ONO PHARMACEUTICAL CO., LTD.

Financial Results Briefing for FY2025 Q3

February 2, 2026

[Number of Speakers]	6	
	Masaki Itoh	Corporate Executive Officer / Division Director, Corporate Strategy & Planning, Business Management Division
	Tatsuya Okamoto	Corporate Officer, Executive Director, Clinical Development
	Hirokazu Kitada	Corporate Officer, Executive Director, Sales and Marketing
	Kunihiko Ito	Corporate Officer, Head of Global Business
	Hiroyuki Takahashi	Director of Oncology Business Division, Sales and Marketing
	Ryuta Imura	Senior Director of Corporate Communications

Presentation

Imura: Thank you very much for attending ONO PHARMACEUTICAL CO., LTD.'s, financial results meeting for Q3 of the fiscal year ending March 31, 2026, today.

To begin, I would like to introduce the attendees. Masaki Itoh, Corporate Executive Officer, Division Director, Corporate Strategy & Planning, Business Management Division. Okamoto, Corporate Officer, Executive Director, Clinical Development. Kitada, Corporate Officer, Executive Director, Sales and Marketing. Kunihiko Ito, Corporate Officer, Head of Global Business. Takahashi, Director of Oncology Business Division, Sales and Marketing.

Agenda

Financial Overview FY2025 Q3 (14:00-14:20)

Masaki Itoh

Corporate Executive Officer / Division Director, Corporate Strategy & Planning, Business Management Division

Development Pipeline Progress Status (14:20-14:35)

Tatsuya Okamoto

Corporate Officer / Executive Director, Clinical Development

Trend of OPDIVO (14:35-14:45)

Hirokazu Kitada

Corporate Officer / Executive Director, Sales and Marketing

Q&A Session (14:45-15:00)

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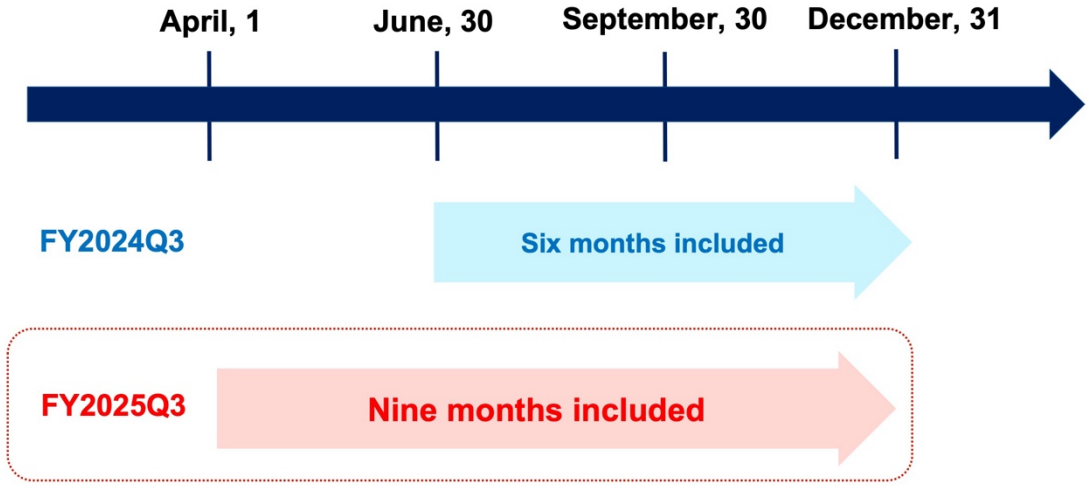
Imura: First, Masaki Itoh, Division Director of Business Management Division, will present an overview of the financial results for Q3 of the fiscal year ending March 31, 2026. Next, Okamoto, Executive Director of Clinical Development, will explain the progress status of our development pipeline. Finally, Kitada, Executive Director of Sales and Marketing, will give an overview of the trend of OPDIVO.

After our presentation, there will be time for questions and answers. And the materials are already posted on our website for your reference.

First of all, Itoh will now explain an overview of the financial results for Q3 of the fiscal year ending March 31, 2026.

Profit and Loss Recognition Period for Deciphera Pharmaceuticals, Inc.

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



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Itoh: First, I would like to share with you some points to keep in mind.

With respect to the inclusion of the results of Deciphera acquired in June 2024, the previous year's results included six months of profit and loss from July 1 to December 31, 2024, and the current year's results include nine months of profit and loss from April 1 to December 31, 2025. Please keep in mind that the current year includes three more months of sales, expenses, and other income/losses for Deciphera than the previous year.

Highlights of Financial Results for FY2025Q3 (Core Basis)

For the FY2025Q3 ending March 2026, we recorded increased revenue and profit.

FY2025Q3 Sales Revenue	**Revenue increased by ¥22.5 billion (6.0%) year on year to ¥397.0 billion, which is the highest third-quarter sales in our history.** **Domestic Sales :** Despite the entry of generic products in December, sales of FORXIGA increased due to its expanded use, particularly in treatment for chronic kidney disease and chronic heart failure. However, overall sales slightly decreased mainly due to a decline in OPDIVO sales. **Overseas Sales :** Sales of QINLOCK increased by ¥11.3 billion to ¥28.6 billion. Sales of ROMVIMZA were ¥5.4 billion. Royalty revenue associated with OPDIVO and other products continued to increase steadily.
FY2025Q3 Core Profit for the Period	**Core profit for the period increased by ¥13.5 billion (17.6%) to ¥90.0 billion.** Although expenses increased due to the inclusion of three additional months of R&D and SG&A expenses for Deciphera compared to the previous year, the increase in sales exceeded these expenses, resulting in the profit increase.
FY2025 Financial Result Forecast	**Sales and profit for the year is expected to increase compared to the previous fiscal year.** Although sales of FORXIGA is expected to decrease due to the entry of generic products, an increase in sales and profits is anticipated mainly due to growth in sales of QINLOCK and ROMVIMZA, as well as an increase in overseas royalty revenue.

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Let me move on to the highlights.

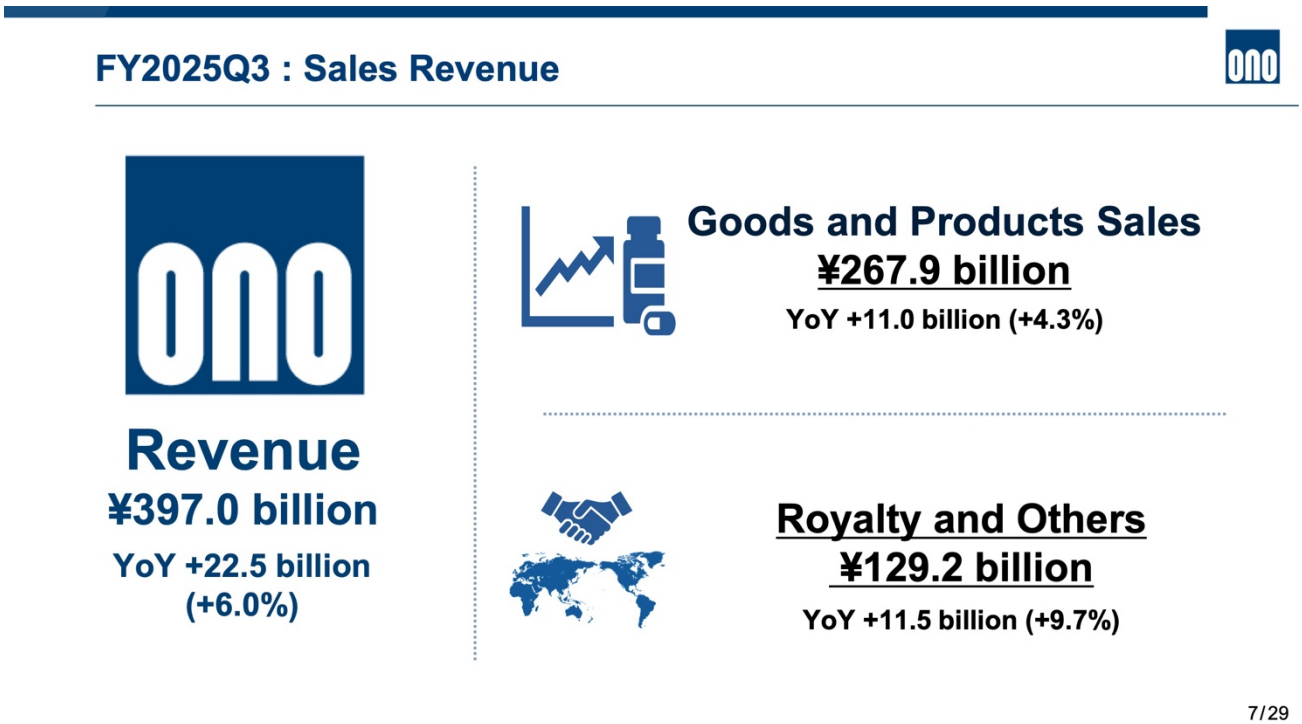
Since Q3 of the previous fiscal year, we have been disclosing financial results on a core basis, so this is a summary of financial results on a core basis. For Q3 of the current fiscal year, both revenue and profit increased. Revenue increased by JPY22.5 billion, or 6% YoY to JPY397 billion, maintaining solid growth and achieving the highest cumulative revenue for the first three quarters in our history. Previously, the highest value was JPY389.9 billion in FY2023.

In Japan, while sales of FORXIGA increased, overall domestic sales decreased due to the decline in sales of OPDIVO in an intensified competitive environment. On the other hand, overseas sales of QINLOCK, a treatment for gastrointestinal stromal tumor acquired through the Deciphera acquisition, increased by JPY11.3 billion YoY to JPY28.6 billion due to the absence of sales recorded in the April-June period of the previous fiscal year, as well as steady sales.

In addition, sales of ROMVIMZA, a treatment for tenosynovial giant cell tumor, which was launched in February last year, amounted to JPY5.4 billion. This is a full-year revenue growth factor compared to the previous year. Overseas royalty income related to OPDIVO and other products from overseas also increased due to strong local sales.

Next is the core operating profit for the quarter. The increase in expenses and the fact that Deciphera's R&D and SG&A expenses include additional three months YoY, were more than offset by the positive effect of increased sales, resulting in a JPY13.5 billion YoY increase to JPY90 billion.

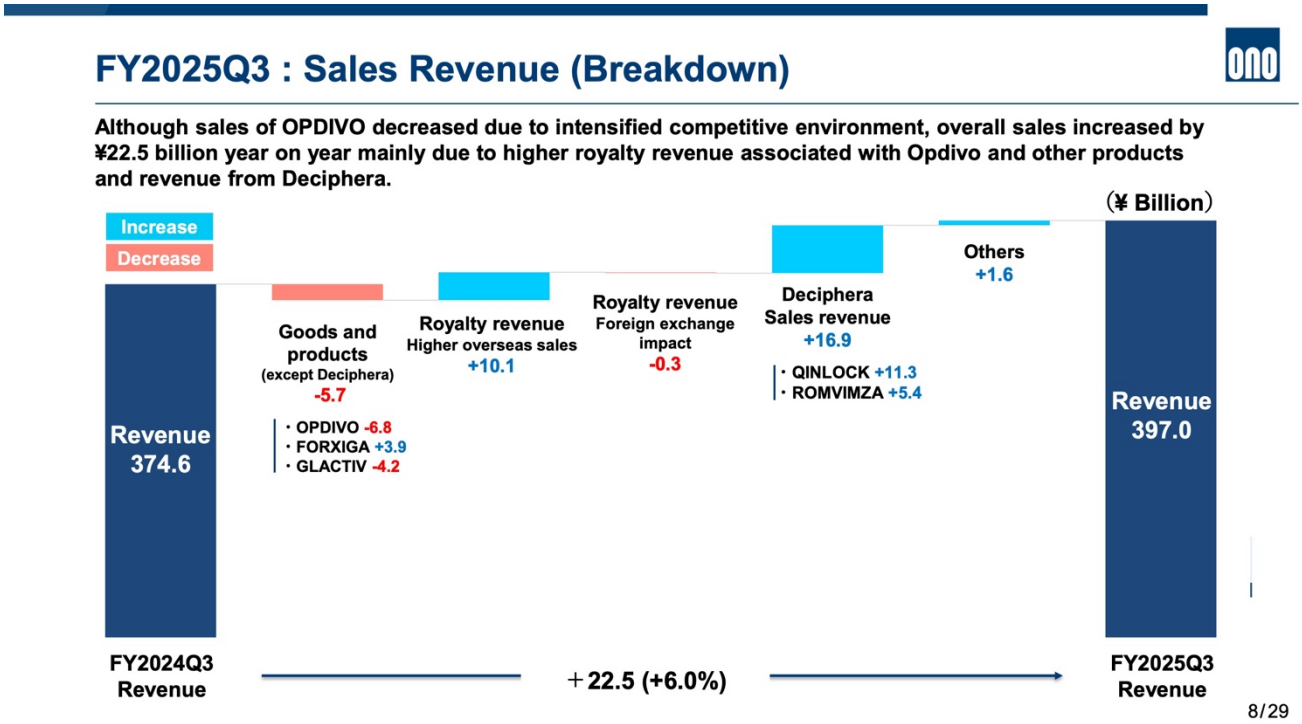
For the full-year earnings forecast for the fiscal year ending March 2026, while a decline in sales is anticipated due to the entry of generic products of FORXIGA, we expect increased revenue and profit as this is offset by growth in revenue from QINLOCK, ROMVIMZA, and overseas royalties.



Now, let me explain the details.

Sales revenue increased by JPY22.5 billion, or 6%, from the same period last year to JPY397 billion, of which domestic and overseas product sales were JPY267.9 billion, an increase of JPY11 billion, or 4.3%, from the

same period last year. Royalties and others totaled JPY129.2 billion, an increase of JPY11.5 billion, or 9.7%, from the same period last year.



The factors behind the increase in revenue are explained in the waterfall chart.

Domestic product sales at the far left were negative JPY5.7 billion, while FORXIGA sales were positive, but OPDIVO and GLACTIV sales were negative, resulting in an overall negative domestic sales figure.

On the other hand, royalties, which are shown separately for local sales volume and the impact of foreign exchange rates, increased by JPY10.1 billion for local sales increase, while the impact of foreign exchange rates on royalties was a negative JPY0.3 billion.

As for overseas sales, Deciphera's sales revenue was a positive JPY16.9 billion, of which QINLOCK accounted for JPY11.3 billion and ROMVIMZA for JPY5.4 billion.

FY2025Q3 : Sales Revenue by Product (Domestic)

¥ in Billion	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	374.6	**397.0**	22.5	6.0%	490.0
Goods and products	256.9	**267.9**	11.0	4.3%	330.0
Royalty and others	117.7	**129.2**	11.5	9.7%	160.0

Goods and Products (Domestic)	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	96.0	**89.2**	-6.8	-7.1%	120.0
FORXIGA Tablets	68.7	**72.7**	3.9	5.7%	80.0
ORENCIA for Subcutaneous Injection	20.8	**21.0**	0.2	1.0%	28.0
GLACTIV Tablets	14.7	**10.4**	-4.2	-28.9%	12.0
VELEXBRU Tablets	8.2	**9.2**	1.0	12.3%	11.0
ONGENTYS Tablets	6.0	**6.9**	1.0	16.6%	9.0
PARSABIV Intravenous Injection	6.6	**6.9**	0.3	5.1%	9.0
KYPROLIS for Intravenous Infusion	6.9	**6.0**	-0.9	-12.9%	9.0

* The consolidated financial forecast for the fiscal year ending 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, let us look at the situation for each product in Japan and overseas. First, we would like to start with the domestic sales by product.

Sales of the anti-cancer treatment OPDIVO Intravenous Infusion decreased by JPY6.8 billion, or 7.1%, to JPY89.2 billion due to the intensified competitive environment. FORXIGA Tablets, a treatment for diabetes-related chronic heart failure and chronic kidney disease, increased by JPY3.9 billion YoY to JPY72.7 billion due to expanded use in chronic kidney disease and heart failure, despite the entry of generic products in December.

Sales of ORENCIA for Subcutaneous Injection, a treatment for rheumatoid arthritis, increased by JPY0.2 billion to JPY21 billion, ONGENTYS Tablets, a treatment for Parkinson's disease, increased by JPY1 billion, or 16.6%, to JPY6.9 billion, and PARSABIV Intravenous injection for dialysis for the treatment of secondary hyperparathyroidism on hemodialysis increased by JPY0.3 billion, or 5.1%, to JPY6.9 billion.

On the other hand, sales of GLACTIV Tablets, a treatment for type 2 diabetes, decreased by JPY4.2 billion, or 28.9%, to JPY10.4 billion due to the significant impact of a 25% NHI price revision sat the beginning of the period, and sales of KYPROLIS for Intravenous Infusion, a treatment for multiple myeloma, decreased by JPY0.9 billion, or 12.9%, to JPY6 billion due to the impact of competitive products.

FY2025Q3 : Sales Revenue by Product / Overseas / Royalty

¥ in Billion	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	**374.6**	**397.0**	**22.5**	**6.0%**	**490.0**
Goods and products	**256.9**	**267.9**	**11.0**	**4.3%**	**330.0**
Royalty and others	**117.7**	**129.2**	**11.5**	**9.7%**	**160.0**

Goods and Products (Overseas)	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO	10.0	**10.8**	0.8	7.8%	13.5
QINLOCK®	17.3	**28.6**	11.3	65.1%	36.0
ROMVIMZA®	–	**5.4**	–	–	8.0

Royalty and others	FY2024Q3	FY2025Q3	YoY		
			Change	Change(%)	
OPDIVO	86.3	**92.5**	6.2	7.2%	
KEYTRUDA®	19.4	**21.5**	2.1	10.6%	

* The consolidated financial forecast for the fiscal year ending 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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Continuing on, overseas sales.

Total sales of OPDIVO in South Korea and Taiwan increased by JPY0.8 billion YoY to JPY10.8 billion. Regarding two products of Deciphera, sales of QINLOCK, a gastrointestinal stromal tumor medicine, increased by JPY11.3 billion to JPY28.6 billion, compared with the same period last year, and are on track to meet our forecast of JPY36 billion. Sales of ROMVIMZA, a treatment for tenosynovial giant cell tumor, amounted to JPY5.4 billion, which is also on track to meet the forecast of JPY8 billion.

Royalties related to OPDIVO increased by JPY6.2 billion to JPY92.5 billion, and those related to KEYTRUDA increased by JPY2.1 billion to JPY21.5 billion.

FY2025Q3 : Core Operating Profit

Core Operating Profit
¥116.3 billion
YoY +18.6 billion (+19.1%)

Revenue ¥397.0 billion
YoY +22.5 billion (+6.0%)

R&D Expense ¥104.6 billion
YoY +1.2billion (+1.1%)

SG&A Expense ¥92.8 billion
YoY +2.6billion (+2.9%)

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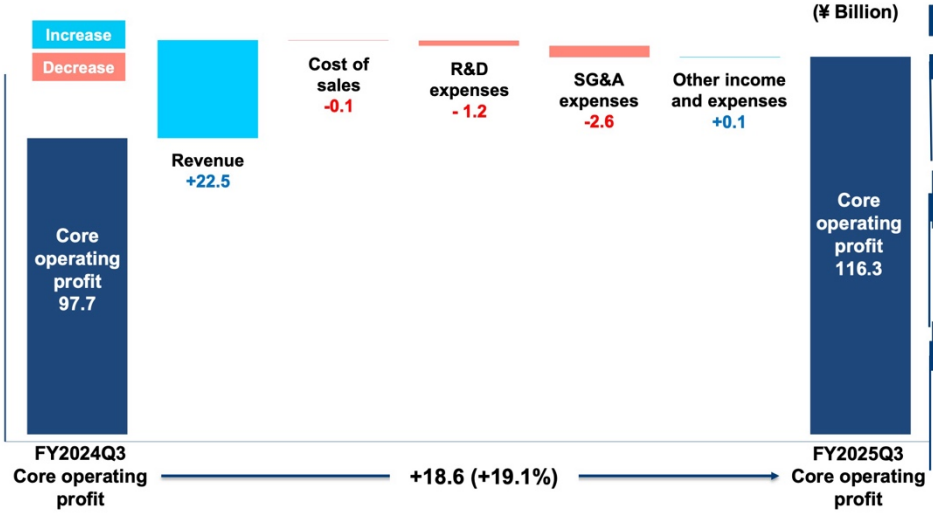
Next is about operating profit. Core operating profit was JPY116.3 billion, an increase of JPY18.6 billion, or 19.1%, from the same period last year. The primary driver of profit growth was a JPY22.5 billion YoY increase in sales revenue, despite higher expenses due to Deciphera's R&D and SG&A costs being included for three additional months compared to the previous year.

FY2025Q3 : Core Operating Profit (Breakdown)

While R&D and SG&A expenses have been recorded by Deciphera (the previous period accounted for six months, and the current period includes nine months), core operating profit increased by ¥18.6 billion year on year to ¥116.3 billion mainly due to an increase in sales revenue.



YoY Breakdown

Sales revenue
Main reason
- Goods and product : +11.0
- Royalty and others : +11.5

R&D expenses
Main reason
- Increase in R&D expenses from Deciphera (previous year : six months, current year : nine months)
- Decrease in research costs

SG&A expenses
Main reason
- Increase in SG&A expenses from Deciphera (previous year : six months, current year : nine months)

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The core operating profit can also be easily understood in the waterfall chart. Although there is an increase in sales revenue and a negative impact from R&D expenses and SG&A expenses, core operating profit has increased significantly.

FY2025Q3 : Financial Overview (Core)

¥ in Billion	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	374.6	397.0	22.5	6.0%	490.0
Cost of sales	83.1	83.2	0.1	0.1%	103.5
R&D expenses	103.4	104.6	1.2	1.1%	150.0
SG&A expenses	90.2	92.8	2.6	2.9%	120.0
Core operating profit	97.7	116.3	18.6	19.1%	114.0
Core profit before tax	100.0	117.8	17.8	17.8%	114.0
Core profit for the period (attributable to owners of the Company)	76.5	90.0	13.5	17.6%	91.0

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

YoY Breakdown

Cost of sales +¥0.1 billion (+0.1%)

COGS ratio : 21.0%

R&D expenses +¥1.2 billion (+1.1%)

R&D ratio : 26.3%

- Increase in R&D expenses from Deciphera (previous year : six months, current year : nine months)
- Decrease in research costs

SG&A expenses +¥2.6 billion (+2.9%)

Main reason

- Increase in SG&A expenses from Deciphera (previous year : six months, current year : nine months)

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This is the overall picture of the performance on the core basis in the cumulative total of Q3.

To reiterate, revenue increased by JPY22.5 billion, or 6%, from the same period last year to JPY397 billion, and core operating profit increased by JPY18.6 billion, or 19.1%, to JPY116.3 billion. The final core profit for the period increased by JPY13.5 billion, or 17.6%, to JPY90 billion.

(Ref) FY2025Q3 : Financial Overview (Full Basis)

¥ in Billion	FY2024Q3	FY2025Q3	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	374.6	397.0	22.5	6.0%	490.0
Cost of sales	102.7	108.7	5.9	5.8%	135.0
R&D expenses	107.1	104.6	-2.5	-2.4%	150.0
SG&A expenses	93.7	92.9	-0.8	-0.9%	120.0
Operating profit	70.8	88.3	17.5	24.8%	85.0
Profit before tax	72.0	89.4	17.3	24.1%	85.0
Profit for the period (attributable to owners of the Company)	56.6	68.9	12.4	21.8%	67.0

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

YoY Breakdown

Cost of sales +¥5.9billion (+5.8%)

Main reason
- Amortization expenses related to intangible assets acquired through acquisitions

R&D expenses -¥2.5 billion (-2.4%)

R&D ratio : 26.3%
Main reason
- Absence of impairment loss related to development compounds

SG&A expenses -¥0.8 billion (-0.9%)

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

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These are reference values, the status of performance on a full basis.

Overall, there are not significant difference from the situation in the core mentioned earlier. While revenue from both core and full operations remained the same, operating profit basis increased by JPY17.5 billion, or 24.8% YoY to JPY88.3 billion, and net profit for the period increased by JPY12.4 billion, or 21.8% YoY to JPY68.9 billion.

(Ref) FY2025Q3 : Reconciliation from Full to Core Basis

¥ in Billion	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Sales revenue	397.0				–	397.0
Cost of sales	108.7	-19.0		-6.4	-25.5	83.2
Gross profit	288.4	+19.0	–	+6.4	+25.5	313.8
R&D expenses	104.6				–	104.6
SG&A expenses	92.9			-0.1	-0.1	92.8
Other income /expenses	-2.6			+2.4	+2.4	-0.2
Operating profit	88.3	+19.0	–	+9.0	+28.0	116.3
Operating profit ratio	22.2%				–	29.3%
Finance income / Finance cost	1.1			+0.4	+0.4	1.5
Profit before tax	89.4	+19.0	–	+9.4	+28.4	117.8
Income tax expense	20.5	+4.9		+2.4	+7.4	27.9
Profit for the year	68.9	+14.1	–	+7.0	+21.0	90.0

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

No Adjustment

SG&A expenses and Other income&expense

Main reason

- Loss on retirement benefit plan amendments : +¥1.7 billion

PPA : Purchase Price Allocation

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Next is the table of reconciliation from full to core basis.

The adjustment items include two cost items, amortization of intangible assets related to acquisitions and in-licensing, JPY19 billion, and the fair value of inventory held by the counterparty at the time of acquisition, JPY6.4 billion for the nine months. In other expenses, a loss of JPY1.7 billion was recorded for the transition associated with the revision of the retirement benefit plan.

FY2025 : Financial Forecast (Core/Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on October 30, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	106.9	103.5	-3.4	-3.1%
R&D expenses	143.3	150.0	6.7	4.7%
SG&A expenses	122.2	120.0	-2.2	-1.8%
Core operating profit	112.7	114.0	1.3	1.2%
Core profit before tax	113.9	114.0	0.1	0.1%
Income tax expense	23.4	23.0	-0.4	-1.8%
Core profit for the period (attributable to owners of the Company)	90.4	91.0	0.6	0.7%

* The exchange rate assumed for the second half of the fiscal year is ¥145 per US dollar.

Breakdown

Cost of sales -¥3.4 billion (-3.1%)

Main reason
- Decrease in domestic sales

R&D expenses +¥6.7 billion (+4.7%)

Main reasons
- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Costs associated with Sapablursen in-licensed from Ionis Pharmaceuticals, Inc.
- Promotion of cost efficiency measures

SG&A expenses -¥2.2 billion (-1.8%)

Main reasons
- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Promotion of cost efficiency measures

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The following is the Full-year forecast.

The full-year forecast on a core basis remains unchanged from the forecast announced on October 30 last year. Although sales are expected to decline in Q4 due to the entry of generic products of FORXIGA, we anticipate increased revenue and profit as this will be offset by income from QINLOCK, ROMVIMZA, and overseas royalties. Revenues are projected to increase by JPY3.1 billion, or 0.6%, to JPY490 billion, core operating profit is projected to increase by JPY1.3 billion, or 1.2%, to JPY114 billion, and core net profit is projected to increase by JPY0.6 billion, or 0.7%, to JPY91 billion.

Sales and profits have been performing well through the Q3 results. However, for sales, a decline in FORXIGA sales is anticipated in January-March period due to the impact of generic products. Additionally, royalties for the January to March period are conservatively estimated, partly due to exchange rate factors. On the expense side, R&D costs and other January-March period expenses, while planned from the outset, account for a significant portion of the annual budget.

FY2025 : Financial Forecast (Sales Revenue by Product)

Goods and Products (¥ in Billion) (Domestic)	FY2024 Actual	FY2025 Forecast	YoY	
			Change	Change(%)
OPDIVO Intravenous Infusion	120.3	120.0	-0.3	-0.3%
FORXIGA Tablets	89.6	80.0	-9.6	-10.7%
ORENCIA for Subcutaneous Injection	26.6	28.0	1.4	5.2%
GLACTIV Tablets	18.3	12.0	-6.3	-34.6%
VELEXBRU Tablets	10.5	11.0	0.5	4.4%
ONGENTYS Tablets	7.6	9.0	1.4	17.8%
KYPROLIS for Intravenous Infusion	8.6	9.0	0.4	4.6%
PARSABIV Intravenous Injection	8.4	9.0	0.6	6.7%
Goods and Products (¥ in Billion) (Overseas)	**FY2024 Actual**	**FY2025 Forecast**	**YoY**	
			Change	**Change(%)**
OPDIVO	13.1	13.5	0.4	2.9%
QINLOCK®	25.5	36.0	10.5	41.2%
ROMVIMZA®	–	8.0	–	

・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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As for the sales forecast by product, we have not made any changes from the full-year forecast as of the end of October last year.

FY2025 : Financial Forecast (Full / Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on October 30th, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	147.9	135.0	-12.9	-8.8%
R&D expenses	149.9	150.0	0.1	0.1%
SG&A expenses	125.7	120.0	-5.7	-4.5%
Operating profit	59.7	85.0	25.3	42.3%
Profit before tax	59.3	85.0	25.7	43.3%
Income tax expense	9.2	18.0	8.8	96.5%
Profit for the year (attributable to owners of the Company)	50.0	67.0	16.9	33.8%

* The exchange rate assumed for the second half of the fiscal year is ¥145 per US dollar.
For the second half of the fiscal year, the sensitivity to exchange rates is assumed to be an increase of ¥0.7 billion in revenue and an increase of ¥0.2 billion in operating profit for every ¥1 depreciation of the yen.

Breakdown

Cost of sales -¥12.9 billion (-8.8%)

Main reasons
- Absence of sales milestone on FORXIGA

R&D expenses +¥0.1 billion (+0.1%)

Main reasons
- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Costs associated with Sapablursen in-licensed from Ionis Pharmaceuticals, Inc.
- Absence of impairment losses on development compounds

SG&A expenses -¥5.7 billion (-4.5%)

Main reasons
- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Promotion of cost efficiency measures

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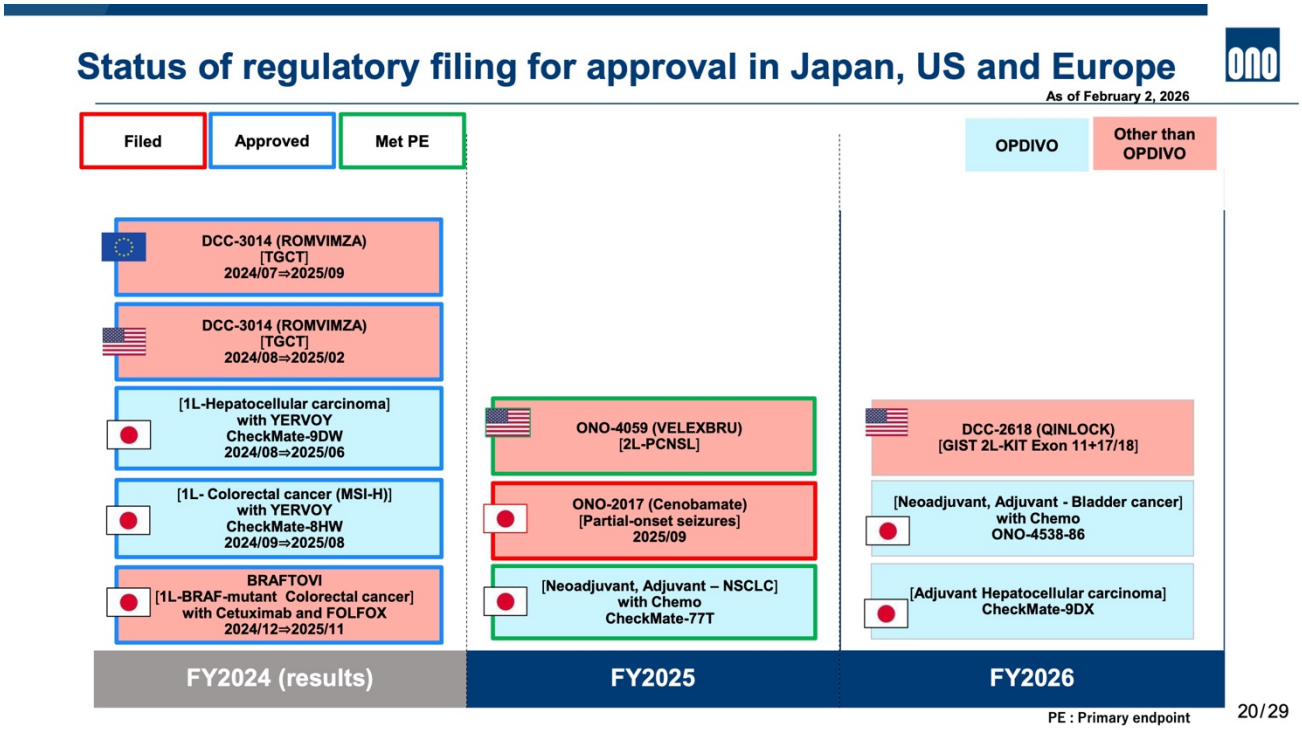
This serves as a reference, but there is no change to the full-year full-base earnings forecast from the previous forecast.

Imura: Next, Okamoto, Executive Director of Clinical Development, will continue with an explanation of the progress status of development pipeline.



Okamoto: I will use the documents which are available on our website, and will focus on the changes that have been made since the last time, on October 30 last year.

First, actual results and schedule of regulatory filing for approval. As you are aware, we have update it since we have received approval in Japan for BRAFTOVI for the first-line treatment of BRAF mutation-positive colorectal cancer.

In the center, ONO-4059, the US application for VELEXBRU. As you know, the US FDA sets a certain period of time before it accepts an application. So, we would like to make a separate announcement regarding the status of the VELEXBRU application in the US once the application is accepted.

The right-hand side of the table shows the planned future applications for QINLOCK, which will be filed in FY2026 in the US for second-line treatment of gastrointestinal stromal tumors with specific genetic mutations. There are no changes to other items.

Development status of OPDIVO

As of February 2, 2026

- Approval or filed/awaiting approval in the past year
- Ongoing key clinical trials for approval

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Non-small cell lung cancer	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Approved	Approved
Colorectal cancer	MSI-H / dMMR (1st)	with Ipi	Approved	–	Approved	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	–	–	–	–
Richter transformation	2nd	Monotherapy	Ⅱ	–	–	–	–
Solid tumor	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	Ⅰ	–	–	Approved	Approved

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after FY2025 Q2 in October

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The next section will discuss the major changes in the development status of OPDIVO.

As in the past, we have indicated the changes from previous data in red and yellow highlighting. This time, there is only one update. The first-line treatment for colorectal cancer with MSI-H, which is a combination therapy with YERVOY, has been approved in Taiwan, and this is updated. There is no more update information regarding the main development status of OPDIVO.

Development pipeline (Oncology) ①

As of February 2, 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 : Filed	JP, US, EU, KR, TW and others*1	NCT04607421
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
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL) ≥2L							FY2027 Primary Completion	US	NCT07104032
	Primary central nervous system lymphoma (PCNSL) 1L, ≥2L							FY2025 Primary Completion (Actual) (Part A)	US	NCT04947319
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*							FY2025 Primary Completion (Actual)	JP, KR, TW	NCT06256328
	Colorectal cancer*							FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*							FY2026 Primary Completion	JP	NCT06542731
	Hormone receptor-positive, HER2-negative breast cancer							FY2026 Primary Completion	JP	NCT06570031
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia Vera (PV)							FY2025 Primary Completion (Actual) Presented at ASH	US, EU and others	NCT05143957
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	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 ClinicaiTrials.gov
F : Filed, A : Approval
EU : European countries
※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after FY2025 Q2 in October

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The following is the progress of the development pipeline in Oncology excluding OPDIVO.

First, regarding BRAFTOVI on the top, as mentioned earlier, we have updated the information as it has received approval in Japan for first-line treatment of BRAF mutation-positive colorectal cancer. In South Korea, approval was also obtained for the same indication in January of this year, and we have updated that information.

The second row from the top, QINLOCK, is in the global Phase III trial for the second-line treatment for GIST with specific genetic mutations, and the timing of acquisition of the primary data, as stated in the public database, has been changed to December 2027.

As I mentioned at the beginning, the application is scheduled to be submitted in FY2026, but the timing of data acquisition has been a bit behind the schedule.

Next, ONO-0530. This is sapablursen for which we acquired the global rights from Ionis, the results of the Phase II trial were announced at the American Society of Hematology (ASH) in December last year, so I am adding a note to that effect.

The anti-CCR8 antibody, ONO-7427, is a compound co-developed with Bristol Myers Squibb. Preliminary efficacy studies are ongoing in the Phase I/II study. Due to this, the timing of obtaining the results has changed compared to the past.

Development pipeline (Oncology) ②

As of February 2, 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-7913 (magrolimab) Anti CD47 antibody	Pancreatic cancer*							FY2026 Primary Completion	JP	NCT06532344
	Colorectal cancer*							FY2027 Primary Completion	JP	NCT06540261
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2025 Primary Completion	US	NCT05079282
								FY2028 Primary Completion	JP	NCT06547528
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	HER2-expressing Solid tumor							FY2029 Primary Completion	US	NCT06241456
ONO-7428 Anti-ONCOKINE-1 antibody	Solid tumor							FY2029 Primary Completion	JP	NCT06816108
DCC-2812 GCN2 Activator	Renal Cell Carcinoma, Urothelial Cancer, Castration-Resistant Prostate Cancer							FY2028 Primary Completion	US	NCT06966024

MOA : Mode of Action
* : Combination with OPDIVO
Estimated study completion date shown in jRCT or ClinicaiTrials.gov
F : Filed, A : Approval
※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after FY2025 Q2 in October

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The third row from the top is ONO-4685, a bispecific antibody against PD-1 and CD3, and the generic name has been decided as besufetamig, which was added in the table.

Development pipeline (Non-oncology)

As of February 2, 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
	Primary generalized tonic-clonic seizures							FY2026 Primary Completion	JP	NCT06579573
VELEXBRU Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	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
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

MOA : Mode of Action
*1 : Development right country: JP, *2 : Development rights countries: JP, KR
Estimated study completion date shown in jRCT or ClinicaiTrials.gov
F : Filed, A : Approval
EU : European countries
※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after FY2025 Q2 in October

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The next section summarizes the status of development pipeline in non-oncology.

ONO-8531, povetacicept, is a dual inhibitor of BAFF/APRIL for which we obtained the rights for development and commercialization in Japan and South Korea from Vertex in the US. The results of the Phase III study for IgA nephropathy being conducted by Vertex have been moved forward by about six months, so we are updating this page.

Development pipeline (Non-oncology)

As of February 2, 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 (jRCT)	JP	jRCT2071220081
								FY2024 Primary Completion (Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2026 Completion (jRCT)	JP	jRCT2071240056

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 Q2 in October

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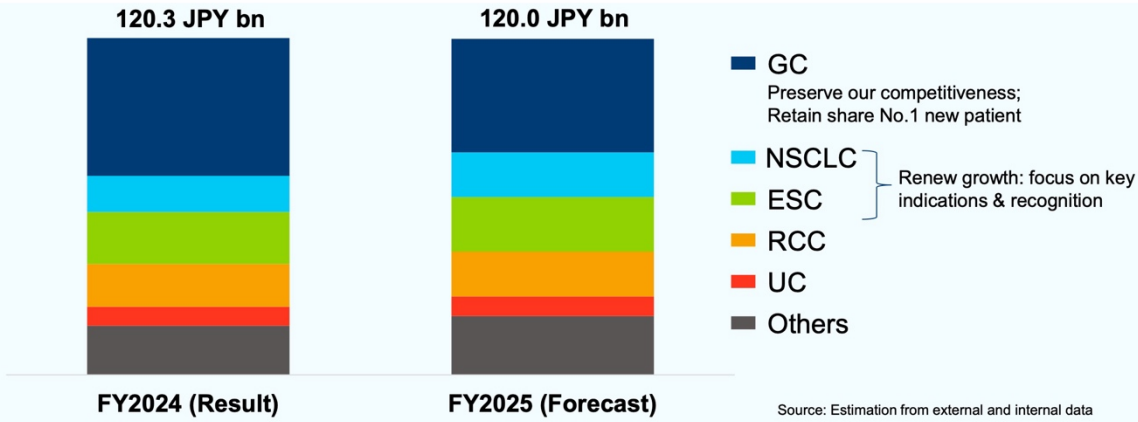
Regarding ONO-4685 in non-oncology, as I mentioned in oncology, this is only an addition due to the fact that the generic name has been decided.

Imura: Next, Kitada, Executive Director of Sales and Marketing, will explain about the trend of OPDIVO.

OPDIVO Sales Trend by Each Cancer



Source: Estimation from external and internal data

Progress Status of Key Indications (Apr–Dec 2025)

- ●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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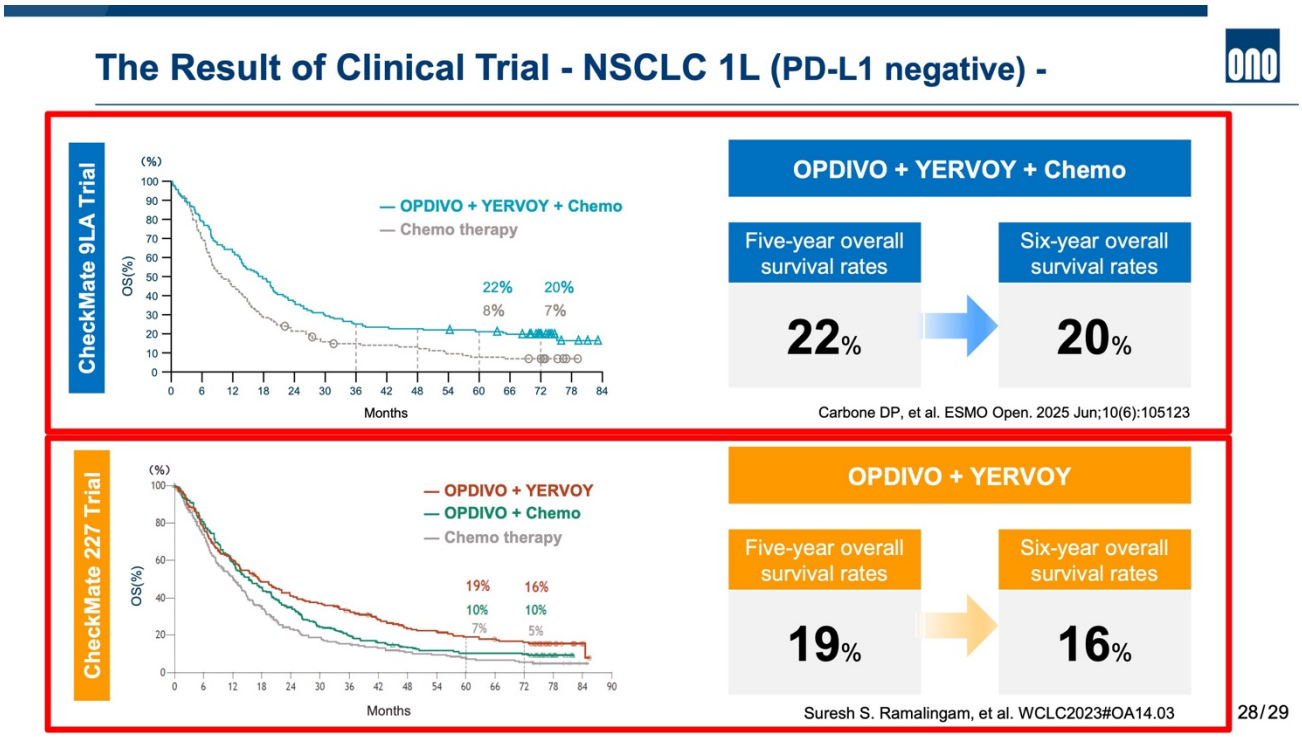
Kitada: I will explain the trend of our main product, OPDIVO.

This is the estimated sales trend of OPDIVO by each cancer. In FY2025, although competition in gastric cancer is intensifying, we aim to minimize the erosion of competition and maintain the number one share of new patients, to gain further recognition for lung cancer and esophageal cancer, which we have designated as the cancer types to focus on this fiscal year, and to achieve JPY120 billion by quickly growing the sales for hepatocellular carcinoma and colorectal cancer, for which indications were added last year.

The following is an overview of the progress of the sales by major cancer types. Although sales for gastric cancer were affected by competing products, they are progressing as the revised plan in October. Although a new competing product entered the esophageal cancer market last May, the share of new prescriptions is increasing and progressing as planned.

For lung cancer, although the share of new prescriptions in the PD-L1-negative segment is growing, it has not reached the goal, and we will strengthen our activities for further expansion.

In addition, the share of new prescriptions for hepatocellular carcinoma and colorectal cancer remained steady. Today, I would like to introduce the progress for lung cancer, hepatocellular carcinoma and colorectal cancer, which we consider important to achieve the plan.



First, let me explain about non-small cell lung cancer. The paper was published last June. In addition to the previous CheckMate-227 study, six-year follow-up data from the CheckMate-9LA study has been published in ESMO Open.

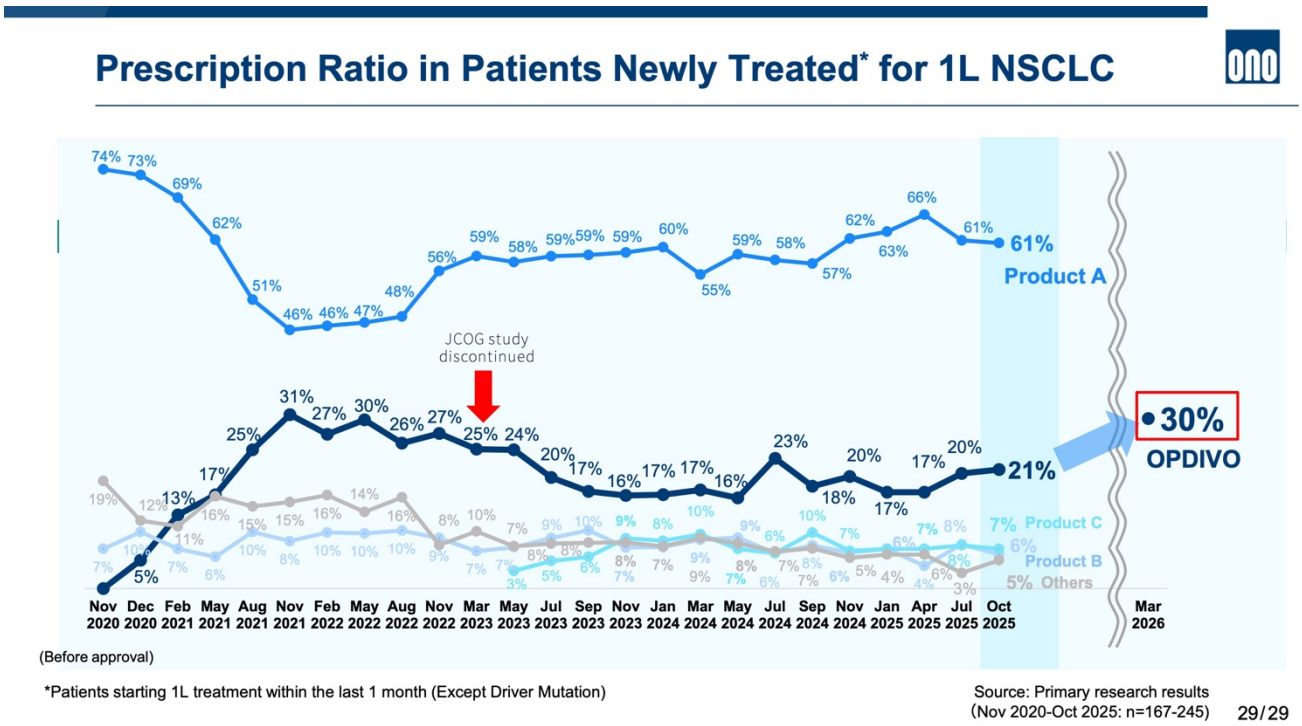
In this analysis, in a group of PD-L1-negative patients with poor prognosis on other treatment options, the combination therapy of OPDIVO and YERVOY demonstrated a 20% six-year survival rate in the overall population, indicating that the majority of patients who were alive for five years were alive as of the sixth year.

Note that the five-year survival rate obtained with other treatment options recommended by the guidelines for PD-L1-negative patients is less than 10%. We believe that this once again shows the features of OPDIVO +

YERVOY combination therapy in order to achieve long-term survival, and we have been promoting this combination therapy.

In addition, as a new topic in lung cancer, a paper was published in the prestigious Lancet Oncology in November last year, suggesting that PD-L1-negative patients with poor prognosis need to be treated with a CTLA-4 inhibitor in order to achieve long-term survival.

This paper is a meta-analysis of six clinical trials of first-line treatment for lung cancer approved in Japan. In PD-L1-negative patients, the combination regimen with a CTLA-4 inhibitor showed a higher five-year survival rate compared to the PD-1 inhibitor-only regimen. This is a positive result for our activities, and we will work to further accelerate the expansion of our reputation.



This shows the share of new prescriptions in the current PD-L1-negative group. As a result of our activities to date, our recent new prescription share has recovered to 38%. Long-term follow-up data from the CheckMate-227 and CheckMate-9LA trials, in addition to the meta-analysis results we have just presented, will further enhance the value of the combination therapy of OPDIVO and YERVOY for PD-L1-negative patients, achieving a new prescription share of more than 50% in the PD-L1 negative group.

If we can achieve more than 50% share of new prescriptions in the PD-L1-negative group mentioned earlier, we can achieve more than 30% share of new prescriptions for the overall first-line treatment of lung cancer, and we will continue to strengthen our activities.

Continuing with hepatocellular carcinoma, the target for new prescription share is set at 30% in December 2026, one year and six months from approval. As of six months after its approval, the share of new prescriptions has increased to 13%, and we expect it to make a further leap forward as a standard treatment for the first-line treatment of hepatocellular carcinoma as experience with its use continues to accumulate and the high efficacy and safety measures become more widespread.

Next is colorectal cancer. In the CheckMate-8HW trial, the OPDIVO + YERVOY group demonstrated a hazard ratio of 0.21 against progression-free survival compared to the control group receiving chemotherapy, confirming high efficacy with a 79% reduction in the risk of death or disease progression. The new prescription

share after three months of approval is 15%, and we aim to achieve 60% of the new prescription share after 18 months of approval.

We believe that the above two cancers, hepatocellular carcinoma and colorectal cancer, will contribute to OPDIVO sales in the next fiscal year and beyond.

Question & Answer

Imura: We will now take your questions. Mr. Yamaguchi of Citigroup Securities, please go ahead.

Yamaguchi : First, I would like to ask you about your progress up to Q3.

I have the impression that the business has been doing quite well even after taking into account the positive aspects of the various areas and the risks you mentioned in Q4. I would like to ask you about SG&A and R&D expenses, in particular. Even if we take out only Q3, the progress is quite restrained, and even though they will be used in Q4 for the full year, it seems to me that they are still quite restrained.

This may be repetitive, it appears that particular focus is being placed on reducing R&D expenses in preparation for the full-year financial results, but could you confirm again the progress?

Masaki Itoh : Regarding the progress of R&D expenses, (at the end of 9 months) about one-third of the total amount still remains, but the plan was originally on-track. We are by no means reducing our R&D expenditures.

Yamaguchi : I see. How about SG&A expenses? Is it the same here?

Masaki Itoh : We have been controlling some of the SG&A expenses, but we see this as almost on-track as well.

Yamaguchi : I see. Also, by the same logic, there are few number of generic products for FORXIGA while there is no AG, but it is increasing now, but it will be Q4, so it may be hard to comment, but can you see Q4 and whether it can swing up or on-track?

Kitada : Regarding FORXIGA, as you know, a generic product of FORXIGA was launched last December for type 2 diabetes indication. Until November, before the launch of generics, the volume-based growth was 10% compared to the same period of the previous year, and we believe that since December, the replacement with generics has been steadily progressing.

By area, sales in the diabetes area decreased by approximately 19% on a volume basis compared to the previous fiscal year, and sales in the chronic heart failure field decreased by approximately 2%. On the other hand, in the area of chronic kidney disease, sales are expected to increase by approximately 4% from the previous year to JPY80 billion in FY2025.

Yamaguchi : That trend, since the beginning of Q4, seems to be changing again. Since the substitution started in December. Does it feel like a continuation of the December trend?

Kitada : That's right. We expect this to have a significant impact during the January-March period.

Yamaguchi : And one more point, I don't understand that the data are included in the application of QINLOCK for the second-line treatment, but the data will be disclosed in December 2027. Does that mean that is true in the Clinical Trials.gov but you said that your company can apply at that timing?

Okamoto : You're right, as you just commented. Currently, the primary data completion of Clinical Trials.gov is a bit conservatively described. On the other hand, we are planning to apply for approval in the next fiscal year, so you may take it as such.

Yamaguchi : I see. So the top line will come out much sooner, in short, in FY2026 and FY2027.

Okamoto : You are correct in your understanding that we will apply in FY2026, which is usually about six months after the top line is issued, including our group.

Imura : Next, Mr. Wakao of J.P. Morgan Securities, please go ahead.

Wakao : First of all, can you tell us about the outlook for R&D expenses?

I understand that the outlook is just in line with the plan in the current term, and the increase is due to the start of the Phase III of ONO-4578 and ONO-2808. Looking at the next fiscal year and beyond, should we expect to see an increase in R&D expenses since development has become quite substantial now?

And as for the next fiscal year, you will see a new case of PoC in the Phase II, and if those things go well, I think you will add another Phase III, so I was wondering if it will rather increase from here. Do you have any idea about it?

Okamoto : First of all, on the point you just asked. As a premise, the trend over the past few years has been Phase III of OPDIVO, and quite a few of these have been underway. On the other hand, the OPDIVO situation is gradually coming to a close, as can be seen from the planned approval application.

We have indicated our policy of taking the PoC-achieved items directly into the Phase III trials to obtain approval. In this sense, we expect an increase in expenses for the Phase III, but this will be offset by a decrease in the OPDIVO Phase III trial, and as a result, we do not expect a significant change in the ratio of R&D expenses in monetary terms between this year and the next year.

Wakao : I understand well that it is the same as before. With that in mind, I would just like to confirm the direction of this profit for the coming year.

After all, I think that royalties and sales of QINLOCK are growing quite a bit right now. While this fiscal year's results seem likely to exceed projections, looking ahead to next quarter, if the R&D ratio remains flat, then next fiscal year should see continued growth from QINLOCK and ROMVIMZA, plus expanding royalties. Setting aside FORXIGA, which is a bit of a wild card, achieving increased profits doesn't seem particularly difficult at this point. Do you share this sense, this feeling? I know this is a bit early to mention, but I would appreciate if you have any comment on that.

Masaki Itoh : Royalties are strong so far, and that is a positive factor in the context of the still expanding sales of QINLOCK and ROMVIMZA. The foreign exchange rate for royalties is difficult to predict. If the current conditions remain unchanged, we expect royalty income to rise or fall depending on medium- and long-term foreign exchange trends in the next fiscal year and the year after that.

Wakao : I understood that basically if the exchange rate does not change, it is ok.

And just one more thing, about QINLOCK. I thought the sales in Q3 grew steadily. What do you think about it? I understand that ROMVIMZA is growing right now, or rather, it is growing because it is expected to have more and more patients. I was wondering if QINLOCK is also in a somewhat mature situation, and what is the reason for its growth in such a situation?

Kunihiko Ito : Sales of QINLOCK have increased by about 20% on a volume basis, but sales have increased by less than 10% due in part to the impact of the IRA. This is a situation in the US.

In Europe, France, Spain, Switzerland, and other countries are reimbursed in 2024, and Portugal and Belgium, although smaller countries, are reimbursed in 2025, resulting in a 30% increase in sales.

Wakao : If anything, the growth in Europe is greater now? I know there is also the exchange rate trend.

Kunihiko Ito : However, in terms of overall portions, sales in the US is higher than Europe, so we are seeing an increase in volume despite the difficult situation due to the impact of the IRA.

Wakao : Since there is also the matter of exchange rate, you are saying that we will land on an upward swing relative to your plan, is that correct?

Imura : I think you can think of it that way. We have not revised our targets, but we are in a position to say that we are doing well.

Next, Mr. Seki of UBS Securities, please go ahead.

Seki : Regarding QINLOCK's second-line treatment, the 2027 date updated in the slides this time was copied directly from the Primary Completion date on Clinical Trials.gov. However, your company actually plans to submit the application in FY2026? Is this understanding correct?

Okamoto : You're correct. First of all, regarding the progress section here, the timing of the acquisition of key data is uniformly listed as it is from Clinical Trials.gov or, in the case of domestic trials, from jRCT or other publicly available databases.

On the other hand, the QINLOCK's second-line treatment, the INSIGHT trial, as you may know if you check the published database, has already completed its recruitment, and when we took it into consideration, the application is expected to be submitted in FY2026, as I mentioned earlier.

Seki : Also, on the same slide, you mentioned that you are going to start the Phase III trial of ONO-4578 for gastric cancer, and I was wondering if you could share with us when you are going to start the trial, the scale of the trial, and maybe the R&D expenses for the next fiscal year. What is the latest situation at the moment?

Okamoto : First of all, we're sorry that we are not able to disclose the study design. On the other hand, we have already announced last year that we have obtained favorable results for Phase II, and we are aiming to start Phase III in FY2026.

Imura : Next, Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi : What has changed about the study on the QINLOCK's second-line treatment from three months ago, and why has the notation changed in this way? Please tell us why the primary endpoint completion date on Clinical Trials.gov has changed and why your company's expected filing date has changed, respectively.

Okamoto : First, the reason for updating the public database is that the registration status has been updated to reflect the not-recruiting situation. The timing of the primary endpoint completion as a result of that change is a little conservative in its description.

On the other hand, regarding the schedule and outlook for filing submissions, we have consistently disclosed this information independently of entries in public databases such as Clinical Trials.gov. Therefore, once registration was complete, we updated the timeline for the FY2026 based on the estimated timing for when the submission would be ready.

Hashiguchi : The second point is the prospect of FORXIGA. I understand that your original assumption was that the AG would come up. Since AG hasn't been released yet, I think this could be an upside factor.

You spoke earlier as if this was not necessarily the case, but I would like to know more about the gap between the actual results and the plan, and how you are currently looking at the release timing of AG for the next fiscal year and beyond.

Kitada : As you say, we see that the progress is indeed lower than expected. If the current trend continues, we estimate that about 60% of the market will be replaced by generics by the end of March.

In that case, JPY80 billion would be upswing, but since the future is unpredictable, I would like to refrain from going into details.

Regarding the next fiscal year, we have heard that AG or several generic manufacturers will release generic products of FORXIGA. Therefore, we expect that the next fiscal year will be even more affected than before.

Imura : Next, Mr. Muraoka of Morgan Stanley Secretaries, please go ahead.

Muraoka : As for the second line of QINLOCK, three months ago, when I did the IR interview, I was told at the IR level that the second line results would be available soon. However, regarding the marketability of that second line, and I would like to check this against my own notes from three months ago, this is limited to patients with gene mutation, unlike the current fourth line. So I think the additional sales potential is approximately JPY20 billion. I think it's close to JPY40 billion just now, and I took a note like that. It says that since the mutation is approximately 15%. Is there anything to add or change to this concept at this time?

Okamoto : There is no change in what you have just mentioned. Because it is a second line in the target population of having a specific genetic mutation. For example, considering that patients who are used in the second-line treatment are not used in the fourth-line, our overall assessment remains unchanged with an additional sales increase of approximately JPY20 billion.

Muraoka : One more thing, about your thinking for the next fiscal year. You mentioned sales and R&D earlier, but the question is about SG&A expenses, and I am asking if SG&A expenses will increase.

You are going to file BTK, VELEXBRU from now on, preparations for the launch will happen, and this QINLOCK has the same indication but you also need to prepare the second line. There would be a reasonable increase considering these issues, I guess. You should be conservative in your estimates at the beginning of the period, maybe. What is your thought about it?

Masaki Itoh : SG&A expenses of next year, will certainly increase where necessary, so I am wondering if we need to control that part somewhere. So, we would like to keep the growth of SG&A expenses as a total as possible.

As you say, we will make sure to pass through where necessary in connection with new activities, and this is also true for R&D, and that is how we are preparing our budget for the next fiscal year by suppressing what needs to be suppressed.

Imura : I would like to add something, and we expect that sales of FORXIGA will probably decrease in the next fiscal year, and we expect that the associated SG&A expenses will be much lower. We are planning to estimate what the total will be, but our current feeling is that it will not increase that much.

Muraoka : I see. Considering the amount by which FORXIGA will decrease, even if you add some costs in the US, will SG&A expenses decrease by an absolute amount?

Imura : At the moment, we have not been able to disclose how much the SG&A expenses are for FORXIGA alone, so I hope you will forgive us for not being able to tell you what that part of the cost will be.

Muraoka : One last thing, you mentioned that 60% will be replaced in the share of FORXIGA after this January and beyond, or at the end of March. Probably I should ask this question to generic manufactures, but do you have a sufficient supply of generics?

I think they have thought a lot about it and prepared for it, thinking that AG is there, but AG is not there now, so I wonder if the supply and demand might be in a difficult situation. From your company's point of view, is there much concern about generics in this aspect?

Kitada : As you mentioned, since the entry of generics this past December, replacement of 5 mg-tablet has been progressing. However, on the other hand, we have heard a little that the generic manufacturers are not actively working here for 10 mg-tablet.

Therefore, we expect that AG and several more generic manufacturers will enter the market in the next fiscal year, which will accelerate the switchover.

Imura : Next, Mr. Ueda of Goldman Sachs Secretaries, please go ahead.

Ueda : Regarding the trends in your main products, I would like to know your current assessment of OPDIVO's performance relative to the plan in the domestic market.

I have the impression that it is low considering the seasonality of Q3 and the end of the year, but I think you mentioned earlier that you are struggling a bit in the area of lung cancer. If you have any comments on how you are evaluating the results by indication and the outlook, please let us know.

Takahashi : We believe that gastric cancer, which is the most common type of cancer, has the greatest impact on our sales. Currently, the share of new prescriptions for gastric cancer is still struggling, and we believe that it is up to us to rewind this area.

On the other hand, we are struggling for the share of new prescriptions, our countermeasures against competing products have progressed to a certain extent, and we believe we can achieve the plan if we can make a comeback in the future. As for non-small cell lung cancer, as Kitada mentioned earlier.

In addition, despite the entry of new products to the market, the prescription share for new esophageal cancer patients has continued to grow. Our strength of having two combination regimens with chemo or CTLA-4, is becoming more widespread. We believe that we can still make progress toward the 60% market share that we have planned.

If we can make a comeback with these major three cancer types, we expect to be able to land the project as planned. Does this answer your question?

Ueda : In that sense, is my understanding correct that you are still on track to achieve the plan for the current fiscal year?

Takahashi : It is in a tough situation, we are doing what we need to do and are aiming to achieve sales JPY120 billion.

Ueda : Secondly, I would like to know about the progress in royalties and other areas.

I think this quarter, even if you exclude a little bit OPDIVO and KEYTRUDA related, I think there are a little bit more, but I'm just wondering if there were any one-time factors. What is your assessment of the progress so far in terms of the planned figures, excluding exchange rates?

Masaki Itoh : It is not that there was anything remarkable, or non-traditional in the royalties. As for progress, yes, as I mentioned, we have been affected by the exchange rate of JPY145, which is an upside of about JPY5 compared to the annual plan. I mentioned that the exchange rate was minus JPY0.3 billion compared to the previous year, but compared to the plan, it was positive. I would also like to mention that the volume base has also exceeded the plan.

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

Wada : Looking at a development product, Phase I of ONO-4578, expected to acquire main data in FY2026. I suppose the Phase I data for breast and lung cancers will be completed around April and September, respectively. I was wondering if you could tell me what this data will be and if there are any plans to release it or something, and what your policy is?

Okamoto : First, this is the Phase I study data, so this primary data is basically about tolerability, safety, plus preliminary efficacy. Therefore, we usually don't schedule any press release for the Phase I. We expect no particular delay in obtaining the results.

Wada : If the results are good, you will proceed directly to Phase II, which will be announced at the financial results meeting like today, right?

Okamoto : Yes. When we proceed to Phase II based on the results of Phase I, we have traditionally made such explanations in our financial results announcements.

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

Matsubara : Just one question. About OPDIVO for gastric cancer. I believe at ASCO GI, there was a report that the combination of VYLOY and OPDIVO increased PFS. Is there a possibility that in the future this VYLOY will not be a competitor, but a synergistic effect that will lead to more prescriptions of OPDIVO?

Okamoto : Since you are talking about the future, I answers your question. First of all, the data you just pointed out, I am actually looking at the data for the OPDIVO combination in Phase II.

On the other hand, as you are likely aware, Phase III trials are currently underway for combination therapy with pembrolizumab. In that sense, we recognize that this will create a competitive relationship for the current OPDIVO, or rather for the future development, that is, ONO-4578 which is waiting for the Phase III trials.

As we have said for some time, we plan to publish data on ONO-4578 at the ASCO meeting in 2026, but at this time, we would appreciate your understanding that we are not able to discuss the results of the detailed analysis.

Imura : Finally, I would like to introduce a few of our upcoming events for institutional investors and business analysts. We are planning to hold an online sustainability Day on March 24 as one of our events for this year. We are planning to share with you the challenge of becoming a global specialty pharma from a sustainable perspective.

In addition, we are planning to hold an R&D Day in a hybrid format on June 8. The venue for this meeting will be our Minase Research institute. The content will include detailed data on ONO-4578 and ONO-2808, which were also discussed today.

This concludes our financial results meeting for Q3 of the fiscal year ending March 31, 2026. Thank you very much for your participation today for long hours.