Sumitomo Pharma Co., Ltd.

Q1 Financial Results Briefing for FY2025

July 31, 2025

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
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[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	Q1 Financial Results Briefing for FY2025
[Fiscal Period]	FY2026 Q1
[Date]	July 31, 2025
[Time]	16:15 - 17:14 (Total: 59 minutes, Presentation: 18 minutes, Q&A: 41 minutes)
[Venue]	Webcast
[Number of Speakers]	4

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; Global Finance Vice President, Head of Global Corporate Strategy

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[Analyst Names]*	Stephen Barker	Jefferies
	Seiji Wakao	JPMorgan Securities
	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities
	Hidemaru Yamaguchi	Citigroup Global Markets

Presentation

Kino: Now that your time has come, Sumitomo Pharma Co., Ltd. will begin the presentation of financial results for Q1 of FY2025. Thank you very much for taking time out of your busy schedule to join us today. I am Kino from the Corporate Governance Department, and I will be your moderator.

This presentation will be webcast live via Zoom webinar from our Tokyo headquarters. First of all, I would like to make an announcement and request to all of you. Please change the participant information displayed on your Zoom screen to your company name and your name.

As for today's schedule, we will explain our financial results in accordance with the presentation materials posted on our website, followed by a question-and-answer session for analysts and investors, and then for the press. The program is scheduled to end at 17:30.

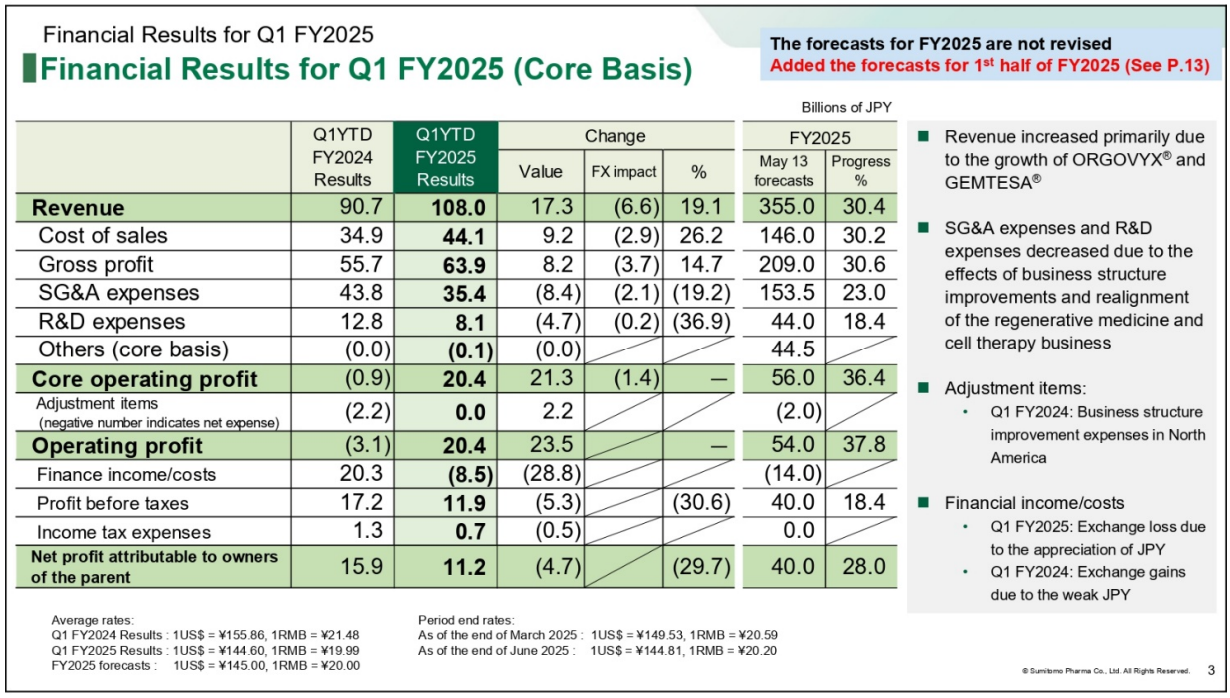
I would like to introduce today's attendees: Dr. Nakagawa, Member of the Board of Directors, Managing Executive Officer; Ms. Sato, Managing Executive Officer; and Mr. Wakemi, Executive Office.

That is all. Thank you in advance for your cooperation.

Now, Mr. Wakemi will explain the Q1 results for FY2025 and the current status of clinical development. Mr. Wakemi, please begin.

Wakemi: Thank you very much. I'm Wakemi from the Global Finance. Thank you.

Based on the presentation materials, I will now report on the Q1 results for 2025 and the current status of clinical development.



Financial Results for Q1 FY2025

Financial Results for Q1 FY2025 (Core Basis)

The forecasts for FY2025 are not revised
Added the forecasts for 1st half of FY2025 (See P.13)

Billions of JPY

	Q1YTD FY2024 Results	Q1YTD FY2025 Results	Change			FY2025	
			Value	FX impact	%	May 13 forecasts	Progress %
Revenue	90.7	**108.0**	17.3	(6.6)	19.1	355.0	30.4
Cost of sales	34.9	**44.1**	9.2	(2.9)	26.2	146.0	30.2
Gross profit	55.7	**63.9**	8.2	(3.7)	14.7	209.0	30.6
SG&A expenses	43.8	**35.4**	(8.4)	(2.1)	(19.2)	153.5	23.0
R&D expenses	12.8	**8.1**	(4.7)	(0.2)	(36.9)	44.0	18.4
Others (core basis)	(0.0)	**(0.1)**	(0.0)			44.5	
Core operating profit	(0.9)	**20.4**	21.3	(1.4)	—	56.0	36.4
Adjustment items (negative number indicates net expense)	(2.2)	**0.0**	2.2			(2.0)	
Operating profit	(3.1)	**20.4**	23.5		—	54.0	37.8
Finance income/costs	20.3	**(8.5)**	(28.8)			(14.0)	
Profit before taxes	17.2	**11.9**	(5.3)		(30.6)	40.0	18.4
Income tax expenses	1.3	**0.7**	(0.5)			0.0	
Net profit attributable to owners of the parent	15.9	**11.2**	(4.7)		(29.7)	40.0	28.0

- Revenue increased primarily due to the growth of ORGOVYX® and GEMTESA®
- SG&A expenses and R&D expenses decreased due to the effects of business structure improvements and realignment of the regenerative medicine and cell therapy business
- Adjustment items:
  - Q1 FY2024: Business structure improvement expenses in North America
- Financial income/costs
  - Q1 FY2025: Exchange loss due to the appreciation of JPY
  - Q1 FY2024: Exchange gains due to the weak JPY

Average rates:
Q1 FY2024 Results : 1US$ = ¥155.86, 1RMB = ¥21.48
Q1 FY2025 Results : 1US$ = ¥144.60, 1RMB = ¥19.99
FY2025 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2025 : 1US$ = ¥149.53, 1RMB = ¥20.59
As of the end of June 2025 : 1US$ = ¥144.81, 1RMB = ¥20.20

 3

Please see page 3. We are pleased to report our Q1 financial results.

It is shown on a core IFRS basis. Revenue was JPY108 billion, an increase of JPY17.3 billion from the same period last year. The main reasons were sales growth of ORGOVYX and GEMTESA in North America.

SG&A expenses and R&D expenses decreased by JPY8.4 billion and JPY4.7 billion, respectively, from the same period last year due to the effects of business structure improvement and reorganization of the regenerative and cell medicine business.

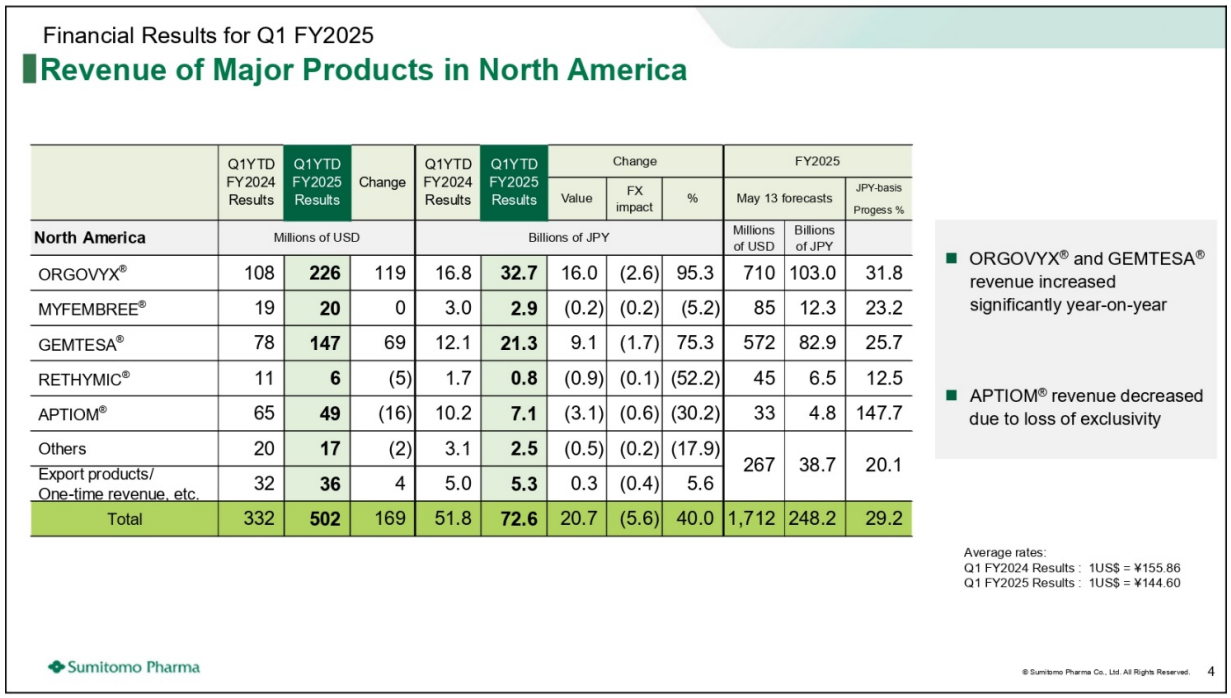
Core operating profit was JPY20.4 billion, an improvement in profit/loss over the same period last year due to increased revenue and decreased expenses.

Operating profit was likewise JPY20.4 billion.

Profit before taxes was JPY11.9 billion, mainly due to a foreign exchange loss of JPY6.7 billion resulting from the appreciation of the yen.

As a result of the above, net profit attributable to owners of the parent increased to JPY11.2 billion.

Although revenues and profits are progressing slightly higher than the annual forecast, the full-year forecast announced at the beginning of the fiscal year remains unchanged due to a number of uncertain variables at this point in time. The Company has also announced a new forecast for H1 of the fiscal year. This will be explained later.



Financial Results for Q1 FY2025

Revenue of Major Products in North America

	Q1YTD FY2024 Results	Q1YTD FY2025 Results	Change	Q1YTD FY2024 Results	Q1YTD FY2025 Results	Change			FY2025		
						Value	FX impact	%	May 13 forecasts		JPY-basis Progess %
North America	Millions of USD			Billions of JPY					Millions of USD	Billions of JPY	
ORGOVYX®	108	**226**	119	16.8	**32.7**	16.0	(2.6)	95.3	710	103.0	31.8
MYFEMBREE®	19	**20**	0	3.0	**2.9**	(0.2)	(0.2)	(5.2)	85	12.3	23.2
GEMTESA®	78	**147**	69	12.1	**21.3**	9.1	(1.7)	75.3	572	82.9	25.7
RETHYMIC®	11	**6**	(5)	1.7	**0.8**	(0.9)	(0.1)	(52.2)	45	6.5	12.5
APTIOM®	65	**49**	(16)	10.2	**7.1**	(3.1)	(0.6)	(30.2)	33	4.8	147.7
Others	20	**17**	(2)	3.1	**2.5**	(0.5)	(0.2)	(17.9)	267	38.7	20.1
Export products/ One-time revenue, etc.	32	**36**	4	5.0	**5.3**	0.3	(0.4)	5.6			
Total	332	**502**	169	51.8	**72.6**	20.7	(5.6)	40.0	1,712	248.2	29.2

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

Average rates:
Q1 FY2024 Results : 1US$ = ¥155.86
Q1 FY2025 Results : 1US$ = ¥144.60

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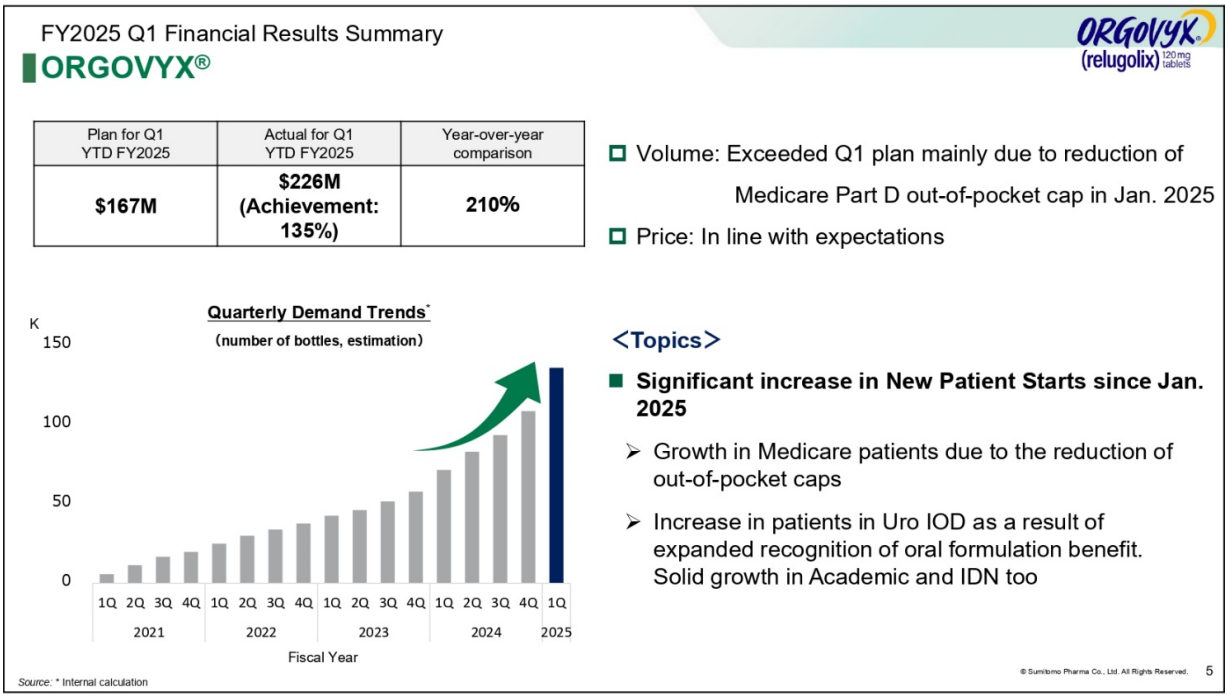
 4

Page 4 shows revenue for the North America segment.

Sales of ORGOVYX and GEMTESA grew, resulting in a JPY20.7 billion increase over the same period last year.

The YoY decrease for APTIOM was due to the end of the exclusivity period in May 2025.

The segment as a whole is performing well, with a 29.2% progress toward the full-year forecast, mainly due to the strong performance of ORGOVYX and a smaller than expected decline in APTIOM.



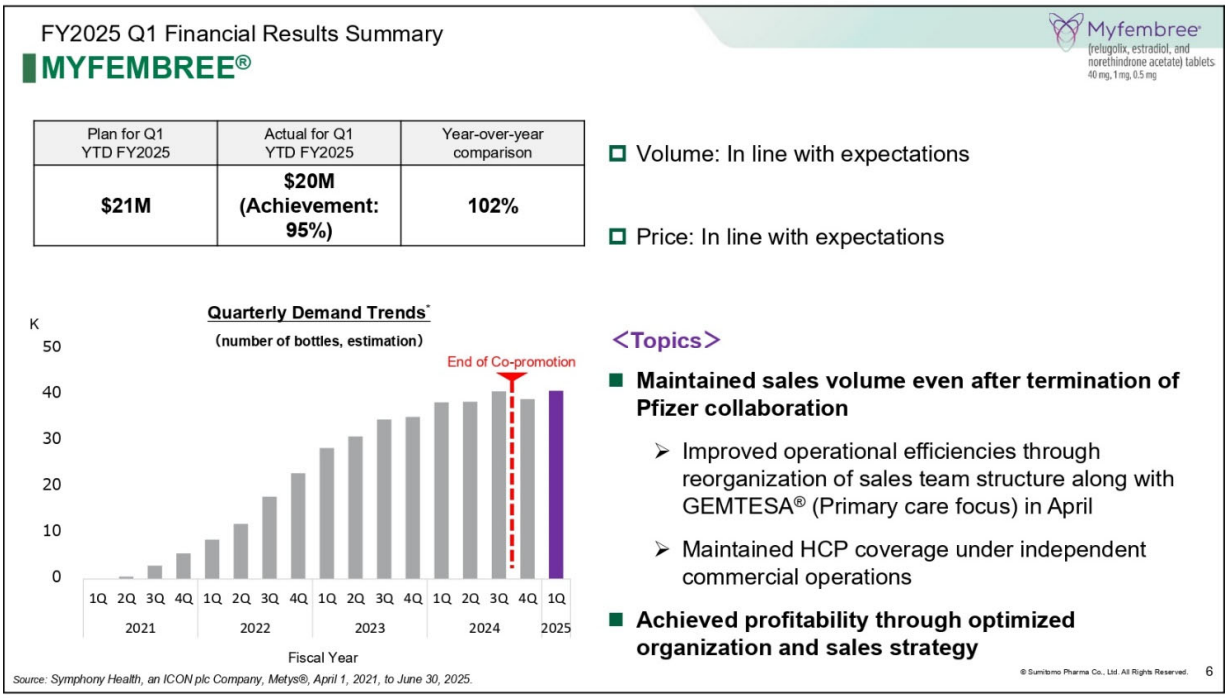
Starting on page 5, we will present the marketing status of our three key products.

In Q1, ORGOVYX achieved $226 million, compared to a plan of $167 million, a very strong achievement rate of 135%. Prices were largely in line with expectations, mainly due to an increase in sales volume.

The increase in volume is due to a cap on patient co-payments under Medicare Part D in January 2024 and a further reduction in that cap from USD3,250 to USD2,000 beginning in January 2025.

The graph on the lower left shows that in addition to the strong growth in FY2024, there has been further growth in Q1 of FY2025.

As noted in the topics on the right, the number of new patients has also increased significantly. The main factors are the increase in the number of Medicare patients due to the reduction in co-payments mentioned earlier, and the widespread use of ORGOVYX, especially in urology departments that prescribe in-hospital due to its advantage of being the only oral drug available.



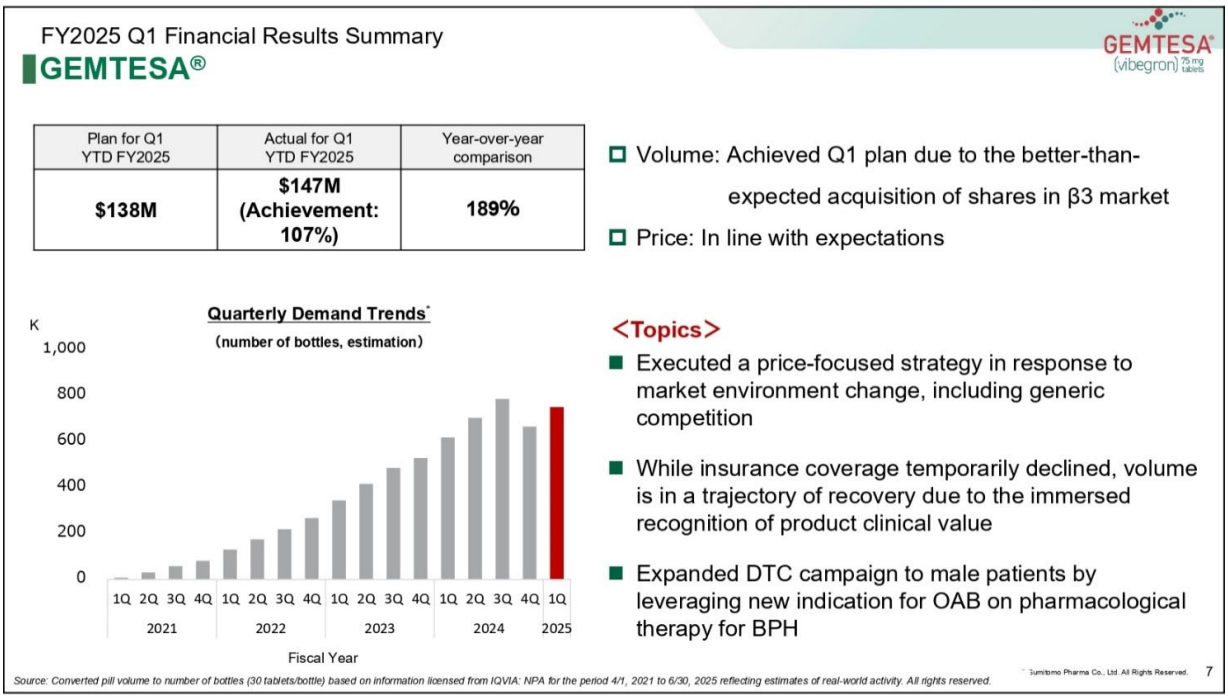
Continuing onto MYFEMBREE.

Actual results were $20 million, compared to the Q1 plan of $21 million. Both volume and price were almost in line with expectations. The slight underachievement was due to the impact of the previous year's adjustments on the price side, which is so-called true-up.

We terminated our marketing alliance with Pfizer at the end of December last year and began marketing the product independently from January this year. Despite this change in structure, we have been able to maintain our sales volume and are off to a good start.

Behind this achievement is a strengthened sales structure. A new community care team was established in April of this year in collaboration with GEMTESA's team for general physicians. By dividing the sales representatives' area more finely, we have been able to increase sales efficiency and maintain sales coverage under the independent marketing structure.

In conjunction with this reorganization, we reviewed our sales strategy and optimized the use of expenses. These efforts have enabled us to achieve profitability in product earnings in Q1 of FY2025.



Let's move onto GEMTESA.

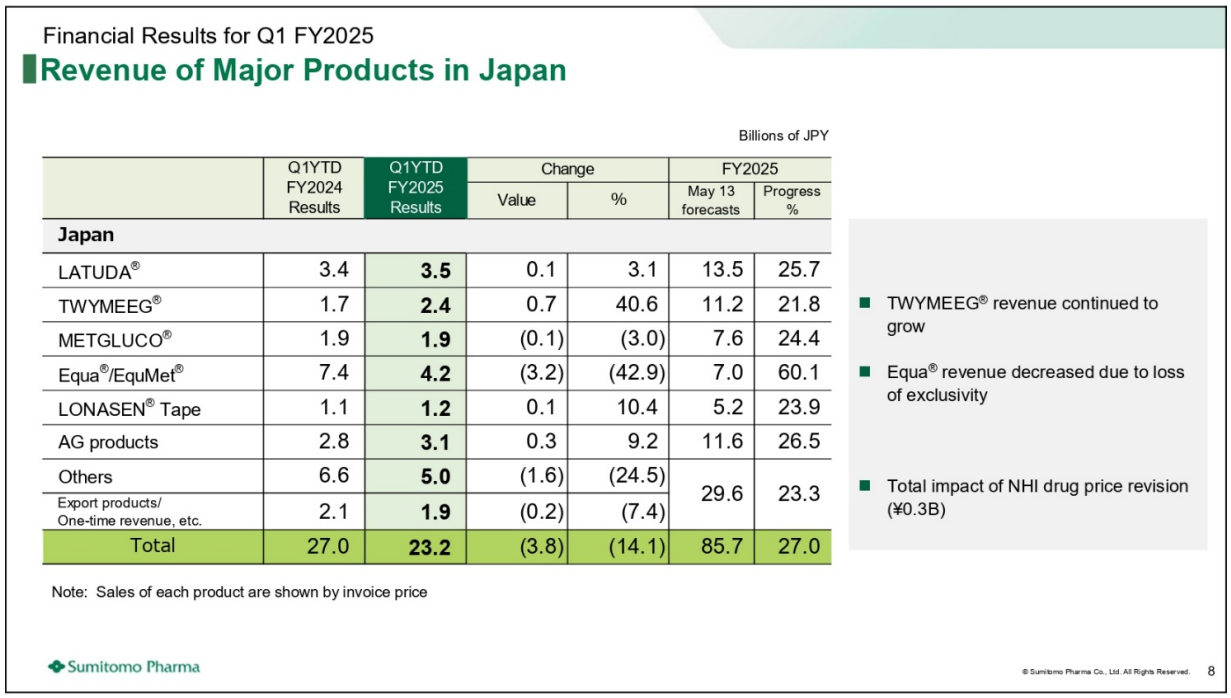
Actual results were $147 million compared to the Q1 plan of $138 million, an achievement rate of 107%. This was due to an increase in volume, which allowed us to gain a larger-than-expected share of product in the β3 market.

From January 2025, we have changed our policy from a strategy that prioritized coverage to one that emphasizes balance in terms of price and other factors.

The graph of volume trends on the left side shows that the volume also decreased due to a temporary decline in coverage in Q4 of FY2024. Volumes are currently recovering as the clinical value of the product, e.g., no warnings of elevated blood pressure, fewer drug interactions, etc., have become more prevalent in the market.

Following the approval of an additional indication for overactive bladder with benign prostatic hyperplasia at the end of last December, we are expanding our DTC measures for male patients.

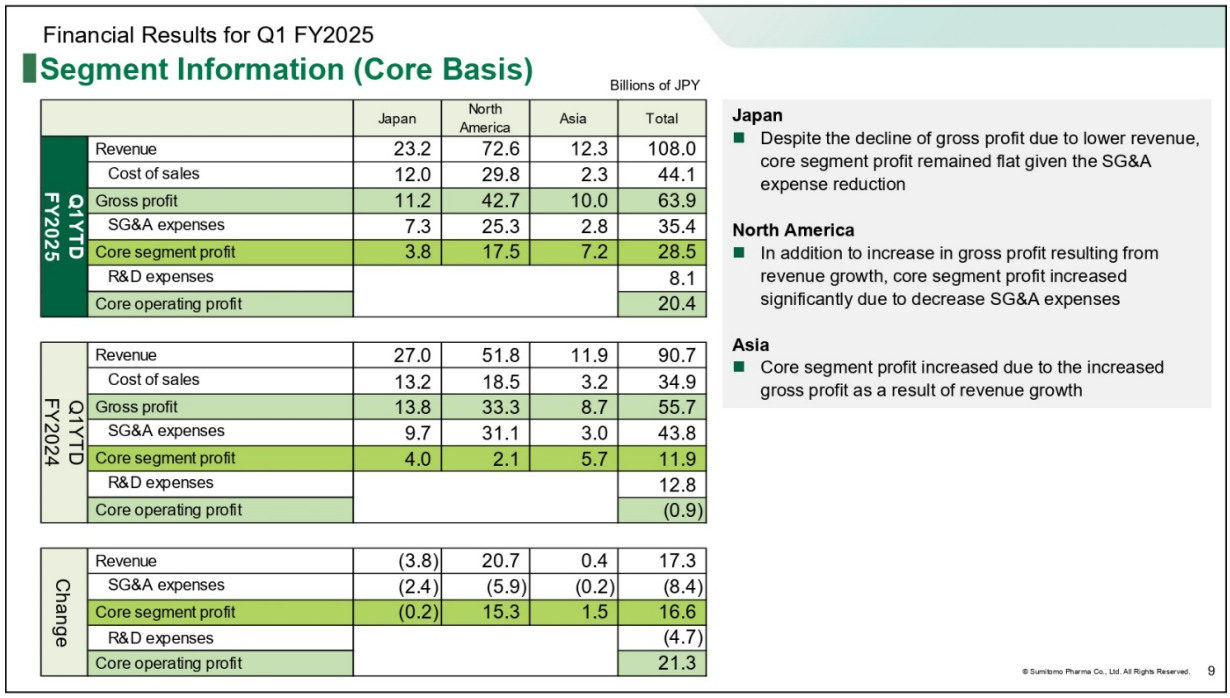
Through this initiative, we hope to further expand the volume in the future.



Page 8 shows revenue in the Japan segment.

The sales in the Japan segment were JPY23.2 billion, down JPY3.8 billion from the same period last year. Although the sales of TWYMEEG increased, overall segment sales declined, mainly due to the end of the exclusivity period for Equa.

Progress against the full-year forecast was 27%, with the segment as a whole progressing largely in line with expectations.



Financial Results for Q1 FY2025

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
Q1YTD FY2025	Revenue	23.2	72.6	12.3	108.0
	Cost of sales	12.0	29.8	2.3	44.1
	Gross profit	11.2	42.7	10.0	63.9
	SG&A expenses	7.3	25.3	2.8	35.4
	Core segment profit	3.8	17.5	7.2	28.5
	R&D expenses				8.1
	Core operating profit				20.4
Q1YTD FY2024	Revenue	27.0	51.8	11.9	90.7
	Cost of sales	13.2	18.5	3.2	34.9
	Gross profit	13.8	33.3	8.7	55.7
	SG&A expenses	9.7	31.1	3.0	43.8
	Core segment profit	4.0	2.1	5.7	11.9
	R&D expenses				12.8
	Core operating profit				(0.9)
Change	Revenue	(3.8)	20.7	0.4	17.3
	SG&A expenses	(2.4)	(5.9)	(0.2)	(8.4)
	Core segment profit	(0.2)	15.3	1.5	16.6
	R&D expenses				(4.7)
	Core operating profit				21.3

Japan
- Despite the decline of gross profit due to lower revenue, core segment profit remained flat given the SG&A expense reduction

North America
- In addition to increase in gross profit resulting from revenue growth, core segment profit increased significantly due to decrease SG&A expenses

Asia
- Core segment profit increased due to the increased gross profit as a result of revenue growth

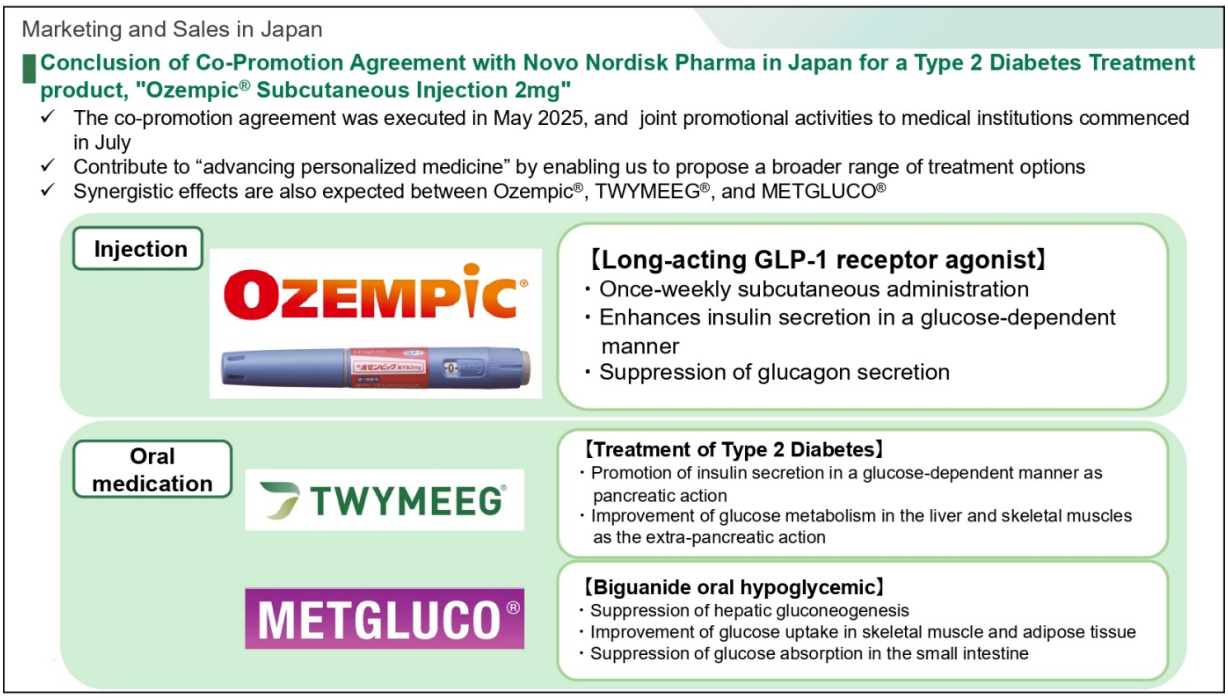
 9

Page 9 shows financial results by segment.

In the Japan segment, core segment profit was largely unchanged at JPY3.8 billion due to a decrease in SG&A expenses resulting from the effect of business restructuring improvements implemented last November, including early retirement, despite a decrease in gross profit due to lower revenue.

In the North America segment, core segment income increased significantly by JPY15.3 billion to JPY17.5 billion due to an increase in gross profit from growth in ORGOVYX and GEMTESA, and a decrease in SG&A expenses from the effects of business structure improvement.

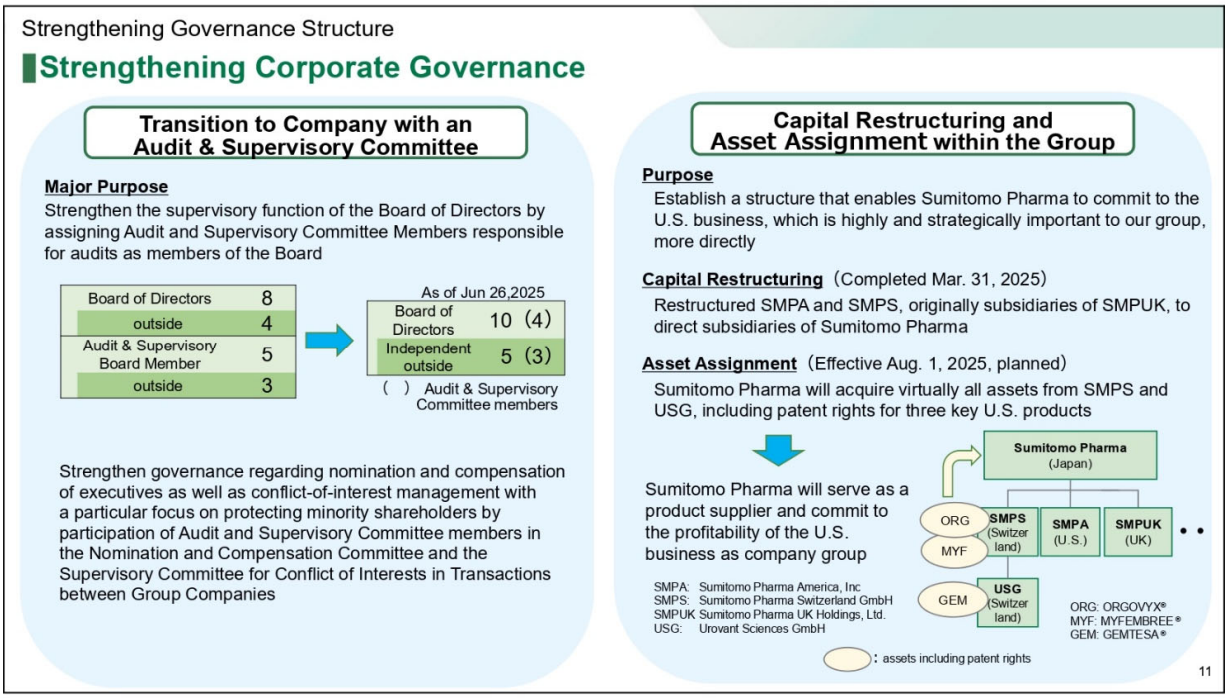
In the Asia segment, core segment profit increased JPY1.5 billion to JPY7.2 billion due to an increase in gross profit from higher sales.



Please see page 10.

As for marketing and sales in Japan, we concluded a co-promotion agreement with Novo Nordisk Pharma for Ozempic, a drug for type 2 diabetes treatment, in Japan, as announced in a press release in May 2025. This July, we began joint activities to provide information to medical institutions.

In our marketing activities in Japan, we are focusing on the diabetes area, and by combining our existing products, such as TWYMEEG and METGLUCO, for which we are currently conducting information provision activities, we will be able to offer a wider range of therapeutic proposals. We also expect that this partnership will contribute to our medium-term profits.



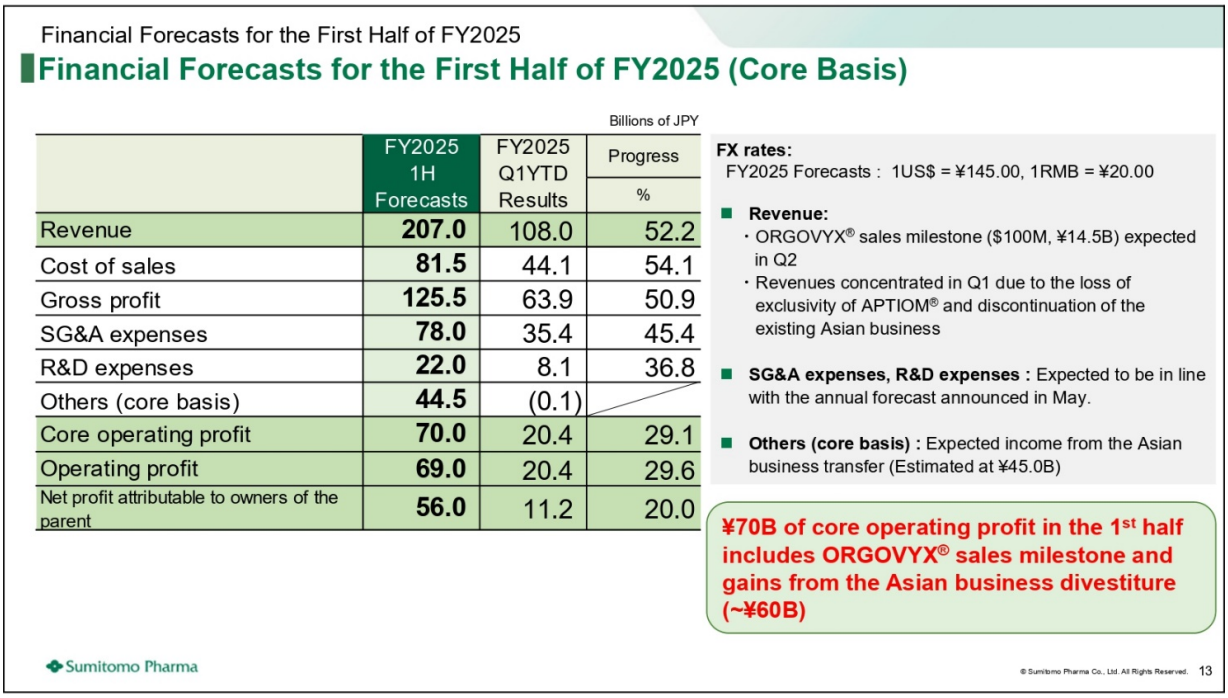
Next, I would like to introduce our efforts to strengthen our corporate governance structure.

With the approval of the annual shareholders' meeting held in June of this year, the Company has transitioned to a company with an Audit and Supervisory Committee. As a result, Audit and Supervisory Committee members will become members of the Board of Directors, strengthening the supervisory function of the Board of Directors. In addition, outside directors who are Audit and Supervisory Committee members will be newly added to the Nomination and Compensation Committee and the Supervisory Committee for Conflict of Interests in Transactions between Group Companies. We expect this to strengthen governance from the perspective of executive nomination and compensation, as well as the protection of minority shareholders.

Next, I would like to introduce the capital restructuring and asset assignment within our group.

In March 2025, the Company acquired the shareholders of the US subsidiary SMPA and the Swiss subsidiary SMPS, making them direct subsidiaries. In addition, as of August 1, 2025, the Company plans to take over patent rights and other rights related to ORGOVYX, GEMTESA, and other products.

This will allow us to further strengthen our involvement in the US business by establishing a structure in which we, as a product supplier, will be directly committed to the profitability of the US business.



Next, I would like to explain the announcement of the H1 financial forecasts.

At the beginning of the fiscal year, we disclosed only our full-year forecast, but we have now decided to announce our forecast for H1 of the fiscal year.

Sales of ORGOVYX in Q1 were strong, and milestone revenue is expected to be recorded in Q2. In addition, the timing of the split of the Asian business has been set for the end of July, and although the amount is still undetermined, revenue recognition for Q2 has been confirmed. As a result, significant profit items will be concentrated in H1, leading to a significant difference in performance between H1 and H2. Therefore, we have decided to disclose the H1 forecast at this stage.

Revenue for H1 is expected to be JPY207 billion. In Q2, we expect to record a sales milestone for ORGOVYX, but we expect revenues to be at the same level as in Q1 because revenues from APTIOM, which has reached the end of its exclusive sales period, and existing business in Asia will be concentrated in Q1.

SG&A and R&D expenses are expected to be incurred as forecasted at the beginning of the period.

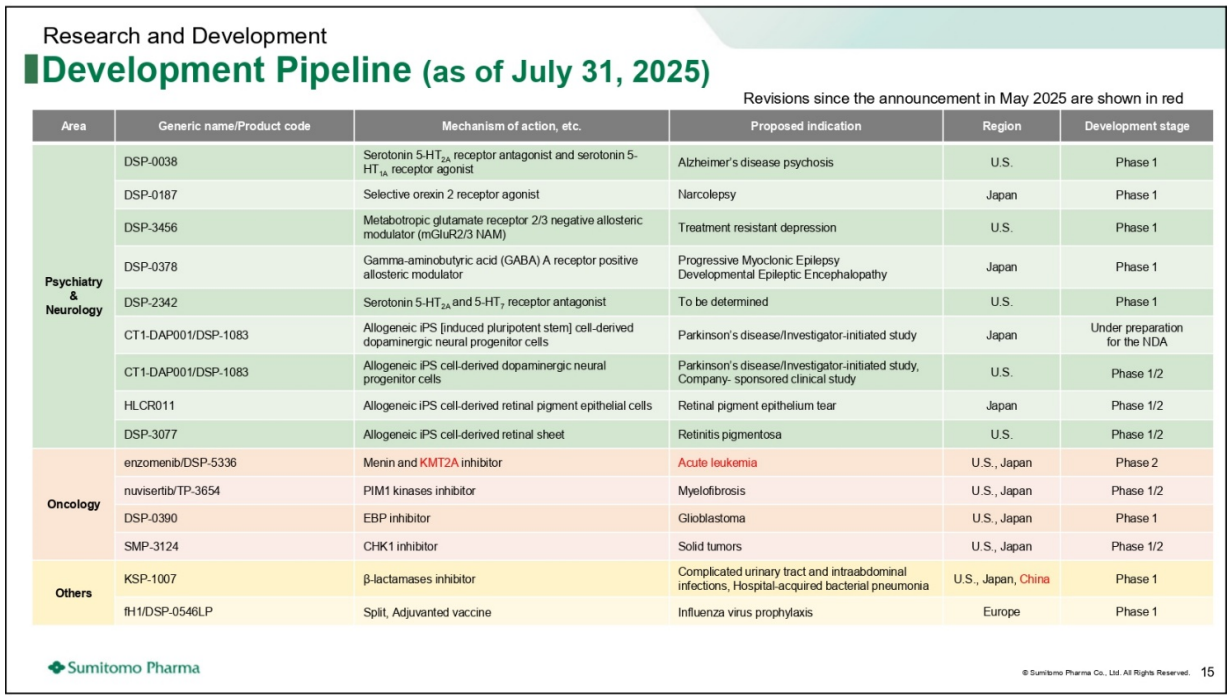
Others (core basis) include JPY45 billion in transfer gains currently expected from the split of the Asian business.

Based on the above, we forecast a high level of core operating profit of JPY70 billion and operating profit of JPY69 billion for H1. This includes a temporary factor of milestone income and gain on transfer of Asian business totaling approximately JPY60 billion.

The full-year forecast announced in May remains unchanged. As we mentioned, the initial forecast also anticipates significant fluctuations between H1 and H2 due to the concentration of major profit items in H1, changes in the profit structure of the Asian business, and other factors.

In Q1, sales, especially in North America, exceeded the plan by a wide margin. Despite the uncertain external environment, we expect this trend to continue in Q2 and beyond as we strive to improve our performance.

At this point, one quarter of the year has passed and the full-year forecast remains unchanged; however, we will closely examine the sales situation of our three key products and other factors, and we believe we will be able to revise the forecast at the time of the interim results.



Research and Development

Development Pipeline (as of July 31, 2025)

Revisions since the announcement in May 2025 are shown in red

Area	Generic name/Product code	Mechanism of action, etc.	Proposed indication	Region	Development stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT_{2A} receptor antagonist and serotonin 5-HT_{1A} receptor agonist	Alzheimer's disease psychosis	U.S.	Phase 1
	DSP-0187	Selective orexin 2 receptor agonist	Narcolepsy	Japan	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment resistant depression	U.S.	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator	Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy	Japan	Phase 1
	DSP-2342	Serotonin 5-HT_{2A} and 5-HT_7 receptor antagonist	To be determined	U.S.	Phase 1
	CT1-DAP001/DSP-1083	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study	Japan	Under preparation for the NDA
	CT1-DAP001/DSP-1083	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company- sponsored clinical study	U.S.	Phase 1/2
	HLCR011	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Japan	Phase 1/2
	DSP-3077	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	U.S.	Phase 1/2
Oncology	enzomenib/DSP-5336	Menin and KMT2A inhibitor	Acute leukemia	U.S., Japan	Phase 2
	nuvisertib/TP-3654	PIM1 kinases inhibitor	Myelofibrosis	U.S., Japan	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	U.S., Japan	Phase 1
	SMP-3124	CHK1 inhibitor	Solid tumors	U.S., Japan	Phase 1/2
Others	KSP-1007	β-lactamases inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	U.S., Japan, China	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Europe	Phase 1

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 15

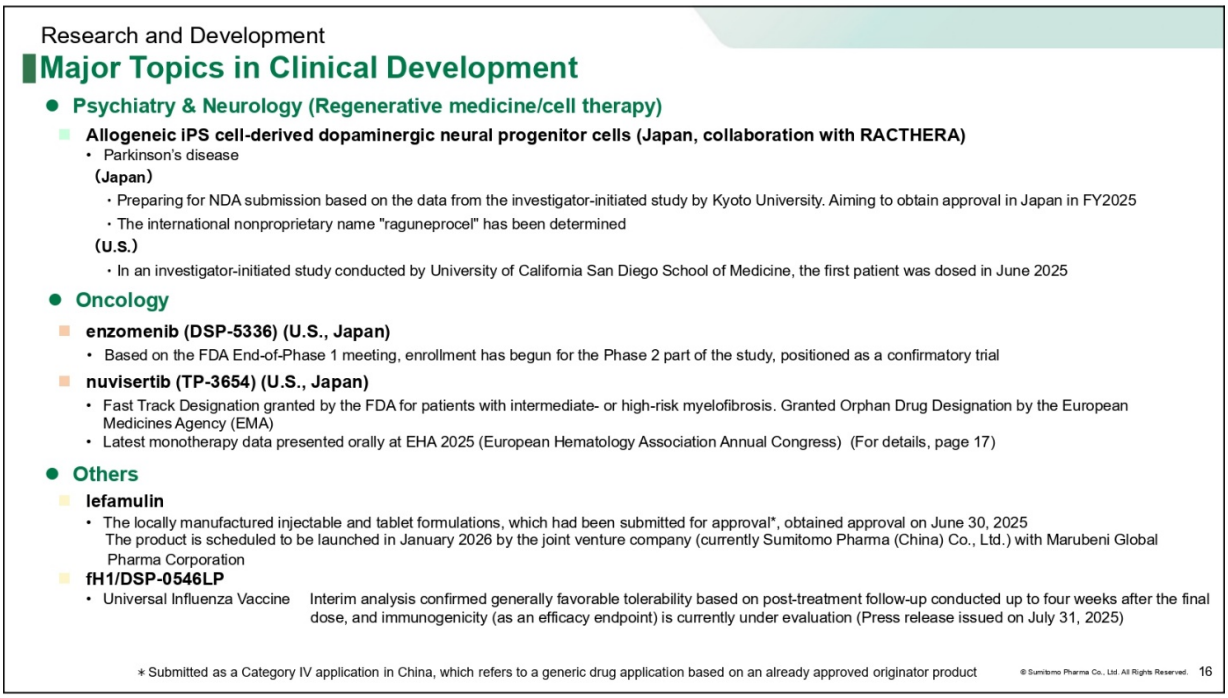
We will now explain the status of our research and development status.

Page 15 is a list of the development stages of our development pipelines. Changes from the previous May closing are shown in red on the slide.

We have previously reported the mechanism of action of enzomenib as Menin and MLL inhibitor, but we have decided to refer to it as Menin and KMT2A inhibitor.

In addition, the proposed indication was changed from acute myeloid leukemia to acute leukemia, due to the inclusion of acute lymphblastic leukemia.

For KSP-1007, China was added to the development region.



Page 16 summarizes the major topics in clinical development.

In the area of psychiatry and neurology, we are preparing to file for approval of allogeneic iPS cell-derived dopaminergic neural progenitor cells in Japan in FY2025, based on data from an investigator-initiated study by Kyoto University. In addition, the international nonproprietary name of this product has been decided as raguneprocel.

In the US, the first patient was dosed in June 2025 in an investigator-initiated study conducted by the University of California San Diego School of Medicine.

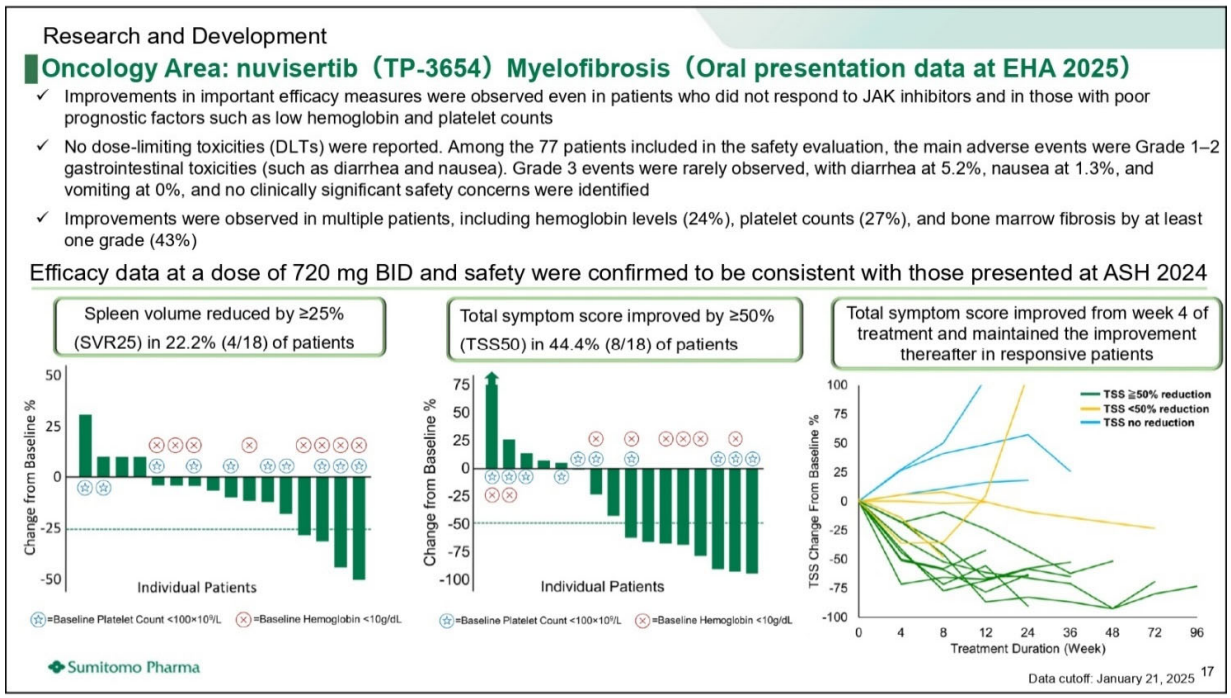
In the area of oncology, End-of-Phase I meeting with the FDA has been completed for enzomenib, and based on this, the Phase II part, which is positioned as a confirmatory trial, has been initiated.

Nuvisertib received Fast Track Designation from the FDA and Orphan Drug Designation from the EMA for myelofibrosis.

We also gave an oral presentation of the latest monotherapy data at the European Hematology Association Annual Congress. This will be reported in detail on the slides that follow.

In other areas, we received an approval in June 2025 for lefamulin, which had been filed as a locally manufactured product.

The Universal Influenza Vaccine we released in a press release today has been confirmed to be generally well tolerated in the interim analysis of post-treatment follow-up conducted up to four weeks after the final dose. Immunogenicity is also being evaluated for efficacy.



The next slide, slide 17, presents data from the presentation at the European Hematology Association on the nuvisertib myelofibrosis Phase I/II trial.

Efficacy showed improvement in important efficacy measures, even in patients who did not respond to JAK inhibitors and in patients with poor prognosis with low hemoglobin and platelet counts.

In terms of safety, no dose-limiting toxicities were observed, the major adverse events were Grade 1-2 gastrointestinal toxicities, with few Grade 3 events, and no clinically problematic events.

This concludes my explanation.

Question & Answer

Barker [Q]: I'm Stephen Barker from Jefferies. Thank you. I would like to ask about the current situation of ORGOVYX. At this point, you have achieved a progress rate of 32%, but I think the current full-year forecast of JPY103 billion is rather conservative.

And I would like to ask about the terms and timing regarding the next milestone from Pfizer. The first milestone, which I believe is expected to be USD100 million in H1, and the second, the conditions and timing of the USD350 million payment, which I believe is expected to be paid upon achieving USD1 billion in annual sales. This Q1, USD226 million, you have already achieved even more, so there is a possibility that that second milestone will be paid next year, even in your company's next fiscal year. What do you think?

Wakemi [A]: Thank you for your questions, Mr. Barker. On the first point, you pointed out that the annual forecast is conservative in terms of the current situation of ORGOVYX. In this regard, we consider the figures announced at the beginning of the fiscal year to be conservative.

Q1 results exceeded the initial plan. Therefore, we have not reviewed our current annual projections at this time, but we consider them to be conservative.

Dr. Nakagawa, who is in charge of North America business, if you have any comments on this point, please give us some comments.

Nakagawa [A]: Yes, I would like to give a few additional explanations. As Mr. Wakemi just explained, we are off to a very good start this year, but we need to further examine the sales situation in the future. We are not only forecasting correctly, but we are also positively considering what measures we can take to further capitalize on this tailwind, and we will review our sales forecast for this fiscal year at the appropriate time, taking into account the extent of such effects.

Therefore, for the second milestone, as for conditions, we will receive 325 million when sales exceed USD1 billion for the calendar year, annually, as predicted. Naturally, whether this will come next year or the year after depends on the forecast.

We are currently in the process of revising this forecast, so we do not have a firm answer right now as to the timing of the revision.

Barker [Q]: Thank you very much. So, if the second milestone is USD325 million, how much would the third be?

Nakagawa [A]: I am sorry, but the specific terms of the milestone after that are not disclosed. Thank you for your understanding.

Barker [M]: I understand. Thank you.

Wakao [Q]: I'm Wakao from JPMorgan. Thank you for your time. Please tell us how the progress of fixed costs, SG&A and R&D expenses in Q1 compared to the full-year plan. It might be better to say, compared to the internal plan.

In particular, the progress of SG&A expenses seems to be a little low and if we look at the US on a dollar basis, it appears that the progress is relatively low compared to the full-year plan. In this regard, I wonder if it is running at a reduced speed by using it efficiently. Please tell us about this point.

Wakemi [A]: Thank you for your question. I would like to answer your question regarding the progress of SG&A expenses in Q1. First of all, as for the actual results of SG&A expenses for Q1, the progress rate is lower than originally planned, and the actual results are lower.

As a result, expenditure in Q1 were delayed compared to the original plan. Since it is the beginning of the fiscal year, we are still in the process of progress. As for the future, as I mentioned in the Q2 forecast, we expect to catch up by Q2.

The same is true for R&D expenses, with the progress rate in the Q1 results slightly below the initial plan.

On the other hand, we expect to catch up with our R&D expenses by Q2, although progress in some clinical trials for enrollment was a little slower than originally planned.

Wakao [Q]: Thank you very much. Next, regarding the cumulative forecast for Q2, on the 13th slide, I think the decrease and temporary revenue are as written, but could you please explain how your three key products and promotion fees are included?

Wakemi [A]: Thank you. I understand that your question is about the sales of our three key products and promotion fees.

First, regarding sales of our three key products, as for the actual results for Q2, we have revised our forecast based on the current situation. On the other hand, SG&A and R&D expenses have been factored in at this time, with expenditure being in line with the original plan by the end of Q2.

Regarding the domestic case, I understand that you are talking about the Ozempic, which has been being arranged most recently.

We have also factored this in the assumption that we will receive a promotion fee for the joint promotion that will begin in July.

Wakao [Q]: Does this mean that this is for three months?

Wakemi [A]: Yes, it is after July and onward.

Wakao [Q]: What kind of scale are you talking about?

Wakemi [A]: Thank you. We are very sorry that we are not disclosing this information.

Wakao [Q]: Also, is it correct to understand that your three key products are basically made in a way that is pulling Q1 growth?

Wakemi [A]: Thank you. We have made our forecast based on the recent situation, and we expect that the recent strong shipments will continue from July onward.

Wakao [Q]: I understand. By the way, ORGOVYX, it is doing very well and given the profile of this drug in the first place and the status of the Medicare Part D redesign, it doesn't seem likely that growth will slow down, though. Is there any chance that you will update this point and peak sales sometime in the future?

Wakemi [M]: Thank you very much. Dr. Nakagawa, who is in charge of North America business, will comment on your point.

Nakagawa [A]: I'm Nakagawa. In terms of your question, I believe that product profiles and the impact of IRA will not disappear unless the system is changed, as you say.

However, as I mentioned earlier, some of the results have been better than we had expected, and we are currently considering how to further optimize our estimates and strategies. In this sense, we would like to refresh our long-term forecasts in the near future.

Therefore, we cannot give a definite answer at this time as to when the peak will be since we have been examining the situation as well.

Wakao [Q]: Thank you very much. Finally, could you give us an update on the partnership activities for nuvisertib and enzomenib?

Wakemi [A]: Thank you for your question. We are actively working toward partnerships for both drugs. In order to maximize the values of these drugs, we have started to consider the alliance in April of this year. As for the companies we are hoping to partner with, we are currently actively pursuing partnerships with companies that agree to promote development and joint sales.

Wakao [Q]: Thank you very much. In terms of changes since the last time, can you give us some more feelings or tones as to whether the target companies have been narrowed down or not?

Wakemi [A]: Thank you. We will report on the details when we are ready to announce them.

Wakao [Q]: I understand. It is okay to understand that it will be fine during the fiscal year, right?

Wakemi [A]: Yes, we hope to proceed so that we can report back to you by the end of the fiscal year.

Wakao [M]: Okay. Thank you. That is all.

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Thank you. Regarding the full-year forecast, I believe you said that you have not revised it this time due to uncertain factors. Could you please tell us what kind of uncertain factors you are currently considering?

Wakemi [A]: Yes, thank you. We believe that there are two major uncertain factors. The first point is whether the current strong sales growth in Q1 will continue at the same level in the future. ORGOVYX, for example, has been selling very well in Q1. We believe that it is necessary to determine how this will grow over the course of the current fiscal year.

Regarding the second point, we are considering the possibility of various institutional changes, mainly in North America. One is that we believe that there are uncertain factors at this point in time as to what the situation will be like in light of the discussions on tariff policies and the drug pricing system for pharmaceuticals.

Hashiguchi [Q]: Thank you. Regarding the system, I think there was a certain amount of uncertainty when your forecast was announced at the beginning of the term. After three months, do you feel that the changes to the system have had a negative impact on your company's performance?

I think it could be said that the risk has not changed for the worse, but rather that the risk has decreased by taking various measures. What do you think?

Wakemi [A]: Thank you for your question. First of all, we believe that at least the situation is not very much worse than it was at the beginning of the year. At the beginning of the year, as for tariffs, first of all, we mentioned that they would be 25%.

However, currently, we have not been impacted by the application in our specific, actual business operations, at least at the end of June. We do not expect any impact on our business by the system already in place at this time during the current fiscal year.

Of course, since various discussions are taking place on a daily basis, we do not know what kind of changes will occur in the future and what kind of systemic changes there will be. We will continue to monitor the situation appropriately and incorporate changes into our forecasts, as necessary.

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

Sakai [Q]: Excuse me. This is Sakai from UBS. I would like to know two things, but since President Kimura is not here today, I am not sure how you can answer my question. It is about your company's future profit calculation method.

Earlier, you mentioned the milestone amount, and I also heard that asset sales, probably the sale of the Asian business, will be the last step. If we assume that profits will increase to some extent in the so-called liquid funds, will you return the increased profits from the liquid funds as profits, or as President Kimura mentioned at the final accounts, will you maintain R&D at the current level of JPY50 billion for the next three years or so? If this is the case, then of course, the profit from the liquid funds is recorded as profit, as it should be.

However, if R&D expenses are inadequate, I think it is possible to think of putting the money into this area or into sales promotion expenses in the US. What are your thoughts on this point and what plans do you have for the future? Please tell me this point first.

Wakemi [A]: Thank you for your question. First of all, I would like to make a few comments on the current situation regarding our approach to profit recognition.

You mentioned our various measures taken. Our view is that the various measures we have implemented since last year will have a one-time impact on profits to some extent, and that this impact will largely be exhausted by H2 of FY2025.

Specifically, the various changes in the framework for the China-Asia project that you mentioned earlier will be resolved by the end of FY2025.

Therefore, we basically believe that our performance will bottom out around H2 of the current 2025, followed by a recovery.

The first step in this process is how to consider profit. First, regarding how we plan to use the profits we have estimated in our business plan, or rather, the profits we had initially planned, as Mr. Sakai mentioned, it will be in accordance with the policy that Kimura announced at the beginning of the fiscal year.

If the Company's performance improves at this point, how it will be used is a matter that remains to be determined, as well as the extent to which it will be able to review its performance. We will also consider where to use the funds and how to record profits in the future.

Sakai [Q]: I apologize for asking a nitpicky question, but does 325 million mean that it will be included in H2 of this fiscal year? Is that correct? Milestone from Pfizer; Dr. Nakagawa mentioned it. I think this is disclosed information because Dr. Nakagawa mentioned it. Milestone from Pfizer for the second time.

Wakemi [A]: Sorry. We apologize if our explanation was unclear. The next milestone, 325 million, is not expected in the current period.

Sakai [Q]: So, it will come again as a one-time gain, regardless of whether it will be in the next fiscal year or the fiscal year after that.

Wakemi [A]: Yes, we will work on that in the future so that it can be recorded as soon as possible. We will determine whether it will be next fiscal year or later.

Sakai [Q]: I understand. Thank you. One more question. The forecast for H2 has been left unchanged at this time because of uncertain factors, and although it is negative, it is assumed to be negative, or rather, to be in the red.

Will this be revised in the next quarterly financial results announcement, or will you make some kind of performance revision in advance? Could you tell us how you plan to time this?

Wakemi [A]: Thank you. First of all, we will revise our financial forecast, as necessary. At this time, we have not determined whether this will be at or before the announcement of financial results.

I am sorry, may I ask you again on your first point?

Sakai [M]: Which one do you mean by the first one?

Wakemi [M]: Is my answer to your question okay?

Sakai [Q]: Yes, if this continues, H2 will be in the red, or rather, profits will decrease in H2. Therefore, my question was based on the premise that if the Company is going to make revisions, and to some extent has stated publicly that it will make revisions, then it would not be very healthy to leave it as it is.

Wakemi [A]: Okay. I understand. As I mentioned earlier, in terms of timing, we will study the issue and make an announcement when necessary. Regarding your point that H2 of the fiscal year may be in the red based on a simple calculation, we will, of course, continue our efforts to make H2 of the fiscal year even or in the black.

Sakai [M]: I understand. Thank you.

Yamaguchi [Q]: This is Yamaguchi from Citigroup Global Markets. Thank you. Sorry, I'm a little confused on the figures, so I would like to go over them again. First of all, is my understanding correct that the 700 figure on the core basis you have given us for the Q2 cumulative total is not related to the full year, but is the latest figure for your company, which incorporates all the figures from Q1, including the Ozempic?

Wakemi [A]: Yes. Thank you, your understanding is correct. This Q2 cumulative total is our latest figure up to Q2 at this point.

Yamaguchi [Q]: I see. Also, as for the sales milestone for ORGOVYX, the gain on transfer of the Asian business was originally included, I suppose, but was the sales milestone for ORGOVYX originally included in the full year? This Q2 is included, but was it originally included in the full year, in your company's?

Wakemi [A]: Yes, thank you. For the full year, we originally included it in our plan for FY2025. In H1, we were certain that we could recognize it by Q2, so we factored it in.

Yamaguchi [Q]: I see. So, for example, at 700 core, Q1, 200, then 500, but the remainder will be mostly out by the Asian business and OROGOVYX, so Q2, at this stage, is also based on the assumption that there will be almost no profit from this business base, even in this latest Q2 forecast. Sorry. That was not the right way to ask.

Wakemi [A]: Thank you for pointing that out. As you pointed out, the calculations, exactly as you mentioned, so you are correct that one-time revenue is a very large proportion of the total.

Yamaguchi [Q]: I see. So, if there is no one-time profit in Q3 and Q4, there will be almost no profit on a core basis, under the current circumstances. When I looked at Q1, there were various irregularities, but since it was 200, I thought it would be fine, but should I assume that Q2, Q3, and Q4 will be basically nothing?

Wakemi [A]: Thank you. In terms of trends, Q1 saw very strong shipments of APTIOM, which I mentioned at the beginning of my presentation.

In addition, the Asian business will be restructured at the end of July, so the figures for Q1 and Q2 and beyond will vary. Such is the case with the Q1 figures.

Based on these factors, as you understand, the initial plan was that H2 would be difficult. On the other hand, there are some upside factors, such as the growth of ORGOVYX in Q1. Based on these points, we will work to further improve our performance in H2, and we will closely examine the figures to see what they will be.

Yamaguchi [Q]: I see. Finally, can you explain quantitatively the difference between this original figure and the actual performance of your company in Q1? In short, how much did you estimate for Q1?

Wakemi [A]: Thank you. Sorry. It is true that there has been an upward trend from the original plan. Sales are also higher than expected and expenses are slightly behind schedule, so they are lower than planned. Therefore, it is true that sales are higher than expected.

I am sorry, but I would like to refrain from giving a quantitative explanation.

Yamaguchi [M]: Okay. Thank you very much for answering various questions. That is all.

Kino [M]: Next, we would like to turn to a question-and-answer session for the press.

Ishii [Q]: I am Ishii from the Iyaku Tsushinsha. You mentioned earlier that sales in North America were better than expected. Could you tell us what factors you thought contributed to this positive performance?

Wakemi [M]: Thank you very much. Dr. Nakagawa, who is in charge of the North America business, will answer your questions.

Nakagawa [A]: Yes, this is Nakagawa. ORGOVYX exceeded our expectations, but rather than any major new factors emerging or omissions in our forecasts, I think it was more a case of our quantitative assessment of what we already understood turning out to be higher than expected.

As mentioned in the previous discussion, we originally considered the drug profile to be excellent, and although there was a slight price difference compared to LEUPLIN, which was one hurdle, there are advantages to the change in the insurance system.

We hope you can understand that the way each of these upward movements was different from what we had expected.

Ishii [M]: I understand very well. Thank you.

Yoshimizu [Q]: I am Yoshimizu from Iyaku Keizaisha. I have three questions. First of all, I would like Dr. Nakagawa to answer my question; the first point is the tariff policy in North America. Please tell us about the impact of the tariff policy, what impact is your company seeing and what measures are you taking?

Secondly, there are reports of various issues arising from FDA reforms in North America. Could you share your impressions of the situation there from the local point of view?

Thirdly, although this is open to anyone to answer, you are aiming to submit an application for Parkinson's disease within the fiscal year. Could you please provide an update on the current progress and outlook? That is all.

Wakemi [M]: Thank you very much. Dr. Nakagawa will answer the first and second points, and Ms. Sato will answer the third point.

Yoshimizu [M]: Yes, please.

Nakagawa [A]: Thank you for your question. The first and second points overlap somewhat, but as you have heard in various news reports, information about tariffs is released from time to time, but nothing concrete has been decided yet. We are therefore considering possible measures based on the information available.

Since it is not possible to make a major move in the supply chain immediately, we need a lead time, so we are still working to gather information at this point.

As for the FDA's reforms, as you mentioned, many employees have been laid off or left, and we have heard various stories including resource shortages, but there are no particular obstacles to the FDA's response to our current R&D pipelines or EMR, so I don't think there will be a major impact at this point.

Regarding the first and second points, we believe that it is necessary for us to gather information quickly and understand the movements of other companies. Therefore, we have rejoined PhRMA, a pharmaceutical company association in the United States, and I myself am attending their meetings to gather information.

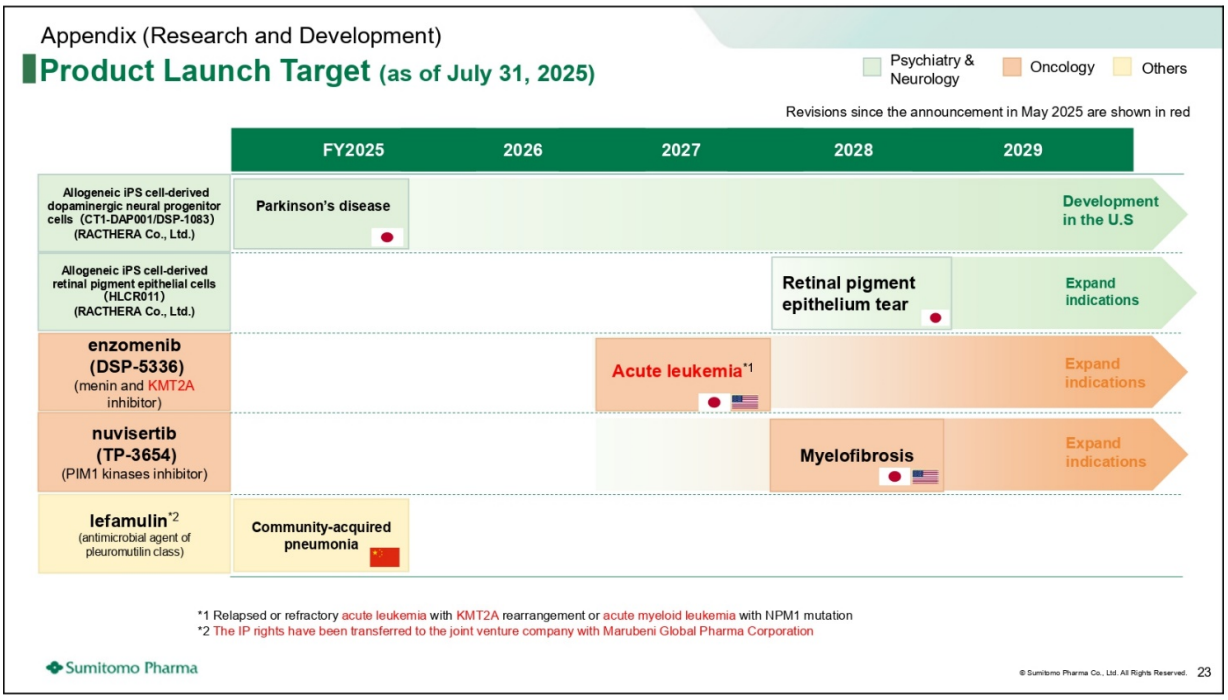
Yoshimizu [Q]: I see. So, specifically, you are not at the stage of considering investing in the local area like other companies.

Nakagawa [A]: We have started to consider this as a potential scenario, but we have not yet gone into concrete steps to implement it or anything like that.

Yoshimizu [Q]: So you are at the stage of considering this as an option.

Nakagawa [A]: Yes, you're right.

Yoshimizu [M]: I understand. Thank you. Well, excuse me, Ms. Sato, please answer the question.



Sato [A]: I am Sato. As for the Parkinson's program, as you can see in the presentation material, we are making good progress in preparing the application with the aim of obtaining approval within this fiscal year.

Yoshimizu [Q]: So, there are no issues that have come up in your dealings with the authorities?

Sato [A]: There are no particular issues at this time. This product has been designated as a fast track assessment, and we are currently working closely with the PMDA to prepare in a form of the fast track assessment consultation.

Yoshimizu [Q]: I see. Thank you. Excuse me, Mr. Nakagawa, I'm going to go back a little, but could you tell me when you rejoined PhRMA?

Nakagawa [A]: This month.

Yoshimizu [Q]: This month, July? This month? Okay. I understand. I'm sorry. And when did you leave?

Nakagawa [A]: It was last year.

Yoshimizu [Q]: Last year. Right. You left in 2024?

Nakagawa [A]: We left last year.

Yoshimizu [M]: Okay. I understand. That is all. Thank you.

Okada [Q]: My name is Okada from Yakuji Nippo. You mentioned that there will be a temporary gain of 60 billion in sales profit at the end of Q2, but if there is 20 billion in Q1 and 60 billion will be added, is it correct to say that sales profit for Q2 alone will be negative?

Wakemi [A]: Yes, thank you. You are correct. Your understanding is correct about the temporary gain in Q2.

Okada [Q]: Thank you. Also, the international generic name for Parkinson's disease here has been decided. Is there any reason, or factor, for the name here?

Sato [A]: Thank you for your question. Sato will answer. The "rag" at the beginning of this name "raguneprocel" comes from "raku" in Japanese, which means "Kyoto" in Japanese, since this program was a collaboration with the University of Kyoto. And our company has always referred to the office for Regenerative And Cellular Medicine Organization as RACMO, and we have combined "raku" and "RACMO" and added it to the beginning of the name.

The back part is called "stem," and the WHO has a standard naming rule depending on the type of the item. There is a rule that substances derived from neural stem cells are named using the suffix "neprocel," and this rule has been applied to create the name "raguneprocel."

Okada [M]: I understand. Thank you.

Seii [Q]: This is Seii of the Asahi Shimbun. Sorry, I would like to know a little more about the US tariffs. First of all, for the pharmaceuticals that were exported to the US in Q1, what percentage of tariffs were on these, or were they zero? Could you please tell us how much it actually was?

Wakemi [A]: Thank you for your question. In Q1 of actual results, there were no tariffs applied.

Seii [Q]: I understand. In the Japan-US negotiations, with mutual tariffs of 15% being discussed, I believe the current understanding is that pharmaceuticals are not excluded at this point. There were some reports a while

ago that Mr. Trump said he was going to raise the rate to 200%, but how do you see this? How much of a risk is it considered to be?

Wakemi [A]: Thank you for your question. At the present time, pharmaceutical products are subject to tariff exclusions. As a result, the Q1 results are zero at this time.

Seii [Q]: I just think it's like, it's not going to be zero in the future. I think there were also reports that Mr. Akazawa said that pharmaceuticals are subject to a 15% tax. So, do you have any projections as to how much those tariffs are likely to be? Is your stance such that you are not totally sure yet?

Wakemi [M]: Thank you for your question. Dr. Nakagawa will comment on your question.

Nakagawa [A]: Information is probably mixed up. Therefore, we do not have a firm answer as well. As you mentioned, if it is found out that tariffs are imposed at some point, it will naturally affect us as well, but I think Mr. Trump is still talking about lowering the price of drugs in the US as well. Raising tariffs is basically the opposite of that.

As I mentioned earlier, the US pharmaceutical industry is naturally considering various measures to deal with this problem.

I think that there is no immediate risk of very high tariffs being imposed, although this is only a guess, of course. I think that is all I can answer at this time.

Seii [Q]: Thank you. Also, what percentage of the drugs that your company currently sells in the US are imported from outside the US? Is that mainly Japan? Can you please tell us a little bit about how you take that medicine and what is in the supply chain, as far as you can tell us?

Nakagawa [A]: Yes, Nakagawa will answer that question as well. We do not always disclose detailed information about our supply chain, so I will refrain from answering that question. At the very least, it is not limited to Japan but is scattered across various countries.

Seii [Q]: I'm going to ask from the other side, is there a certain amount of production in the US? Is there not much?

Nakagawa [A]: To a certain extent, there is, but the quantities are undisclosed.

Seii [M]: Thank you very much.

Kino [M]: This concludes the financial results briefing of Sumitomo Pharma for Q1 of FY2025. Thank you very much for your participation today.

[END]