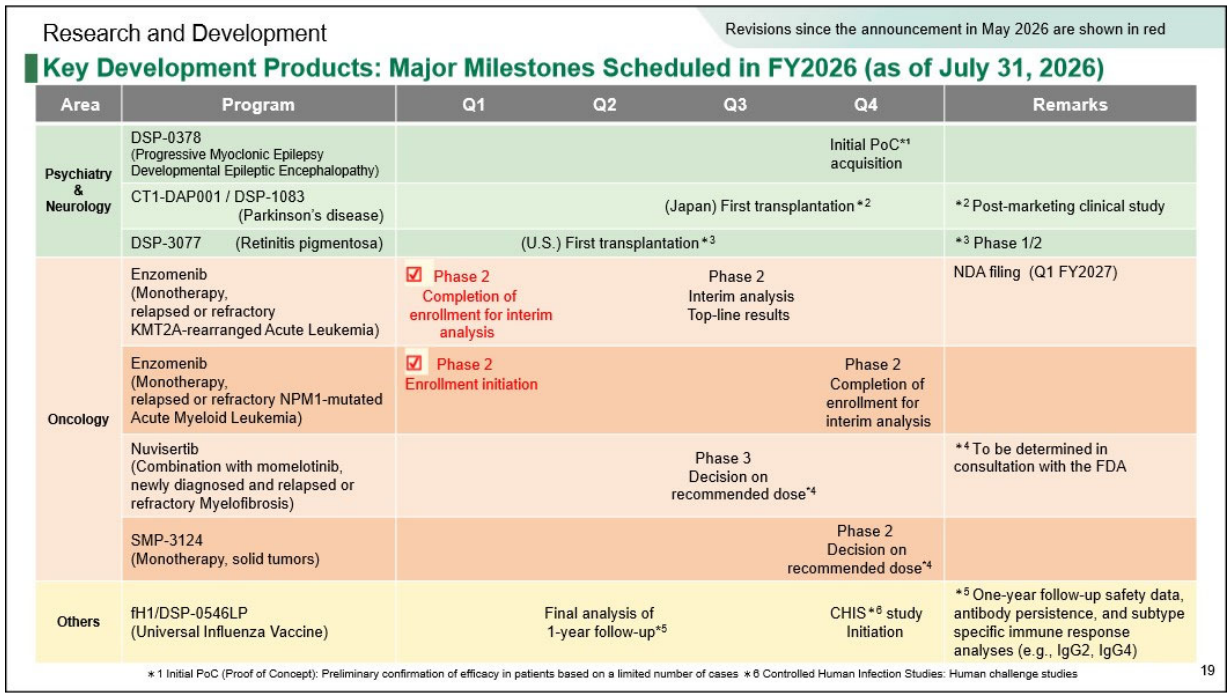
We have obtained results that support the concept of liposome formulation that we previously introduced, and we are currently conducting dose-optimization trials for ovarian cancer and other indications where signs of efficacy have been observed.



Next up is vaccine adjuvants.

Our company possesses proprietary TLR7 adjuvant technology and is developing DSP-0546E and DSP-0546LP.

The products listed on the right utilizes the liposome formulation I mentioned earlier. Recognizing the adjuvant market—which is expected to grow—as a business opportunity, we have established a new Vaccine and Adjuvant Business Development Office to strengthen our commercialization capabilities. Through open innovation and external partnerships, we aim to commercialize our vaccine adjuvants.



Research and Development

Revisions since the announcement in May 2026 are shown in red

Key Development Products: Major Milestones Scheduled in FY2026 (as of July 31, 2026)

Area	Program	Q1	Q2	Q3	Q4	Remarks
Psychiatry & Neurology	DSP-0378 (Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy)				Initial PoC*1 acquisition	
	CT1-DAP001 / DSP-1083 (Parkinson's disease)			(Japan) First transplantation*2		*2 Post-marketing clinical study
	DSP-3077 (Retinitis pigmentosa)		(U.S.) First transplantation*3			*3 Phase 1/2
Oncology	Enzomenib (Monotherapy, relapsed or refractory KMT2A-rearranged Acute Leukemia)	☑ Phase 2 Completion of enrollment for interim analysis		Phase 2 Interim analysis Top-line results		NDA filing (Q1 FY2027)
	Enzomenib (Monotherapy, relapsed or refractory NPM1-mutated Acute Myeloid Leukemia)	☑ Phase 2 Enrollment initiation			Phase 2 Completion of enrollment for interim analysis	
	Nuvisertib (Combination with momelotinib, newly diagnosed and relapsed or refractory Myelofibrosis)			Phase 3 Decision on recommended dose*4		*4 To be determined in consultation with the FDA
	SMP-3124 (Monotherapy, solid tumors)				Phase 2 Decision on recommended dose*4	
Others	fH1/DSP-0546LP (Universal Influenza Vaccine)		Final analysis of 1-year follow-up*5		CHIS*6 study Initiation	*5 One-year follow-up safety data, antibody persistence, and subtype specific immune response analyses (e.g., IgG2, IgG4)

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

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Finally, here is the schedule of major events planned for FY2026.

Please take a look at Q1. Regarding the Phase II trial of enzomenib as a monotherapy for KMT2A rearrangements, we completed enrollment for the interim analysis as planned during Q1. Also, regarding the NPM1 mutation—as I mentioned earlier—we have begun enrolling patients for the Phase II trial as planned.

Although this has been a brief explanation, that concludes my remarks.

We would appreciate it if you could ask us any questions you may have.

Question & Answer

Maruyama [M]: We would now like to move on to the Q&A session with analysts and investors. The question-and-answer session will end at 17:15.

Mr. Wakao of JPMorgan Securities, please.

Wakao [Q]: Thank you. This is Wakao from JPMorgan.

First, you mentioned the Q1 results, the full-year outlook, and the resumption of dividend payments if this fiscal year's targets are met. Could you please elaborate on that? In your explanation, you mentioned that actual results exceeded the Company's internal projections. If this situation continues into Q2, is it likely that the full-year forecast will be revised in the Q2 earnings report? Will a dividend resumption be announced in connection with that?

Sakai [A]: Thank you for your question, Mr. Wakao.

As I explained, we believe the start of Q1 is proceeding smoothly compared to our plans. That said, since only three months have passed, I believe it is too early to revise our full-year outlook at this stage. Since various factors could affect the situation, we will refrain from commenting on the full-year outlook at this time.

As you pointed out, I believe we got off to a very good start in Q1. As I mentioned earlier, I feel that achieving ORGOVYX's milestones has become more certain over the past three months.

Therefore, as you mentioned, I believe we will be able to discuss shareholder returns and dividends when we release our interim financial results.

Wakao [Q]: Thank you.

The second point concerns GEMTESA. I think GEMTESA's Q1 results were very strong. You mentioned that sales volume is growing steadily, the payer mix has improved, and prices are... I'd especially like to know about the prices. I assume the gross-to-net ratio has improved as a result of the improvements to the payer mix, but I'd like to know a little more about the reasons behind that improvement. Also, is this going to last? Could you tell us if levels are likely to remain similar starting in Q2?

Sakai [A]: As you said, the gross-to-net ratio improved more than we had anticipated in Q1. I believe we need to assess the situation a little further to determine whether this will continue indefinitely.

As you are probably aware, GEMTESA has been removed from the coverage plans of some payers. However, I believe that, in the long run, the coverage rate will increase. At this stage, I think it might be a bit too optimistic to assume that we can maintain the Q1 gross-to-net ratio going forward.

Dr. Nakagawa, please let us know if you have any additional comments.

Nakagawa [A]: This is Nakagawa, in charge of US operations. As Mr. Sakai just mentioned, there have been some changes to the listings in GEMTESA's formulary. In 2025, this has been outside the coverage for many payers, but it has been steadily returning since January or April 2026, and coverage has improved.

In that context, since there were a relatively large number of patients—what we might call “non-formulary” patients—who purchased this out-of-pocket rather than using insurance, the G to N ratio, so to speak, or pricing, showed a slight improvement this quarter. This is the mechanism for this period.

However, as coverage expands gradually, I believe the number of such patients will gradually decrease. Therefore, the results from Q1 will not carry over into Q4; rather, this effect will gradually fade away. However, since sales volume is expected to continue growing, we are hopeful that for the full fiscal year, we will meet our budget or perhaps even slightly exceed it. However, given that there are still some uncertainties, we are maintaining our annual forecast at this time.

Wakao [Q]: I understand well. At the beginning of the period, I was quite surprised that the gross-to-net price had been lowered, so I was actually a little surprised that it went up this time. However, when I heard that there were many non-formulary patients, I understood. Thank you very much.

Finally, regarding the slides on enzomenib presented today, I believe it was mentioned that, with respect to KMT2A, a submission would be made if the interim analysis data were favorable. This chart contains various expressions such as "criteria met" and "not met." How should I interpret the terms “criteria not met,” “final analysis,” and “criteria met” listed below? Are you simply trying to say that a scenario like this is possible?

Sato [A]: This is Sato from R&D.

When conducting an interim analysis, we strictly define the criteria for both the final analysis and the interim analysis and consult with the regulatory authorities; however, we do not disclose the criteria themselves.

Therefore, as a general rule, you can submit an application if the criteria are met in the interim analysis. If the criteria are not met, we will conduct a final analysis and decide whether to submit the application based on the results. We illustrated that process.

Wakao [Q]: I understand.

I understood that the slide contained general information. Regarding the interim analysis of KMT2A, the criteria for the interim analysis are based on the data obtained so far, so the bar isn’t set unusually high, is it? I understood that if the data from this interim analysis was favorable, things would move forward toward a partnership with your partner next year. Does that mean, conversely, that if the criteria aren’t met in the interim analysis, the partnering process will also be delayed?

Sato [A]: I believe that if we can continue to achieve the results we’ve reported so far in the interim analysis, we’ll be able to submit the application, and that’s the basis for our target schedule.

However, as I mentioned earlier, even if the criteria are not met at this stage, there is, of course, a possibility that satisfactory results will be obtained in the final analysis. I think how far the partnership discussions will go depends on the information that can be disclosed.

Wakao [Q]: I understand. That said, your company’s stance to date—that you will actively pursue partnerships if the interim analysis data is favorable—hasn’t changed, has it?

Sato [A]: It hasn't changed.

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

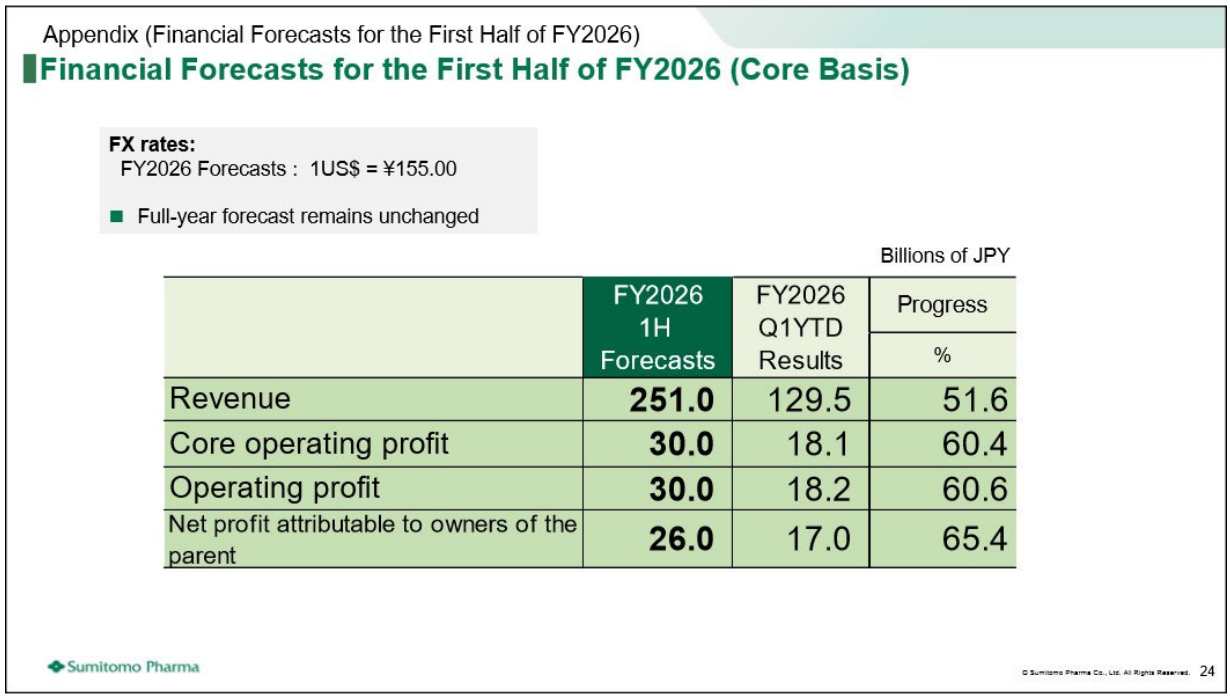
Maruyama [M]: Thank you very much, Mr. Wakao.

Next, we’d like to hear from Mr. Lee of Morgan Stanley MUFG Securities.

Lee [Q]: This is Lee from Morgan Stanley. Thank you for giving me the opportunity to ask a question.

I'd also like to start by asking about the full-year financial results. With ORGOVYX's sales milestones coming up in H2, I, too, felt that you've made excellent progress and gotten off to a great start. Like Mr. Wakao, I also felt that there was a possibility you might exceed your plan for the full fiscal year. However, Mr. Sakai commented that there are fluctuating factors and the fact that only three months have passed. Does your company currently view any particular factors as risks?

Sakai [A]: While I personally do not believe the risk is particularly high at this point, depending on the most severe scenario, the impact of US policy could potentially begin to materialize in the 2027 calendar year—which corresponds to Q4 of our fiscal year. I said that with that in mind. However, at this point, I personally do not consider that to be such a significant risk factor.



Appendix (Financial Forecasts for the First Half of FY2026)

Financial Forecasts for the First Half of FY2026 (Core Basis)

FX rates:
FY2026 Forecasts : 1US$ = ¥155.00

- Full-year forecast remains unchanged

Billions of JPY

	FY2026 1H Forecasts	FY2026 Q1YTD Results	Progress %
Revenue	**251.0**	129.5	51.6
Core operating profit	**30.0**	18.1	60.4
Operating profit	**30.0**	18.2	60.6
Net profit attributable to owners of the parent	**26.0**	17.0	65.4

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Lee [Q]: Thank you. I understand that you are making a conservative estimate.

I am looking at page 24 of the document. This time, your company has provided its forecast for H1 (cumulative total for the first six months). Just to be sure, let me confirm this. If you subtract Q1 from the cumulative forecast for H1, it appears that Q2 will show a QoQ decline. This is merely the plan at the start of the fiscal year, and as I mentioned at the beginning, since performance in Q1 has been very strong, I understand that there is a possibility that Q2 results could exceed the cumulative forecast for H1. Is this line of thinking correct?

Sakai [A]: Although I probably shouldn't say this given that we've already made this information public, our H1 plan was calculated based on an exchange rate of JPY155, and since we cannot change our full-year forecast at this stage, we are using the same basis.

The actual exchange rate for Q1 averaged around JPY160, and as you probably realize, this will likely result in an accounting discrepancy in Q2, which, when factored in, will result in a negative figure.

In addition, we currently expect that selling, general, and administrative expenses, as well as research and development expenses, will be slightly higher in Q2 than in Q1.

As for sales, as mentioned earlier, we did not formulate this plan on the assumption that GEMTESA's strong pricing performance in Q1 would continue at the same level. So, I suppose you could certainly call this conservative.

Lee [Q]: Thank you.

As for individual products—and this is a minor point—I think the performance of products like MYFEMBREE and RETHYMIC, in addition to GEMTESA, was also solid when viewed in dollar terms. Is this just a fluke, or is this your true ability?

Sakai [A]: Our analysis indicates that MYFEMBREE's strong performance is due to temporary factors.

Nakagawa [A]: To add to what said about RETHYMIC, there was a surge in patients at the very beginning of the year. However, we have not revised our annual patient volume forecast. We expect patient numbers to even out over the course of the year.

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

Finally, I'd like to ask Ms. Sato a question about R&D. This is about enzomenib. I understand that an update for KMT2A is scheduled for this fiscal year. You said that patient enrollment for the interim analysis of the NPM1 mutation would be completed by Q4. Can we expect to see the interim data around next summer? If the data is favorable, will you proceed with the approval application using this data, just as you did with KMT2A?

Sato [A]: That is correct. For the interim analysis, we will use the data from six months after the last participant among those included in the interim analysis. This data is from six months after the completion of patient enrollment for the interim analysis; since the analysis takes a little time, it will take a little over six months. That is generally correct. As you are aware, if the results of the interim analysis are favorable, we plan to submit the application afterward.

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

Looking at the clinical trial information, I see that the Horizon 1 trial is being conducted even for first-line treatment and newly diagnosed patients, and the primary completion date is set for June 30 of next year. If the data is good, I think we can look forward to events like next year's ASH—what do you think? This is the last question.

Sato [A]: Regarding first-line therapy, we are also moving forward with the initial data from the Phase I study on combination therapy for first-line treatment. I believe we will make some progress on that data as well during this fiscal year, and I expect we'll be able to provide some explanation at next year's ASH meeting.

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

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

Next, we'd like to hear from Mr. Wada of SMBC Nikko Securities.

Wada [Q]: This is Wada from SMBC Nikko Securities. Thank you very much. Could I ask you two questions about the development pipeline?

The first one is nuvisertib. I think the data on page 15 is from when the press release was issued in June. Compared to the R&D briefing in February, I think the number of cases has probably increased by about 6. I would like to ask for your interpretation of this data.

It states that no dose-limiting toxicity was observed. The number has increased from 18 to 26 cases, but are those six additional cases high-dose cases?

As you move forward with development, if you are able to set the dosage at a higher level, I believe you will see even stronger data on efficacy than what has been presented so far. Could you also tell us about the rationale behind the dose escalation?

Sato [A]: Thank you for your question.

Regarding the data on combination therapy with momelotinib that we presented at the February R&D briefing—although we did not go into detail—the data were based on administration while the patient was fasting, that is, on an empty stomach. What we've explained today is known as "postprandial administration," and the data presented here was collected after the subjects had eaten a meal. I apologize for not providing sufficient details. Therefore, these figures were compiled using a different method than last time.

Overall, the trend is the same as when we explained it in February. In terms of the overall score, the TSS is working well, and the size of the spleen has improved significantly.

On the other hand, side effects such as nausea and diarrhea—commonly referred to as gastrointestinal symptoms—have been less frequent this time than last time. I think the post-meal data will show slightly lower doses. As a result, adverse events related to the digestive system have been decreasing.

Although the overall trend remains the same, I believe the drug continues to demonstrate good efficacy, and its side effect profile has improved. We will continue in this vein, adding a few more cases, and determine the specific dosage for Phase III.

Wada [Q]: Thank you. I understand.

Regarding efficacy, has a dose-dependent effect been observed?

Sato [A]: We are currently accumulating data to confirm dose-dependency, so it is difficult to say at this point at which specific dose that effect is observed.

Wada [Q]: I got it. Thank you very much.

One more point—I think investors have fairly high expectations for the development of a platform for liposome nanoparticles, which is discussed on the next page. At this point, how much do you actually know about which types of cancer and which drugs are compatible? Could you please give us some general information?

For example, when it comes to vaccine adjuvants, I think you'll see a wide variety of modalities emerge, such as protein-based formulations. Could you also explain the restrictions on molecular weight and other factors?

Sato [A]: As you mentioned in your question, I understand that you'd like to get a better sense of what "platforming" entails.

First, regarding 3124, which we are developing in the field of oncology, we are approaching this as a drug delivery system (DDS) in which we encapsulate the compound within a lipid bilayer—a spherical membrane composed of lipids—with the aim of expanding the margin between safety and efficacy for compounds where development has been difficult to advance using existing methods due to safety concerns and the trade-off between efficacy and safety.

The SMP-3124 is the first model to incorporate this concept. While we are considering follow-up products based on a similar concept, we will evaluate on a case-by-case basis exactly how large the compounds can be.

Do you have any other questions?

Wada [M]: No, I understand now. Thank you very much.

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

We would like to take the final question from the analysts and investors during the Q&A session.

Mr. Wakao, please.

Wakao [Q]: I'd like to ask just one thing. I understand that when you refer to the risks starting in January 2027, you are talking about the implementation of the GLOBE and GUARD models, the GUARD requirements imposed on Medicare Part D. Is that correct? Also, you mentioned that you don't view this as much of a risk—what are the reasons behind that? Is it perhaps because the policy debate hasn't really progressed very far yet? Is it perhaps because there isn't much of a price difference between overseas and the US, even if that were actually implemented?

Sakai [A]: What I had in mind was GUARD. You're absolutely right. I said that as a personal opinion. First of all, even if it is implemented, it won't take effect until January of this fiscal year at the earliest, so I don't think it will have much of an impact. Furthermore, based on information indicating that there has been significant opposition to this policy—as evidenced by public comments and other sources—I believe it will likely take some time before it is enacted into law.

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

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

Thank you for your patience. Next, we would like to move on to the question-and-answer session with the press. The event will end at 17:45.

We've received a question from Mr. Azuchi from NHK.

Now, I'd like to read the question.

Azuchi [Q]: Regarding the use of iPS cells for Parkinson's disease, when do you expect the first case from the post-marketing surveillance to be? Also, could you please tell us about the progress of the clinical trials in the US aimed at obtaining FDA approval?

Sato [A]: Thank you for your question.

As Mr. Sakai explained, regarding the first case in the Phase IV trial for AMCHEPRY, preparations such as the contract with Kyoto University progressed last week, and we have just begun the process of enrolling subjects. Next, we will proceed with manufacturing the product and making preparations at Kyoto University. At this point, we are making arrangements and preparations so that the first dose can be administered this October.

As for development in the United States, we intend to continue focusing on this.

Maruyama [M]: Thank you for your question, Mr. Azuchi.

Next, we'd like to hear from Mr. Ishii of Iyaku Tsushinsha.

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

First, I'd like to ask Executive Vice President Sakai for his thoughts on the start of FY2026.

Sakai [A]: Thank you for your question.

As I mentioned at the beginning of my presentation, I believe we've gotten off to a solid start in Q1.

Ishii [Q]: Things are going well—how do you feel about that? Is there anything else you'd like to add?

Sakai [M]: Are you asking about our financial performance or something like that?

Ishii [M]: Yes.

Sakai [A]: Now that the new fiscal year has begun, there will be various changes. Regarding our start to Q1, for example, I mentioned the milestone revenue from ORGOVYX in my earlier explanation. I believe that how Q1 gets off to a start is extremely important for forecasting the future. In that sense, it was really great that we got off to a smooth start on the sales front.

Ishii [Q]: Thank you.

I'd like to hear about the future outlook and expectations regarding Wegovy's first domestic sales campaign in the MASH sector.

Sakai [A]: I would prefer to refrain from commenting on financial performance and related matters. In addition to the existing obesity treatment market, we recognize that this will lead to the expansion of new market opportunities. As this is the first drug of its kind to be approved in Japan, we hope to contribute to expanding treatment options in this field. At the same time, we believe this will also lead to an expansion of the scope of our information-sharing activities, and we intend to focus our efforts on this aspect as well.

Ishii [M]: Thank you very much.

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

Do you have any other questions?

Ms. Nagao, thank you for submitting your question via chat.

I will now read this aloud.

Nagao [Q]: Was the transplant at Kyoto University Hospital the first one? A total of 35 post-marketing surveillance studies will be conducted, but the schedule shown here covers about 30 of them. Could you please give me an overview of the overall schedule again?

Sato [A]: Regarding the first point, as you mentioned, the transplant at Kyoto University is the first of its kind. Preparations for the first transplant are underway at Kyoto University.

You asked for an overview of the planned 35 cases in total. As shown here, the number of cases will range from 10 to 20 through FY2028, for a total of just over 30 cases. Building on that, we are working toward our goal of completing 35 transplants by H1 FY2029.

Maruyama [M]: Ms. Nagao, does this answer your question? Thank you very much. We really appreciate you confirming this.

Do you have any other questions?

Mr. Yoshimizu of Iyaku Keizaisha, please.

Yoshimizu [Q]: Thank you.

Following the previous question, I would like to ask; the number of facilities is listed below the case studies. Is that all? Or will it go up even further to 35? Please tell us what the outlook is.

Sato [A]: Regarding post-marketing clinical trials, given that the transplant procedure itself is technically very challenging and that PET is a specialized imaging method, we plan to conduct these trials at a total of seven facilities**:** Kyoto University, as shown here, and six additional institutions.

Yoshimizu [Q]: I understand. So, everything is going according to plan.

Sato [A]: Yes. Everything is proceeding as scheduled.

Yoshimizu [Q]: I understand.

Regarding the liposome nanoparticle platform—which was also the subject of a question from an analyst earlier—are you making progress in exploring follow-up products for vaccine adjuvants?

Sato [A]: I'd like to explain once again the process of turning our technology into a platform, as shown on page 16. It is a very common concept to create a ball-like structure using a lipid bilayer—specifically, a liposome composed of a lipid bilayer on the left.

In response to this, we consider how we want to maneuver the liposomes within the body—using concepts such as incorporating the compound into the interior of the liposome, placing it within the lipid bilayer that forms the liposome, placing it on the outside, or attaching it to the edge—and then mix the compound with the liposomes to create the final product. Furthermore, we will synthesize the compound not just at the experimental level, but at a standard and volume suitable for clinical trials or manufacturing. We will use this know-how to build a platform.

Regarding the adjuvant you asked about, as stated on our vaccine page, we are currently using liposomes—which are created by incorporating a Toll-like receptor 7 agonist we refer to as DSP-0546 into a lipid membrane—in our universal influenza vaccine.

In addition, there are emulsion formulations that are not double-layered but consist of a mixture. We plan to use these two types to move forward with our work on vaccine adjuvants.

Yoshimizu [M]: I understand. It really helped me organize my thoughts. Thank you very much. That's all from me.

Sato [M]: Thank you very much.

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

Do you have any other questions?

I will now read aloud a question from Mr. Abe of Kyodo News.

Abe [Q]: I'd like to ask three questions about AMCHEPRY. First, on what date in July did Kyoto University Hospital begin enrolling participants? Second, is the first transplant scheduled for some time in October? Third, regarding the seven facilities participating in Phase IV, do you plan to disclose the names of all of them by the end of December 2026?

Sato [A]: First, Kyoto University Hospital began accepting applications on July 24, last Friday.

Second, as you are aware, the first transplant is scheduled for October.

Third, you asked whether we plan to announce all facilities by the end of December. We are currently coordinating various details with the facilities we are preparing to partner with, and if everything goes according to plan, we hope to announce the names of the remaining six facilities by the end of the year. However, if coordination with each hospital is delayed, the timing may change.

Maruyama [M]: Thank you for your question, Mr. Abe.

Do you have any other questions? Finally, we would like to take questions not only from the reporters here, but also from analysts and investors.

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

This concludes Sumitomo Pharma's earnings briefing for Q1 FY2026. Thank you very much for joining us today.

[END]