



ONO PHARMACEUTICAL CO., LTD.

FY2026 Q1 Financial Result Earnings Call

July 31, 2026

[Number of Speakers]

5

Masaki Itoh

Corporate Executive Officer / Chief Officer of
Finance and Accounting Division

Tatsuya Okamoto

Corporate Officer, Executive Vice President,
Clinical Development

Hirokazu Kitada

Corporate Officer, Executive Vice President,
Sales and Marketing

Kunihiko Ito

Corporate Officer, Executive Vice President,
Global Business

Ryuta Imura

Vice President, Corporate Communications

Presentation

Imura: Thank you very much for your participation to the ONO PHARMACEUTICAL CO., LTD. FY2026 Q1 financial results meeting today.

First, let me introduce today's attendees. Masaki Itoh, Corporate Executive Officer and Chief Officer of Finance and Accounting Division; Okamoto, Corporate Officer, Executive Vice President, Clinical Development; Kitada, Corporate Officer, Executive Vice President, Sales and Marketing; and Kunihiro Ito, Corporate Officer, Executive Vice President, Global Business.

Agenda



FY2026Q1 Financial Results (14:00-14:15)

Masaki Itoh

Corporate Executive Officer /
Chief Officer of Finance & Accounting Division

Development Pipeline Progress Status (14:15-14:30)

Tatsuya Okamoto

Corporate Officer /
Executive Vice President, Clinical Development

Q&A Session (14:30-15:00)

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First of all, Itoh, Chief Officer of Finance and Accounting, will present an overview of the financial results for Q1 of FY2026, followed by an update on the progress of the development pipeline by Okamoto, Executive Vice President, Clinical Development. After our presentation, there will be time for questions and answers, and the materials are already posted on our website for your reference.

Itoh will now explain the overview of the financial results for Q1 of FY2026.

Main Points of the Financial Results (Core Basis)



FY2026Q1 results showed lower revenue but higher profit.

FY2026Q1 Sales Revenue	<u>Revenue decreased by 11.4 JPY billion (8.9%) YoY to 116.2 JPY billion</u> Japan: Revenue declined due to the termination of the FORXIGA co-promotion agreement. Overseas: Qinlock sales increased by 2.8 JPY bn YoY to 11.7 JPY bn, and Romvimza sales rose by 3.1 JPY bn YoY to 4.1 JPY bn. Overseas royalty income from Opdivo and other products also continued to grow steadily.
FY2026Q1 Core Profit for the Period	<u>Core operating profit increased by 7.1 JPY billion (+22.5%) YoY to 38.7 JPY billion, and core profit for the period rose by 5.4 JPY billion (+21.9%) YoY to 30.2 JPY billion.</u> Profit increased due to the absence of FORXIGA-related cost of sales and co-promotion expenses, as well as lower R&D expenses reflecting the reversal of one-time costs incurred in the prior-year period.
FY2026 Financial Forecast	<u>No Update from the recent forecast. Revenue and Profit are expected to decline YoY.</u> 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 for future growth. Core operating profit is expected to be 124.0 JPY bn (-9.6% YoY) due to proactive investments and declining revenue

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Itoh: I would now like to begin with an overview of our financial results for Q1 of the current fiscal year. Please note that the presentation is based on our core financial results.

First, here is the overview. Revenue for the quarter decreased by JPY11.4 billion or 8.9% YoY to JPY116.2 billion.

In Japan, revenue declined mainly due to the termination of the co-promotion agreement with AstraZeneca for FORXIGA at the end of the previous fiscal year, which was March 31 of this year.

Overseas, however, QINLOCK sales increased by JPY2.8 billion YoY to JPY11.7 billion, while ROMVIMZA sales increased by JPY3.1 billion YoY to JPY4.1 billion. Royalty income related to OPDIVO and other products also continued to grow steadily.

Turning next to core profit, the absence of cost of sales and co-promotion expenses related to FORXIGA, together with lower R&D expenses due to the absence of one-time costs recorded in the prior year period, contributed to increases in both core operating profit and core quarterly profit. Core operating profit increased by JPY7.1 billion or 22.5% YoY to JPY38.7 billion. Core quarterly profit increased by JPY5.4 billion or 21.9%, YoY to JPY30.2 billion.

Accordingly, our Q1 results on a core basis showed lower revenue and higher profit.

There is no change to our full-year financial guidance for FY2026. We continue to forecast lower revenue and lower profit for the full year compared with the previous fiscal year.

FY2026Q1 : Sales Revenue



Revenue
116.2 JPY bn
 YoY -11.4 JPY bn
 (-8.9%)



Goods and Products Sales
67.9 JPY bn
 YoY -19.8 JPY bn (-22.6%)



Royalty and Others
48.2 JPY bn
 YoY +8.5 JPY bn (+21.2%)

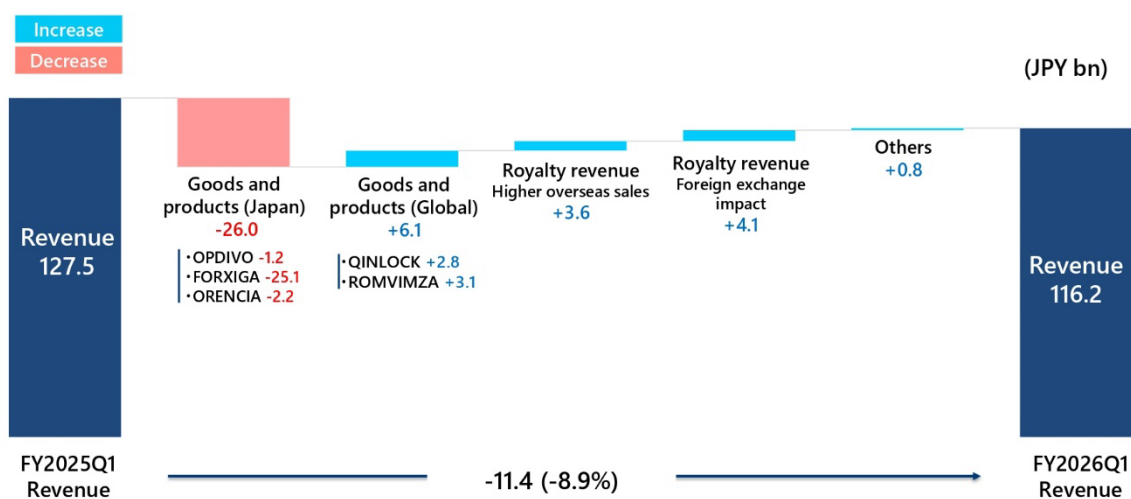
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Product sales decreased by JPY19.8 billion YoY to JPY67.9 billion. Royalties and other revenue increased by JPY8.5 billion YoY to JPY48.2 billion. As a result, total revenue decreased by JPY11.4 billion YoY to JPY116.2 billion.

FY2026Q1 : Sales Revenue (Breakdown)



Revenue declined by 11.4 JPY billion to 116.2 JPY billion YoY, primarily due to the loss of FORXIGA sales after the co-promotion agreement terminated, despite growth in Opdivo royalties and Deciphera-related revenue.



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I will explain the major drivers behind the YoY change in revenue.

Domestic product sales decreased by JPY26 billion overall, mainly due to lower sales of OPDIVO Intravenous Infusion resulting from intensifying competition, loss of FORXIGA tablet sales following the termination of the

co-promotion agreement with AstraZeneca, and lower ORENCIA for subcutaneous injection sales as a result of NHI price revisions.

On the other hand, overseas revenue increased. QINLOCK increased by JPY2.8 billion, and ROMVIMZA increased by JPY3.1 billion. In addition, royalty revenue from OPDIVO, Keytruda, and other products, increased by JPY7.7 billion, partly reflecting the weaker yen, in addition to the sales increase.

Although overseas sales and royalty income remained strong, they could not fully offset the significant decline in domestic sales, and total revenue decreased by JPY11.4 billion YoY to JPY116.2 billion.

FY2026Q1 : Sales Revenue by Product / Japan



JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	<u>116.2</u>	-11.4	-8.9%	455.0
Goods and products	87.8	<u>67.9</u>	-19.8	-22.6%	270.0
Royalty and others	39.8	<u>48.2</u>	8.5	21.2%	185.0
Goods and Products (Japan)					
			Change	Change(%)	FY2026 Forecast*
OPDIVO Intravenous Infusion	29.4	<u>28.2</u>	-1.2	-4.1%	120.0
ORENCIA for Subcutaneous Injection	7.0	<u>4.8</u>	-2.2	-31.6%	19.0
VELEXBRU Tablets	3.0	<u>3.2</u>	0.1	4.6%	12.0
PARSABIV Intravenous Injection	2.2	<u>2.4</u>	0.2	10.0%	10.0
ONGENTYS Tablets	2.3	<u>2.6</u>	0.4	16.9%	10.0
GLACTIV Tablets	3.6	<u>3.1</u>	-0.4	-11.8%	9.5
BRAFTOVI Capsules	1.3	<u>2.0</u>	0.7	51.1%	8.5
KYPROLIS for Intravenous Infusion	2.0	<u>1.8</u>	-0.2	-12.0%	7.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, 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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Turning to domestic product sales. Sales of OPDIVO Intravenous Infusion, an antineoplastic drug, declined by JPY1.2 billion or 4.1% YoY to JPY28.2 billion, mainly due to intensifying competition.

FORXIGA, a treatment for diabetes, chronic heart failure, and chronic kidney disease, generated sales of JPY25.1 billion in the prior year quarter. However, no sales were recorded this year following the termination of the co-promotion agreement.

Among our other key products, ONGENTYS tablets, a treatment for Parkinson's disease, benefited from continued market penetration, with sales increasing by JPY0.4 billion or 16.9% YoY to JPY2.6 billion. PARSABIV, a treatment for secondary hyperparathyroidism in patients undergoing hemodialysis, recorded sales of JPY2.4 billion, up JPY0.2 billion or 10% YoY, reflecting broader adoption of guideline-based CKD-MBD management. BRAFTOVI capsules, an antineoplastic agent, recorded sales of JPY2 billion, up JPY0.7 billion or 51.1% YoY, driven by expanded use in first-line treatment of colorectal cancer.

On the other hand, ORENCIA SC, a treatment for rheumatoid arthritis, was significantly affected by NHI price reductions, with sales decreasing by JPY2.2 billion or 31.6% YoY to JPY4.8 billion.

FY2026Q1 : Sales Revenue by Product / Overseas / Royalty

JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	<u>116.2</u>	-11.4	-8.9%	455.0
Goods and products	87.8	<u>67.9</u>	-19.8	-22.6%	270.0
Royalty and others	39.8	<u>48.2</u>	8.5	21.2%	185.0

Goods and Products (Overseas)	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
OPDIVO®	3.3	<u>3.5</u>	0.2	7.3%	13.0
QINLOCK®	8.9	<u>11.7</u>	2.8	31.5%	43.0
ROMVIMZA®	1.1	<u>4.1</u>	3.1	289.3%	19.0

Royalty and others	FY2025Q1	FY2026Q1	YoY		
			Change	Change(%)	
OPDIVO®	29.2	<u>34.7</u>	5.5	18.9%	
KEYTRUDA®	6.5	<u>7.9</u>	1.3	20.5%	

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, 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 me explain overseas sales.

Sales of OPDIVO in South Korea and Taiwan totaled JPY3.5 billion, an increase of JPY0.2 billion YoY.

QINLOCK, a treatment for gastrointestinal stromal tumors, increased by JPY2.8 billion YoY to JPY11.7 billion, driven by continued market penetration. Performance remains on track toward our full-year revenue forecast of JPY43 billion.

ROMVIMZA, a treatment for tenosynovial giant cell tumor, TGCT, generated sales of JPY4.1 billion, an increase of JPY3.1 billion from the prior year. Growth was supported not only by continued treatment of existing patients, but also by expansion into additional commercial territories, including Europe.

Royalty revenue from OPDIVO increased by JPY5.5 billion YoY to JPY34.7 billion. Royalty revenue from Keytruda increased by JPY1.3 billion to JPY7.9 billion.

FY2026Q1 : Core Operating Profit



Core Operating Profit
38.7 JPY bn
 YoY +7.1 JPY bn
 (+22.5%)



Revenue 116.2 JPY bn

YoY -11.4 JPY bn (-8.9%)



Cost of Sales 20.6 JPY bn

YoY -7.5 JPY bn (-26.5%)



R&D Expense 32.4 JPY bn

YoY -3.8 JPY bn (-10.6%)



SG&A Expense 23.9 JPY bn

YoY -7.2 JPY bn (-23.1%)

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Let me now turn to core operating profit.

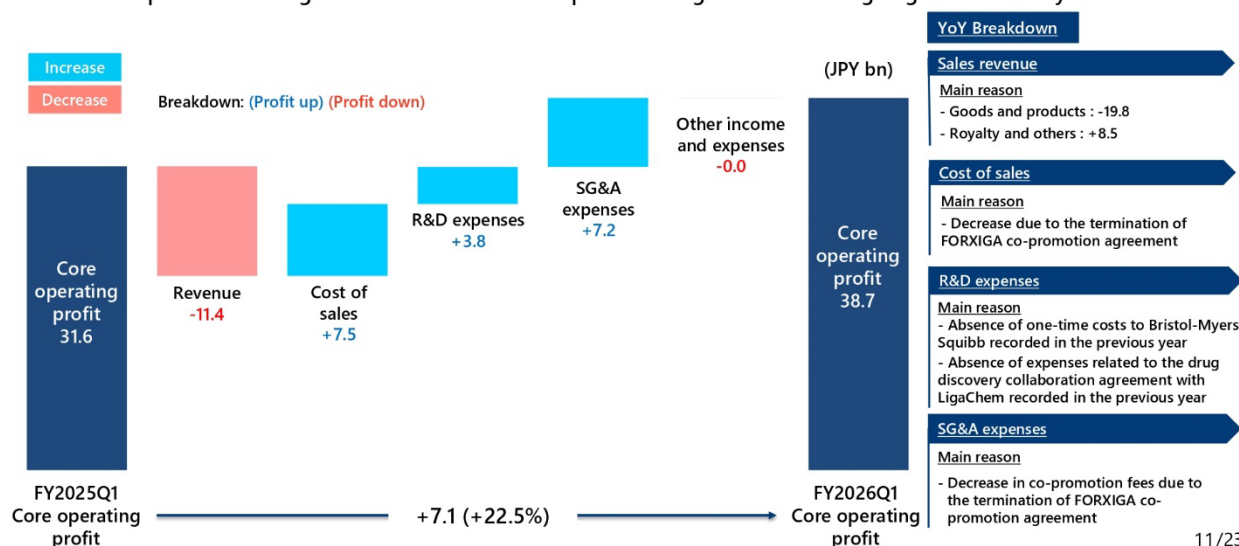
Core operating profit increased by JPY7.1 billion or 22.5% YoY to JPY38.7 billion.

Although revenue declined during the quarter, the decline was more than offset by lower cost of sales, lower R&D expenses, and lower SG&A expenses, resulting in higher profits.

FY2026Q1 : Core Operating Profit (Breakdown)



Core operating profit increased by 7.1 JPY billion YoY to 38.7 JPY billion, driven by the absence of FORXIGA sales-related expenses following the termination of the co-promotion agreement and ongoing cost-efficiency initiatives.



11/23

About the factors in each item of the core operating profit, cost of sales decreased by JPY7.5 billion, primarily reflecting lower sales including the expiration of the FORXIGA tablets co-promotion agreement. R&D

expenses decreased by JPY3.8 billion, mainly due to the absence of expenses related to our drug discovery collaboration agreement with LigaChem Biosciences and development milestone expenses paid to Bristol Myers Squibb that were recorded in the prior year period. SG&A expenses decreased by JPY7.2 billion, reflecting lower co-promotion expenses related to FORXIGA tablets.

As a result, the reduction in expenses more than offset the decline in revenue, leading to an increase in core operating profit of JPY7.1 billion.

FY2026Q1 : Financial Overview (Core)



JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	<u>116.2</u>	-11.4	-8.9%	455.0
Cost of sales	28.1	<u>20.6</u>	-7.5	-26.5%	84.0
R&D expenses	36.3	<u>32.4</u>	-3.8	-10.6%	143.0
SG&A expenses	31.1	<u>23.9</u>	-7.2	-23.1%	101.0
Core operating profit	31.6	<u>38.7</u>	7.1	22.5%	124.0
Core profit before tax	32.2	<u>39.3</u>	7.1	21.9%	124.0
Core profit for the period (attributable to owners of the Company)	24.8	<u>30.2</u>	5.4	21.9%	93.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

YoY Breakdown

Cost of sales -7.5 JPY bn (-26.5%)

COGS ratio : 17.8%

Main reason

- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -3.8 JPY bn (-10.6%)

R&D ratio : 27.9%

Main reason

- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -7.2 JPY bn (-23.1%)

SG&A ratio : 20.6%

Main reason

- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Core operating profit ratio : 33.3%

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Let me briefly summarize our core consolidated results.

To reiterate, revenue decreased by JPY11.4 billion or 8.9% to JPY116.2 billion. Cost of sales decreased by JPY7.5 billion or 26.5% to JPY20.6 billion. R&D expenses decreased by JPY3.8 billion or 10.6% to JPY32.4 billion. SG&A expenses decreased by JPY7.2 billion or 23.1% to JPY23.9 billion. As a result, core operating profit increased by JPY7.1 billion or 22.5% to JPY38.7 billion, and core quarterly profit increased by JPY5.4 billion or 21.9% to JPY30.2 billion.

(Ref) FY2026Q1 : Financial Overview (Full Basis)



JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	116.2	-11.4	-8.9%	455.0
Cost of sales	37.0	28.7	-8.3	-22.5%	114.0
R&D expenses	36.3	32.4	-3.8	-10.6%	143.0
SG&A expenses	31.1	23.9	-7.2	-23.1%	101.0
Operating profit	22.0	30.7	8.7	39.4%	94.0
Profit before tax	22.6	31.3	8.6	38.0%	94.0
Profit for the period (attributable to owners of the Company)	17.7	24.2	6.5	36.7%	71.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

YoY Breakdown

Cost of sales -8.3JPY bn (-22.5%)

COGS ratio : 24.7%

Main reason

- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -3.8 JPY bn (-10.6%)

R&D ratio : 27.9%

Main reason

- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -7.2 JPY bn (-23.1%)

SG&A ratio : 20.6%

Main reason

- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Operating profit ratio : 26.4%

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This is for your reference. These are our IFRS full-basis consolidated results.

Revenue was unchanged from the core basis at JPY116.2 billion. Operating profit increased by JPY8.7 billion or 39.4% YoY to JPY30.7 billion. Quarterly profit increased by JPY6.5 billion or 36.7% to JPY24.2 billion. On a full basis as well, the quarter showed lower revenue and higher profit.

(Ref) FY2026Q1 : Reconciliation from Full to Core Basis



JPY bn	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Revenue	116.2					116.2
Cost of sales	28.7	-6.0		-2.0	-8.0	20.6
Gross profit	87.5	+6.0	—	+2.0	+8.0	95.5
R&D expenses	32.4				—	32.4
SG&A expenses	23.9				—	23.9
Other income /expenses (- Exp)	-0.5				—	-0.5
Operating profit	30.7	+6.0	—	+2.0	+8.0	38.7
Operating profit ratio	26.4%				—	33.3%
Finance income / Finance cost (- Exp)	0.6				—	0.6
Profit before tax	31.3	+6.0	—	+2.0	+8.0	39.3
Income tax expense	7.1	+1.5		+0.5	+2.0	9.0
Profit for the period	24.2	+4.5	—	+1.5	+6.1	30.2

Breakdown

Cost of sales

Main reason

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

R&D expenses

Main reason

- None

SG&A expenses and Other income&expense

Main reason

- None

*PPA : Purchase Price Allocation

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This slide presents the reconciliation from full-basis to core-basis results.

The principal adjustment items are included within cost of sales, namely amortization of intangible assets associated with licensing transactions totaling JPY6 billion, as well as JPY2 billion related to inventory step-up expenses arising from purchase price allocation at the time of the acquisition.

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



There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

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 reason - 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.

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Let me now turn to our full-year guidance on a core basis.

As for the core-based forecast, there has been no change to the guidance announced on May 8, 2026.

We continue to expect full-year revenue of JPY455 billion, representing a decrease of 11.8% from the previous fiscal year, primarily reflecting the termination of the FORXIGA tablets co-promotion agreement.

On the expense side, we will continue investing in R&D at approximately 30% of revenue in support of future growth.

We will strive to improve efficiency in other expenses. However, reflecting continued strategic investment and lower revenue, we forecast core operating profit of JPY124 billion, down 9.6% from the previous fiscal year. We also forecast core profit of JPY93 billion, down 10.1% from the previous fiscal year.

Although we expect a decline in profit, the operating profit margin is projected to improve, from 26.6% in the previous fiscal year to 27.3%.

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



There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

JPY bn	FY2025 Actual	FY2026 Forecast	Change	Change (%)	Breakdown
Revenue	515.8	<u>455.0</u>	-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	<u>114.0</u>	-27.7	-19.6%	
R&D expenses	147.0	<u>143.0</u>	-4.0	-2.7%	R&D expenses -4.0 JPY bn (-2.7%) R&D ratio: 31.4% Main reason - 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	<u>101.0</u>	-22.7	-18.3%	
Operating profit	92.2	<u>94.0</u>	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	<u>94.0</u>	1.3	1.5%	
Income tax expense	22.7	<u>23.0</u>	0.3	1.1%	
Profit for the year (attributable to owners of the Company)	69.8	<u>71.0</u>	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.

17/23

Finally, this is about the performance forecast on a full basis.

There are no changes to this forecast either from the earnings forecast announced on May 8. On a full basis, both operating profit and profit are expected to increase YoY. That's all from me. Thank you very much.

Imura: That is all for the summary of the financial results. Next, Okamoto, Executive Vice President, Clinical Development, will continue with an explanation of the progress of the development pipeline.

Launch Projections - POC Pipeline-



As of July 31, 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 VELEXBRU R/R SCNSL	OPDIVO Unresectable anaplastic Thyroid Cancer 1L OPDIVO HCC Adjuvant ONO-2017 cenobamate Primary generalized tonic-clonic seizures	ripretinib (QINLOCK) GIST 2L VELEXBRU Pemphigus 2L 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

New additions to this earnings call

19/23

Okamoto: I will use the development pipeline progress status materials available on our website and focus mainly on updates since our previous earnings presentation on May 8.

First, let me walk you through our upcoming approval projections as shown here.

In June of this year, we submitted two regulatory applications in Japan, and these have now been reflected in the updated pipeline and added to the section enclosed in the red box.

First, for VELEXBRU, we filed an application in Japan for the indication of central nervous system involvement of malignant lymphoma in patients with inadequate response to existing therapies or in whom such therapies are not appropriate. This filing is based on the results of an investigator-initiated Phase 2 study led by the National Cancer Center Hospital.

VELEXBRU is already approved for primary central nervous system lymphoma (PCNSL), which is defined as extranodal lymphoma confined to the central nervous system with no other lesions observed outside the central nervous system at diagnosis. In contrast, the indication under filing is secondary central nervous system lymphoma (SCNSL), a condition in which lymphoma originating in other organs infiltrates the central nervous system.

VELEXBRU was granted orphan drug designation in May of this year and is eligible for priority review. Accordingly, we expect to obtain approval within the current fiscal year. The annual incidence of SCNSL in Japan is estimated to be approximately 2,800 patients.

The results of this investigator-initiated trial were presented at the European Hematology Association Congress, EHA2026, in June of this year.

Next is OPDIVO. We filed a regulatory application in Japan for the indication of unresectable anaplastic thyroid cancer. This filing is based on the results of an investigator-initiated Phase 2 trial led by the National Cancer Center Hospital East.

This will be a combination therapy with lenvatinib, one of the current standard treatment options. Anaplastic thyroid cancer is also a rare disease. Estimates of the patient population in Japan vary depending on the source, but the number is believed to be up to approximately 1,640 patients.

The indication also received orphan drug designation in May of this year. However, it will undergo standard review, unlike VELEXBRU, and we therefore expect approval around May 2027.

The results of this investigator-initiated trial were also presented at ASCO in June of this year.

I will come back later to provide an overview of the two investigator-initiated trials, including the study results, disease epidemiology, and treatment landscape.

Next, in the middle, regarding ONO-2017, cenobamate, for primary generalized tonic-clonic seizures, we had previously projected approval in FY2028. However, patient enrollment progressed ahead of schedule, and we have therefore moved our projected approval timeline forward by one year to FY2027.

There are no changes from the previous update. That concludes the review of our approval achievements and projections.

Development pipeline (Oncology) ①

As of July 31, 2026



Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-4059 (tirabrutinib) BTK inhibitor	PCNSL 1L, ≥2L							2026.2 US : Filed (Part A)	US	NCT04947319
	SCNSL							2026.6 JP : Filed	JP	JRCT2031220529
	PCNSL ≥2L							FY2027 Primary Completion	US	NCT07104032
QINLOCK DCC-2618 (ripretinib) KIT inhibitor	GIST 2L KIT Exon 11+17/18							FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
	GIST 4L							FY2027 Primary Completion	JP	NCT07618377
ONO-0530 (sapabursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia vera (PV)							FY2028 Primary Completion	JP, US, EU, KR, TW and others	NCT07429266
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
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*							FY2031 Primary Completion	JP, US, EU and others*	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced malignancies (with ripretinib)							FY2026 Primary Completion	US, EU	NCT05957367

PCNSL: Primary central nervous system lymphoma
SCNSL: Relapsed or refractory secondary central nervous system lymphoma
GIST: Gastrointestinal Stromal Tumor

MOA: Mode of Action
*: Combination with OPDIVO

*1: 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 2025 financial result in May 2026

20/23

Next, I will review progress in our oncology development pipeline.

Starting with VELEXBRU in the second row, as I mentioned earlier, we filed a regulatory application in Japan in June.

Next, for QINLOCK, we submitted a regulatory application in Japan in March of this year. In parallel, a domestic Phase 1 study has been initiated, and trial information has been disclosed in a public database, which is reflected in this update.

In addition, ONO-7427, our anti-CCR8 antibody, being jointly developed with Bristol Myers Squibb, has been updated. Due to the addition of combination cohorts and other changes, Bristol Myers Squibb has updated the timing of the primary data readout.

Development pipeline (Oncology) ②



As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
DCC-3009 Pan-KIT inhibitor	GIST							FY2028 Primary Completion	US	NCT06630234
ONO-4685 (besufetamid) PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2027 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	NCT06960024
ONO-7429 Anti-L1CAM ADC	Solid tumor							FY2028 Primary Completion	JP	Under registration

GIST: Gastrointestinal Stromal Tumor

* : Combination with OPDIVO

Estimated study completion date shown in JRCT or ClinicalTrials.gov

F : Filed, A : Approval

Red: Update after announcement of FY 2025 financial result in May 2026

21/23

Continuing with the oncology pipeline, there have been no changes since our previous update.

Development pipeline (Non-oncology) ①



As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
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	NCT07594158
	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
	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
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial giant cell tumor (TGCT)							—	JP	Under registration
	Chronic graft versus host disease (cGVHD)							FY2029 Primary Completion	US	NCT06619561
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
EU : European countries

Red: Update after announcement of FY 2025 financial result in May 2026

22/23

Next, let me turn to progress in our non-oncology pipeline.

ONO-2017, cenobamate, has entered a domestic Phase 3 study in pediatric patients with focal onset seizures. Trial information has now been posted in a public database, and we have updated the pipeline accordingly.

We have also added ROMVIMZA or vimseltinib following the initiation of a Phase 2 study in Japan for tenosynovial giant cell tumor or TGCT.

Development pipeline (Non-oncology) ②



As of July 31, 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 (besufetamid) 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 disease							FY2027 Completion	JP	JRCT2071250147
ONO-3310	Kidney disease							FY2027 Completion	JP	JRCT2071260026
ONO-6414	Autoimmune disease							FY2027 Primary Completion	US	Under registration
ONO-3401	Neurological disease							FY2027 Completion	JP	JRCT2071260067

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 2025 financial result in May 2026

23/23

For this section, we have updated the pipeline to reflect disclosure of trial information for the domestic Phase 1 study of ONO-3310, which had already been initiated.

In addition, ONO-3401, at the bottom, has newly entered clinical development and has therefore been added. The target therapeutic area is somewhat broad, not specifying a particular disease, but we are advancing our programs for neurological diseases into clinical development.

As for ONO-1110, proof-of-concept studies are currently ongoing in Japan across five different indications. Because the timelines for obtaining results from these studies are very close to one another, and because of similarities among the target indications while we are currently conducting POC trials for three pain disorders and two psychiatric conditions, we plan to make our go/no-go decision, in other words, determine whether proof-of-concept has been established, only after the results from all five studies become available.

Therefore, we appreciate your patience and ask that you wait a little longer for further updates. Thank you very much.

The pipeline update concludes here. I would now like to provide an overview of the investigator-initiated trials that served as the basis for the two regulatory filings submitted in Japan in June of this year, VELEXBRU for secondary central nervous system lymphoma and OPDIVO for anaplastic thyroid cancer.

Let me begin with VELEXBRU.

The patients enrolled in the investigator-initiated trial that served as the basis for the filing were diagnosed with secondary central nervous system lymphoma (SCNSL).

SCNSL refers to a condition in which systemic malignant lymphoma infiltrates the central nervous system, either at initial diagnosis or at relapse. Because it is a rare disease, it is difficult to provide a precise patient count. Our estimate covers a relatively broad range, but we believe there are approximately 2,000 to 12,000 patients in Japan. SCNSL is associated with an extremely poor prognosis. The median overall survival has been reported to be less than approximately six months, which is very severe.

VELEXBRU is already approved for primary central nervous system lymphoma (PCNSL). PCNSL is confined to the central nervous system at diagnosis. In contrast, patients with SCNSL have disease outside the central nervous system at initial presentation. At relapses, some patients may have disease only in the central nervous system, while others may also have disease outside the central nervous system.

One way to think about SCNSL is as the lymphoma equivalent of brain metastases of lung cancer or gastric cancer in solid tumors. In other words, I imagine you might be thinking of cases where the primary tumor is in the lung or stomach and the metastases have spread to the brain or where the primary tumor was removed, and then recurred in the brain. I think it would be helpful if you could visualize this as a condition that occurs in lymphoma.

Drug treatment for SCNSL typically begins with regimens containing high-dose methotrexate, like PCNSL. However, there is no recommended treatment for patients who are ineligible for such therapy or who relapse after receiving it. Median overall survival following a relapse after completion of the high-dose methotrexate therapy in these patients has been reported to range from 0.9 to 4.9 months.

Against this background, an investigator-initiated trial was conducted by the National Cancer Center Hospital and several collaborating institutions in patients who were refractory or intolerant to high-dose methotrexate-containing treatment.

The results were presented with posters at the European Hematology Association Congress in June of this year.

This trial, was conducted in patients with no disease outside the central nervous system.

The primary endpoint was objective response rate assessed by independent central review.

The primary endpoint, objective response rate assessed by central review, was 66.7%. Importantly, the lower bound of the 95% confidence interval exceeded the pre-specified threshold of 10% and the trial is considered successful, and the primary endpoint has been met.

Median progression-free survival and overall survival were 2.7 months and 6.7 months, respectively.

This slide summarizes the safety findings. The investigators concluded that the toxicity profile of VELEXBRU in patients with SCNSL was manageable.

As I mentioned earlier, while regimens containing high-dose methotrexate for SCNSL in Japan, there has been no recommended treatment option for patients who become refractory or intolerant to high-dose methotrexate-based therapy. Therefore, assuming a successful review and approval, we believe VELEXBRU could provide an important new treatment option for these patients.

Next, I would like to explain the application of OPDIVO for the indication of anaplastic thyroid cancer.

The investigator-initiated trial supporting this application was conducted in patients with unresectable anaplastic thyroid cancer. Anaplastic thyroid cancer is a rare malignancy, with an estimated patient population in Japan of approximately 170 to 1,640 patients. It is also one of the most aggressive cancers with a particularly poor prognosis, with a reported one-year survival rate of only 5% to 20%.

For unresectable anaplastic thyroid cancer, patients with BRAF V600E mutations, which account for approximately 40% of cases, may receive targeted treatment with a BRAF inhibitor, plus a MEK inhibitor.

For BRAF V600E-positive cases, our products BRAFTOVI and MEKTOVI are already contributing to patient care in this setting.

On the other hand, for patients without BRAF mutations or as is characteristic of this type of cancer, for patients whose disease progresses so rapidly that genomic testing results are not yet available, regarding the presence or absence of genetic mutations or which specific mutations are present, treatment typically begins with lenvatinib, a multikinase inhibitor.

However, the reported response rate for lenvatinib monotherapy is 23.5%, and there remains a need for more effective treatment options.

Against this background, an investigator-initiated trial was conducted by the National Cancer Center Hospital East and several collaborating institutions.

The results were presented orally at ASCO in June.

In this investigator-initiated trial, the efficacy and safety of adding OPDIVO to standard lenvatinib treatment were evaluated. The primary endpoint was objective response rate assessed by independent central review.

The primary endpoint, objective response rate assessed by central review, was 47.6%. The lower bound of the confidence interval was 33.4%, exceeding the pre-specified threshold of 23.5%, which corresponded to the reported response rate for lenvatinib monotherapy.

Median duration of response was 12.91 months, which is very long. We believe this reflects one of the characteristic features of immune checkpoint inhibitors, namely the durability of response once efficacy is achieved.

Median overall survival was 15.2 months. As I mentioned earlier, the one-year survival rate ranges from 5% to 20%. Given that anaplastic thyroid cancer has such a low one-year survival rate, I believe that the one-year survival rate of 57.1% observed in this trial is highly encouraging, although, of course, we recognize that direct comparisons should be interpreted with caution.

Finally, I will explain the safety findings. Overall, the investigators concluded that the toxicity profile of the combination of lenvatinib and OPDIVO was manageable.

As I mentioned earlier, patients with BRAF-mutant disease, which is said to account for 40% of all cases, already have access to treatment, including BRAFTOVI and MEKTOVI, as valuable treatment options. However, we believe this new regimen could provide a promising treatment option for patients without actionable mutations, including BRAF mutations, as well as for patients who cannot wait for genomic testing results because of the rapidly progressive nature of the disease.

That's all from me. Thank you very much.

Imura: This is the end of our presentation.

Question & Answer

Imura : We will now take your questions. Mr. Yamaguchi of Citigroup Global Markets, could you please go ahead?

Yamaguchi : First, regarding the VELEXIBLU for SCNSL, that you just explained, you talked about R&D topic today, but compared to current indications, the patient population seems quite large, and I also got the impression that it has significant commercial potential. How do you view that?

Okamoto : Since SCNSL is a rare disease with high-dose methotrexate as the prior therapy, the estimated percentage of patients who can actually move on to second-line therapy varies widely. Therefore, regarding whether we can actually reach the number of patients shown here once the drug is approved and used in clinical practice, our stance is to remain quite cautious.

Yamaguchi : Still, since there probably aren't that many patients even with the current PCNSL, in comparison to that, you can still manage quite well even at the lower end, right? Isn't it something like that?

Okamoto : As you pointed out, it is true that the figure of 2,172 is high relative to the number of PCNSL patients.

However, since we have submitted an application and it is under review, the scope of patients eligible for treatment has not yet been finalized. Specifically, for example, the distinction between the patient group included in the clinical trial and the group not included, we expect these details to be determined during the upcoming regulatory review process. Therefore, we can't say anything for certain at this point.

Yamaguchi : I see, thank you. Also, regarding the financial results, could you briefly share any organ-specific trends regarding OPDIVO's performance, if there are any?

Kitada : Regarding first-line treatment for gastric cancer, our current share of new prescriptions stands at 60%. For lung cancer, our share of new prescriptions in first-line treatment is 17%, and for esophageal cancer, our share of new prescriptions in first-line treatment is 50%.

Yamaguchi : What do you think? Do you think you'll make it for the full year, or is it still a bit of a struggle for gastric cancer, lung cancer, and so on?

Kitada : Looking ahead, the competitive environment is becoming increasingly challenging. However, our share of new prescriptions for gastric and esophageal cancer has improved, and we expect the number of prescriptions to continue to grow going forward.

On the other hand, regarding lung cancer, where we are running a bit behind, we plan to focus our efforts on the PD-L1 negative segment, where OPDIVO has a key strength. By doing so, we aim to drive reevaluation, recover prescriptions, and make a strong comeback.

In addition, given the positive factors stemming from the expanded indications we added last year, including first-line treatment for hepatocellular carcinoma and first-line treatment for MSI-high colorectal cancer, we believe that, with last fiscal year marking the bottom, we are now poised to enter a phase of growth.

Imura : The next question, Mr. Seki of UBS Securities, please go ahead.

Seki : First, I'd like to ask for your overall assessment of the Q1 financial results. I think exchange rates and the timing of R&D expenditure might have been a bit delayed, but if exchange rates continue at this level, I do get the sense that you might actually exceed your full-year targets. What are your thoughts on this? This is the first point.

Itoh : As you say, the exchange rate assumption we're using for our current earnings forecast is JPY155. Given that the current rate of around JPY160 has continued for the remaining nine months, one month has already passed, so the remaining eight months, (Looking solely at exchange rates,) I do think both sales and profits will exceed our forecasts.

On an annual basis, our sensitivity to exchange rate fluctuations is JPY1.5 billion per yen for sales and JPY500 million for operating profit. Four months have passed under these circumstances, exchange rate hovering around JPY 160 to the dollar, and if this continues, it will add to the upside accordingly.

Regarding R&D expenses while progress in Q1 has not been particularly strong compared to our overall plan, we are on track to spend nearly JPY 150 billion on R&D on a core basis for the full year.

Seki : Thank you very much. My second point is regarding the cash flow statement, which shows the sale of intangible assets totaling JPY8.4 billion. Have you discussed this at all?

Itoh : This was already recognized in the P&L last year, but following the termination of the sales agreement for FORXIGA, this represents the final settlement related to the remaining intangible assets, an adjustment for the difference between the intangible assets we held at the end of the fiscal year and the amount received from the partner.

Seki : It will be helpful. Thank you very much. Finally, my third point is regarding R&D. Could you share any information, such as the study initiation timing for Phase 3 of ONO-4578 and ONO-2808 or the progress made since the R&D day in June?

Okamoto : First, as a point of background, consultations with US regulatory authorities have been completed for both in preparation for the start of the global Phase3. Therefore, we plan to file a clinical trial notification with an IND amendment by the end of this year, and we expect to enroll the first patient within this fiscal year.

I hope you will understand that we are proceeding according to plan, just as I mentioned earlier.

Seki : You mean both trials are scheduled to have their first patients within this calendar year?

Okamoto : No, I mean this fiscal year, by the end of March next year.

Imura : Continuing on, Mr. Wakao of JPMorgan, please go ahead.

Wakao : Please let me know about R&D. I'd like to ask about ONO-2020. For ONO-1110, you mentioned that the plan is to move forward once all target indications are ready. How about ONO-2020?

I think the Alzheimer's trial will be over sooner. Looking at ClinicalTrials.gov, it seems the trial will end at the end of August, so based on that, I think the results for Alzheimer's will be released first. How is the situation? This is the first question.

Okamoto : I believe that results regarding Alzheimer's disease will be available at the timing of database released. We'll need a little time to review this internally, but unlike ONO-1110 trial so in principle, I think we'll be able to provide some kind of update once we have the results for Alzheimer's disease.

Wakao : I see. Yes, so it sounds like there will be some kind of announcement before the financial results are released.

Okamoto : Yes, when we achieved the POC for ONO-4578 and ONO-2808, we issued the press release, that we had obtained promising results supporting progression to the next phase. Similarly, we expect we will be able to report promising results that could allow us to move on to the next phase, though, of course, this will depend on the results.

Wakao : I see, thank you. Second, this is also about ONO-2020. Could you please explain once again the concept behind this drug and the rationale behind the design of Phase2 or rather, why it was designed this way?

Based on the design of Phase2, I think the target population is people with mild to moderate Alzheimer's dementia, but I'd like to know if this will remain the final design. Also, looking at the design for this Phase 2 trial, with one group of 80 cases, the ADAS-cog 12, and a 26-week duration, my impression is that it's a rather rigorous design.

Since I assume this study design was chosen on the expectation that a statistically significant difference would be observed, could you please provide, to the extent possible, any information that would demonstrate the validity of this study design in light of the previously obtained P 1 data and preclinical results?

Okamoto :Regarding the study design, particularly the sample size you mentioned or the specific criteria for determining efficacy or futility, I am afraid that, as per our standard policy, we do not disclose these details until the results are available because they concern the very core of the trial itself. Therefore, I would like to refrain from answering at this time.

Regarding whether we saw any signals to predict efficacy during Phase 1 that guided us into Phase 2, unlike oncology trials, this Phase 1 study was not conducted in patients. Therefore, it is not the case that our Phase 2 design was determined based on such findings from the Phase 1 study.

Wakao : Also, in terms of the drug itself, what kind of role do you ultimately aim for it to play? Currently, we have anti-amyloid beta antibodies like LEQEMBI, as well as Aricept, on the market. Given this landscape, what kind of positioning are you aiming for with this drug?

Okamoto : Regarding Aricept, it will basically be in a state where it is already taken as a base treatment. This epigenetic regulation mechanism is a difficult area to express.

Since the concept is to act on the parts involved in the progression of Alzheimer's disease itself through a mechanism different from LEQEMBI, whether Aricept is included as a baseline or even if it is not included, we are drawing a product profile that suppresses progression through a different mechanism from standard progression suppression and a different mechanism from LEQEMBI.

Wakao : Sorry for going on so long, but just one more question, is there potential for this to be used for MCI, similar to LEQEMBI, or to target an even earlier stage?

Okamoto : Since this relates to our development strategy, I'd rather not go into too much detail, basically, LEQEMBI's mechanism is by suppressing the accumulation of abnormal proteins, proteins that damage the central nervous system, so if it is in a mild state, this can halt its progression, conversely speaking, for those that have already progressed, I think it might be difficult, but as for our ONO-2020, I can at least state that it is not based on that kind of concept.

Imura : The next question, Mr. Matsubara of Nomura Securities, please go ahead.

Matsubara : Please let me know about QINLOCK first. I believe the progress is strong, with Q1 sales reaching JPY11.7 billion. In the previous financial results meeting, you mentioned that while competitors will enter the market, it will also activate the market itself. Given that, I believe there is a possibility that results may exceed your forecast for this fiscal year. Could you please comment on this?

Ito : While things are certainly going well, this is a rare disease, and we often face frequent increases and decreases in the number of new patients. Since only three months have passed so far, we are not currently considering revising our forecast and would like to wait and see how things develop a little longer.

Matsubara : I see. Thank you very much. Next, as for ONO-3401, I believe the indications for this drug have not been disclosed as you explained in the presentation. Please tell me whether this involves the glia-targeted drug discovery that your company excels at and also whether the target disease is different from the pipeline products you are currently developing.

Okamoto : Regarding the point you asked about, I am very sorry, but if we were to answer that, there would be no point in making this disclosure, so I hope you will understand.

Imura : The next question, Mr. Wada of SMBC Nikko Securities, please go ahead.

Wada : I also would like to ask about the development project, ONO-2020. Just one question, the patent that has been issued by your company, and when it comes to Alzheimer's-related areas, you have a patent for a KDM5 inhibitor. Since it is a histone demethylase inhibitor, I am speculating that this might be the one.

This might overlap a bit with Mr. Wakao's question, but I'd like to ask whether any signs have been observed in Phase 1. I believe that only the Alzheimer's drug is being developed in both Japan and the US, so please let me know the background behind this.

Okamoto : First, regarding the point about linking this to patent information, I'm afraid I cannot answer that. However, since the Phase 1 trial itself is conducted on healthy adults, I hope you understand that it is difficult to detect any signals in the first place.

As for the Japan-US aspect, since we also conducted Phase 1 trials for 2808 in both Japan and the US, as part of our global development strategy or rather, when we set a course to develop and market products globally on our own, it just so happened that trials for ONO-2808 and this ONO-2020 were conducted in both Japan and the US.

Imura : Continuing on, Mr. Muraoka of Morgan Stanley Securities, please go ahead.

Muraoka : I'd like to ask a question similar to the one Mr. Wada just asked about ONO-1110. The answer might be similar, but looking at the patent, it seems that an ABHD6 antagonist might fit somewhat. Is that the mechanism we should be thinking of?

Okamoto : We don't disclose the target here. Controlling endocannabinoids means controlling the cannabinoids produced inside the human body, and through this, we believe it will show efficacy for pain or psychiatric disorders, so I hope you will accept this explanation. I am sorry.

Muraoka : Thank you. I am truly sorry for asking a similar question again, but although I don't know whether this was a Phase 1 study in healthy volunteers, did you actually see a fairly clear signal? I'm sorry, I might have asked you this before, but my memory is a bit fuzzy.

Okamoto : Generally speaking, since Phase 1 trials in non-oncology indications are conducted in healthy adults, there is no signal there. On the other hand, conversely, regarding the diseases we have selected as candidate

indications, all of them are a group of diseases for which exogenous cannabinoids, in other words, medical marijuana, are known to show efficacy.

In that sense, I believe that, while evidence in humans comes externally, it does exist to a certain extent.

Muraoka : I see. Regarding the announcement timing, you mentioned earlier that you would bundle all five indications together for ONO-1110, but as a general image, should we wait until Q3, around February, or perhaps even further ahead, beyond the end of the fiscal year? What is the rough feeling?

Okamoto : At our next financial results meeting, regardless of whether the results are good or bad, we expect to provide some kind of update on our own initiative.

Muraoka : I see, so by the time we get to Q2, we'll have some sort of clarity on both ONO-2020 and ONO-1110, is that right?

Okamoto : As for ONO-2020, as I mentioned earlier, we'll need to collect the data, run analyses, and discuss the findings internally, so it's a bit uncertain at this point. However, regarding ONO-1110, as I mentioned earlier, we expect I'll be able to share some information on that at our next meeting.

Imura : The next question, Mr. Ueda from Goldman Sachs Securities. Please go ahead.

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

Regarding the part that has increased YoY, specifically the incremental increase outside of OPDIVO and Keytruda which are listed individually, is there no temporary one-time factor here, and can we assume that these figures recorded in Q1 reflect actual ongoing performance? I think things are generally making good progress in this area, so I'd appreciate it if you could let me know.

Itoh : As far as sales are concerned, they are exceeding our initial projections, so progress is ahead of expectations accordingly. As for the drugs, other than OPDIVO and Keytruda, that is correct, as you have confirmed.

Ueda : Thank you very much. Therefore, regarding this as well, can I understand that the figures do not include any specific one-time factors?

Itoh : Yes. It is as you say.

Ueda : Thank you very much. Also, as a second point, I would like to ask about the progress of the expenses. Although you explained that R&D expenses will be spent according to plan, I feel that the progress is somewhat lower even compared to last fiscal year. What kind of triggers will lead to increased spending from Q2 onwards toward full budget consumption? Could you tell me about the trend a bit more?

Okamoto : Since we are about to begin preparations for the global Phase 3 trials of ONO-4578 and ONO-2808, there may be points raised that Q1 progress seems a bit slow. However, as preparations for such large-scale Phase 3 trials get underway from here on out, we expect that expenses will increase accordingly.

Imura : We would like to close the question-and-answer session. Thank you very much. This concludes the FY2026 Q1 financial results meeting. Thank you very much for your participation today.