Sumitomo Pharma Co., Ltd.

Q2 Financial Results Briefing for FY2025

October 31, 2025

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.
[Company ID]	4506-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	Q2 Financial Results Briefing for FY2025
[Fiscal Period]	FY2026Q2
[Date]	October 31, 2025
[Time]	17:00 – 17:52 (Total: 52 minutes, Presentation: 19 minutes, Q&A: 33 minutes)
[Venue]	Webcast
[Number of Speakers]	6

Toru Kimura	Representative Director, President and CEO
Motoyuki Sakai	Representative Director, Executive Vice President Global Corporate Strategy; Global Finance Administration External Affairs; Corporate Governance; IT Management and Data Analytics
Tsutomu Nakagawa	Member, Board of Directors, Managing Executive Officer North America Business

		President and CEO, Sumitomo Pharma America, Inc.
	Yumi Sato	Managing Executive Officer Research and Development Division Senior Vice President, Head of Research and Development Division Chief Development Officer, Sumitomo Pharma America, Inc.
	Yutaka Wakemi	Executive Officer Global Corporate Strategy; Global Finance
	Koichi Kino	Vice President, Head of Corporate Governance
[Analyst Names]	Seiji Wakao	JPMorgan Securities
	Stephen Barker	Jefferies
	Kazuaki Hashiguchi	Daiwa Securities
	Hiroshi Wada	SMBC Nikko Securities
	Fumiyoshi Sakai	UBS Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities

Presentation

Kino: We will now begin the Sumitomo Pharma financial results briefing for Q2 of FY2025, intended for analysts and investors. Thank you very much for taking time out of your busy schedule to join us today. I am Kino, Corporate Governance Department, Sumitomo Pharma, and I will be your moderator. This presentation will be streamed live via Zoom webinar from our Tokyo headquarters.

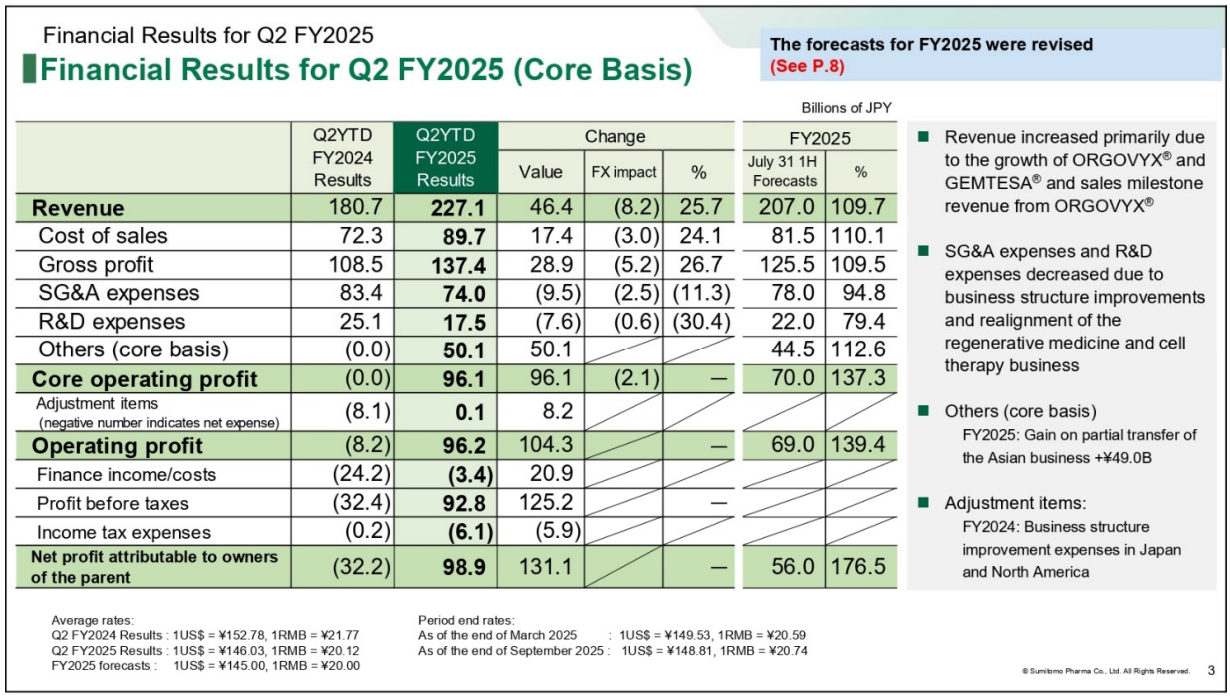
First of all, I would like to make an announcement and request to all of you. Please change the participant information displayed on your Zoom screen to your company name and name.

The flow of today's meeting will begin with an explanation of the financial presentation materials posted on our website, followed by a question-and-answer period. The scheduled closing time is 18:10 PM.

Let me now introduce today's attendees. Representative Director, President and CEO Kimura, Representative Director, Executive Vice President Sakai, Member of Board of Directors, Managing Executive Officer Nakagawa, Managing Executive Officer Sato, and Executive Officer Wakemi. Thank you very much for your cooperation.

Now, Kimura will explain our business results for Q2 of FY2025 and the current status of clinical development. Dr. Kimura, please go ahead.

Kimura: I am Kimura, Representative Director and President. Thank you for joining us today for the presentation of the financial results for Q2 of FY2025. I will then explain according to the materials.



Financial Results for Q2 FY2025

Financial Results for Q2 FY2025 (Core Basis)

The forecasts for FY2025 were revised
(See P.8)

Billions of JPY

	Q2YTD FY2024 Results	Q2YTD FY2025 Results	Change			FY2025	
			Value	FX impact	%	July 31 1H Forecasts	%
Revenue	180.7	**227.1**	46.4	(8.2)	25.7	207.0	109.7
Cost of sales	72.3	**89.7**	17.4	(3.0)	24.1	81.5	110.1
Gross profit	108.5	**137.4**	28.9	(5.2)	26.7	125.5	109.5
SG&A expenses	83.4	**74.0**	(9.5)	(2.5)	(11.3)	78.0	94.8
R&D expenses	25.1	**17.5**	(7.6)	(0.6)	(30.4)	22.0	79.4
Others (core basis)	(0.0)	**50.1**	50.1			44.5	112.6
Core operating profit	(0.0)	**96.1**	96.1	(2.1)	—	70.0	137.3
Adjustment items (negative number indicates net expense)	(8.1)	**0.1**	8.2				
Operating profit	(8.2)	**96.2**	104.3		—	69.0	139.4
Finance income/costs	(24.2)	**(3.4)**	20.9				
Profit before taxes	(32.4)	**92.8**	125.2		—		
Income tax expenses	(0.2)	**(6.1)**	(5.9)				
Net profit attributable to owners of the parent	(32.2)	**98.9**	131.1		—	56.0	176.5

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

Average rates:
Q2 FY2024 Results : 1US$ = ¥152.78, 1RMB = ¥21.77
Q2 FY2025 Results : 1US$ = ¥146.03, 1RMB = ¥20.12
FY2025 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

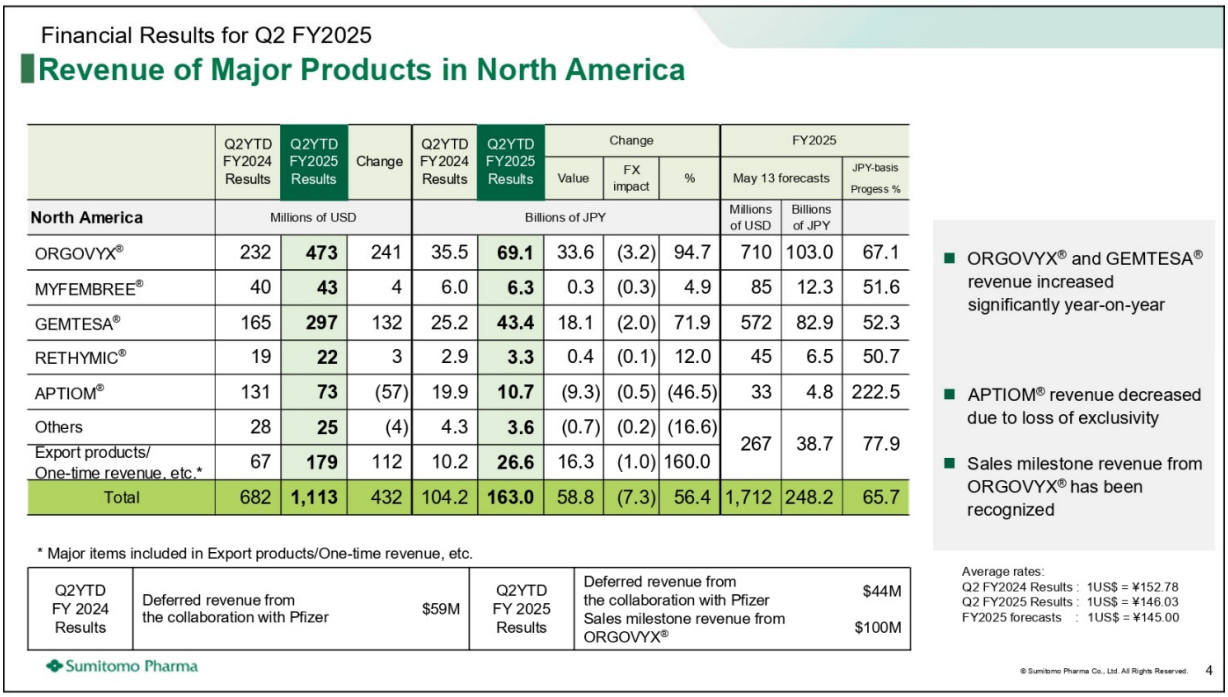
Period end rates:
As of the end of March 2025 : 1US$ = ¥149.53, 1RMB = ¥20.59
As of the end of September 2025 : 1US$ = ¥148.81, 1RMB = ¥20.74

 3

First, please see page three. The financial results for Q2 of FY2025 on a core basis. As you can see, revenue was JPY227.1 billion. Compared to the revised Q2 forecast announced in July, the increase is JPY20.1 billion. Compared to last year, this represents an increase of JPY46.4 billion.

On the other hand, SG&A expenses and R&D expenses have been well controlled, with SG&A expenses down JPY4 billion and R&D expenses down JPY4.5 billion from the figures announced in July. Compared to the previous fiscal year, the amount of these items was JPY9.5 billion and JPY7.6 billion, respectively, which is well controlled.

Since we have recorded a JPY49 billion gain on the transfer of the China-Asia business, the total core operating profit is JPY96.1 billion. This is an increase of JPY26.1 billion compared to the projected figure in July. Operating profit was JPY96.2 billion, followed by a reversal of deferred income tax liabilities for income tax expenses of JPY6.1 billion, resulting in an interim net profit of JPY98.9 billion. This is a JPY42.9 billion increase. Both sales and profit are over the Q2 forecast announced in July, and we are issuing a press release today to announce the revised forecast.



Financial Results for Q2 FY2025

Revenue of Major Products in North America

North America	Q2YTD FY2024 Results (Millions of USD)	Q2YTD FY2025 Results (Millions of USD)	Change (Millions of USD)	Q2YTD FY2024 Results (Billions of JPY)	Q2YTD FY2025 Results (Billions of JPY)	Change Value (Billions of JPY)	Change FX impact (Billions of JPY)	Change %	FY2025 May 13 forecasts Millions of USD	FY2025 May 13 forecasts Billions of JPY	FY2025 JPY-basis Progess %
ORGOVYX®	232	**473**	241	35.5	**69.1**	33.6	(3.2)	94.7	710	103.0	67.1
MYFEMBREE®	40	**43**	4	6.0	**6.3**	0.3	(0.3)	4.9	85	12.3	51.6
GEMTESA®	165	**297**	132	25.2	**43.4**	18.1	(2.0)	71.9	572	82.9	52.3
RETHYMIC®	19	**22**	3	2.9	**3.3**	0.4	(0.1)	12.0	45	6.5	50.7
APTIOM®	131	**73**	(57)	19.9	**10.7**	(9.3)	(0.5)	(46.5)	33	4.8	222.5
Others	28	**25**	(4)	4.3	**3.6**	(0.7)	(0.2)	(16.6)	267	38.7	77.9
Export products/ One-time revenue, etc.*	67	**179**	112	10.2	**26.6**	16.3	(1.0)	160.0			
Total	682	**1,113**	432	104.2	**163.0**	58.8	(7.3)	56.4	1,712	248.2	65.7

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

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

Q2YTD FY 2024 Results	Deferred revenue from the collaboration with Pfizer	$59M	Q2YTD FY 2025 Results	Deferred revenue from the collaboration with Pfizer	$44M
				Sales milestone revenue from ORGOVYX®	$100M

Average rates:
Q2 FY2024 Results : 1US$ = ¥152.78
Q2 FY2025 Results : 1US$ = ¥146.03
FY2025 forecasts : 1US$ = ¥145.00

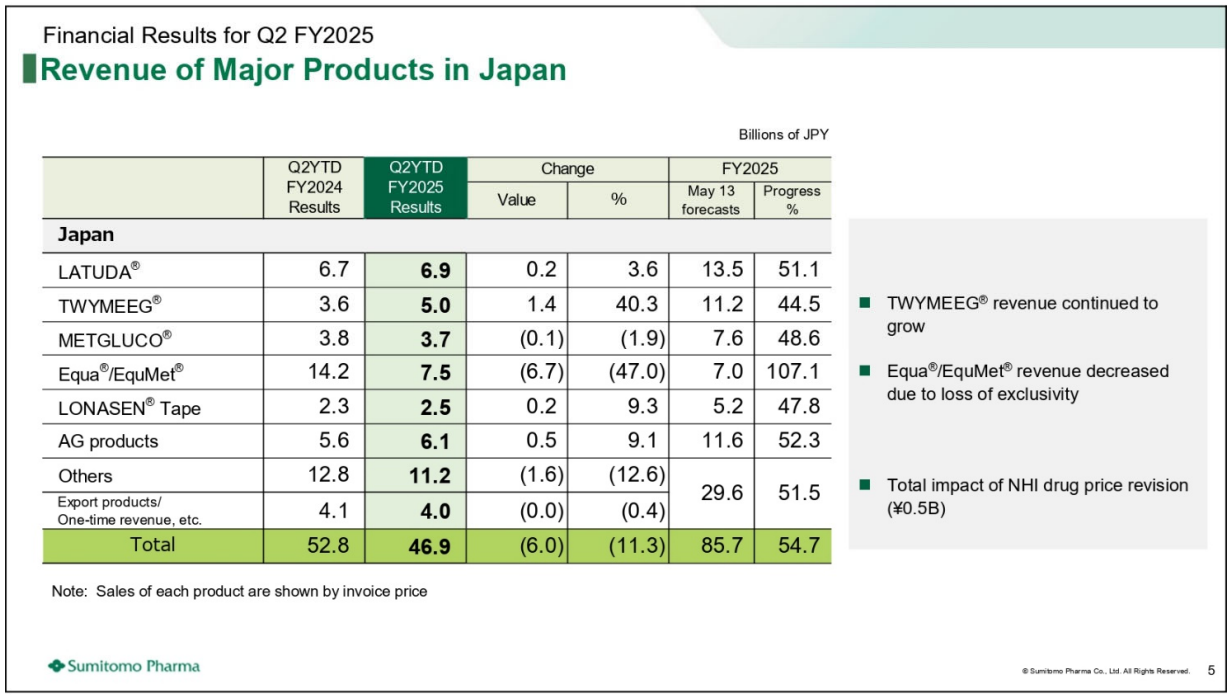
Sumitomo Pharma

 4

I would like to continue with an overview of Q2 financial results, and I will first explain the revenue of our main products, starting with the figures for North America.

ORGOVYX is doing very well, with JPY69.1 billion. This is an increase of JPY33.6 billion over last year, or 95%. GEMTESA is also JPY43.4 billion, which is an increase of JPY18.1 billion or 72%. APTIOM had LOE, so the total amount was JPY10.7 billion, a decrease of JPY9.3 billion.

We had originally projected a milestone of USD500 million in sales for ORGOVYX in Q3, but since sales have been strong and we are now in Q2, we have included a milestone of USD100 million, or JPY14.9 billion. In total, sales in North America were JPY163 billion, a JPY58.8 billion or 56.4% increase over the previous fiscal year.



Financial Results for Q2 FY2025

Revenue of Major Products in Japan

Billions of JPY

	Q2YTD FY2024 Results	Q2YTD FY2025 Results	Change		FY2025	
			Value	%	May 13 forecasts	Progress %
Japan						
LATUDA®	6.7	**6.9**	0.2	3.6	13.5	51.1
TWYMEEG®	3.6	**5.0**	1.4	40.3	11.2	44.5
METGLUCO®	3.8	**3.7**	(0.1)	(1.9)	7.6	48.6
Equa®/EquMet®	14.2	**7.5**	(6.7)	(47.0)	7.0	107.1
LONASEN® Tape	2.3	**2.5**	0.2	9.3	5.2	47.8
AG products	5.6	**6.1**	0.5	9.1	11.6	52.3
Others	12.8	**11.2**	(1.6)	(12.6)	29.6	51.5
Export products/ One-time revenue, etc.	4.1	**4.0**	(0.0)	(0.4)		
Total	52.8	**46.9**	(6.0)	(11.3)	85.7	54.7

Note: Sales of each product are shown by invoice price

- TWYMEEG® revenue continued to grow
- Equa®/EquMet® revenue decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥0.5B)

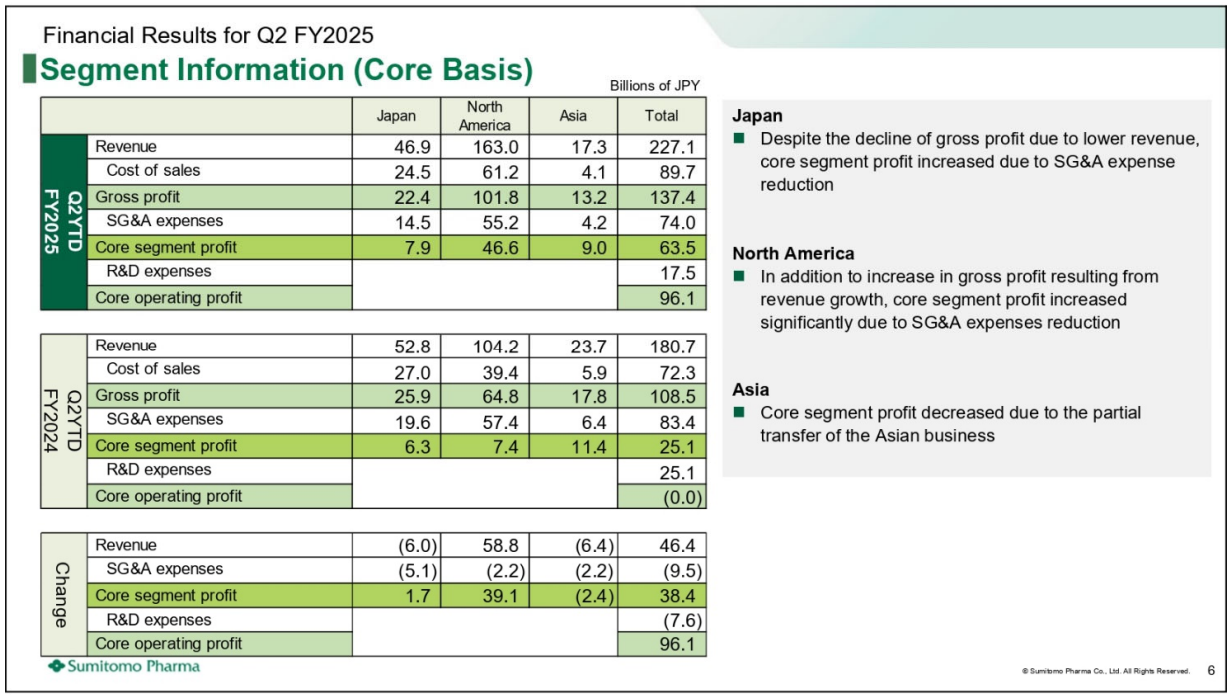
Sumitomo Pharma

 5

I would like to continue by presenting the revenue from sales of our major products in Japan.

First, Japan as a whole is down JPY6 billion to JPY46.9 billion. This is due to the fact that Equa/EquMet had their LOEs, and after last year's LOE of TRERIEF, sales continued to increase, but then gradually decreased. This has had an impact on our business. On the other hand, the sales of TWYMEEG increased by 40.3% to JPY5 billion.

Compared to the initial forecast at the beginning of the fiscal year, 54.7%, as shown in the lower right-hand corner, indicates that we are making good progress.



Financial Results for Q2 FY2025

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
Q2YTD FY2025	Revenue	46.9	163.0	17.3	227.1
	Cost of sales	24.5	61.2	4.1	89.7
	Gross profit	22.4	101.8	13.2	137.4
	SG&A expenses	14.5	55.2	4.2	74.0
	Core segment profit	7.9	46.6	9.0	63.5
	R&D expenses				17.5
	Core operating profit				96.1
Q2YTD FY2024	Revenue	52.8	104.2	23.7	180.7
	Cost of sales	27.0	39.4	5.9	72.3
	Gross profit	25.9	64.8	17.8	108.5
	SG&A expenses	19.6	57.4	6.4	83.4
	Core segment profit	6.3	7.4	11.4	25.1
	R&D expenses				25.1
	Core operating profit				(0.0)
Change	Revenue	(6.0)	58.8	(6.4)	46.4
	SG&A expenses	(5.1)	(2.2)	(2.2)	(9.5)
	Core segment profit	1.7	39.1	(2.4)	38.4
	R&D expenses				(7.6)
	Core operating profit				96.1

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

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

Asia
- Core segment profit decreased due to the partial transfer of the Asian business

Sumitomo Pharma

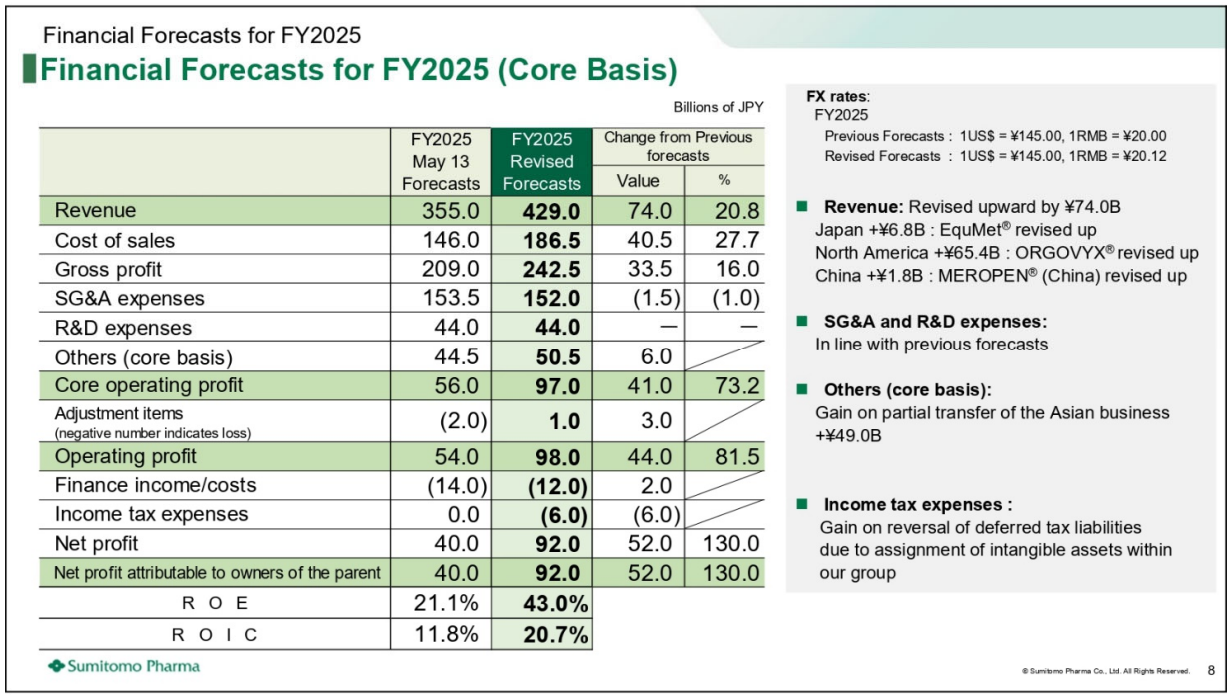
 6

The next page shows financial results by segment.

As shown at the bottom of the slide, the difference between the results of Q2 of last year and this year's results, Japan's sales decreased, but the results of business structure reforms are showing results, and core segment profit increased by JPY1.7 billion.

As mentioned earlier, sales in North America are performing well. Alongside a JPY58.8 billion increase in revenue, the results of structural reforms are also emerging here, with effective control of SG&A expenses leading to a JPY39.1 billion increase in core segment profit.

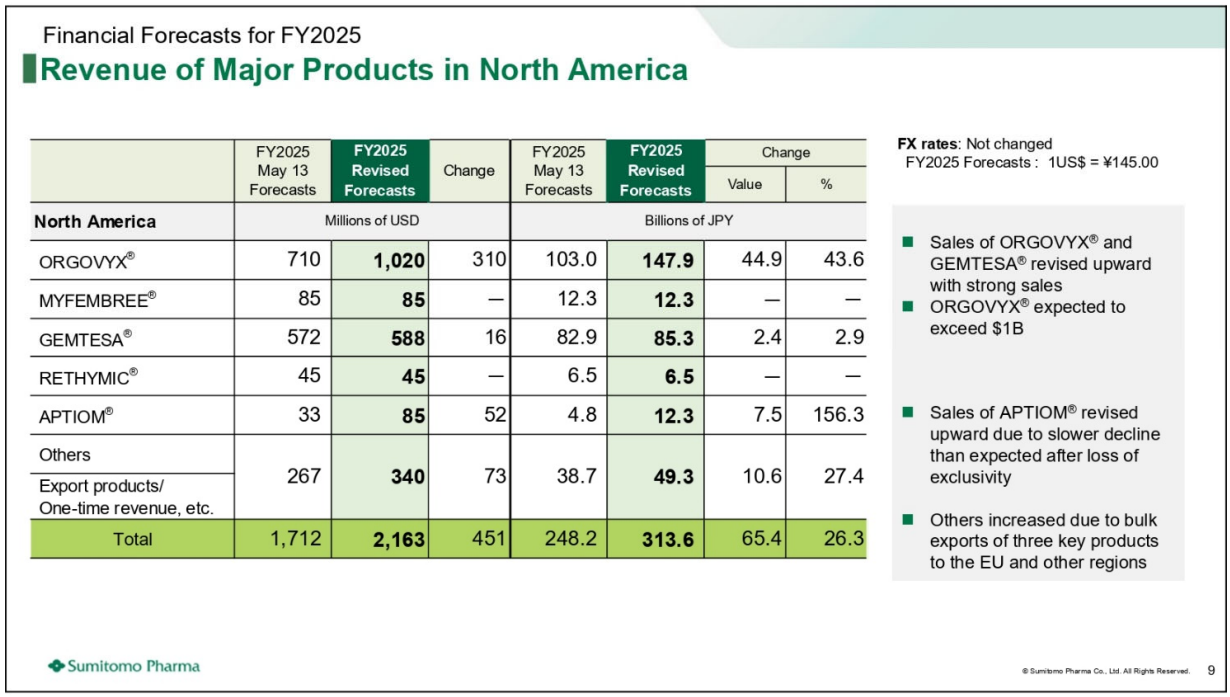
Since the China-Asia business was transferred to a joint venture with Marubeni Corporation in August, there are some comparative obstacles with regard to the figures for Asia.



Continuing on with the Q2 results, which were very strong, we have revised our forecast for the current fiscal year. Please see page eight.

The forecast for revenue is JPY429 billion, an increase of JPY74 billion from the previous forecast. On the other hand, SG&A and R&D expenses were much lower in H1 of the fiscal year but are almost on par with the initial budget for the fiscal year.

In the core, other than that, there is the JPY49 billion gain from the transfer of the China-Asia business that I mentioned earlier, and we are forecasting JPY97 billion in core operating profit. This is an increase of JPY41 billion over the initial figure. Finally, we are forecasting JPY92 billion in net profit attributable to owners of the parent, an increase of JPY52 billion over the initial figure. Both core operating profit and net profit are the highest figures we have ever achieved.



Financial Forecasts for FY2025

Revenue of Major Products in North America

	FY2025 May 13 Forecasts	FY2025 Revised Forecasts	Change	FY2025 May 13 Forecasts	FY2025 Revised Forecasts	Change Value	Change %
North America	Millions of USD			Billions of JPY			
ORGOVYX®	710	**1,020**	310	103.0	**147.9**	44.9	43.6
MYFEMBREE®	85	**85**	—	12.3	**12.3**	—	—
GEMTESA®	572	**588**	16	82.9	**85.3**	2.4	2.9
RETHYMIC®	45	**45**	—	6.5	**6.5**	—	—
APTIOM®	33	**85**	52	4.8	**12.3**	7.5	156.3
Others Export products/ One-time revenue, etc.	267	**340**	73	38.7	**49.3**	10.6	27.4
Total	1,712	**2,163**	451	248.2	**313.6**	65.4	26.3

FX rates: Not changed
FY2025 Forecasts : 1US$ = ¥145.00

- Sales of ORGOVYX® and GEMTESA® revised upward with strong sales
- ORGOVYX® expected to exceed $1B
- Sales of APTIOM® revised upward due to slower decline than expected after loss of exclusivity
- Others increased due to bulk exports of three key products to the EU and other regions

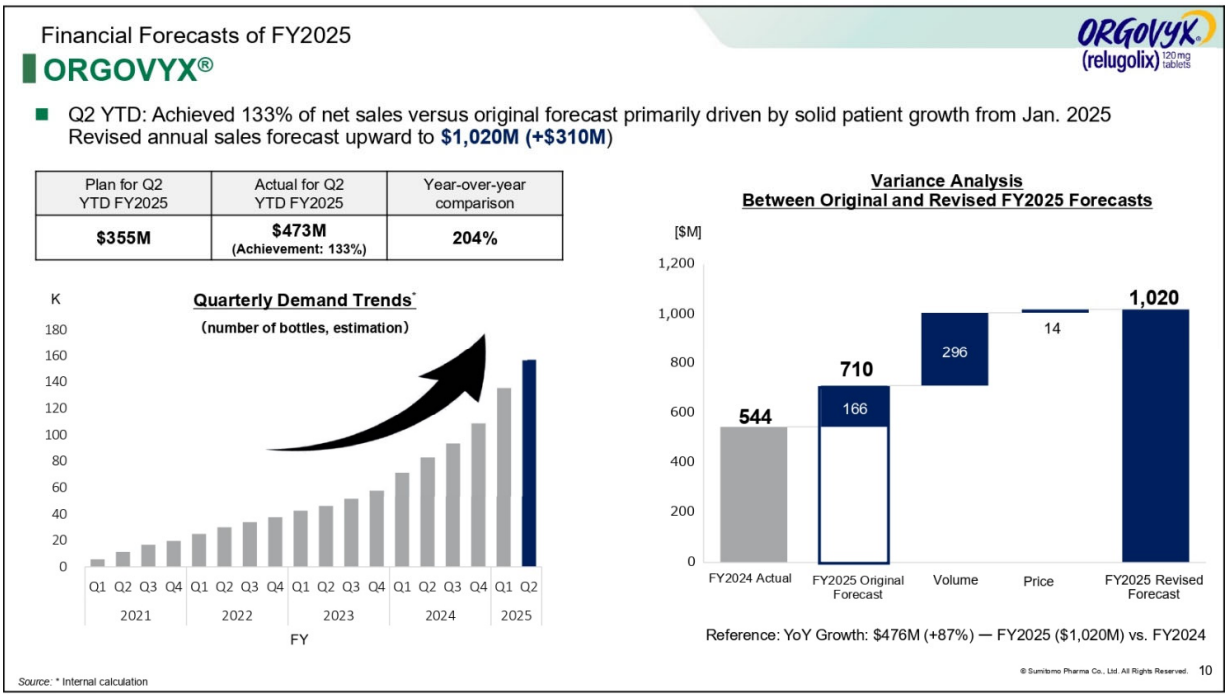
Sumitomo Pharma

 9

The forecast for FY2025 is shown below, with figures for North America and revenue from sales of our main products.

ORGOVYX is doing very well, and our revised forecast is JPY147.9 billion in yen terms and USD1,020 million in dollar terms, which means that we expect to reach sales of USD1 billion. As for sales of MYFEMBREE, which will be explained later as well, they are in line with expectations. GEMTESA is up JPY2.4 billion to JPY85.3 billion.

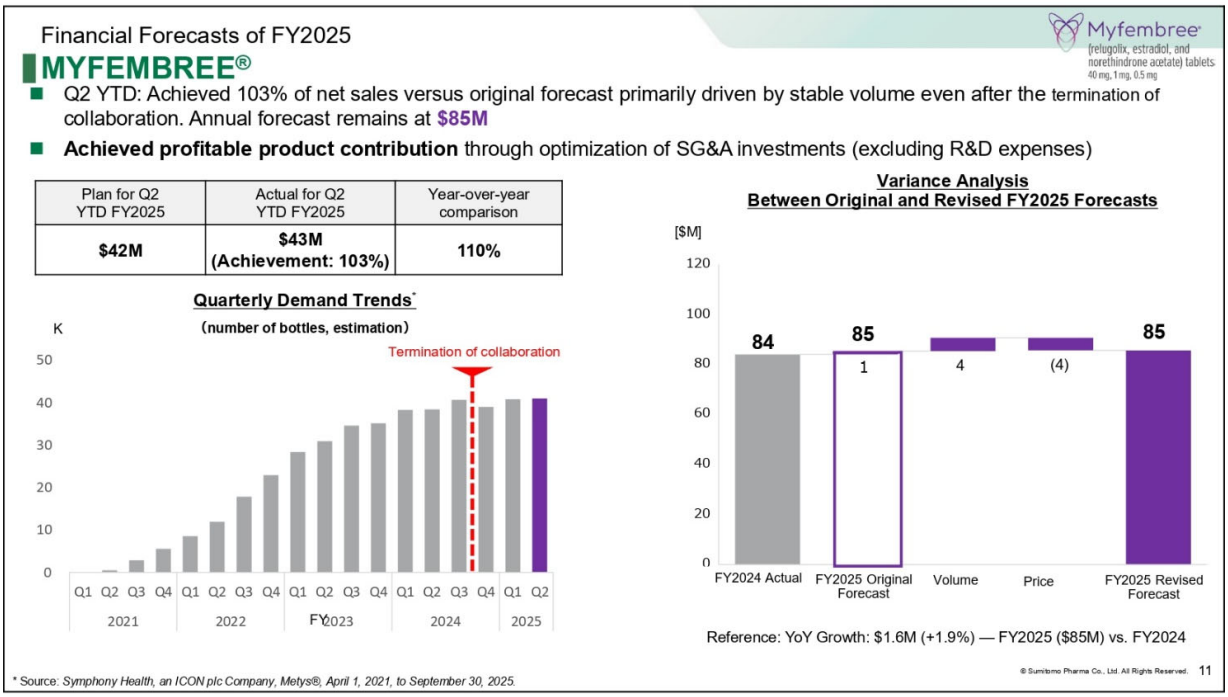
Exports to Europe are also strong, so we have added exports, which are expected to increase by JPY10.6 billion to JPY49.3 billion, for total sales in North America of JPY313.6 billion. This is an increase of JPY65.4 billion compared to the previous forecast figure.



Let me continue with a brief explanation of each product.

ORGOVYX is doing very well, which is USD473 million against the Q2 plan, or 133% of the achievement rate. Compared to the previous fiscal year, this is almost double the amount of the previous year.

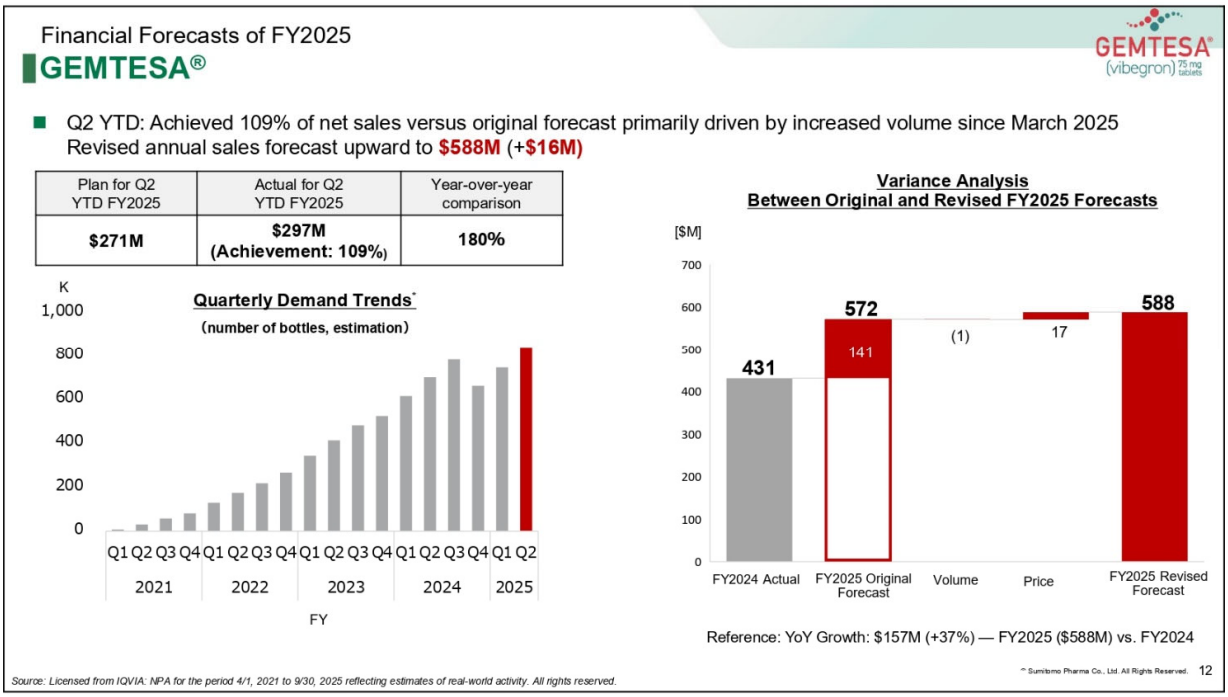
In particular, if you look at the bottom right-hand side, we have broken down the contents, and most products show good quantities. The fact that it is an oral drug and that it is very easy to take due to safety and other factors has become widespread, and at the same time, the maximum NHI price has been capped at USD2,000 by the IRA.



Next is MYFEMBREE.

As I mentioned earlier, sales were almost in line with our forecast, up 10% YoY, but as you can see on the lower left, we terminated our sales collaboration with Pfizer in Q4 of last fiscal year, the beginning of this year. Since then, we have been selling the products independently, and we have been devising sales strategies even while reducing our sales force.

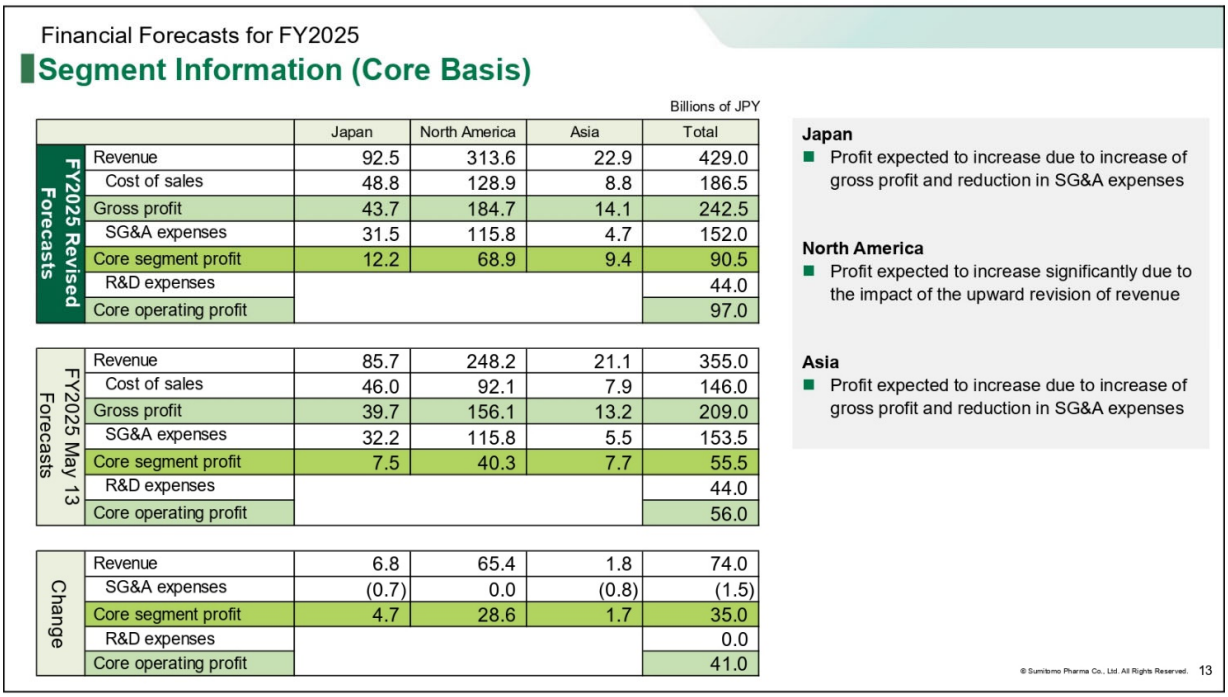
Until now, Pfizer and our company have invested the same sales force to expand the market, but now we are working on this alone, and we are also reducing our sales expenses to two-thirds of what they would have been. As a result, although sales appear to have remained almost flat, there has been a very significant qualitative change in the way profits are generated from single products.



Next is GEMTESA.

The achievement rate for Q2 of 2025 was 109%, which is 1.8 times that of the same period of the previous year, so we are doing very well.

As I explained last term, due to the drug price issue, we have been negotiating on Medicare Part D about removal from the list of a certain payers, and we accepted to be removed. This strategy has proven successful, yielding positive results in pricing. Coverage that had previously dropped off is steadily returning. In terms of volume, while the beginning of this calendar year, as well as last fiscal year's Q4 and Q1, fell below the previous year's levels, starting from this year's Q2, we have returned to record highs.



Financial Forecasts for FY2025

Segment Information (Core Basis)

Billions of JPY

		Japan	North America	Asia	Total
FY2025 Revised Forecasts	Revenue	92.5	313.6	22.9	429.0
	Cost of sales	48.8	128.9	8.8	186.5
	Gross profit	43.7	184.7	14.1	242.5
	SG&A expenses	31.5	115.8	4.7	152.0
	Core segment profit	12.2	68.9	9.4	90.5
	R&D expenses				44.0
	Core operating profit				97.0
FY2025 May 13 Forecasts	Revenue	85.7	248.2	21.1	355.0
	Cost of sales	46.0	92.1	7.9	146.0
	Gross profit	39.7	156.1	13.2	209.0
	SG&A expenses	32.2	115.8	5.5	153.5
	Core segment profit	7.5	40.3	7.7	55.5
	R&D expenses				44.0
	Core operating profit				56.0
Change	Revenue	6.8	65.4	1.8	74.0
	SG&A expenses	(0.7)	0.0	(0.8)	(1.5)
	Core segment profit	4.7	28.6	1.7	35.0
	R&D expenses				0.0
	Core operating profit				41.0

Japan
- Profit expected to increase due to increase of gross profit and reduction in SG&A expenses

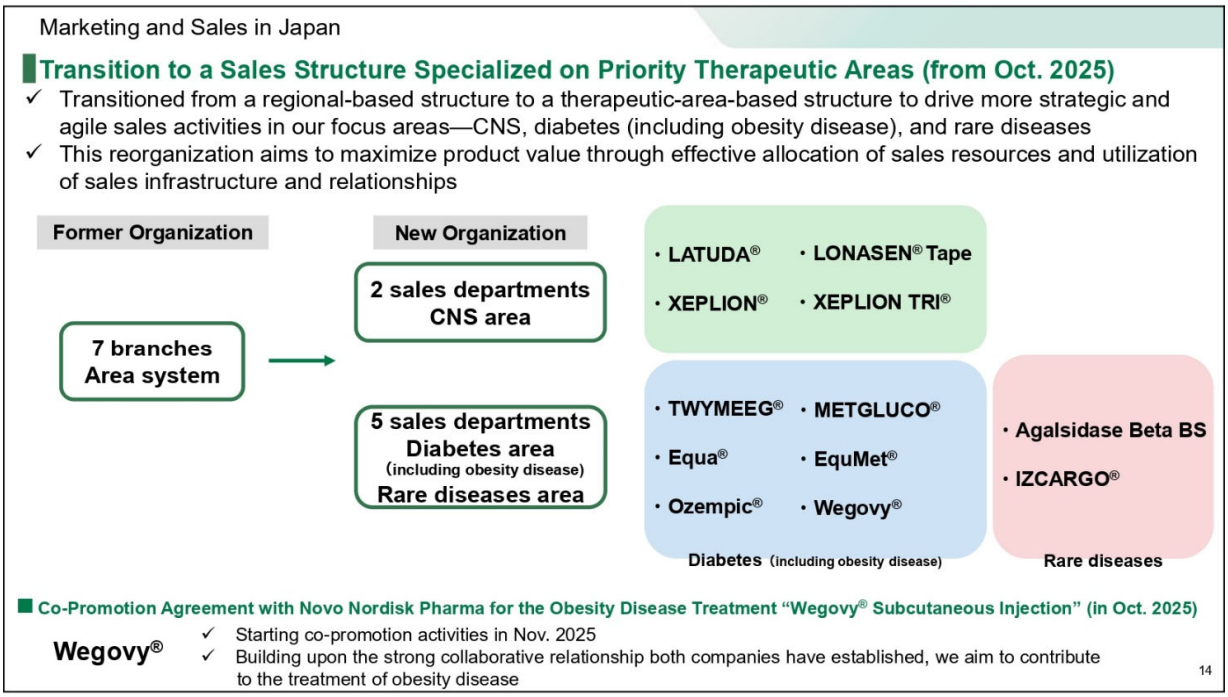
North America
- Profit expected to increase significantly due to the impact of the upward revision of revenue

Asia
- Profit expected to increase due to increase of gross profit and reduction in SG&A expenses

 13

The forecast by segment is shown here on a core basis, and the difference from the previous forecast is shown at the bottom of the page.

Again, North America is doing very well, and Japan is also becoming more profitable.



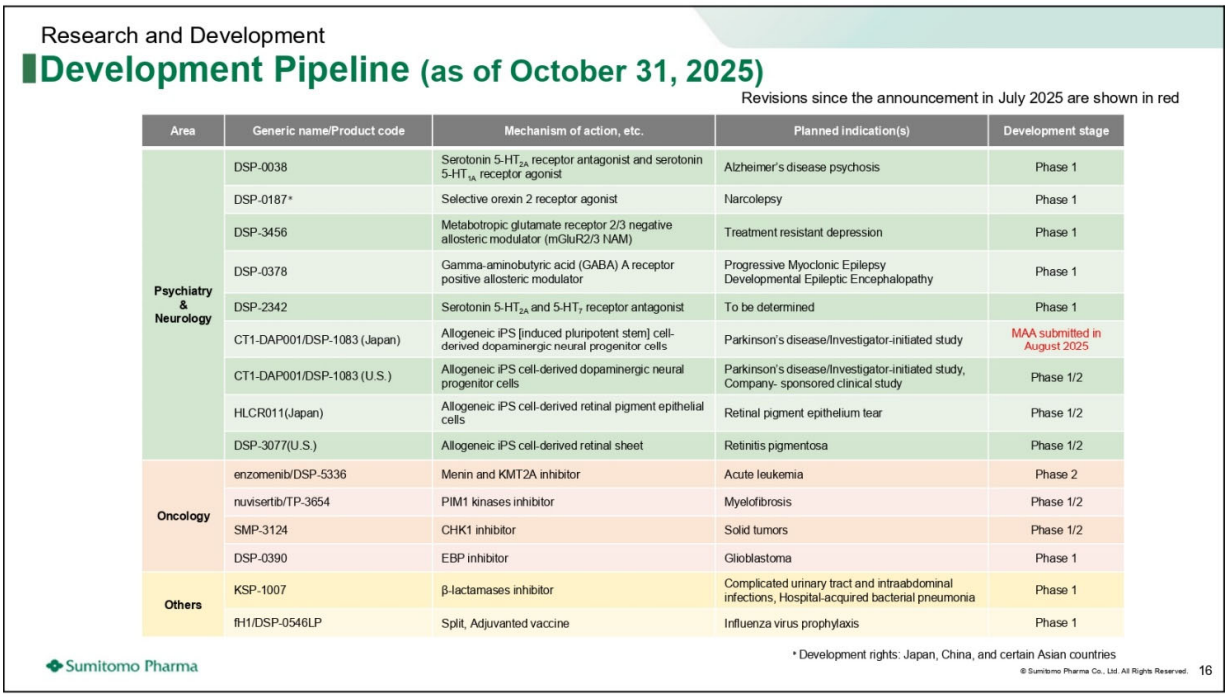
Let me continue by explaining that we have been making a major effort since the first of October.

Last fiscal year, while undertaking a very large-scale business restructuring, we also saw a decline in our product portfolio. Consequently, we implemented a regional sales structure domestically, called the Area system, assigning each MR a designated area and having them handle all our products—CNS, diabetes, and others. We have been operating under this system since December of last year.

On the other hand, since the beginning of this year, we have established sales alliances with XEPLION and XEPLION TRI for CNS, and Ozempic and Wegovy for diabetes and obesity, so the number of products has increased, and we have reverted to the previous regional MR allocation system.

The MRs in the CNS area will mainly focus on four products shown here, and for diabetes, which also includes obesity, the MRs here will now focus their sales activities on enhancing expertise around six products shown here.

We apologize for any inconvenience caused to hospital doctors and others by the change in our sales structure, but we intend to continue to compete with the same highly specialized sales capabilities as before.



Research and Development

Development Pipeline (as of October 31, 2025)

Revisions since the announcement in July 2025 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
	CT1-DAP001/DSP-1083 (Japan)	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study	MAA submitted in August 2025
	CT1-DAP001/DSP-1083 (U.S.)	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated study, Company- sponsored clinical study	Phase 1/2
	HLCR011(Japan)	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077(U.S.)	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	Phase 1/2
Oncology	enzomenib/DSP-5336	Menin and KMT2A inhibitor	Acute leukemia	Phase 2
	nuvisertib/TP-3654	PIM1 kinases 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-lactamases inhibitor	Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Phase 1

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

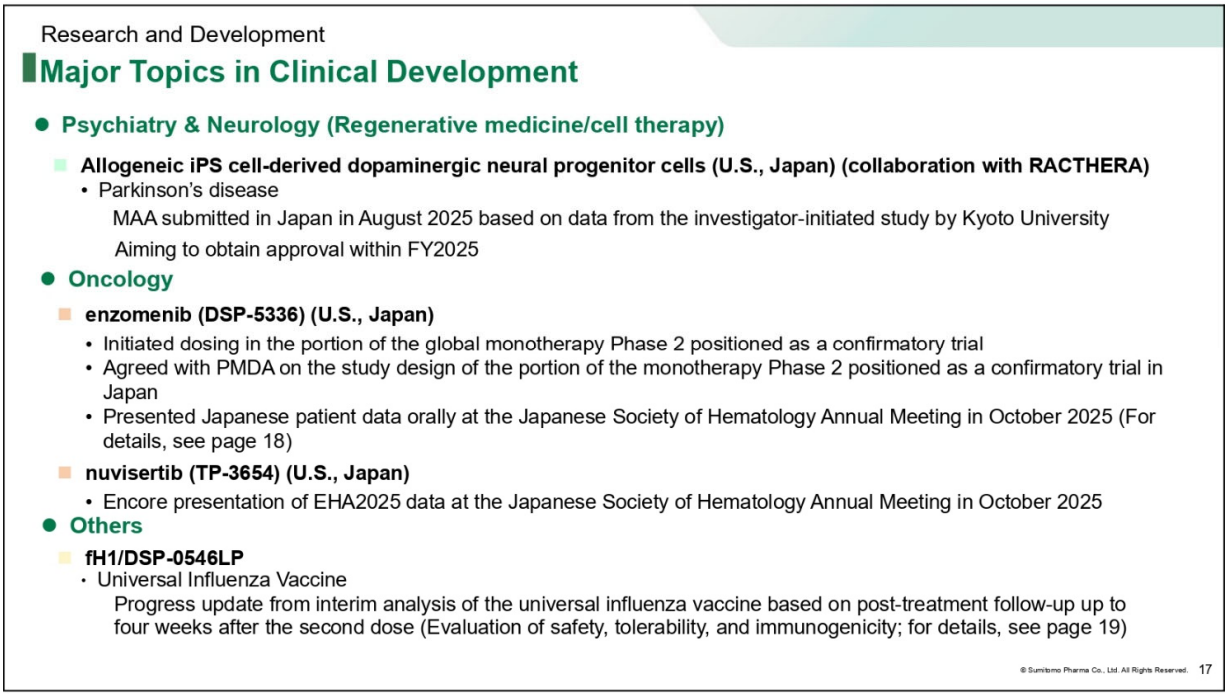
Sumitomo Pharma

 16

Next, research and development.

This is the overall table. Previously, we included a column for development regions, but since products are fundamentally globalized regardless of where development occurs, we have removed the development region column.

On the other hand, for regenerative medicine and cell therapy, each country has its own circumstances, so we have made a change to clearly state in which country the clinical trial is being conducted. There is one other major change, which will be explained on the next page.



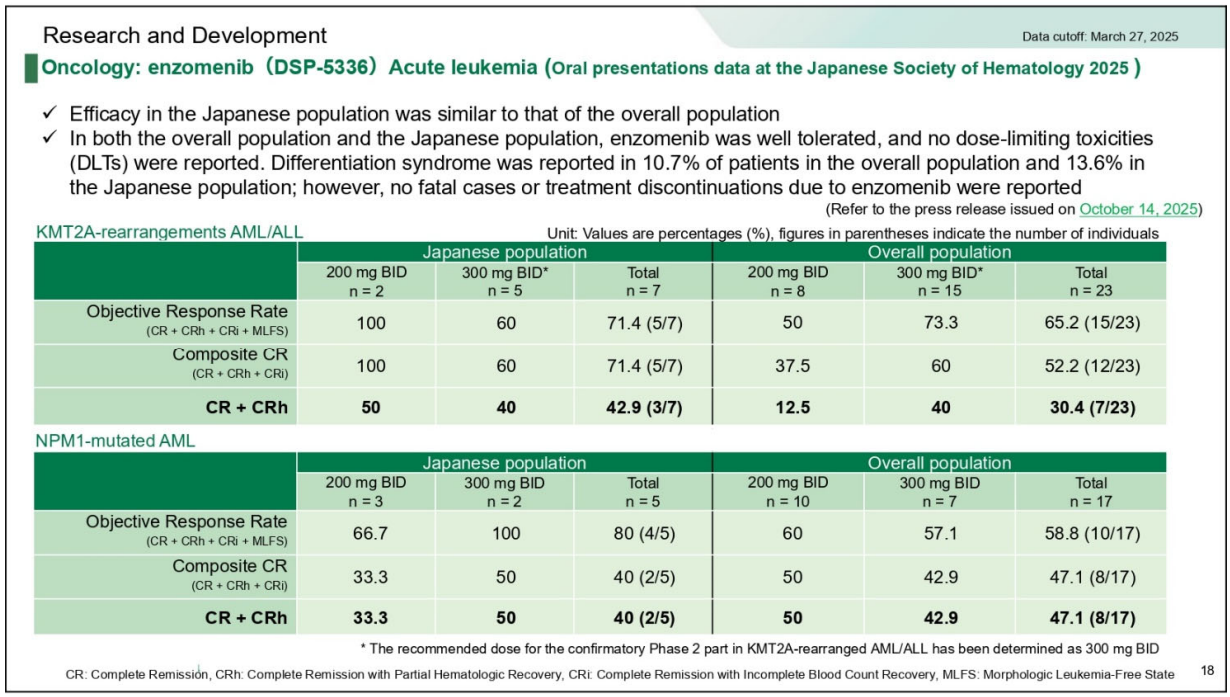
The following are the major topics in clinical development.

Topics since the Q1 announcement: First, in the psychiatry and neurology field, including regenerative medicine and cell therapy, we completed the regulatory submission for allogeneic iPS cell-derived dopaminergic neural progenitor cells on August 5th this year, based on data from the investigator-initiated study by Kyoto University. We are currently working to obtain approval by the end of this year.

In oncology, enzomenib has already been administered as a single agent in a validation study and a pivotal study. In Japan, we have made great progress in completing the single-agent part of the pivotal study and agreeing on the design with PMDA, and we are in the process of presenting the Japanese data at the annual meeting of the Japanese Society of Hematology, as I will explain later.

On the other hand, TP-3654, nuvisertib, was also presented at the Japanese Society of Hematology as an encore presentation.

As for other topics, we have received samples up to four weeks after the second dose of the universal influenza vaccine, and we are presenting some of the results of the post-treatment follow-up. This will also be explained with the illustration later.



Research and Development

Data cutoff: March 27, 2025

Oncology: enzomenib (DSP-5336) Acute leukemia (Oral presentations data at the Japanese Society of Hematology 2025)

- ✓ Efficacy in the Japanese population was similar to that of the overall population
- ✓ In both the overall population and the Japanese population, enzomenib was well tolerated, and no dose-limiting toxicities (DLTs) were reported. Differentiation syndrome was reported in 10.7% of patients in the overall population and 13.6% in the Japanese population; however, no fatal cases or treatment discontinuations due to enzomenib were reported

(Refer to the press release issued on October 14, 2025)

KMT2A-rearrangements AML/ALL

Unit: Values are percentages (%), figures in parentheses indicate the number of individuals

	Japanese population			Overall population		
	200 mg BID n = 2	300 mg BID* n = 5	Total n = 7	200 mg BID n = 8	300 mg BID* n = 15	Total n = 23
Objective Response Rate (CR + CRh + CRi + MLFS)	100	60	71.4 (5/7)	50	73.3	65.2 (15/23)
Composite CR (CR + CRh + CRi)	100	60	71.4 (5/7)	37.5	60	52.2 (12/23)
CR + CRh	**50**	**40**	**42.9 (3/7)**	**12.5**	**40**	**30.4 (7/23)**

NPM1-mutated AML

	Japanese population			Overall population		
	200 mg BID n = 3	300 mg BID n = 2	Total n = 5	200 mg BID n = 10	300 mg BID n = 7	Total n = 17
Objective Response Rate (CR + CRh + CRi + MLFS)	66.7	100	80 (4/5)	60	57.1	58.8 (10/17)
Composite CR (CR + CRh + CRi)	33.3	50	40 (2/5)	50	42.9	47.1 (8/17)
CR + CRh	**33.3**	**50**	**40 (2/5)**	**50**	**42.9**	**47.1 (8/17)**

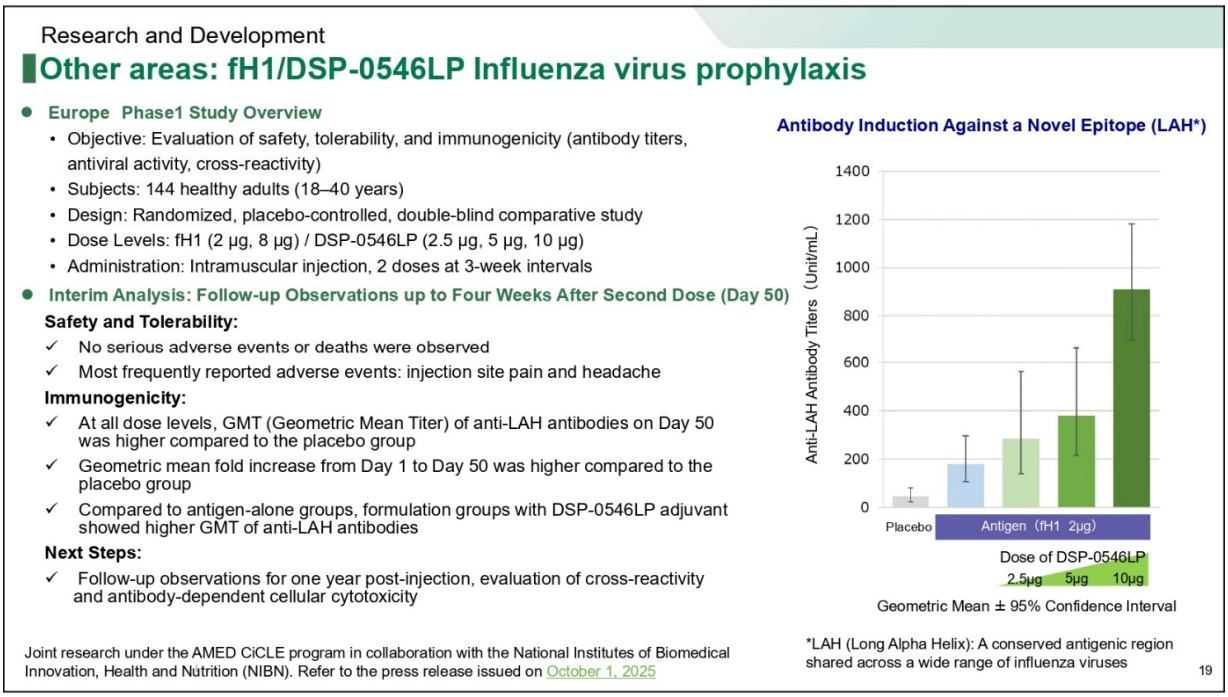
* The recommended dose for the confirmatory Phase 2 part in KMT2A-rearranged AML/ALL has been determined as 300 mg BID

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

18

This is the data on efficacy of enzomenib in Japanese population with cancer.

The total numbers of the Japanese population are shown around the middle, and even when focusing solely on the Japanese population, the results obtained are nearly identical to the data in the far right of the overall population column.



This will be the last of my presentations.

This shows the results of the universal influenza vaccine. First of all, as a result of the follow-up observation for four weeks after the second dose, no serious adverse events or deaths were observed, and the most frequently observed adverse events were pain at the injection site and headache, which are side effects that frequently happen with vaccines.

On the other hand, as shown on the right, the data show that the titer of attacking antibodies increased as expected as the amount of adjuvant was increased. In the future, follow-up observation after one year is a matter of course, and we will use this collected sample to determine the most crucial factor, cross-reactivity, whether it reacts to a different type of virus than the antigen it was immunized with. Or, we are also looking forward to confirming whether antibody-dependent cytotoxicity or ADCC activity can be observed in vitro by the end of this year, and we hope to have such data by the end of the year.

That is all the explanation from me.

Question & Answer

Wakao [Q]: Thank you very much. I am Wakao from JP Morgan. Thank you for your time.

First, please tell us about the difference between your revised plan for H2 of this fiscal year and H2 of the previous plan. Fundamentally, we expect top-line growth in H2, with previously scheduled milestones shifting from H2 to H1. However, looking at the profit side, the plan only projects about JPY900 million in core operating profit for H2. Could you please elaborate a bit more from the perspective of how this compares to the original plan?

Kimura [A]: Thank you for your question. That is precisely the case. The H1 saw excellent results, and this momentum carried directly into the annual core operating profit and net income. This base is somewhat conservative due to the fact that H1 saw the transfer of the China-Asia business and the LOE of APTIOM, which were very significant events.

On the other hand, as I explained earlier, the figures for the cost portion, SG&A, and R&D expenses are almost the same as in H1. We are also taking a conservative view of the situation, partly because of President Trump, but also because of the fact that there may still be instability.

However, as you know, the temporary factor will end in H1 of this year, and from H2 of this year, the results will be the result of our current capabilities, in a sense. Initially, we received comments suggesting we might post a loss in H2, but based on the figures we're seeing now, we can achieve a solid profit. Through our efforts, we hope to exceed that JPY900 million.

Wakao [Q]: Thank you very much. I understand that you have factored in various risks and are being conservative in your approach, but where exactly are you being conservative? Is it sales or expenses? Where exactly is the risk factored in?

Kimura [A]: The point we are being most conservative is on the cost side. For example, we have explained that R&D expenses were JPY4 billion short in H1 of the fiscal year, but we are going to spend JPY44 billion as planned for the fiscal year.

If so, we will accelerate our R&D activities only in H2, and we are actually forecasting that, but as I said, we are somewhat conservative in our estimates as to whether the numbers will reach this level.

Sales figures remain exceptionally strong, but as you know, there are uncertainties such as the entry of generic versions of Mirabegron. Therefore, we are presenting figures that we are confident we can achieve.

Wakao [Q]: I understand. Incidentally, regarding this R&D expenditure, based on your current explanation, it seems the actual amount will likely fall short of the planned figure. Consequently, should any delays in development or similar issues arise, is it acceptable not to be concerned about them?

Kimura [A]: There was no delay in development, but there was a delay of a few months because we had to make some modifications to the protocol when we started the enzomenib validation test and pivotal phase.

On the other hand, we have already started enrollment and administration, and we hope to catch up in the future.

Wakao [Q]: Thank you very much. The second question is about the trend of three products. I understand that all of them are doing well, especially ORGOVYX, though.

ORGOVYX, while it may be influenced by IRA, is clearly highly effective and safe when taken orally compared to existing drugs, as you mentioned. Therefore, I don't really anticipate its growth slowing down once the IRA effect runs its course. However, I wonder whether the current trend will continue steadily going forward. Could you tell us what you are thinking at this point?

Kimura [A]: If you look at the monthly sales by month, as you can see here, they have been rising since the turn of the year this year, around Q4 of 2024. I don't think this growth trend will accelerate dramatically going forward, but there's still plenty of potential, so I expect it to continue growing. Specifically, since we have Nakagawa handling North America, I'll have him provide his comments.

Nakagawa [A]: I am Nakagawa, in charge of North America. As you have just pointed out, I believe that ORGOVYX originally had very good product characteristics. Furthermore, with the cap on patients' out-of-pocket expenses being lowered, I believe this is creating a tailwind.

How long this trend will continue will depend on our sales efforts to make various doctors and patients aware of the power of our products. We are working with Pfizer to develop a sales strategy to ensure that this trend continues for as long as possible.

Wakao [Q]: Thank you very much. Can you tell us about your current patient share and how much you think you can increase your market share?

Nakagawa [A]: In terms of how far the peak will extend in the future, and in terms of the peak in the overall market, the current trend is a little off our forecast, and we are now reassessing the situation. At present, we are not in a position to answer much about future peaks.

Wakao [Q]: I understand. I think the patient share now is a little more than 10%, I believe.

Nakagawa [A]: In terms of the current situation, it amounts to over 10%.

Wakao [Q]: Finally, if you could briefly tell us about the status of the licensing activities for enzomenib and nuvisertib. Regarding the timeframe within the fiscal year, is it correct to understand that there will be no change?

Kimura [A]: I'm Kimura. We are in the process of working on this project, and since we have a partner, we cannot go into details, but I hope you will understand that we are moving forward so that we can make a presentation to you by the end of the fiscal year.

Wakao [Q]: I understand. Do you have any hint as to whether the goal by the end of the fiscal year is becoming tougher or more realistic?

Kimura [A]: Given that this involves contract negotiations, various factors—such as unexpected delays at the very last minute—can arise, so I cannot be overly optimistic. However, as I mentioned, our goal is to strive to report to everyone within the fiscal year, and I hope you understand that we are working hard toward that end.

Wakao [M]: Very well understood, thank you. That is all.

Barker [Q]: I'm Stephen Barker, from Jefferies. Thank you very much.

I would like to ask about sales and sales milestones for ORGOVYX. Based on my understanding, I believe the next milestone will be when you reach USD1 billion in annual revenue. Since Q2 sales are already at USD473 million, I expect you'll likely achieve that milestone sometime next fiscal year.

I understand that the scale is USD300 million, is that correct?

Kimura [A]: I think it was USD325 million, but we have not announced the sales forecast for the next fiscal year, but the sales for the current fiscal year have already exceeded USD1 billion, and this is counted based on the calendar year. So although there is a slight deviation, we believe the probability of achieving next year's milestones is now very high.

Barker [Q]: Thank you. And enzomenib and nuvisertib, do you expect to present the data at ASH, the month after next?

Kimura [A]: Yes. All of these are oral presentations, and we will be happy to provide the data. We believe we can present data on nuvisertib for combination therapy.

Barker [Q]: I understand that you would like to license this out as well, but is your company going to hold the rights to co-development or joint marketing, etc.?

Kimura [A]: We do not generally anticipate licensing out either compound. Instead, we are seeking partners within a framework of joint development and joint sales with our company.

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

Hashiguchi [Q]: I'm Hashiguchi, from Daiwa Securities. Thank you for your time. I would like to ask about expenses, including SG&A expenses and R&D expenses. Since you say conservative repeatedly, I would like to understand more about how much more or less likely it is to increase in H2 compared to H1.

For example, while you held back a bit in H1, you want to spend more in H2, taking into account the strong sales performance. Or, as mentioned earlier regarding ORGOVYX, there's still room for promotion to increase its penetration. In that sense, if you want to increase investment further.

If you have a clear idea of what you would like to increase this or that, could you please introduce it to us? I imagine some of people might have thought, just listening to the story, that H1 and H2 weren't any different at all. Regarding the areas where you consider to increase, I thought it might be better to discuss them to some extent, compared to H1, which is why I'm asking.

Kimura [A]: Kimura will start the explanation first, and then I will ask Sakai to add any additional information, if there is any.

First of all, we are not considering anything special for H2 for both R&D and SG&A expenses. We are still in the process of restructuring, so our basic stance is to use expenses in a controlled and managed manner.

On the other hand, as I mentioned a little earlier, one of the reasons for the shortfall in R&D expenses is the slightly delayed start of the enzomenib pivotal. Since we have opened nearly 100 sites, we have money to accelerate the process, so we want to encourage the research department to accelerate the process, so we have left the numbers as they are.

Mr. Sakai, if you have anything to add.

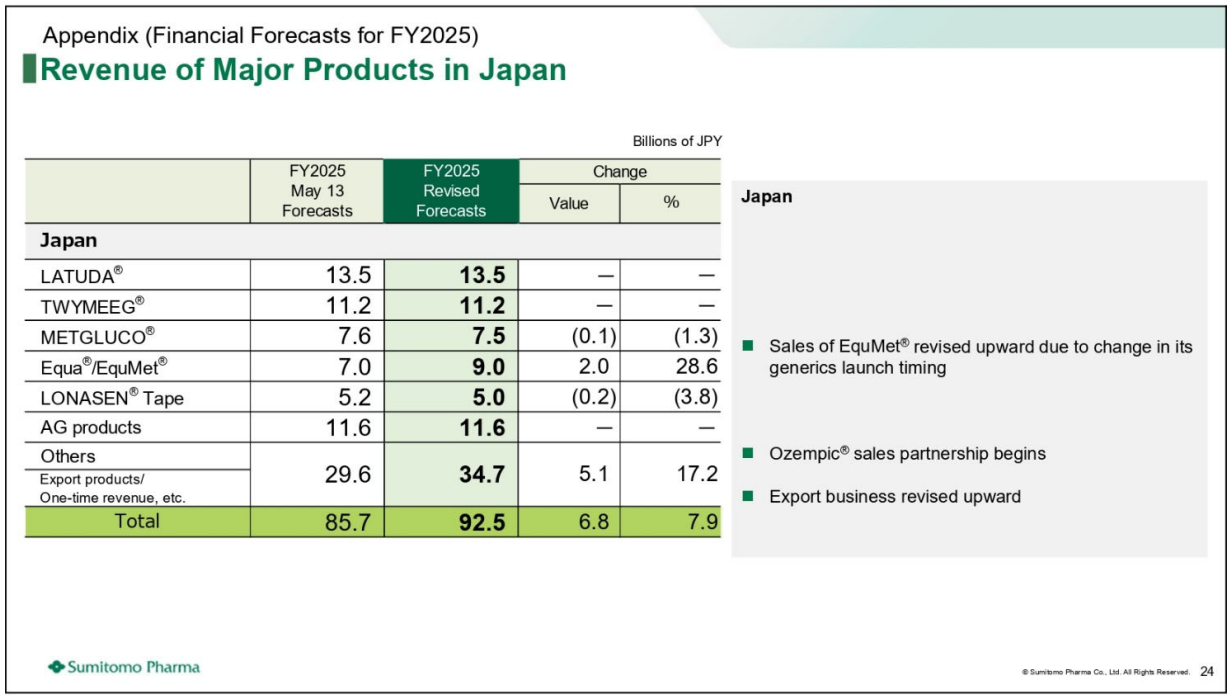
Motoyuki Sakai [A]: I'm Sakai. Thank you very much. Regarding SG&A expenses, since last, year we have been particularly cautious about expense execution. The departments in charge both in Japan and the US have maintained considerable discipline in this regard, so there is a tendency for expense execution to lag somewhat.

I believe that during last year's interim results as well, the figures were lower in H1 and increased in H2. While I don't recall the exact numbers, I think H2 figures were higher. Originally, we anticipated a slight increase in expense execution during the latter half of the fiscal year.

Also, although I won't mention them individually, there is a forecast that there will be special expenses for licenses only in H2, for example. That is all.

Hashiguchi [Q]: So you are anticipating the possibility that additional costs may be incurred by the license that were not incurred in H1? Regarding the newcomer.

Motoyuki Sakai [A]: That is what is happening in relation to sales.



Appendix (Financial Forecasts for FY2025)

Revenue of Major Products in Japan

Billions of JPY

	FY2025 May 13 Forecasts	FY2025 Revised Forecasts	Change	
			Value	%
Japan				
LATUDA®	13.5	**13.5**	—	—
TWYMEEG®	11.2	**11.2**	—	—
METGLUCO®	7.6	**7.5**	(0.1)	(1.3)
Equa®/EquMet®	7.0	**9.0**	2.0	28.6
LONASEN® Tape	5.2	**5.0**	(0.2)	(3.8)
AG products	11.6	**11.6**	—	—
Others Export products/ One-time revenue, etc.	29.6	**34.7**	5.1	17.2
Total	85.7	**92.5**	6.8	7.9

Japan

- Sales of EquMet® revised upward due to change in its generics launch timing
- Ozempic® sales partnership begins
- Export business revised upward

Sumitomo Pharma

 24

Hashiguchi [Q]: Okay, thank you. One more point, on page 24, I am now looking at the revised forecast for the Japan business. There is JPY34.7 billion for others, an increase of JPY5.1 billion from the previous JPY29.6 billion, has been revised, and two reasons are written on the right side of this page. Can you give us a better picture of how much impact each of these had?

I'd appreciate any hints as to whether there are no particular negative factors, or if these two items make up the breakdown of JPY5.1 billion, or which one is larger.

Kimura [A]: First of all, I can't tell you about the figures based on sales tie-up for Ozempic because we have promised not to disclose it at this time, but exports of Meropen to Pfizer and LATUDA to Latin America are doing well, which accounts for a large part of JPY5.1 billion.

Hashiguchi [Q]: So, would you say that the impact of this fiscal year is limited with regard to Ozempic?

Kimura [A]: I think the word "limited" should be well suited, but we are not able to disclose the figure itself at this time, so I hope you understand.

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

Wada [Q]: Thank you very much. I'm Wada, SMBC Nikko Securities. Although you have already described it in the materials. Regarding whether iPS cell approval in Japan is likely to happen within FY2025, I'd like to ask for your assessment—specifically, whether you have a clear view on the timing or other concrete details. What are your thoughts?

Kimura [A]: I'm Kimura. This is a matter for discussion with the authorities, so we cannot decide it on our own. However, as we have stated, we believe approval within this fiscal year is achievable. Accordingly, we are preparing our entire company structure with the assumption that sales will commence next fiscal year.

Wada [Q]: Thank you very much. We recognize that there may be competing products globally. Could you please clarify your competitive advantages, development strategy, and key differentiators against those competitors? What do you think?

Kimura [A]: You mean globally?

Wada [M]: Yes.

Kimura [A]: In the US, clinical trials like the one using ES cells are on board. The clinical trial is being conducted by an affiliate of Bayer called BlueRock, and since that company is ahead of us in North America, we are now working to accelerate our clinical trials in North America.

On the other hand, in terms of superiority, the shape and other aspects of the products are quite different, and head-to-head comparisons have not been made. The results of the preclinical trials were published in the form of papers in Nature this past April, and they also yielded similar findings. It is not possible to say specifically that this one is inferior or superior to the other.

Wada [Q]: Thank you very much. On a completely different note, and this is the last point, regarding the framework for the enzomenib and nuvisertib collaboration—since your company is aiming for a development partnership, I imagine you envision the R&D costs being split fifty-fifty. Is that understanding correct? I wanted to ask you about this.

What I'd like to ask is about what would happen to the R&D expenses. For instance, if you were able to secure a development partnership early on and the partner were to push development very aggressively, could that lead to a substantial increase in R&D expenses? What are your thoughts on this?

Kimura [A]: First of all, as you said, as a framework, whether it will be 50 to 50, or 40 to 60, that depends on the other party, but we are thinking of sharing it between both parties.

On the other hand, if the development plan becomes too extreme, it could lead to the situation you just mentioned. Naturally, we would establish a joint development committee and negotiate the development plan together. While we are also formulating plans to maximize each party's interests, the increase will not be that extreme.

On the other hand, it is certain that costs will increase. If we are to proceed with development within disciplined R&D budgets, it becomes essential for us that the other party bear the increased portion. We are looking for a partner who can work well with us in that sense.

Wada [M]: I understand very well. Thank you very much.

Fumiyoshi Sakai [Q]: My name is Sakai from UBS. President Kimura, I believe you mentioned that starting in FY2026, your capabilities will be put to the test. That said, you also suggested the possibility of a milestone payment of USD325 million next fiscal year upon achieving the threshold from Pfizer.

Next, regarding the remaining residual value of share transfer from Marubeni, I believe it amounts to approximately JPY27 billion, my first question is whether it can be finalized to be in FY2029.

Kimura [A]: We recognize that milestone-based interim payments remain a significant factor for us going forward, and we do not operate solely on our actual abilities alone, so we kindly ask that this point not be misunderstood.

Also, for the China-Asia business, cash of JPY27 billion is expected in the future, and we have included all of it in our PL this time. On the other hand, while the timing is set for three years from now, the contract allows for some flexibility in the timing. Therefore, I cannot specify the exact quarter of which year at this time. Please understand that the target date is three years from now.

Fumiyoshi Sakai [Q]: So you said that this is deferred revenue or something, and that it is recorded on an annual basis?

Kimura [A]: It is very complicated, so I ask Sakai to answer this.

Motoyuki Sakai [A]: I'm Sakai. Thank you for your question. Although only 60% of the shares were transferred for consolidated financial statement purposes, the method used on the income statement calculates them 100%. That is the current practice under international accounting standards, so it is not a matter of deferral or anything like that.

That is all.

Fumiyoshi Sakai [Q]: So, would it be correct to say that everything will be processed in the financial statements for the fiscal year ending March 31, 2026?

Motoyuki Sakai [A]: Basically, yes. Until we receive the second payment, there is a possibility that unrealized gains or losses may appear. So, if you ask whether they will never appear at all, I cannot say they will never appear. However, please understand that, fundamentally, the capital gains are recognized in a lump sum.

Fumiyoshi Sakai [Q]: Okay, thank you. Another thing I was a little concerned about in 2029 is that I think the substance patent for ORGOVYX will expire in 2029, and if so, under the current rules, this would be the target of IRA, Part D. No, B. I think there is a possibility of being a target of reform, ORGOVTX.

Since this is a gross-to-net, we cannot estimate how much it will impact your company's sales, but I don't believe it will result in increased revenue. Please allow me to confirm whether this perspective is correct.

You mean 2028, since the price negotiations will start the previous year.

Kimura [A]: First, Kimura will explain, and then Nakagawa will provide additional details. We anticipate that negotiations of that nature will come up around that time.

On the other hand, regarding the timing of that impact, we believe it will be a little later than you just mentioned. Nakagawa will explain the current sensitivity, including its magnitude.

Nakagawa [A]: Thank you. Nakagawa, in charge of North American operations, will answer your questions.

First of all, in terms of that time period, I think the trigger is that the drug has been on the market for about seven years, rather than a patent. As you pointed out, we assume that this will be a target of negotiations, and we recognize that it will be a negative factor for a certain level of sales.

Therefore, we are positively considering how we can increase our market share by then and how we can overcome this obstacle.

Fumiyoshi Sakai [Q]: I'm a bit concerned about the third milestone payment from Pfizer; I suppose that's the minimum you'd want to secure. It is 2029, so 2028, and there is still a time frame, for lack of a better word, a probationary period, is that correct?

Nakagawa [A]: Regarding the conditions for the third milestone, we are unable to disclose them, so it is difficult for us to provide specific details. However, as you mentioned, our approach is to generate revenue as early as possible and secure as many milestones as feasible; that is how we are proceeding.

Fumiyoshi Sakai [M]: I understand. Thank you very much.

Muraoka [Q]: Thank you very much. Morgan Stanley, Muraoka. I am sorry, I am asking this question in a situation that I don’t fully understand.

Regarding the relationship between this quarter's guidance and the partnering of enzomenib and nuvisertib: If partnering for these two drugs is finalized by March, this likely isn't included in the current revised forecast. If finalized, it would trigger a one-time gain, leading to an upward revision. If both are finalized, it would trigger two upward revisions. In theory, or formally, would it be possible?

Kimura [A]: Yes. Formally, as you understand, if we proceed with the contract based on current projections, a front payment should likely be forthcoming; however, we have not factored this in.

Muraoka [Q]: I understand. I'm just wondering what kind of partner you would like to work with. In other words, since we can't afford to increase our dependence on Pfizer any further, I wonder if Pfizer is the only one excluded, no matter how advanced the cancer is. I apologize for this oddly preconceived question, but is that the right way to think about it?

Kimura [A]: In terms of our partnership strategy, we are not considering Pfizer's difficulties. Rather, we are considering the most suitable partner for maximizing the potential of each of our two cancer products.

Muraoka [Q]: I understand. I’m talking about milestones for ORGOVYX in the next term, I mean next April and beyond. I think the probability of achieving USD1 billion is very, very high, but when creating next period's forecast, should we only include it once? I feel, given the current momentum, that it would be safer to see it go in for the next two quarters.

That's because, though you haven't mentioned it, if we consider that five milestones of USD500 million each are set, even if two come in next quarter, it wouldn't be surprising given the current momentum. Actually, I think it would be better to anticipate that way so as not to deviate from your company's guidance for the next fiscal year. Please let me know what you can within the scope of what you can disclose.

Kimura [A]: There is nothing I can say at this moment. We would also prefer to get payment, including the milestone, in the next fiscal year, but since we have not yet prepared sales forecasts for the next fiscal year and cannot disclose the trigger for the next milestone, we are unable to provide any further details at this time.

We hope that you will create a forecast for our company that includes this information.

Muraoka [M]: I was just confirming that, so as to avoid creating a negative surprise.

Kimura [A]: Unfortunately, I cannot say for certain at this time. One thing, USD1 billion for the calendar year figure I mentioned earlier, we now believe has a very high probability of occurring.

Muraoka [M]: I understand. Thank you very much, that is all.

Kino [M]: This concludes the presentation of Sumitomo Pharma's financial results for Q2 of fiscal year 2025. Thank you very much for your participation today.

[END]