



ONO PHARMACEUTICAL CO., LTD.

FY2025 Financial Announcement

May 8, 2026

[Number of Speakers]	5	
	Toichi Takino	Representative Director, President and Chief Operating Officer
	Masaki Itoh	Corporate Executive Officer/Chief Officer of Finance & Accounting Division
	Tatsuya Okamoto	Corporate Officer, Executive Vice President, Clinical Development
	Hirokazu Kitada	Corporate Officer, Executive Vice President, Sales and Marketing
	Ryuta Imura	Vice President, Corporate Communications

Presentation

Imura: Thank you very much for joining us today at ONO PHARMACEUTICAL's financial results meeting for the fiscal year ended March 31, 2026.

At the outset, I would like to introduce our attendees.

Takino, Representative Director, President, and Chief Operating Officer.

Okamoto, Corporate Officer, Executive Vice President, Clinical Development.

Itoh, Corporate Executive Officer, Chief Officer of Finance & Accounting Division.

Kitada, Corporate Officer, Executive Vice President, Sales and Marketing.

Agenda



FY2025 Financial Results and Future Vision (14:00-14:30)

Toichi Takino

Representative Director,
President and Chief Operating Officer

Pipeline Progress Status (14:30-14:45)

Tatsuya Okamoto

Corporate Officer /
Executive Vice President, Clinical Development

Q&A Session (14:45-15:15)

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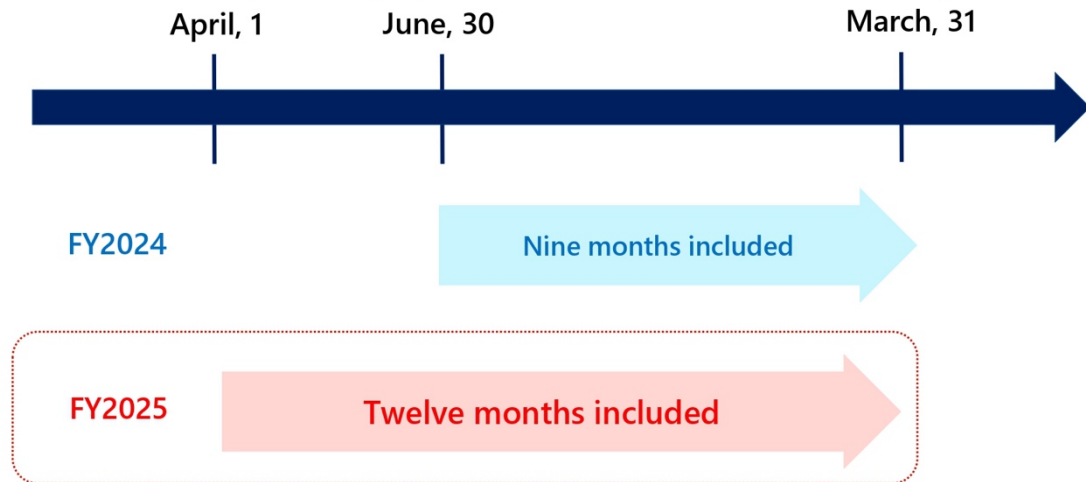
Imura: First, Takino, President, will explain the financial results for the fiscal year ended March 31, 2026, and the outlook for the future, and then Okamoto, Executive Vice President of Clinical Development, will explain the progress of the development pipeline. The material has already been posted on the Company's website. Please refer to it as necessary.

Takino, President, will now explain our financial results for the fiscal year ended March 31, 2026, and our future vision.

Profit and Loss Recognition Period for Deciphera Pharmaceuticals, Inc.



Regarding the profit and loss recognition for Deciphera Pharmaceuticals, Inc., nine months were recorded in the same period last year, while twelve months have been recorded this year.



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Takino: I would like to report our full-year financial results for the fiscal year ended March 31, 2026.

At the outset, I would like to provide a brief note on the financial reporting for the fiscal year under review. As for Deciphera Pharmaceuticals, Inc., which was acquired in June 2024, nine months of profit and loss were taken into account in the previous year's financial results and 12 months are in the financial results of the fiscal year under review. Please note that three more months of sales and profit and expenses are recorded for Deciphera in the fiscal year under review than in the previous fiscal year.

Main Points of the Financial Results



Achieved revenue and profit growth and record-highest earnings ever.

<p>Full-Year Result (FY2025)</p>	<p>FY2025: Record-High Revenue and Profit with Strong Year-on-Year Growth Revenue increased to 515.8 JPY bn (+5.9% YoY), driven by strong growth in overseas products, reaching a record high. Core operating profit increased to 137.1 JPY bn (+21.7% YoY), supported by improved cost efficiency. Core profit attributable to owners of the Company reached 103.5 JPY bn (+14.5% YoY), the highest level since the introduction of core indicators.*</p>
<p>Full-Year Forecast (FY2026)</p>	<p>FY2026 Outlook: Lower Revenue and Profit with Continued R&D Investment Revenue is expected to be 455.0 JPY bn (-11.8% YoY), mainly due to the termination of the co-promotion agreement with AstraZeneca for Forxiga. The Company plans to continue investing in research and development at approximately 30% of net sales, in order to advance global clinical trials aimed at expanding its pipeline. Therefore, core operating profit is expected to be 124.0 JPY bn (-9.6% YoY).</p>
<p>Research & Development</p>	<ul style="list-style-type: none"> - Tirabrutinib is under FDA review following NDA acceptance. - Sapablursen has entered a global Phase 3 trial. - Phase 2 data for ONO-4578 and ONO-2808 are expected to be presented at scientific meetings. - Four new pipelines have advanced into Phase 1 trials.

* Core indicators have been introduced starting from the FY2025. 6/39

Here are the key points of today's briefing.

As you can see in the top row, we achieved record-high revenue and profit growth for the full fiscal year ended March 31, 2026.

Revenue increased 5.9% YoY to JPY515.8 billion due to better-than-expected sales of Deciphera products acquired last year, QINLOCK, a treatment for gastrointestinal stromal tumor GIST; and ROMVIMZA, a treatment for tenosynovial giant cell tumor TGCT.

On the expense side, as a result of appropriate cost management and streamlining of expenses, core operating profit increased 21.7% YoY to JPY137.1 billion, and core profit attributable to owners of the Company increased 14.5% to JPY103.5 billion, the highest profit since the introduction of the core index.

Next, I will discuss the full-year forecast for the fiscal year ending March 31, 2027. Due to the termination of the co-promotion agreement with AstraZeneca for FORXIGA and so on, revenue is expected to decrease by 11.8% from the previous year to JPY455 billion.

On the other hand, we intend to continue to invest in R&D at the level of approximately 30% of sales in order to promote global trials of sapablursen and ONO-4578, which will drive future growth. As a result, core operating profit is expected to decrease by 9.6% YoY to JPY124 billion.

In R&D, the FDA has accepted the application for tirabrutinib, a pipeline product in the spotlight, and is expected to approve it in December.

In addition, a Phase 3 study of sapablursen has been initiated. The results of the P2 studies of ONO-4578 and ONO-2808, which are currently being prepared for Phase 3, will be presented at international conferences in the near future.

In addition, four new compounds have entered Phase 1 and the pipeline continues to expand.

FY2025 : Sales Revenue



Revenue
515.8 JPY bn
YoY +28.9 JPY bn
(+5.9%)



Goods and Products Sales

342.6 JPY bn
YoY +11.8 JPY bn (+3.6%)



Royalty and Others

173.2 JPY bn
YoY +17.1 JPY bn (+10.9%)

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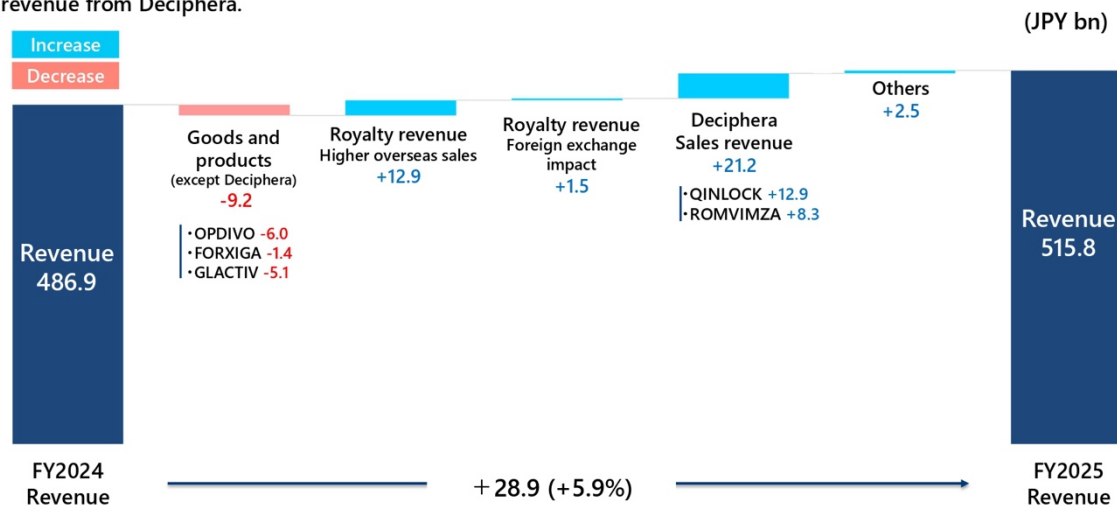
I will discuss the full-year results.

Of the total revenue for the fiscal year ended March 31, 2026, product sales, increased by JPY11.8 billion or 3.6% to JPY342.6 billion, and royalty and others increased by JPY17.1 billion or 10.9% to JPY173.2 billion. Total revenue, increased JPY28.9 billion or 5.9% from the previous year to a record high of JPY515.8 billion.

FY2025 : Sales Revenue (Breakdown)



Although sales of OPDIVO decreased due to intensified competitive environment, overall sales increased by 28.9 JPY bn year on year, mainly due to higher royalty revenue associated with OPDIVO and other products and revenue from Deciphera.



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Here is the breakdown of the increase or decrease in sales revenue.

Sales from goods and products, excluding Deciphera, decreased JPY9.2 billion due to lower sales of OPDIVO, GLACTIV, and other products.

On the other hand, royalty revenue increased by JPY14.4 billion due to the increase in local sales and the effect of foreign exchange rates on royalties related to OPDIVO and KEYTRUDA. In addition, sales of Deciphera's QINLOCK and ROMVIMZA increased by a combined JPY21.2 billion.

Driven by an increase in overseas sales, sales revenue increased JPY28.9 billion from JPY486.9 billion in the previous year to JPY515.8 billion.

FY2025 : Sales Revenue by Product / Japan



JPY bn	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	486.9	515.8	28.9	5.9%	490.0
Goods and products	330.8	342.6	11.8	3.6%	330.0
Royalty and others	156.1	173.2	17.1	10.9%	160.0
Goods and Products (Japan)	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	120.3	114.3	-6.0	-5.0%	120.0
FORXIGA Tablets	89.6	88.2	-1.4	-1.5%	80.0
ORENCIA for Subcutaneous Injection	26.6	26.6	-0.0	-0.0%	28.0
GLACTIV Tablets	18.3	13.2	-5.1	-27.9%	12.0
VELEXBRU Tablets	10.5	11.9	1.4	12.8%	11.0
ONGENTYS Tablets	7.6	9.0	1.3	17.3%	9.0
PARSABIV Intravenous Injection	8.4	9.0	0.6	6.6%	9.0
KYPROLIS for Intravenous Infusion	8.6	7.5	-1.1	-12.9%	9.0
BRAFTOVI Capsules	4.2	5.6	1.4	33.8%	—

* The consolidated financial forecast for the fiscal year ended March 2026, announced on October 30, 2025, is provided.

· Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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Here is an overview of domestic sales by product.

Sales of OPDIVO decreased 5% from the previous year to JPY114.3 billion due to an increasingly competitive environment. Sales of FORXIGA decreased 1.5% from the previous year to JPY88.2 billion due to the entry of generics at the end of last December.

In other products, sales of GLACTIV, a drug for diabetes treatment, decreased 27.9% to JPY13.2 billion, affected by the approximately 25% reduction in NHI prices. Sales of KYPROLIS, a treatment for multiple myeloma, decreased 12.9% to JPY7.5 billion due to the impact of competitive products.

Meanwhile, sales of ORENCIA for subcutaneous injection, a drug for rheumatoid arthritis treatment, remained unchanged from the previous year at JPY26.6 billion. Sales of VELEXBRU, a treatment for primary CNS lymphoma, increased 12.8% to JPY11.9 billion due to steady market penetration. Sales of ONGENTYS, a Parkinson's disease treatment, increased 17.3% to JPY9 billion as its use continued to grow steadily. Sales of PARSABIV, a treatment for secondary hyperparathyroidism, increased 6.6% to JPY9 billion. Sales of anti-cancer agent BRAFTOVI increased 33.8% YoY to JPY5.6 billion, due in part to the addition of an indication for the first-line treatment of unresectable advanced recurrent colorectal cancer with BRAF mutation V600E.

FY2025 : Sales Revenue by Product / Overseas / Royalty



JPY bn	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	486.9	<u>515.8</u>	28.9	5.9%	490.0
Goods and products	330.8	<u>342.6</u>	11.8	3.6%	330.0
Royalty and others	156.1	<u>173.2</u>	17.1	10.9%	160.0
Goods and Products (Overseas)	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO®	13.1	<u>14.2</u>	1.0	8.0%	13.5
QINLOCK®	25.5	<u>38.4</u>	12.9	50.6%	36.0
ROMVIMZA®	N/A	<u>8.3</u>	—	—	8.0
Royalty and others	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO®	113.0	<u>122.3</u>	9.3	8.2%	
KEYTRUDA®	26.4	<u>29.5</u>	3.0	11.4%	

* The consolidated financial forecast for the fiscal year ended March 2026, announced on October 30, 2025, is provided.

· Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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Next is overseas sales by product.

OPDIVO sales in Korea and Taiwan totaled JPY14.2 billion, up 8% from the previous year.

Sales of Deciphera also increased 50.6% from the previous year to JPY38.4 billion due to the inclusion of three months more sales of QINLOCK than in the previous year and expanded use in Europe and other regions in addition to the United States. This was JPY2.4 billion higher than the announced forecast of JPY36 billion.

Sales of ROMVIMZA, which was launched last year, amounted to JPY8.3 billion, also exceeding the announced forecast of JPY8 billion, as a result of its steady evaluation as the first-line treatment for TGCT patients with a kinase inhibitor TKI.

Royalties related to OPDIVO increased 8.2% YoY to JPY122.3 billion due to increased OPDIVO sales in the local market. Royalties on KEYTRUDA also increased 11.4% from the previous year to JPY29.5 billion.

FY2025 : Core Operating Profit



Core Operating Profit
137.1 JPY bn
 YoY +24.5 JPY bn
 (+21.7%)



Revenue 515.8 JPY bn
 YoY +28.9 JPY bn (+5.9%)



R&D Expense 145.1 JPY bn
 YoY +1.8 JPY bn (+1.2%)



SG&A Expense 123.6 JPY bn
 YoY +1.4 JPY bn (+1.1%)

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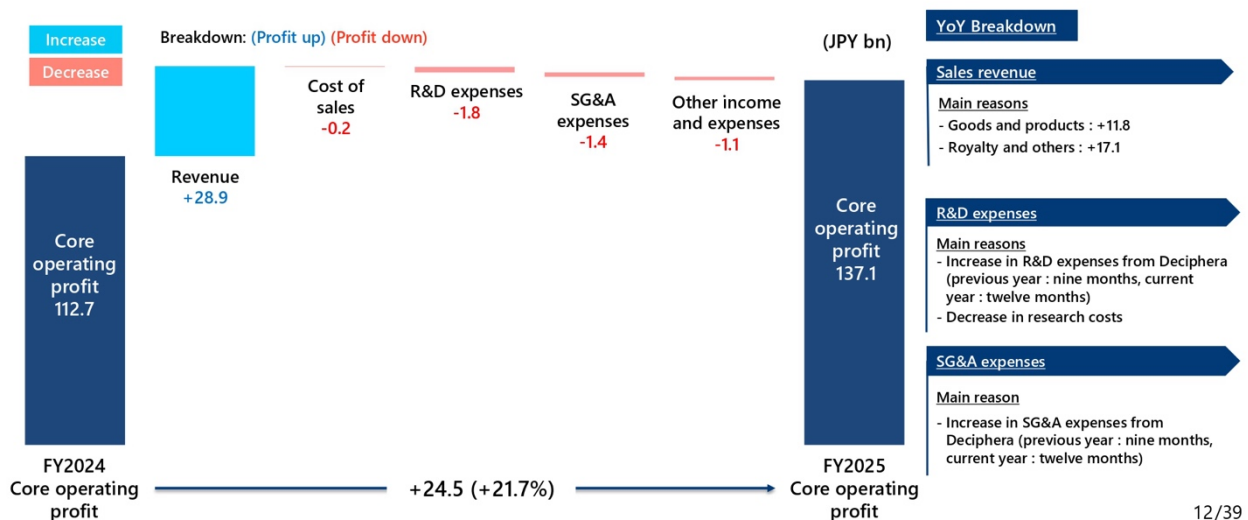
Core operating profit increased JPY24.5 billion or 21.7% from the previous year to JPY137.1 billion.

This was due to a JPY28.9 billion or 5.9% YoY increase in sales revenue, while R&D expenses increased only JPY1.8 billion or 1.2%; and selling, general, and administrative expenses increased JPY1.4 billion or 1.1%, YoY, despite the inclusion of three months more of Deciphera's R&D and SG&A expenses compared to the previous year.

FY2025 : Core Operating Profit (Breakdown)



While R&D and SG&A expenses have been recorded by Deciphera (the previous period accounted for nine months, and the current period includes twelve months), core operating profit increased by 24.5 JPY bn year on year to 137.1 JPY bn mainly due to an increase in sales revenue and promotion of cost efficiency.



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Here is the breakdown of the change in core operating profit that I just mentioned.

While revenue increased by JPY28.9 billion, expenses remained virtually unchanged from the previous year, thanks to tight control of cost of sales, R&D expenses, and SG&A expenses. As a result, core operating profit increased JPY24.5 billion to JPY137.1 billion.

FY2025 : Financial Overview (Core)



JPY bn	FY2024	FY2025	YoY		FY2025 Forecast*	YoY Breakdown
			Change	Change(%)		
Revenue	486.9	<u>515.8</u>	28.9	5.9%	490.0	Cost of sales +0.2 JPY bn (+0.2%) COGS ratio : 20.8%
Cost of sales	106.9	<u>107.0</u>	0.2	0.2%	103.5	
R&D expenses	143.3	<u>145.1</u>	1.8	1.2%	150.0	R&D expenses +1.8 JPY bn (+1.2%) R&D ratio : 28.1% Main reason - Increase in R&D expenses from Deciphera (previous year : nine months, current year: twelve months)
SG&A expenses	122.2	<u>123.6</u>	1.4	1.1%	120.0	
Core operating profit	112.7	<u>137.1</u>	24.5	21.7%	114.0	
Core profit before tax	113.9	<u>138.3</u>	24.4	21.4%	114.0	SG&A expenses +1.4 JPY bn (+1.1%) SG&A ratio : 24.0% Main reason - Increase in SG&A expenses from Deciphera (previous year : nine months, current year : twelve months)
Core profit for the year (attributable to owners of the Company)	90.4	<u>103.5</u>	13.1	14.5%	91.0	Core operating profit ratio : 26.6%

* The consolidated financial forecast for the fiscal year ended March 2026, announced on October 30, 2025, is provided.

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Here is the overall income statement on a core basis.

I have already mentioned that sales revenue increased by JPY28.9 billion or 5.9% from the previous year to JPY515.8 billion, reaching a new record high. This is significantly higher than the announced forecast of JPY490 billion.

Core operating profit increased JPY24.5 billion or 21.7% to JPY137.1 billion, also exceeding the announced forecast of JPY114 billion. Core profit attributable to owners of the Company also increased by JPY13.1 billion or 14.5% to JPY103.5 billion, well above the announced forecast of JPY91 billion.

(Ref) FY2025 : Financial Overview (Full Basis)



JPY bn	FY2024	FY2025	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	486.9	515.8	28.9	5.9%	490.0
Cost of sales	147.9	141.7	-6.2	-4.2%	135.0
R&D expenses	149.9	147.0	-2.8	-1.9%	150.0
SG&A expenses	125.7	123.7	-2.0	-1.6%	120.0
Operating profit	59.7	92.2	32.5	54.4%	85.0
Profit before tax	59.3	92.7	33.3	56.2%	85.0
Profit for the year (attributable to owners of the Company)	50.0	69.8	19.7	39.4%	67.0

YoY Breakdown

Cost of sales -6.2JPY bn (-4.2%)

COGS ratio : 27.5%

Main reason

- Absence of the sales milestone payment recorded in the previous fiscal year.

R&D expenses -2.8 JPY bn (-1.9%)

R&D ratio : 28.5%

Main reasons

- Increase in R&D expenses from Deciphera
- Absence of impairment loss related to development compounds recorded in the previous fiscal year

SG&A expenses -2.0 JPY bn (-1.6%)

SG&A ratio : 24.0%

Main reasons

- Increase in SG&A expenses from Deciphera
- Absence of expenses associated with the acquisition of Deciphera

Operating profit ratio : 17.9%

* The consolidated financial forecast for the fiscal year ended March 2026, announced on October 30, 2025, is provided.

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For your reference, I will explain the consolidated results on a full basis for the full fiscal year ended March 31, 2026.

Revenue does not change from core-based revenue. Operating profit increased JPY32.5 billion or 54.4% from the previous year to JPY92.2 billion. Profit attributable to owners of the Company increased JPY19.7 billion or 39.4% from the previous year to JPY69.8 billion.

In other words, also on a full basis, both revenue and profit increased, exceeding the announced forecasts.

(Ref) FY2025 : Reconciliation from Full to Core Basis



JPY bn	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Revenue	515.8				-	515.8
Cost of sales	141.7	-25.6		-9.1	-34.7	107.0
Gross profit	374.1	+25.6	-	+9.1	+34.7	408.7
R&D expenses	147.0		-1.9		-1.9	145.1
SG&A expenses	123.7			-0.1	-0.1	123.6
Other income /expenses (- Exp)	-11.1		+0.2	+8.0	+8.2	-2.9
Operating profit	92.2	+25.6	+2.1	+17.2	+44.9	137.1
Operating profit ratio	17.9%				-	26.6%
Finance income / Finance cost (- Exp)	0.4			+0.7	+0.7	1.1
Profit before tax	92.7	+25.6	+2.1	+17.9	+45.6	138.3
Income tax expense	22.7	+6.5	+0.6	+4.8	+11.9	34.6
Profit for the year	69.8	+19.2	+1.5	+13.1	+33.7	103.5

Breakdown

Cost of sales

Main reasons

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- Amortization expenses related to inventories from *PPA

R&D expenses

Main reason

- Amortization expenses related to development compounds

SG&A expenses and Other income&expense

Main reasons

- Loss on retirement benefit plan amendments
- Loss on product recall related to OPDIVO
- Loss on the termination of the co-promotion agreement for FORXIGA Tablets

*PPA : Purchase Price Allocation

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Here you see a full-base to core-base adjustment table.

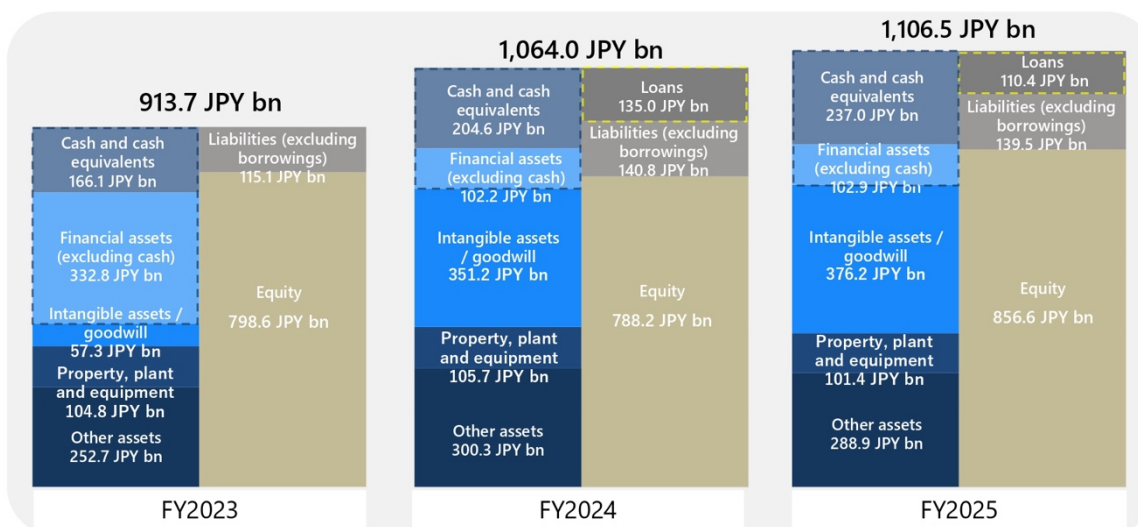
Adjustment items are mainly cost of sales items, including JPY25.6 billion in amortization of intangible assets related to acquisitions and in-licensing, and JPY9.1 billion in amortization expenses related to inventories from purchase price allocation.

In other expenses, we adjusted for the loss associated with the termination of the FORXIGA co-promotion agreement, the loss associated with the revision of the retirement benefit plan, and the loss related to the voluntary recall of OPDIVO.

Balance sheet (Consolidated)



Structural transformation toward growth driven by proactive strategic investments

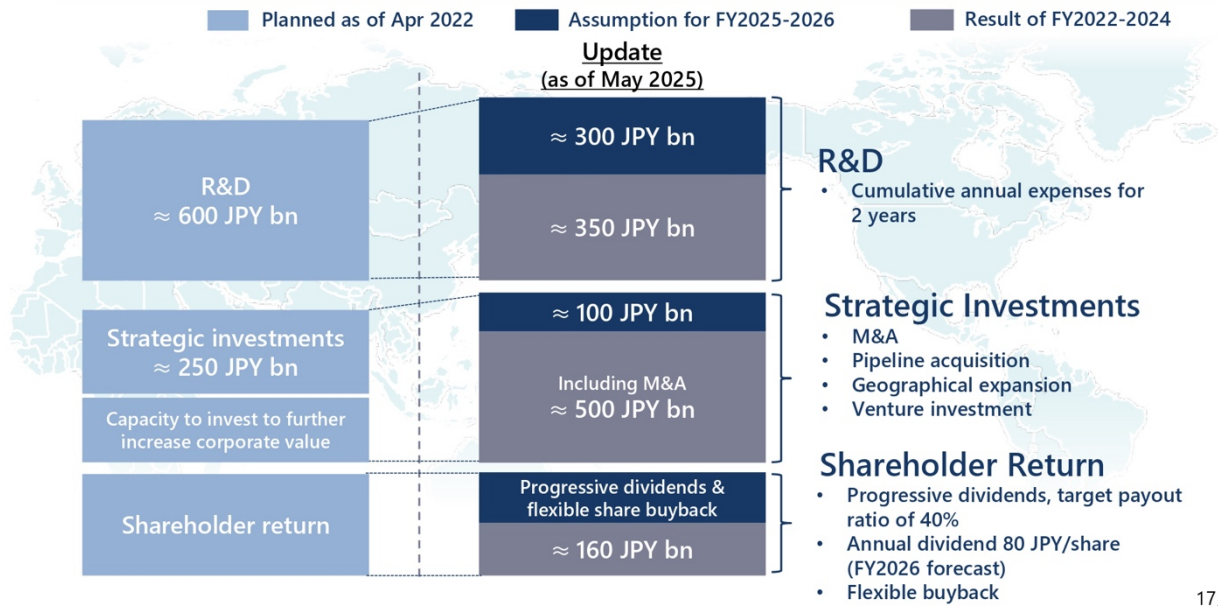


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This chart shows the change in B/S from before the Deciphera acquisition to the current most recent period.

We have been actively shifting financial assets to intangible assets and expanding our pipeline. Along with this, we are making steady progress in repaying our debt and are actively considering opportunities for our next strategic investment.

Capital Allocation (FY2022-2026)



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This is the capital allocation policy that we presented last year as well.

We are aggressively investing in growth and strategic investments, including R&D investments and acquiring products through in-licensing, to strengthen the development pipeline that will support the growth following OPDIVO.

FY2026 : Financial Forecast



Goods and Products Sales
270.0 JPY bn

YoY -72.6 JPY bn (-21.2%)



Royalty and Others
185.0 JPY bn

YoY +11.8 JPY bn (+6.8%)

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I would like to move on to the full-year forecasts for the next fiscal year.

Revenue is projected to decrease JPY60.8 billion or 11.8% from the previous year to JPY455 billion.

Breakdown. Goods and product sales are projected to decrease by JPY72.6 billion or 21.2% from the previous year to JPY270 billion due to the impact of the sales decrease resulting from the termination of the FORXIGA co-promotion agreement. Royalty and others are projected to increase by JPY11.8 billion or 6.8% from the previous year to JPY185 billion.

The exchange rate is assumed to be JPY155 to the dollar.

FY2026 : Financial Forecast (Sales by Product)



JPY bn

Goods and Products (Japan)	FY2025	FY2026 Forecast	YoY	
			Change	Change (%)
OPDIVO Intravenous Infusion	114.3	120.0	5.7	5.0%
ORENCIA for Subcutaneous Injection	26.6	19.0	-7.6	-28.6%
VELEXBRU Tablets	11.9	12.0	0.1	0.9%
PARSABIV Intravenous Injection	9.0	10.0	1.0	11.2%
ONGENTYS Tablets	9.0	10.0	1.0	11.5%
GLACTIV Tablets	13.2	9.5	-3.7	-28.1%
BRAFTOVI Capsules	5.6	8.5	2.9	51.5%
KYPROLIS for Intravenous Infusion	7.5	7.0	-0.5	-6.6%

Goods and Product (Overseas)	FY2025	FY2026 Forecast	YoY	
			Change	Change (%)
OPDIVO®	14.2	13.0	-1.2	-8.2%
QINLOCK®	38.4	43.0	4.6	12.1%
ROMVIMZA	8.3	19.0	10.7	129.4%

* Sales revenue of domestic products is shown in a gross sales basis (shipment price).

* Sales revenue of overseas products is shown in a net sales basis.

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Here are sales by product.

FORXIGA, which had sales of JPY88.2 billion in the previous fiscal year, will not be recorded this fiscal year due to the termination of the contract.

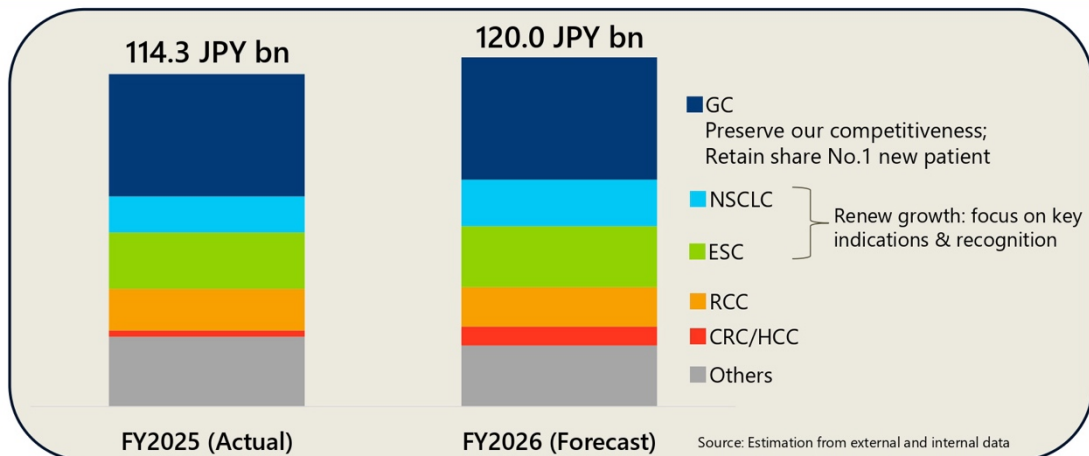
While the competitive environment is intensifying, we expect sales of OPDIVO to increase 5% YoY to JPY120 billion due to the expected expansion of use in hepatocellular carcinoma and colorectal cancer, which were added as new indications last year.

As for other major products, we forecast sales of VELEXBRU to increase 0.9% YoY to JPY12 billion, PARSABIV sales to increase 11.2% YoY to JPY10 billion, ONGENTYS sales to increase 11.5% YoY to JPY10 billion, and BRAFTOVI sales to increase 51.5% YoY to JPY8.5 billion.

On the other hand, sales of ORENCIA for subcutaneous injection are expected to decrease by 28.6% YoY to JPY19 billion due to the NHI price revision, sales of GLACTIV are expected to decrease by 28.1% YoY to JPY9.5 billion, and sales of KYPROLIS are expected to decrease by 6.6% YoY to JPY7 billion.

Overseas sales by product, we expect total sales of OPDIVO in South Korea and Taiwan to decrease by 8.2% YoY to JPY13 billion, sales of QINLOCK to increase by 12.1% YoY to JPY43 billion, and sales of ROMVIMZA to increase by 129.4% YoY to JPY19 billion.

OPDIVO Sales Trend by Each Cancer



Progress Status of Key Indications (Apr. 2025 – Mar. 2026)

- GC : Progressed as per revised plan despite impact of competing products
- NSCLC : New prescription share in the PD-L1 negative segment is growing, but has not reached the plan; further activities are being strengthened to further expansion
- ESC : Although new competing products have entered the market, new prescription share increased and progress is on track
- HC / CRC : New prescription share remains steady

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Here are OPDIVO sales forecasts for the current fiscal year for each of the major cancer types.

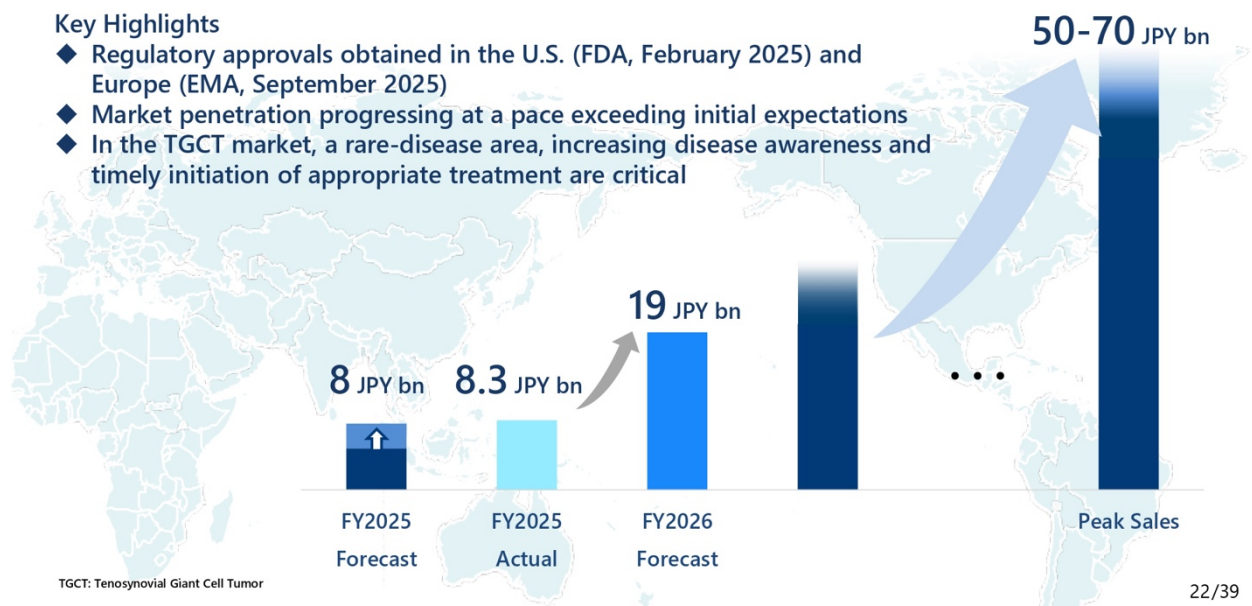
Sales for gastric cancer are expected to remain flat among competitors. We will refocus sales on non-small cell lung cancer and esophageal cancer. We will grow sales for hepatocellular carcinoma and colorectal cancer, for which additional indications have been added. As a result, sales of OPDIVO are planned to reach JPY120 billion.

ROMVIMZA – Commercial Progress



Key Highlights

- ◆ Regulatory approvals obtained in the U.S. (FDA, February 2025) and Europe (EMA, September 2025)
- ◆ Market penetration progressing at a pace exceeding initial expectations
- ◆ In the TGCT market, a rare-disease area, increasing disease awareness and timely initiation of appropriate treatment are critical



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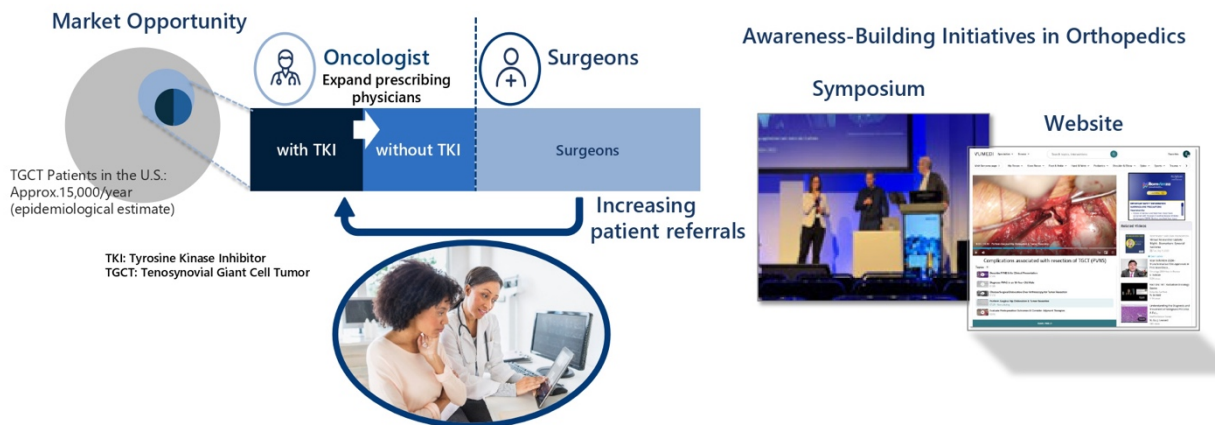
I would also like to mention a few things about ROMVIMZA.

Sales of ROMVIMZA have been growing steadily since its launch last spring and amounted to JPY8.3 billion in the previous fiscal year. Sales for the current fiscal year are expected to be more than double last year's level. I have the impression that the drug is growing extremely well.

ROMVIMZA Growth Opportunities in the TGCT Market



- ◆ In the TGCT market, a rare-disease area, increasing disease awareness and timely initiation of appropriate treatment are critical



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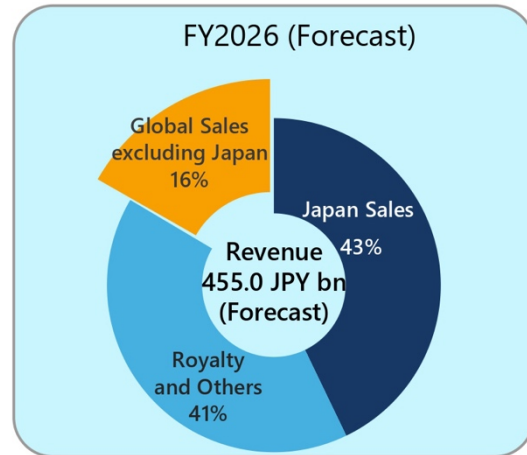
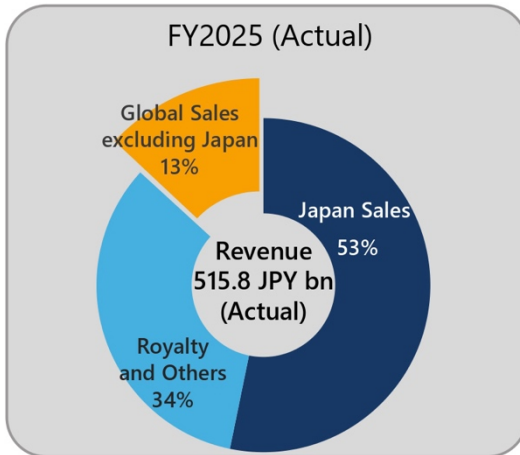
In the European and US markets, we are working primarily with oncologists. As a result of the first understanding of the characteristics of ROMVIMZA, it is now being used as the first choice for treatment with kinase inhibitors, the so-called TKIs.

In addition to this, we are developing activities to raise awareness of the disease and expand recognition of the disease, as shown on the right. We are working diligently to create an environment in which TGCT patients are seen early by specialists and receive appropriate treatment, and we look forward to further expansion of the use of this drug.

Expansion and Acceleration of Global Business



Expand the share of global sales excluding Japan



24/39

This is the ratio of overseas sales to total sales.

As you can see, we are making steady progress in expanding our global business, in addition to Korea and Taiwan, through the acquisition of Deciphera. We intend to increase the ratio of overseas sales by expanding overseas sales and sales regions, including sales of QINLOCK and ROMVIMZA.

FY2026 : Financial Forecast (Core Operating Profit)



Core Operating Profit
124.0 JPY bn

YoY -13.1 JPY bn
(-9.6%)



Revenue 455.0 JPY bn
YoY -60.8 JPY bn (-11.8%)



R&D Expense 143.0 JPY bn
YoY -2.1 JPY bn (-1.5%)



SG&A Expense 101.0 JPY bn
YoY -22.6 JPY bn (-18.3%)

25/39

Next, I will move on to core operating profit.

Core operating profit is projected at JPY124 billion, a decrease of JPY13.1 billion or 9.6% from the previous year.

As already explained, we expect revenue to decrease by JPY60.8 billion or 11.8% from the previous year. R&D expenses are expected to decrease by JPY2.1 billion or 1.5% from the previous year; and selling, general, and administrative expenses are expected to decrease by JPY22.6 billion or 18.3% from the previous year.

(Ref) FY2026 : Financial Forecast (Core/Compared to the Previous Year)



JPY bn	FY2025 Actual	FY2026 Forecast	Change	Change (%)	Breakdown
Revenue	515.8	<u>455.0</u>	-60.8	-11.8%	Cost of sales -23.0 JPY bn (-21.5%) COGS ratio : 18.5% Main reason - Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement
Cost of sales	107.0	<u>84.0</u>	-23.0	-21.5%	
R&D expenses	145.1	<u>143.0</u>	-2.1	-1.5%	R&D expenses -2.1 JPY bn (-1.5%) R&D ratio : 31.4% Main reasons - A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses - Increase in global clinical trial costs
SG&A expenses	123.6	<u>101.0</u>	-22.6	-18.3%	
Core operating profit	137.1	<u>124.0</u>	-13.1	-9.6%	
Core profit before tax	138.3	<u>124.0</u>	-14.3	-10.3%	SG&A expenses -22.6 JPY bn (-18.3%) SG&A ratio : 22.2% Main reason - The termination of co-promotion agreement for FORXIGA Tablets
Income tax expense	34.6	<u>31.0</u>	-3.6	-10.5%	
Core profit for the year (attributable to owners of the Company)	103.5	<u>93.0</u>	-10.5	-10.1%	Core operating profit ratio : 27.3%

* The exchange rate assumed in the financial forecast is ¥155 per US dollar.

26/39

Breakdown. Cost of sales is expected to decrease by 21.5% YoY to JPY84 billion due to the decrease in sales following the termination of the FORXIGA co-promotion agreement.

R&D expenses are expected to decrease 1.5% from the previous year to JPY143 billion. We plan to continue to invest aggressively in R&D, with global development investments in sapablursen, ONO-4578, and others, accounting for more than 30% of sales.

However, R&D expenses are expected to decrease slightly as a result of the reclassification of some Deciphera expenses, which were previously treated as R&D expenses, to selling, general, and administrative expenses.

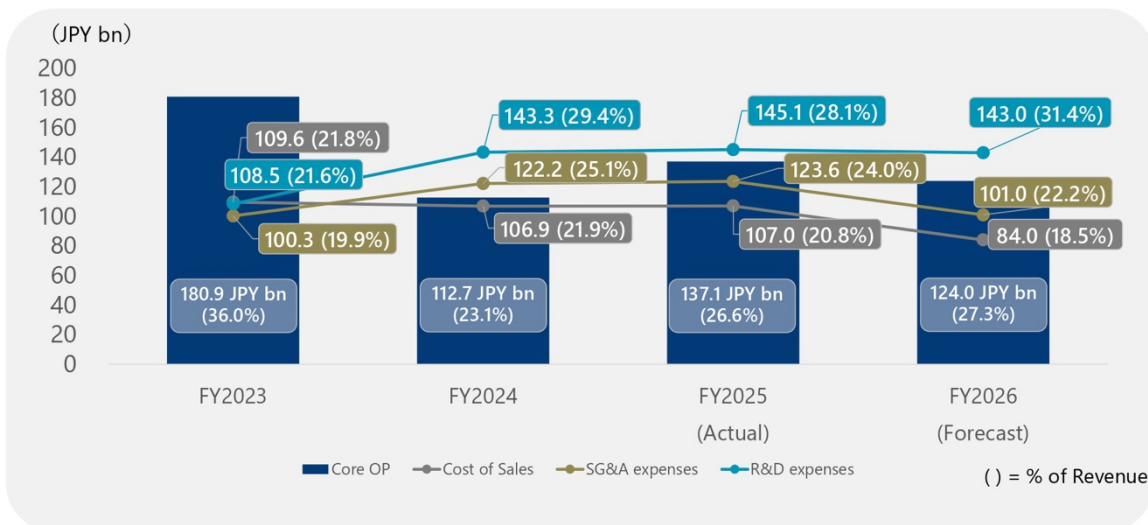
Selling, general, and administrative expenses are expected to decrease by 18.3% YoY to JPY101 billion due to a decrease in co-promotion expenses as a result of the termination of the FORXIGA co-promotion agreement, as well as continued efforts to improve cost efficiency.

As a result of the above, core operating profit is projected to decrease by 9.6% YoY to JPY124 billion, and core profit attributable to owners of the Company is projected to decrease by 10.1% YoY to JPY93 billion.

Core Operating Profit and Other Expense Trends



In FY2026, continue R&D investment, while anticipating reductions in SG&A expenses and cost of sales.



27/39

Here is a summary of core operating profit and each expense over the past several years.

In the current fiscal year, as indicated by the blue broken line, we will continue to invest aggressively in R&D while at the same time holding down cost, indicated by the gray broken line; and SG&A expenses, indicated by the ochre broken line, by a little over JPY20 billion each. As a result, core operating profit, shown in the bar graph, is expected to be JPY124 billion; and the core operating margin is expected to remain at more than 27%, more than the same level as the previous year.

FY2026 : Financial Forecast (Full / Compared to the Previous Year)



JPY bn	FY2025 Actual	FY2026 Forecast	Change	Change (%)	Breakdown
Revenue	515.8	455.0	-60.8	-11.8%	Cost of sales -27.7 JPY bn (-19.6%) COGS ratio : 25.1% Main reason - Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement
Cost of sales	141.7	114.0	-27.7	-19.6%	
R&D expenses	147.0	143.0	-4.0	-2.7%	R&D expenses -4.0 JPY bn (-2.7%) R&D ratio : 31.4% Main reasons - A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses - Increase in global clinical trial costs
SG&A expenses	123.7	101.0	-22.7	-18.3%	
Operating profit	92.2	94.0	1.8	1.9%	SG&A expenses -22.7 JPY bn (-18.3%) SG&A ratio : 22.2% Main reason - The termination of co-promotion agreement for FORXIGA Tablets
Profit before tax	92.7	94.0	1.3	1.5%	
Income tax expense	22.7	23.0	0.3	1.1%	
Profit for the year (attributable to owners of the Company)	69.8	71.0	1.2	1.8%	Operating profit ratio : 20.7%

* The exchange rate assumed in the financial forecast is ¥155 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥1.5 billion in revenue and an increase of ¥0.5 billion in operating profit for every ¥1 depreciation of the yen.

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Here, for your reference, is the consolidated forecast on a full basis for the fiscal year ending March 31, 2027.

There is no change in revenue from core-based revenue.

Operating profit is expected to increase 1.9% from the previous year to JPY94 billion due to the absence in the current year of onetime expenses that were recorded in the previous year and excluded from the core-based results.

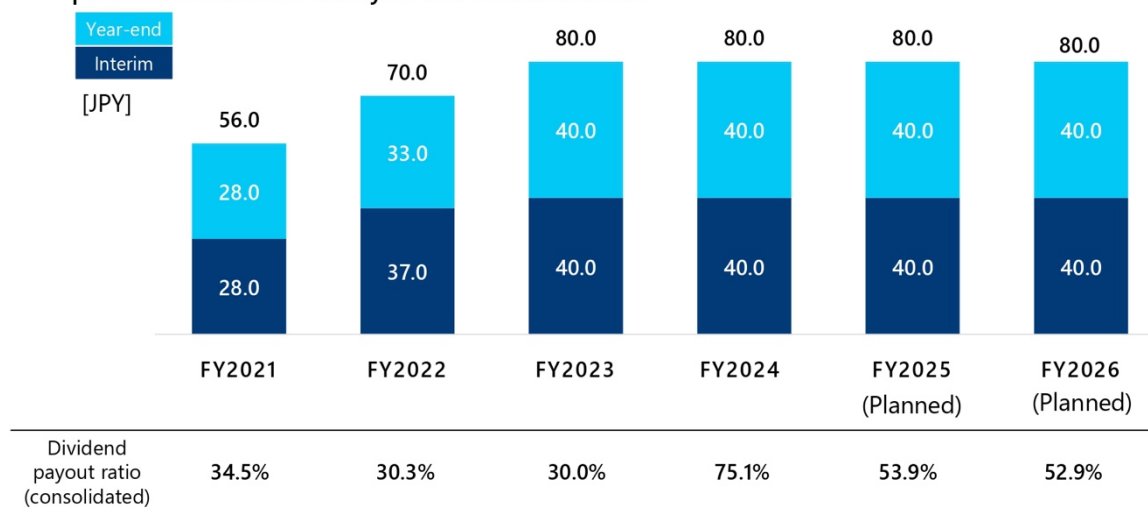
Profit attributable to owners of the Company is expected to be JPY71 billion, up 1.8% from the previous year.

As a result, on a full basis, we expect a decrease in revenue but an increase in profit.

Profit Distribution (Dividend)



Dividends are to be paid out in accordance with a progressive policy of maintaining or increasing the annual dividend each year, with a target payout ratio of 40%, taking into account the performance of each fiscal year and various indices.



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Shareholder returns.

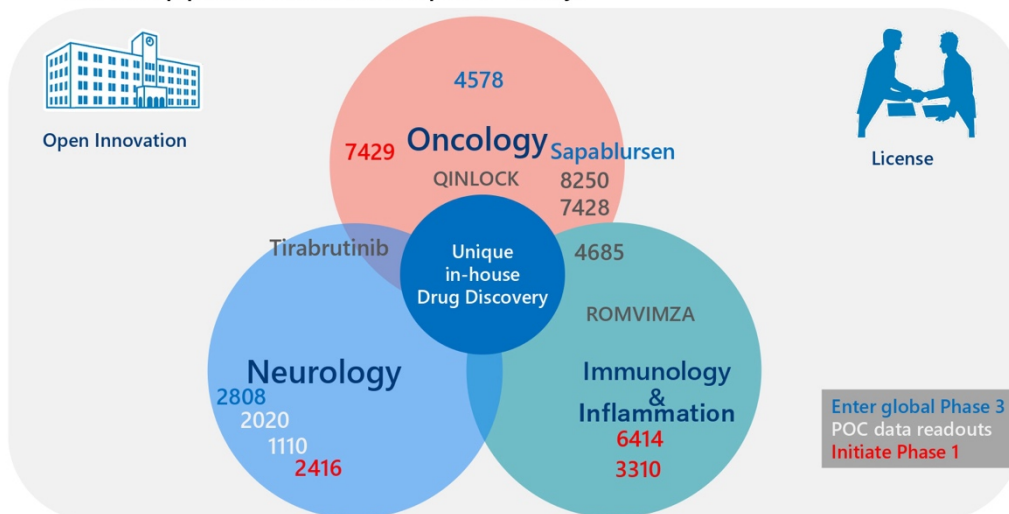
We have already announced that we have a progressive dividend policy and that we are targeting a dividend payout ratio of 40%. As of now, we plan to pay an annual dividend of JPY80 per share for FY2025 and FY2026.

Key Development Pipeline Milestones



As of May 8, 2026

- Initiation of three global Phase 3 and data readouts from seven POC studies in FY2026
- In the priority areas of oncology, immunology & inflammation, and neurology, four new pipelines have initiated phase 1 study.



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There are three slides left for my explanation. We have some exciting progress in the pipeline.

We have three projects that are starting Phase 3 trials, seven trials that will yield results from POC trials to detect efficacy signals in humans, and four new Phase 1 studies or projects that have entered the clinical stage. Details will be provided by Mr. Okamoto of clinical development.

As for research and development, as shown in this picture, we are actively promoting both highly original in-house drug discovery and open innovation and licensing with academia and biotech around the world. We look forward to an exciting year of progress in this area.

Tirabrutinib Development Status in the United States



Tirabrutinib is an oral, highly selective Bruton's tyrosine kinase (BTK) inhibitor that is currently under review by the U.S. FDA for the treatment of relapsed or refractory primary central nervous system lymphoma (R/R PCNSL).

- Positive results from Phase 2 PROSPECT study demonstrated overall response rate of 67%, complete response rate of 44%
- PDUFA date set for 12/18/2026
- Preparing for U.S. commercialization
- Recruiting patients for Global Phase 3 confirmatory study

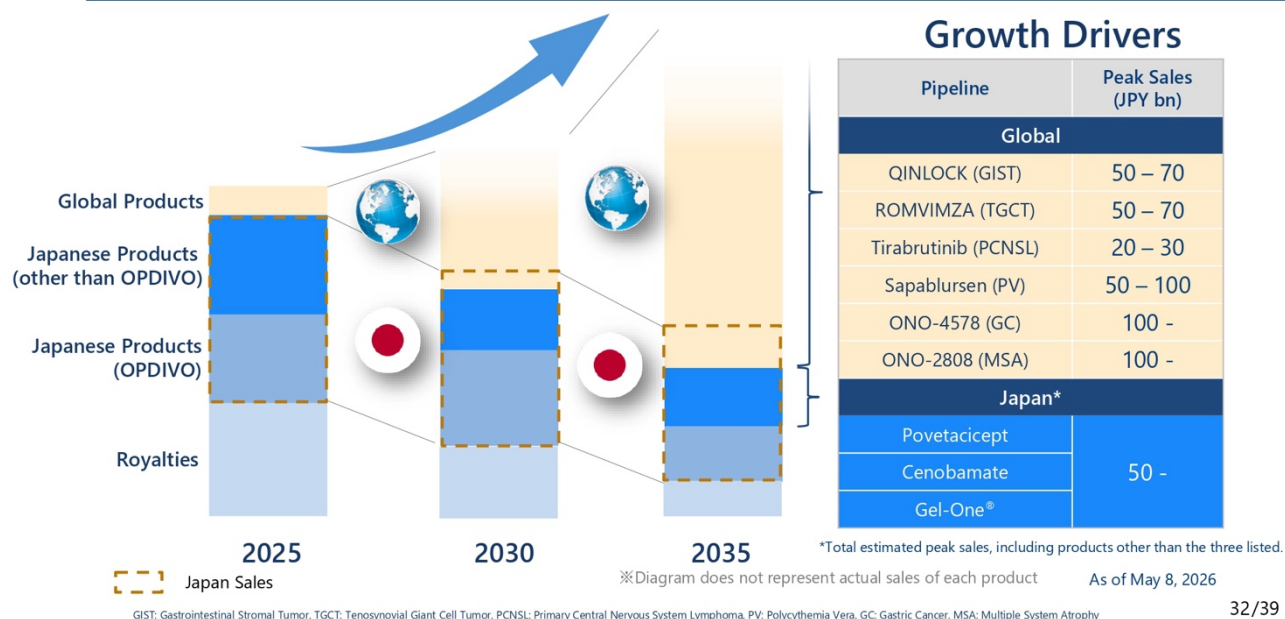


Source: PCNSL Disease Awareness Website <https://www.navigatingpcnsl.com/>

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One of these, tirabrutinib, ONO-4059, is currently under review for approval by the US FDA. We are looking forward to this being our third global product as we prepare for its launch this fiscal year.

Prospect for the Future



Here is the last slide I will show you. We have updated the image map of future growth, which we showed you last year.

At present, the Deciphera-derived products, QINLOCK and ROMVIMZA, are growing extremely well. We are responding well to the steady and firm progress in the global development of our development pipeline, which is expected to be a growth driver in the future.

Last year, we saw that you did not quite understand this image when we presented it to you. However, I feel that everyone's understanding of OPDIVO's future growth story as we move toward our goal of becoming a Global Specialty Pharma is gradually deepening.

In the next few years, we expect sales to rise and fall due to the expiration of patents on current products and other factors, but we will continue to work so that the seeds for steady growth will come out. We hope that you will be excited about it. That's all. Thank you very much.

Imura: Thank you very much. Next, Okamoto, Executive Vice President of Clinical Development, will explain the progress of the development pipeline.

Launch Projections - POC Pipeline-



As of May 8, 2026

■ Approved ■ Filed and preparing for filing

	FY2025	FY2026	FY2027	FY2028	FY2029 -	
US 		ONO-4059 (VELEXBRU) PCNSL	QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
EU 	ROMVIMZA TGCT		QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
JP 	OPDIVO HCC 1L OPDIVO MSI-H CRC 1L BRAFTOVI CRC 1L FOLFOX	ONO-2017 cenobamate Partial-onset seizures QINLOCK GIST 4L	OPDIVO HCC Adjuvant	ripretinib (QINLOCK) GIST 2L VELEXBRU Pemphigus 2L ONO-2017 cenobamate Primary generalized tonic-clonic seizures ONO-8531 povetacicept IgAN	ONO-5532 Gel-One Osteoarthritis ONO-2017 cenobamate Partial-onset seizures pediatric vimseltinib (ROMVIMZA) TGCT OPDIVO sc	ONO-0530 sapablursen PV ONO-8531 povetacicept pMN ONO-4578 GC 1L ONO-2808 MSA

PCNSL: Primary Central Nervous System Lymphoma, GIST: Gastrointestinal Stromal Tumor, PV: Polycythemia Vera, GC: Gastric Cancer, MSA: Multiple System Atrophy, TGCT: Tenosynovial Giant Cell Tumor, HCC: Hepatocellular Carcinoma, CRC: Colorectal Cancer, IgAN: IgA Nephropathy, pMN: Primary Membranous Nephropathy

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Okamoto: I will use the document on the progress of pipeline, which are available on our website, to introduce the main changes that have been made since February 2 of this year.

Here is the slide that shows launch projections.

Conventionally, this document showed the schedule for the three years before and after the current year, including the current year, but from now on, it shows the approval schedule for the next several years from a more mid-term perspective.

The pipelines shown in this table are all after the establishment of the POC. In FY2025 that ended, we received a total of four approvals in Europe and Japan. The contents are as indicated.

Next, we plan to obtain a total of three approvals in the US and Japan in FY2026.

In Japan, we plan to obtain approval for two drugs: ONO-2017, cenobamate, for which we filed an application in September last year; and QINLOCK, for which we filed an application in March at the end of FY2025 for the treatment of gastrointestinal stromal tumor (GIST) that has become aggravated after cancer chemotherapy.

QINLOCK received orphan drug designation in Japan in March of this year.

As for VELEXBRU, as President Takino mentioned earlier, we filed an application in the US last December, and the application was accepted in February of this year. Approval is expected by the end of this year.

Among those expected to be approved in FY2027, i.e., filed for approval this year, are OPDIVO for the adjuvant therapy of postoperative hepatocellular carcinoma in Japan and QINLOCK for the secondary treatment of GIST, a gastrointestinal stromal tumor with certain genetic mutations, in the United States and Europe.

On the other hand, we participated in a global Phase 3 trial conducted by BMS for OPDIVO for preoperative and postoperative adjuvant therapy of bladder cancer, which we had planned to submit this year, but unfortunately, the trial did not yield the expected results, and we have removed the trial from our plan to submit the application.

Our mission for the next few years is to ensure that development proceeds smoothly. However, on the assumption that the pipeline progresses smoothly, we expect to receive approval for additional indications for existing products, as well as for new pipeline products that are expected to grow in size, such as ONO-0530 (sapablursen) for which we have obtained global commercialization rights, or ONO-4578 and ONO-2808, which were discovered and developed in-house. In addition, we expect to launch ONO-8531 (povetacicept) for which we in-licensed the rights in Japan and Korea from Vertex in the US; and ONO-5532, Gel-One, for which we acquired the domestic marketing rights from Seikagaku in Japan. We place a high expectation on these drugs to contribute to our performance.

This is all about the track record of obtaining approvals and plan.

Development pipeline (Oncology) ①



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
BRAFTOVI Capsule (encorafenib) BRAF inhibitor	Colorectal cancer 1L BRAF-mutation (with cetuximab and chemo (FOLFOX))							2025.11 JP : Approval 2026.1 KR : Approval	JP, US, EU, KR, TW and others*1	NCT04607421
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL) 1L, ≥2L							2026.2 US : Filed (Part A)	US	NCT04947319
	Primary central nervous system lymphoma (PCNSL) ≥2L							FY2027 Primary Completion	US	NCT07104032
QINLOCK DCC-2618 (ripretinib) KIT inhibitor	Gastrointestinal Stromal Tumor (GIST) 2L KIT Exon 11+17/18							FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
	Gastrointestinal Stromal Tumor (GIST) 4L							FY2026 Primary Completion	JP	Under registration
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMRSS6	Polycythemia Vera (PV)							FY2028 Primary Completion	JP, US, EU, KR, TW and others	NCT07429266
	Gastric cancer*							FY2025 Primary Completion (Actual)	JP, KR, TW	NCT06256328
ONO-4578 PG receptor (EP4) antagonist	Colorectal cancer*							FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*							FY2026 Primary Completion	JP	NCT06542731
ONO-4482 (relatlimab) Anti-LAG-3 antibody	Melanoma*							FY2024 Primary Completion (Actual)	JP, US, EU and others	NCT01968109
ONO-7427 Anti-CCR8 antibody	Solid tumor*							FY2028 Primary Completion	JP, US, EU and others*2	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced Malignancies (with ripretinib)							FY2026 Primary Completion	US, EU	NCT05957367

MOA : Mode of Action
* : Combination with OPDIVO

*1 : Development rights countries: JP, KR, *2 : Development right country: JP
Estimated study completion date shown in JRCT or ClinicalTrials.gov

F : Filed, A : Approval
EU : European countries

※ Red: Update after announcement of FY 2024 financial result in May 2025
※ Red: Update after FY2025 Q3 in February

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Next is the progress of the development pipeline in the field of oncology.

I have already mentioned earlier about VELEXBRU on the second row from the top. FDA has accepted for filing the New Drug Application (NDA) under the accelerated approval pathway for tirabrutinib in February of this year and have updated the data.

We have also updated the data for QINLOCK below that, as I mentioned earlier, since it was filed domestically in March at the end of the fiscal year. This application for approval was filed using the results of the overseas Phase 3 study, and in parallel, a Phase 1 study is being conducted in Japan.

Phase 3 trials have been initiated for ONO-0530 (sapablursen). The study is being conducted as a global Phase 3 study, and the countries involved include Japan as well as the United States and Europe.

As you are already aware, the results of the POC study, a Phase 2 study of ONO-4578 for the first-line treatment of gastric cancer, will be presented at ASCO, USA, on June 1. Based on the results of this study, we plan to initiate a global Phase 3 study this year.

On the other hand, we suspended the development of a Phase 1 study for hormone receptor-positive, HER2-negative breast cancer in Japan for strategic reasons.

This differs from the gastric, colorectal, and non-small cell lung cancers that I have just presented and are not combined with OPDIVO and chemotherapy. Aromatase inhibitors, so-called hormone therapy, in combination with CDK4/6 inhibitors are the current standard of care for this disease. The study that was terminated was a study in which ONO-4578 was administered in combination with this drug, which was slightly different in concept from the other studies under development.

Specifically, in gastric and colorectal cancer, the combination is used to enhance anti-tumor immunity, but for breast cancer, the concept was slightly different.

In any case, the development of this product was discontinued for strategic reasons only, not for safety reasons, etc.

Development pipeline (Oncology) ②



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
DCC-3009 Pan-KIT inhibitor	Gastrointestinal Stromal Tumor (GIST)							FY2028 Primary Completion	US	NCT06630234
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2027 Primary Completion	US	NCT05079282
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	HER2-expressing Solid tumor							FY2028 Primary Completion	JP	NCT06547528
ONO-7428 Anti-ONCOKINE-1 antibody	Solid tumor							FY2029 Primary Completion	US	NCT06241456
DCC-2812 GCN2 Activator	Renal Cell Carcinoma, Urothelial Cancer, Castration-Resistant Prostate Cancer							FY2029 Primary Completion	JP	NCT06816108
ONO-7429 Anti-L1CAM ADC	Solid tumor							FY2028 Primary Completion	US	NCT06966024
								FY2028 Primary Completion	JP	Under registration

MOA : Mode of Action

* : Combination with OPDIVO
Estimated study completion date shown in JRCT or ClinicalTrials.gov

F : Filed, A : Approval

Red: Update after announcement of FY 2024 financial result in May 2025
Red: Update after FY2025 Q3 in February

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I will continue with the oncology area.

The second from the top, ONO-4685, a bispecific antibody for PD-1 and CD3, has so far been well tolerated and safe, and case registrations are progressing steadily in both Japan and the United States.

However, on the flip side, the level of dosing has exceeded our initial expectations. Since we are continuing dose escalation and searching for the optimum applicable dose, we have changed the timing of data acquisition to FY2027, which is later than in the plan.

The bottom line, ONO-7429, is an anti-L1CAM ADC antibody for which global commercialization rights were acquired from LigaChem of Korea in October 2024. We have recently started a Phase 1 study in Japan, and have added the information.

The development of ONO-7913, an anti-CD47 antibody, which was being developed under commercialization rights in Japan, Korea, Taiwan and ASEAN countries from Gilead, then known as Forty Seven, has been discontinued and removed from the list for strategic reasons and portfolio management.

Development pipeline (Non-oncology) ①



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial Giant Cell Tumor (TGCT)							FY2024 US : Approval FY2025 EU : Approval	US, EU and others	NCT05059262
	chronic Graft Versus Host Disease (cGVHD)							FY2029 Primary Completion	US	NCT06619561
ONO-2017(cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	Partial-onset seizures							FY2025 JP : Filed	JP, KR and others*1	NCT04557085
	Partial-onset seizures (pediatric)							FY2028 Primary Completion	JP	Under registration
VELEXBRU Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	Primary generalized tonic-clonic seizures							FY2026 Primary Completion	JP	NCT06579573
	Pemphigus							FY2027 Primary Completion	JP	NCT06696716
ONO-8531 (povetacicept) BAFF/APRIL dual antagonist	IgA Nephropathy							FY2027 Primary Completion	JP, US, EU, KR, TW and others*2	NCT06564142
	Primary Membranous Nephropathy					*3		FY2028 Primary Completion	US, EU, KR and others*2	NCT07204275
ONO-5532 (Gel-One) Cross-linked hyaluronate	Knee osteoarthritis							FY2027 Completion	JP	JRCT2031240621
	Hip osteoarthritis							FY2027 Completion	JP	JRCT2061240110
ONO-2808 S1P5 receptor agonist	Multiple System Atrophy (MSA)							FY2025 Primary Completion (Actual)	JP, US	NCT05923866

*1 : Development right country: JP, *2 : Development rights countries: JP, KR, *3 : P II b/III
MOA : Mode of Action Estimated study completion date shown in JRCT or ClinicalTrials.gov

F : Filed, A : Approval ※ Red : Update after announcement of FY 2024 financial result in May 2025
EU : European countries ※ Red : Update after FY2025 Q3 in February

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Here is a summary of the development status in the non-oncology area.

Regarding ONO-2017, cenobamate, we have started a Phase 3 study in Japan for partial-onset seizures in children with epilepsy.

The addition was made because Vertex has initiated Phase 2/3 studies for ONO-8531 (povetacicept) in patients with membranous nephropathy, for which we in-licensed the commercialization rights in Japan and South Korea from Vertex.

This is not a progress update, but as I mentioned earlier, the results of ONO-2808 at the bottom will be presented at the World Parkinson Congress, WPC, to be held in the United States at the end of May. As with ONO-4578, we plan to initiate a global Phase 3 study of this drug in patients with multiple system atrophy this year.

Development pipeline (Non-oncology) ②



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-1110 Endocannabinoid regulation	Postherpetic Neuralgia							FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia							FY2026 Primary Completion	JP	NCT06752590
	Hunner Type Interstitial Cystitis							FY2026 Primary Completion	JP	NCT06752603
	Major Depressive Disorder							FY2026 Primary Completion	JP	NCT06792136
	Social Anxiety Disorder							FY2026 Primary Completion	JP	NCT06805565
ONO-2020 Epigenetic Regulation	Alzheimer's Disease							FY2026 Primary Completion	JP, US	NCT06881836
	Agitation Associated with Dementia Due to Alzheimer's Disease							FY2026 Primary Completion	JP	NCT06803823
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	Autoimmune disease							FY2024 Completion	JP	jRCT2071220081
								FY2024 Primary Completion (Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2026 Completion	JP	jRCT2071240056
ONO-2416	Psychiatric disorders							FY2027 Completion	JP	jRCT2071250147
ONO-3310	Kidney disease							FY2027 Completion	JP	Under registration
ONO-6414	Autoimmune disease							FY2027 Primary Completion	US	Under registration

MOA : Mode of Action

Estimated study completion date shown in jRCT or ClinicalTrials.gov
Shaded boxes indicate studies on healthy volunteers.

F : Filed, A : Approval
EU : European countries

Red: Update after announcement of FY 2024 financial result in May 2025
Red: Update after FY2025 Q3 in February

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Here we have updated the bottom three rows.

ONO-2416, ONO-3310, and ONO-6414 have all entered a new clinical stage as products created in-house.

As the table also states MOA, modality, the mechanism of action was previously disclosed at the same time as the clinical transition. In addition, the indications were disclosed close to the indications obtained approval for the future. However, due to the recent intensification of the competitive environment, we regret to inform you that we will refrain from disclosing such information, at least at the stage of clinical transition.

ONO-2808

7th World Parkinson Congress

Title : Safety, Tolerability, and Preliminary Efficacy of ONO-2808,
a Sphingosine-1-Phosphate Receptor 5 Agonist, in Multiple System Atrophy
Abstract No. : LBP37.09, Poster session
Time : Wednesday, May 27, 2026 11:30 am – 1:30pm (MST)

ONO-4578

ASCO 2026 (American Society of Clinical Oncology)

Title : ONO-4578 combined with nivolumab and chemotherapy as first-line treatment for patients with
HER2-negative unresectable advanced or recurrent gastric/gastroesophageal junction cancer: a
randomized, double-blind, phase 2 trial (ONO-4578-08)
Abstract No. : 4007, Oral presentation
Time : Monday, June 1, 2026, 9:45 am to 12:45 pm (CT)
Presenter : Sung Hee Lim, Samsung Medical Center, Sungkyunkwan University School of Medicine,
Seoul, Republic of Korea

The data details will be presented at the R&D day to institutional investors and business analysts on June 8.

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Finally, I would like to introduce the presentation of data from the POC study.

ONO-2808 will be presented in the United States on May 27 at the 7th World Parkinson Congress.

We will be giving an oral presentation at the ASCO meeting on June 1 regarding ONO-4578 for the first-line treatment of gastric cancer.

I will again present the details of the data at the R&D meeting scheduled to be held on June 8. That is all from me.

Question & Answer

Imura: We would now like to take your questions.

Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi : I have two quick questions. First of all, it is helpful that you have provided information such as peak sales, when you plan to be approved, and various mid-term plans. Is the peak sales you provided a peak sales that has not been adjusted for risk?

Takino : This is an estimate at this stage, so the accuracy and precision are low, and risk adjustment and probability adjustment are not well taken into account.

Yamaguchi : ROMVIMZA, which performed well in the previous fiscal year, is expected to grow by about double in the current fiscal year. Initially, I believe you presented the number of patients at Deciphera to be targeted as 700, 700, and 1,300 patients. Could you please explain a little about the assumptions on which these projections are based or where you are aiming to be in the next fiscal year?

Takino : Broadly speaking, we wrote the illustration following the pattern we showed you last time. This is based on information provided by physicians. On that premise, our ROMVIMZA is now on the market and TKI therapy is now available. The number of physicians prescribing TKI therapy is increasing as they know that the TKI is easy to use and has solid efficacy. This is indicated by the white arrow in the middle.

So, the numbers that we showed you last time, 700, 700, 1,300 patients, as I recall, have probably changed a bit. Since we are not in a position to provide an exact figure, we will provide an illustration like this in the future. We hope you understand.

Yamaguchi : The projection to increase from JPY8.3 billion to JPY19 billion this fiscal year means that you are expanding your market share within this first 700 patients. You haven't reached second 700 patients at all yet, have you?

Takino : You are right. The premise represented the state before ROMVIMZA was launched. In that sense, we think that if this TKI treatment is to be performed mainly by ROMVIMZA in the future, the zone of doctors with TKI on the far left may become the so-called first step.

Imura : Next, Mr. Seki from UBS Securities, please.

Seki : I would like to ask you two simple questions.

The first point is the outlook for royalties. I think the forecast for FY2026 is JPY185 billion, which is slightly stronger than the consensus. Are there any special or temporary factors contributing to this? Also, I recall that the percentages will remain the same.

Itoh : As for our royalty assumptions, we basically base our royalty plans on the sales projections we receive from BMS. Rates, as you say, have not changed. Also, the prospect of sales expansion has been adjusted.

Seki : So, there are no particular special factors other than Bristol and Merck.

Itoh : No, no special factors are included.

Seki : The second point is the outlook for research and development expenses. You mentioned that you changed the accounting classification. Excluding that, what is the real increase or decrease?

Also, I thought that R&D expenses would increase a little more since Phase 3 trials for ONO-4578 and ONO-2808 are about to start. The reason it doesn't increase much is that it starts in the middle of the period, so it doesn't increase much on a 12-month basis?

Itoh : Regarding this accounting change, the projected R&D expense of JPY143 billion for the next fiscal year is after the change. In an apples-to-apples comparison, R&D expenses are planned to increase slightly in the current fiscal year ending March 31, 2027.

As for R&D expenses over the next few years, while new clinical trials are being initiated, we plan to control R&D expenses as a whole and try to keep the R&D ratio at around 30% of sales at the level of around JPY145 billion to JPY150 billion.

Even if we start development from the beginning of the term or at the end and incur expenses for a full year, we do not expect to see a significant increase or decrease from the current level of R&D expenses for the next few years.

Imura : Next, Mr. Wakao of JP Morgan Securities, please.

Wakao : I have three questions. The first is a simple check. There were quite a few other expenses in Q4 that ended, and I think this was an unexpected factor that pushed down the deposit profit in the previous fiscal year. I would like to know what is in it. There is a breakdown in the summary of financial results, where it says product recall, and in the presentation material it says OPDIVO related. Please tell us what was the JPY1.4 billion loss related to the voluntary recall related to OPDIVO.

Takino : With respect to the event that occurred?

Wakao : With respect to the event that happened.

Takino : This is something that has been well informed and promoted to medical institutions. It occurred during the manufacture of OPDIVO that the possibility that a foreign substance may have entered some of the products could not be ruled out. After following the appropriate procedures with the authorities, the product was quickly recalled and replaced with a risk-free product, just in case. Such items were recorded as a loss on disposal, although not by a very large amount.

Wakao : So, this is a problem that has already been resolved and will not incur any further costs this fiscal year?

Takino : Yes, that's correct.

Wakao : Second, I would like to know the assumptions of your plans for this year for QINLOCK and ROMVIMZA. As for QINLOCK and ROMVIMZA, I had expected that you would present a higher level of plans, but they were unexpectedly low. I would like to know if there are any factors.

QINLOCK has already penetrated the market to some extent in the United States. Considering that last year's growth was mainly in Europe, I think it is an appropriate level, since there is not much more approval contribution in Europe. I would like to know a little bit about that.

ROMVIMZA was rather strong in the last fiscal year, Q1 and Q2, but growth appears to have slowed somewhat since then. Looking at monthly sales, this seems a bit sluggish. Should we take that into consideration? Or is this a forecast that takes into account the fact that you will have a competing product this year?

Takino : First of all, both QINLOCK and ROMVIMZA are equally difficult to predict. Some people may perceive this forecast as conservative, while others may perceive it as aggressive.

First, regarding QINLOCK, as you commented, its use up to the last line of GIST is well established in the US.

In Europe, however, there is still a bit of geographic expansion going on. In the US, as you know, Cogent's drug will be added to the second line of treatment for GIST.

This has an impact. In addition, the application for additional indications for the second-line indications that we are currently working on will be submitted at the end of the fiscal year or next year.

This changes the dynamism or paradigm of the second line of treatment a bit. The fact that the Cogent's product coming in may not necessarily be negative for us also makes it very difficult to predict.

Taking these factors into consideration, we have placed our forecasted values based on our expectation that the penetration of the US market, which has been growing by more than 10% every year up to now, will continue to deepen in the same manner this year.

As for ROMVIMZA, it was indeed a bit weak from the end of the year to the end of the fiscal year, but we have heard from the local market that the timing of the insurance renewal may have had an impact on this. Basically, we are projecting these numbers based on the assumption that the current momentum will be maintained all the way through and penetration will continue.

So, even if it is perceived as conservative, it may be so, and there also may be a view that it is by no means so.

We believe that if we need to make corrections along the way, we should make them.

Wakao : You have also factored in the impact of competing products in the ROMVIMZA forecast.

Takino : Yes. We do not expect to see a competing product for ROMVIMZA until later in the fiscal year. In any case, we understand that TGCT is a bit of a niche disease, and the treatment flow is a bit tricky, if that is the right word, so there is a lot of importance in educating people about the disease.

So, there is a positive side to having two products in there, rather than just one company or one product, which will improve and expand awareness of appropriate treatment and accelerate the process for both companies. With that in mind, we made these projections.

Wakao : I would like to make one last point. I would like to ask about your image of future sales growth on page 32. The pipeline is becoming more complete, and the growth potential, especially after 2030, is very high.

However, the growth through 2030 is mainly due to sales contributions from QINLOCK, ROMVIMZA, and tirabrutinib. I am particularly concerned about whether QINLOCK and ROMVIMZA will be able to achieve this sales growth by 2030 and not delay, while the competing products you mentioned are also on the way. I would like to know about this point.

This is an image of sales growth, but I wonder if you could share with us how you see your company's profit growth, especially between 2025 and 2030.

Takino : The part you pointed out is, of course, still a projection at this stage, and in that sense, I think you are right that there may be some vulnerability in the projection.

However, from here, povetacicept and Gel-One will come out in Japan, and later this year, cenobamate for epilepsy. And as I'm sure you know, we are still working to strengthen our pipeline in relation to business development. So, we are quite confident that we will be able to rise at least from 2030.

Until then, however, there will be some ups and downs. As I and Itoh explained earlier, we would like to keep costs down to maintain operating profit as much as possible, while continuing to invest in future growth and R&D, so that we can regrow from around 2030 onward.

Imura : Next, Mr. Hashiguchi of Daiwa Securities, please proceed.

Hashiguchi : I would like to know more about the concept of the peak sales forecast you have presented this time on page 32. Sales forecasts for ONO-4578 and 2808 are shown as over JPY100 billion each. What are your thoughts on the limit? Do you think the upper limit is in the JPY100 billion range, or are you looking at JPY200 billion or even JPY300 billion?

Regarding ONO-4578, what kind of patients do you expect it to be used primarily for? I understand that, as for ONO-2808, too, the development of Lundbeck's amlenetug, which has a slightly similar mechanism of action, is proceeding. Could you also comment on which positioning of the drug you expect as a premise to anticipate these sales?

Takino : First of all, regarding this estimate, we are by no means denying the possibility of exceeding JPY200 billion. However, as you know, I would like to indicate that with respect to the ONO-4578 area or the ONO-2808 area, considering the level of unmet that remains, it will be a solid number scale, although of course it will depend on the environment.

On that basis, I will make a few comments about ONO-2808 first. While it is true that Lundbeck's development of an antibody to synuclein is ahead of ours, we are not yet in a position to compare the effectiveness of our compound with that of Lundbeck.

Considering the mechanism of action, we believe that our product may show advantages over that product, which is simply a direct antibody to synuclein, and that our product may be more convenient because it is an oral formulation. However, we are not presenting a figure that incorporates all of these factors.

However, considering that there is no drug for MSA itself and that the patient situation is very desperate, I hope you understand that we are hopeful that if we can bring the product to market, its penetration will be quite robust.

Okamoto will comment a bit on ONO-4578.

Okamoto : Regarding ONO-4578, if I give you too much detail, I will be approaching the data that will be presented at ASCO. We recognize that the current global standard of care for gastric cancer is to combine PD-1 antibody and chemotherapy if the CPS is positive.

As in the case of Claudin positivity/negative, I think the current first-line treatment, at least for patients with positive PD-L1 expression, would be a combination of PD-1 antibody and chemotherapy.

As we have mentioned for some time, we expect ONO-4578 to enhance anti-tumor immunity by T cells. Inevitably, we expect that patients for whom PD-1 antibody plus chemotherapy will be used as the standard of care will be totally captured if Phase 3 of ONO-4578 is successful.

As for ONO-2808, as President Takino commented, the results of Phase 3 did not show any difference. But we think there is a difference between competitor is antibody that trapping free synuclein and ONO-2808 is a small molecule that cutting off α -synuclein from the source. We have not started Phase 3 yet, and I think we cannot say anything until we see the results. At least at this point, we believe that the oral formulation has the advantage over the injectable formulation, which requires a hospital visit for administration, in this disease.

Hashiguchi : Do you think that ONO-4578 will be able to capture areas that the HER2-targeted drugs and Claudin18.2-targeted drugs are now used, or do you not expect it so much?

Okamoto : With regard to HER2, we have been developing HER2-negative drugs since the discovery stage. So, I think we can acquire a population that is HER2-negative, PD-L1-positive, and currently has antibodies to PD-1 and chemotherapy as the global standard.

Regarding Claudin, I would like to refrain from giving a detailed answer today.

Imura : Next, Mr. Matsubara of Nomura Securities, please.

Matsubara : Let me ask you two questions. First of all, can you tell us quickly what you think the impact of pamicotinib on ROMVIMZA is?

Takino : As I mentioned earlier, TGCT is not a simple disease and is not well known. Abnormalities in the joints are the first main complaint. Therefore, it is also very important base that the concept of TGCT is first communicated to orthopedic surgeons and that they are educated about the disease.

The patient is then referred to an oncologist who treats it, an oncologist who treats it with a TKI. In this way, patients will increasingly use drugs such as TKIs, mainly ROMVIMZA. We may have to share patients with pamicotinib, but in terms of expanding the overall size of the market by increasing the number of such patients, we see the entry of pamicotinib as not just a negative.

In addition to this, a comparison of the data, although limited, by no means shows any inferiority of ROMVIMZA's data to pamicotinib's data. In this sense, we have made our forecast, taking into consideration the fact that we can enjoy the benefit of first-mover advantage as much as possible, which is to create the soil for doctors to use the product ahead of others.

Matsubara : I understand that market activation positively affects the market. The second question is about strategic investments. Looking at the current pipeline, there are a number of things that are moving forward to P2 and P3, and some that are starting P1. You must have a frame for these strategic investments, of course, but what do you have in mind at the moment? Can you tell us if you are thinking of something specific or if you have any perspective on this?

Takino : I am very happy that you have received this positively. On the other hand, as we have discussed, we really want to make the growth story more solid.

In that sense, we are not particularly focused on whether or not we choose M&A or any other form, and conversely, we do not exclude it. As for our business development activities, we are still eagerly looking for new growth materials that we can enhance for the future.

You asked what areas we are targeting. ROMVIMZA and QINLOCK currently target areas such as gastrointestinal cancer and sarcoma. But tirabrutinib for PCNSL treatment, we will target the area of blood and brain tumors, basically a hybrid of brain tumors, blood and neurology and neurosurgery.

After that, we go in the blood area with sapablursen. Such a trend is surely the first step. In this context, ONO-4578 is in the field of gastrointestinal cancer, which was mentioned earlier, and I think it is fair to say that we will be more than aware of the fact that we can have a cluster of strengths in this area and will be active in this area. I would like to refrain from giving a specific answer as to which one we will target.

Imura : Next, Mr. Wada of SMBC Nikko Securities, please.

Wada : I would like to ask about the mid- to long-term perspective on the expenses on page 27.

You mentioned that there may be ups and downs in sales from now until 2030 and that you would like to keep profit in that period. I think you have to control SG&A expenses because you still need to invest in R&D and you cannot control costs very much. I would like to ask how much you expect SG&A expenses to be controllable.

Itoh : First of all, you mentioned that the cost of sales will not change much, but I think the cost of sales rate will decrease slightly from now on due to our own products and the difference in product mix between domestic and overseas.

As for SG&A expenses, we are currently thinking of promoting flexible control of SG&A expenses, both in Japan and overseas, in terms of labor costs, etc. I believe we can control that to some extent, taking account of the sales situation and cash position over the next few years.

Wada : SG&A ratio of 22% is presented in the plan for this fiscal year. Do you expect to maintain this level to some extent?

Itoh : I think it depends on the sales area, but depending on the situation, we will keep this ratio a little lower or invest a little more in the start of sales in a flexible manner. We will, of course, continue to invest in research and development. But we plan to decide while looking at profits whether to keep this ratio below, say, 20%, as appropriate, depending on the situation.

Wada : Regarding R&D expenses, do you plan to maintain this figure as an absolute quota? Do you envision a ratio of about 30%?

Itoh : Roughly 30% is one guideline, but I think there are a certain number of amounts needed the investment for growing. Taking this into consideration, we will not always say 30% but will consider it depending on the situation, looking at the ratio to sales and the timing of the investment.

Wada : The second point is about ONO-2808, the MSA pipeline.

The society for this is the Parkinson Society, and the synucleinopathy includes not only MSA but also Parkinson's disease and Lewy body dementia. Are you thinking of expanding your adaptation to that area? Since you have also indicated a goal of JPY100 billion in peak sales, I would like to ask about the upside.

Okamoto : The current sales forecast we are showing is only an estimate based on MSA alone. On the other hand, someone has asked about the additional indications before on this occasion. I am sorry, but for strategic reasons, we will not be able to answer your question, although we believe that the mechanism is indeed promising.

Imura : Next, Mr. Ueda of Goldman Sachs Securities, please.

Ueda : First, I would like to ask you about the assumptions of this year's plan for royalties.

Can you tell us a little more about the major factors behind the increase this fiscal year, for example, the increase in OPDIVO and Opdualag, the LAG-3 antibody? Can you also tell us if Opdualag can be expected to contribute in the long term to some extent, like SC of OPDIVO?

Itoh : Regarding the royalty of OPDIVO, it is difficult to answer the ratio of, for example, SC or fixed-dose combination with Opdualag, because of the BMS.

All we can say is that we expect royalties to increase as overall sales increase.

Ueda : Second, we have received an update on the schedule for obtaining approval. I believe that after FY2029, there will be quite a few new products globally, even in areas that are different from the past. Can you give us a rough strategy for bringing the product to market, including which ones will cost more to bring to market, which ones will not cost much in additional costs, and in some cases, whether or not a partnership is necessary?

Takino : In the diagram Okamoto showed you earlier, although it overlaps with what I said earlier about strategic areas, sapablursen is in the hematology area and ONO-4578 is mainly considered for gastrointestinal cancers. ONO-2808 targets highly unmet niche neurodegenerative diseases. At this time, we do not anticipate any major hurdles that would make it difficult for us to work on this project.

I am sure that there will be situations like the one you mentioned regarding other projects in the future. In any case, we intend to continue to follow the line of doing as much as we can ourselves first and adding value.

Ueda : I believe that the investment will be made while considering the percentage to sales. Is there any need to envision any discontinuous, large, upfront investment in, for example, the establishment of a sales structure?

Takino : Now, I don't think it is necessary for you to take that into consideration in the assumptions that Mr. Ueda and others make.

Imura : Next, Mr. Muraoka of Morgan Stanley Securities, please proceed.

Muraoka : Regarding the chart on page 32, I am sorry to be persistent, but the sales forecast for tirabrutinib, VELEXBRU, is JPY20 billion to JPY30 billion, but I think there was talk previously of aiming for about JPY50 billion. This is JPY20 billion to JPY30 billion because only for the second line, and if the first line added, it would be about JPY50 billion? Or have you changed your mindset as you have come closer to various aspects of reality?

Takino : This is basically a prospect based on R/R PCNSL, the second line.

Muraoka : So, if you can get to the first line, you can expect about JPY50 billion?

Takino : Yes, although we don't know if we can really get to the first line or if we will consider other developments. I hope you understand that we have a clear path for RR at this time and are presenting it to you in this manner.

Muraoka : Likewise, I would like to ask about domestic OPDIVO on the left side of the chart on page 32.

I know it may not be a good idea to ask for details about 2030 or 2035. Regarding OPDIVO in Japan, I think there is a trend that the Ministry of Finance is becoming more aware of the recent patent expiration of PD-1 and is now saying that you should switch to biosimilars.

In 2035, I think sales of this of more than JPY50 billion are included, but can you expect that scale of sales? If not, will the SC grow considerably? What is the premise of this diagram?

Takino : This picture is only an image. I would like to refrain from answering the question about what amount this is, because it could be misleading.

Certainly, as Mr. Muraoka pointed out, we understand that the world is beginning to move in that direction with regard to reducing spending on biologics. On the other hand, we will also produce SC formulations, and I hope you understand that we are creating this image taking into account the whole picture.

Muraoka : Likewise, I was wondering if you could aim so much royalties for 2035, but I'm not going to ask questions about this.

Last question. Regarding ONO-2808, I believe Lundbeck has received a breakthrough therapy designation. If the data is good and the drug is easy to use, I think ONO-2808 could be a breakthrough.

Did you say that you have made that application? I have forgotten our previous discussions, so it would be helpful if you could let me know.

Okamoto : I think the point you asked is an important one, but I am very sorry, but as in the past, we will refrain from responding to your question about our communication with the authorities until something is made public.

Muraoka : In general, if you have Phase 2 data, you can make a decision on the breakthrough designation and apply for it.

Okamoto : Yes, as you pointed out, in the US, it is common to have an end-of-phase 2 meeting after phase 2 is completed to discuss how to proceed with the development, including the design of Phase 3.

In the process, I am sure that there will be things that we will do, for example, because the results are good, but I will refrain from answering the details at this time.

Imura : Next, Mr. Ishi of iyaku Tsushinsha, please.

Ishii : You mentioned earlier that you are expanding the ratio of overseas sales. I would like to know how much you plan to expand in the medium term, including the enhancement of your pipeline.

Takino : We do not have an overseas sales ratio target at this time. However, I have no doubt that the ratio of overseas sales will eventually exceed half once our current efforts take solid shape.

We have presented this with the idea that we would pay attention to this as one of our performance indicators. It will exceed half, but we do not have a specific end goal at this time.

Ishii : When will it exceed half?

Takino : This figure for 2030 to 2035 is not quantitative at all. I understand that you are asking about images, and to answer your question, I would say that the time will come about between 2030 and 2035.

Imura : Next, Mr. Okada of Yakuji Nippo, please.

Okada : I would like to ask about the development of ROMVIMZA in Japan. I believe you have said in the past that you would consider development. This is included in 2029 and beyond, so you will certainly consider this. Can you tell us about the current status of the development and the target timing of the market launch?

Okamoto : We have already launched ROMVIMZA for TGCT treatment in the US and Europe, and as mentioned earlier, we are aware that there is a very high unmet medical need. Naturally, this is the Ono Group's pipeline, and we will continue to develop it in Japan.

The POC has already been established in this pipeline. We need to develop a strategy to obtain approval in Japan, and as you can see here, we hope to obtain approval in Japan by a reasonable time after 2029.

Okada : Can you tell us when the peak sales forecast for the ROMVIMZA market of JPY50 billion to JPY70 billion is, and whether the region is only Europe and the US or whether it includes Japan and other countries?

Takino : Basically, we wrote this assuming global sales. The time frame is not specified.

Okada : Finally, as for what will fill the holes in FORXIGA, the most promising ones right now would be QINLOCK and ROMVIMZA?

Takino : Yes, I would like to see QINLOCK and ROMVIMZA as drivers for the global as a whole. As mentioned in presentation and during the Q&A, the same is true for OPDIVO. I believe that momentum is now building for greater penetration of ONGENTYS, ORENCIA, and PARSABIV in the primary, and non-oncology areas as well.

We will raise what we can, and although we do not think we will be able to fill the JPY88 billion hole in sales, we expect to limit the decline to about JPY60 billion this year at least, through JPY15 billion in overseas sales of ROMVIMZA and QINLOCK and less than JPY15 billion in royalty.

Imura : Next, Mr. Suwa of Asahi Shimbun, please.

Suwa : I believe you mentioned earlier that the pipeline is not yet a solid foundation for patent cliffs. However, that will come in a few years, so how prepared do you judge now that you are?

Takino : The answer may be that it depends on which point in time you look at. As for the OPDIVO patent cliff, the patent will expire in 2031 in Japan, 2030 in Europe, and 2028 in the United States.

In the US and Europe, our partner Bristol Myers Squibb is doing the business. So, the royalty income from this will be phased out in 2028 and 2030.

In this sense, if we set the timing for 2031, we can offset the decrease by enhancing the pipeline, launching new products, and increasing the number of new products.

As we have discussed, we expect some ups and downs before 2030 or 2031, and honestly, we would like to have more materials.

I would like to make one more comment. We have been talking about OPDIVO cliffs, but the OPDIVO cliffs we are talking about now are only for the intravenous infusion formulation. In fact, in the US and Europe, subcutaneous formulations have already been on the market for a year or six months.

If all of them were converted to subcutaneous formulations from intravenous formulations, we could say that the patent cliff has been pushed back, but that is not going to happen.

Bristol Myers Squibb seems to be saying that in Europe and the United States, about 40% or just under 40% will change to a subcutaneous formulation. If that were true domestically, the patent cliff could turn into a bit of a gentle transition.

I think it is important to anticipate and be prepared for such unpredictable aspects. In that sense, we still have plenty of strength to add a little more to our pipeline.

Taking this into consideration, we would like to continue to invest in growth for the future while maintaining a balance between short- and medium-term performance. Such themes will not change significantly. We will do our best to strengthen the pipeline and expand globally.

However, as we have seen with Gel-One and povetacicept, we would like to make full use of our domestic sales strengths, even for domestic in-licensing. I think we will design such things comprehensively.

Imura : This concludes the earnings call for the fiscal year ended March 31, 2026. Thank you very much for joining us today.