



ONO PHARMACEUTICAL CO., LTD.

Business Results Meeting for the Fiscal Year Ended March 2025

May 8, 2025

[Number of Speakers]	6	
	Toichi Takino	Representative Director, President and Chief Operating Officer
	Masaki Itoh	Corporate 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
	Hiroyuki Takahashi	Director of Oncology Business Division, Sales and Marketing
	Ryuta Imura	Senior Director, Corporate Communications

Presentation

Imura: Thank you very much for attending ONO's financial results meeting for the fiscal year ended March 2025 today.

Agenda



2025年3月期 業績および今後の見通し

Financial Overview FY 2024 / New-term vision (14:00-14:25)

代表取締役 社長 COO

Representative Director, President and Chief Operating Officer

滝野 十一

Toichi Takino

開発品の進捗状況

Development Pipeline Progress Status (14:25-14:40)

執行役員 開発本部長

Corporate Officer / Executive Director, Clinical Development

岡本 達也

Tatsuya Okamoto

オペジーボの動向

Trend of OPDIVO (14:40-14:55)

執行役員 営業本部長

Corporate Officer / Executive Director, Sales and Marketing

北田 浩一

Hirokazu Kitada

質疑応答

Q&A Session (14:55-15:30)

3/44

Imura: First of all, Takino, President, would like to present our financial results for the fiscal year ended March 31, 2025, as well as our outlook for the future. Next, Okamoto, Executive Director, Clinical Development, will give an update on the progress of development products, and finally, Kitada and Takahashi of, Sales and Marketing, will give an update on OPDIVO.

Please refer to today's materials, which are already posted on the Company's website.

Key Points of this Meeting



Fiscal year ended March 31, 2025 Full-year results	Decreased revenue and profit in FY2024 compared to FY2023 <ul style="list-style-type: none"> Revenue, Core Operating Profit, and Core Profit for the Year achieved full-year forecasts Full-basis operating profit and profit for the period were not achieved as FORXIGA sales milestones fell short
Fiscal year ended March 31, 2026 Full-Year Forecast	For the fiscal year ending March 2026, revenue and profit are expected to increase year on year <ul style="list-style-type: none"> Forecasts reflect 12 months of sales and expenses related to Deciphera Increase in OPDIVO Japan sales and royalty income Decrease in sales of FORXIGA due to drug price reductions and entry of generic products
R & D	In March 2025, Ionis will introduce sapablursen to treat polycythemia vera <ul style="list-style-type: none"> P2 study expected to be completed by the first half of 2025 Phase 2 study of ONO-4059 to be completed <ul style="list-style-type: none"> Filing for approval in the US planned by the end of FY2025
Cross-shareholdings Investment Allocation	Cross-shareholdings: Less than 10% of net assets <ul style="list-style-type: none"> Reduction to continue Updated investment allocation planned for 2022 to 2026

5/44

Takino: I would like to share with you a summary of our financial results for the full year ended March 31, 2025. First of all, since the acquisition of Deciphera about a year ago, we have been disclosing our core financial indicators in order to communicate the performance of our core business as clearly as possible. Therefore, we are planning to report mainly on a core basis today as well.

First, we summarize the key points of our issues this time in this slide. As for the results for the fiscal year ended March 31, 2025, although sales and profits decreased compared to the previous year, revenue, core operating profit, and core profit all exceeded the full-year forecast.

On the other hand, due to the strong sales of FORXIGA, the sales achievement milestone was incurred at the end of the fiscal year, and the full-year forecast was not achieved on a full basis.

For the next fiscal year, FY2025, we expect a slight increase in overall sales and profits. As for R&D, we acquired Sapablursen from Ionis in the US in March, and we will proceed with its development on a global basis. We plan to file ONO-4059, tirabrutinib, for approval in the US in FY2025.

In addition, our efforts to reduce cross-shareholdings are progressing well, and we have updated our capital allocation for the period from 2022 to 2026, which I would like to introduce later.

Highlights of Financial Results for FY2024 (Core Basis)



➤ **Revenue decreased by 3.1% compared to the previous year, totaling ¥486.9 billion, surpassing the revised full-year forecast (announced on October 31, 2024) of ¥485.0 billion.**

The decrease was due to the revision of drug price of OPDIVO, the decline in royalty income from Merck and others due to lower royalty rates, and the absence of the lump-sum payment of ¥17.0 billion from the settlement of a patent-related lawsuit with AstraZeneca recorded in the previous year. However, this was offset by sales of "FORXIGA Tablets" and "QINLOCK" from the Deciphera Pharmaceuticals, LLC.

➤ **Expense increased compared to the previous year due to the addition of "research and development expenses", and "selling, general, and administrative expenses" from Deciphera Pharmaceuticals, LLC.**

- Research and Development Expenses: Continued proactive investment in research and development, including costs related to the drug discovery partnership agreement with LigaChem Biosciences.
- Selling, General, and Administrative Expenses: Expenses remained at the same level as the previous period, except co-promotion costs for "FORXIGA Tablets".

➤ **Core operating profit decreased by 37.7% compared to the previous year, totaling ¥112.7 billion, surpassing the revised full-year forecast (announced on October 31, 2024) of ¥110.0 billion.**

6/44

This is a summary of the financial results.

Revenue decreased 3.1% from the previous year to JPY486.9 billion, exceeding the revised full-year forecast of JPY485 billion announced on October 31. The impact of the price reduction for OPDIVO, a decrease in royalty income from Merck in the US and others due to a decline in the royalty rate, and a one-time payment of JPY17 billion related to the settlement of a patent-related lawsuit with AstraZeneca, which was recorded in the previous fiscal year, resulted in a decrease in revenue.

However, the decline in sales was more than offset by increased sales of FORXIGA and Deciphera's QINLOCK.

Expenses increased from the previous year due to the addition of Deciphera's R&D and SG&A expenses. As for research and development expenses, we continued to invest aggressively in R&D, including expenses related to the alliance with LigaChem, and selling, general, and administrative expenses were almost the same level as the previous year, except for co-promotion expenses for FORXIGA.

Core operating profit decreased 37.7% from the previous year to JPY112.7 billion. We report that we have landed at the result exceeding JPY110 billion announced in the revised October announcement.

FY2024 : Sales Revenue



Goods and Products Sales
¥330.8 billion
YoY +13.8 billion (+4.3%)



Royalty and Others
¥156.1 billion
YoY -29.6 billion (-15.9%)

7/44

I would now like to explain in order starting with Revenue.

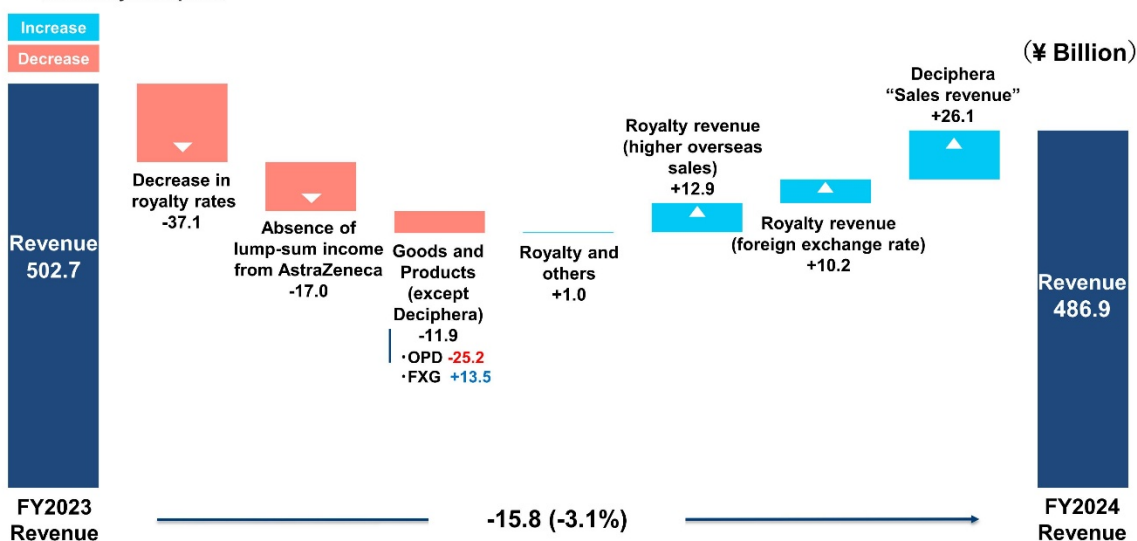
Revenues for the period totaled JPY486.9 billion, down JPY15.8 billion, or 3.1%, from the previous period.

The breakdown is as follows: on the right hand, goods and products sales increased by JPY13.8 billion, or 4.3%, from the previous year to JPY330.8 billion. On the other hand, royalty and others, shown in the lower right, decreased JPY29.6 billion, or 15.9%, from the previous year to JPY156.1 billion.

FY2024 : Sales Revenue (Breakdown)



- Revenue was decreased mainly due to the revision of drug price of OPDIVO, despite an increase in sales of FORXIGA Tablets.
- Royalty revenue was decreased mainly due to a decrease in royalty rates from Merck, despite an increase in royalty revenue from Bristol-Myers Squibb.



8/44

This slide shows the details of the increase and decrease in sales revenue.

The decrease in sales was due to several factors, including a decrease in sales resulting from the OPDIVO drug price reduction, a decrease in royalty income resulting from a decrease in royalty rates from Merck & Co. in the US, and a decrease due to the absence of income from the patent-related litigation settlement with AstraZeneca in the previous fiscal year. They contributed to the significant decrease in sales in this fiscal year compared to the previous fiscal year.

On the other hand, sales of FORXIGA grew steadily due to its expanded use in chronic kidney disease, and the negative factors were covered by an increase in royalty income from BMS related to OPDIVO, the positive impact of the weaker yen, and the addition of sales of QINLOCK and other products obtained through the acquisition of Deciphera resulting in a decrease of only JPY15.8 billion from the previous fiscal year to JPY486.9 billion.

FY2024 : Sales Revenue by Product (Domestic)



¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Goods and products	317.0	330.8	13.8	4.3%	333.0
Royalty and others	185.7	156.1	(29.6)	(15.9%)	152.0

Goods and Products (Domestic)	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
OPDIVO Intravenous Infusion	145.5	120.3	(25.2)	(17.3%)	125.0
FORXIGA Tablets	76.1	89.6	13.5	17.7%	89.0
Orencia for Subcutaneous Injection	25.8	26.6	0.8	3.0%	27.0
Glactiv Tablets	21.2	18.3	(2.8)	(13.4%)	18.5
Velexbru Tablets	10.2	10.5	0.3	3.1%	10.0
Kyprolis for Intravenous Infusion	9.1	8.6	(0.5)	(5.9%)	9.5
Parsabiv Intravenous Injection	8.2	8.4	0.2	2.5%	8.5
Ongentys Tablets	6.3	7.6	1.3	21.0%	7.5

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

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

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

9/44

Next is domestic sales revenue by product.

Sales of OPDIVO intravenous infusion decreased by JPY25.2 billion, or 17.3%, to JPY120.3 billion, mainly due to the impact of a price reduction. FORXIGA sales amounted to JPY89.6 billion, up JPY13.5 billion or 17.7% from the previous year, due to its expanded use in chronic kidney disease.

Other major products such as Orencia, Velexbru, Parsabiv, and Ongentys have increased YoY, and the figures for each of them are as shown in the table. On the other hand, Glactiv, here, decreased by JPY2.8 billion from the previous year to JPY18.3 billion, and Kyprolis also decreased by JPY0.5 billion to JPY8.6 billion.

FY2024 : Sales Revenue by Product (Overseas) / Royalty



¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Goods and products	317.0	330.8	13.8	4.3%	333.0
Royalty and others	185.7	156.1	(29.6)	(15.9%)	152.0

Goods and Product (Overseas)	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
OPDIVO	12.0	13.1	1.1	9.3%	13.5
QINLOCK	—	25.5	—	—	25.0

Royalty and others	FY2023	FY2024	YoY		
			Change	Change (%)	
OPDIVO	97.9	113.0	15.1	15.4%	
KEYTRUDA®	53.0	26.4	(26.6)	(50.1%)	

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

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

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

10/44

Next is overseas sales revenue by product and royalty.

First, the sales of overseas products in the middle row are the total sales of OPDIVO in South Korea and Taiwan, and increased by JPY1.1 billion from the previous year to JPY13.1 billion. Sales of QINLOCK, a treatment for gastrointestinal stromal tumors (GIST) acquired through the Deciphera acquisition, totaled JPY25.5 billion for the nine-month period from July 2024 to March 2025.

Moving on to the bottom section, regarding royalty and others, royalty income from BMS related to OPDIVO increased by JPY15.1 billion or 15.4% YoY to JPY113 billion, while royalty income from Merck & Co. in the US related to KEYTRUDA decreased by JPY26.6 billion, 50.1% to JPY26.4 billion due to a decrease in the royalty rate.

FY2024 : Core Operating Profit



**Core Operating Profit
¥ 112.7 billion**

**YoY -68.3 billion
(-37.7%)**



Revenue ¥ 486.9 billion

YoY -15.8 billion (-3.1%)



R&D Expense ¥143.3 billion

**YoY +34.9 billion
(+32.1%)**



SG&A Expense ¥122.2 billion

YoY +21.9 billion (+21.8%)

11/44

Next is core operating profit.

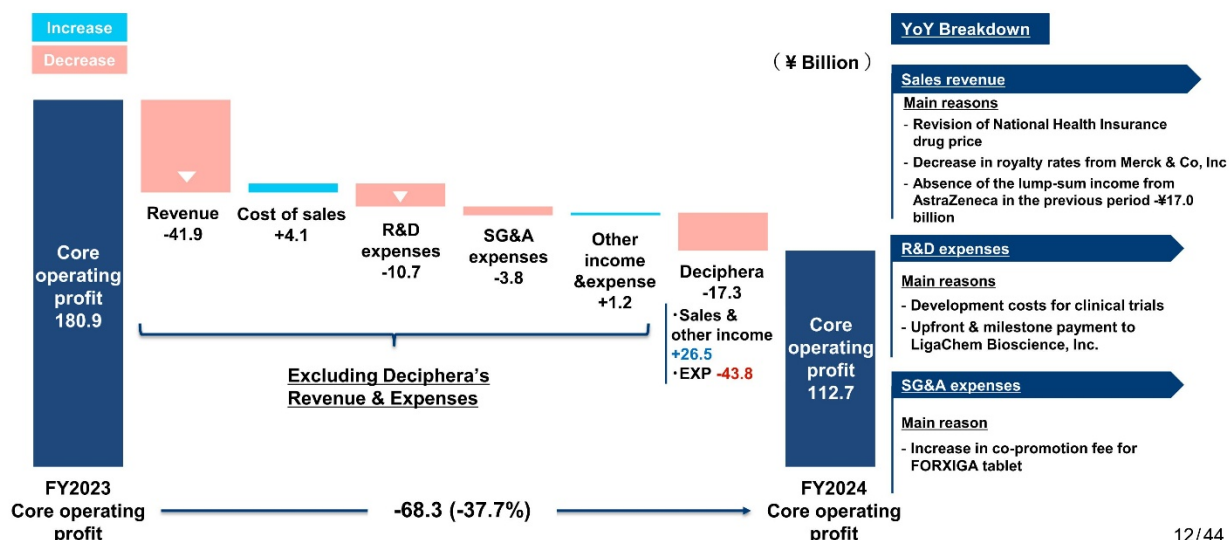
On the left side, core operating profit decreased by JPY68.3 billion, or 37.7%, to JPY112.7 billion compared to the previous fiscal year.

On the right side, revenue decreased by JPY15.8 billion from the previous year, R&D increased by JPY34.9 billion from the previous year, and SG&A expenses increased by JPY21.9 billion from the previous year.

FY2024 : Core Operating Profit (Breakdown)



• While revenue decreased, R&D expenses and SG&A expenses increased, and an operating loss was recorded by Deciphera Pharmaceuticals, LLC., resulting in a decrease of ¥68.3 billion from the same period last year to ¥112.7 billion.



12/44

I would now like to show you the content of the increase and decrease.

The decrease was mainly due to a decrease in revenue itself, an increase in R&D costs, and an increase in SG&A expenses, as well as an operating loss of JPY17.3 billion for Deciphera, with expenses of JPY43.8 billion compared to sales of JPY26.5 billion.

FY2024 : Financial Overview (Core)



¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*	YoY Breakdown
			Change	Change(%)		
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0	R&D expenses +¥34.9 billion (+32.1%) R&D ratio : 29.4% Main reasons - Development costs for clinical trials - R&D expenses from Deciphera +¥24.2 billion - Upfront & Milestone payment to LigaChem Bioscience, Inc.
Cost of sales	109.6	106.9	(2.7)	(2.5%)	109.0	
R&D expenses	108.5	143.3	34.9	32.1%	143.0	
SG&A expenses	100.3	122.2	21.9	21.8%	120.0	
Other income	0.6	1.0	0.4	66.2%	0.5	
Other expenses	4.0	2.8	(1.2)	(30.6%)	3.5	
Core operating profit	180.9	112.7	(68.3)	(37.7%)	110.0	SG&A expenses +¥21.9 billion (+21.8%) Main reasons - Co-promotion fees for FORXIGA Tablets - SG&A expenses from Deciphera +¥18.1 billion
Core profit before tax	184.7	113.9	(70.8)	(38.3%)	110.5	
Core profit for the period (attributable to owners of the Company)	142.5	90.4	(52.2)	(36.6%)	81.0	

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

13/44

This table shows the breakdown of consolidated core results.

Costs of sales decreased by 2.5%, or JPY2.7 billion, to JPY106.9 billion. R&D expenses increased JPY34.9 billion, or 32.1%, from the previous year to JPY143.3 billion, mainly due to increased development expenses for clinical trials and expenses related to the alliance with LigaChem, as well as expenses related to research and development for Deciphera.

SG&A expenses increased by 21.8%, or JPY21.9 billion, to JPY122.2 billion due to an increase in co-promotion expenses associated with the sales expansion of FORXIGA, as well as expenses related to the business operations of Deciphera, which was acquired.

As a result of the above, core operating profit decreased by JPY68.3 billion, or 37.7%, to JPY112.7 billion, exceeding the revised forecast of JPY110 billion for core operating profit announced in October by JPY2.7 billion.

On the other hand, as for core profit for the period, tax expenses decreased by JPY18.7 billion from the previous year, mainly due to an increase in tax credits for testing and research expenses. Core profit for the period was JPY90.4 billion, down JPY52.2 billion, or 36.6%, from the previous year, and JPY9.4 billion higher than the JPY81 billion in core profit forecasted.

(Ref) FY2024 : Financial Overview (Full Basis)



¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Cost of sales	127.1	147.9	20.8	16.4%	130.0
R&D expenses	112.2	149.9	37.7	33.6%	147.0
SG&A expenses	100.3	125.7	25.4	25.3%	123.0
Operating profit	159.9	59.7	(100.2)	(62.6%)	82.0
Profit before tax	163.7	59.3	(104.4)	(63.8%)	81.5
Profit for the period (attributable to owners of the Company)	128.0	50.0	(77.9)	(60.9%)	58.0

YoY Breakdown

Cost of sales +¥20.8 billion

Main reasons

- Amortization expenses for intangible assets and inventory assets evaluated at fair value +¥21.5 billion
- Absence of impairment losses on sales licenses recorded in the previous fiscal year -¥11.1 billion
- Recording of sales milestone associated with FORXIGA +¥13.6 billion

R&D expenses +¥37.7 billion R&D ratio : 30.8%

Main reasons

- Increase of development costs for clinical trials
- R&D expenses from Deciphera +¥24.2 billion
- Impairment loss for itolizumab and ONO-7018 +¥6.0 billion
- Upfront & Milestone payment to LigaChem Bioscience, Inc.

SG&A expenses +¥25.4 billion

Main reasons

- Increase of co-promotion fees for FORXIGA Tablets
- R&D expenses from Deciphera +¥18.1 billion
- Expenses associated with the acquisition of Deciphera

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

14/44

This slide is for reference only, but it shows the consolidated financial overview on a full basis.

While revenue was the same as on the core basis, operating profit decreased JPY100.2 billion, or 62.6%, from the previous year to JPY59.7 billion.

The difference between this figure and core operating profit of JPY112.7 billion is JPY53 billion. As shown in the reconciliation table on the next slide, the main factors are, the recognition of a total of JPY21.5 billion in amortization expenses for intangible assets related to the Deciphera acquisition and the fair value adjustment of inventory assets, the recognition of JPY13.6 billion in sales milestone payments under the co-promotion agreement with AstraZeneca for FORXIGA, and the recognition of an impairment loss of JPY6 billion on intangible assets due to the decision to discontinue the development of itolizumab or ONO-7018.

(Ref) FY2024 : Reconciliation from Full to Core Basis



¥ in Billion	IFRS (Full) basis	Adjustment			Core basis
		Amortization	Impairment loss	Others	
Sales revenue	486.9				486.9
Cost of sales	(147.9)	14.6		26.5	(106.9)
Gross profit	338.9	14.6	—	26.5	380.0
R&D costs	(149.9)		6.0	0.5	(143.3)
SG&A expenses	(125.7)			3.5	(122.2)
Other income /expenses	(3.7)		2.0	(0.2)	(1.8)
Operating profit	59.7	14.6	8.0	30.3	112.7
Operating profit ratio	12.3%				23.1%
Finance income / Finance cost	(0.5)			1.8	1.2
Profit before tax	59.3	14.6	8.0	32.0	113.9
Income tax expense	(9.2)	(4.0)	(2.3)	(8.0)	(23.4)
Profit for the year	50.0	10.7	5.7	24.0	90.4

Breakdown

Cost of sales -¥41.1 billion

Main reasons

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- FORXIGA sales milestone ¥13.6 billion
- Amortization expenses related to inventories from PPA

R&D expenses -¥6.5 billion

Main reasons

- Impairment loss from itolizumab ¥3.5 billion
- Impairment loss from ONO-7018 ¥2.5 billion

SG&A expenses and Other income&expense -¥5.3 billion

Main reasons

- Expenses related to the acquisition of Deciphera
- Impairment losses related to the integration of Deciphera & Ono Pharma US

15/44

Please refer to this table as this is the reconciliation from full to core basis.

FY2025 : Financial Forecast



Revenue
¥490.0 billion
YoY +3.1 billion
(+0.6%)



Goods and Products Sales
¥330.0 billion

YoY -0.8 billion (-0.2%)



Royalty and Others
¥160.0 billion

YoY +3.9 billion (+2.5%)

16/44

I would now like to show you the consolidated financial forecast for the fiscal year ending March 31, 2026.

Left hand, revenue is projected to increase by JPY3.1 billion, or 0.6%, from the previous year to JPY490 billion.

The breakdown on the right shows that goods and products sales are expected to decrease 0.2%, or JPY0.8 billion, to JPY330 billion, while royalty and others are expected to increase 2.5%, or JPY3.9 billion, to JPY160 billion.

FY2025 : Financial Forecast (Sales by Product)



¥ in Billion

Goods and Products (Domestic)	FY2024	FY2025 Forecast	YoY	
			Change	Change (%)
Opdivo Intravenous Infusion	120.3	125.0	4.7	3.9%
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%
Kyprolis for Intravenous Infusion	8.6	9.0	0.4	4.6%
Parsabiv Intravenous Injection	8.4	9.0	0.6	6.7%
Ongentys Tablets	7.6	9.0	1.4	17.8%

Goods and Product (Overseas)	FY2024	FY2025 Forecast	YoY	
			Change	Change (%)
OPDIVO	13.1	13.5	0.4	2.9%
QINLOCK	25.5	34.0	8.5	33.4%
ROMVIMZA	N/A	5.0	—	—

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

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

17/44

Here are the sales forecasts for the product.

In the domestic market, while the competitive environment for OPDIVO intravenous infusion is intensifying, we expect sales to increase by JPY4.7 billion, or 3.9%, to JPY125 billion, due to anticipated expansion of indications for non-small cell lung cancer and esophageal cancer.

On the other hand, with respect to FORXIGA, we assume JPY80 billion, a decrease of JPY9.6 billion from the previous year, due to the possibility of generic products being marketed after December 2025.

As for other major products, we expect Orencia to increase by JPY1.4 billion to JPY28 billion, Velexbru by JPY0.5 billion to JPY11 billion, Kyprolis by JPY0.4 billion to JPY9 billion, Parsabiv by JPY0.6 billion to JPY9 billion, and Ongentys by JPY1.4 billion to JPY9 billion.

On the other hand, as you know, Glactiv is forecasted to decrease by JPY6.3 billion from the previous year to JPY12 billion due in part to the return of the price maintenance premium (PMP).

Next, the bottom row shows overseas sales by product. First, sales of OPDIVO in South Korea and Taiwan totaled JPY13.5 billion, up JPY0.4 billion from the previous year.

With regard to QINLOCK, which is sold by Deciphera, the acquisition date was at the end of June 2024, which means that 12 months of sales will be recorded for the current period, compared to nine months in the previous period, resulting in an increase of JPY8.5 billion over the previous period to JPY34 billion.

In addition, sales of ROMVIMZA, a drug for tenosynovial giant cell tumor (TGCT), which will be launched in February 2025, are expected to reach JPY5 billion in the first year.

FY2025 : Financial Forecast (Core Operating Profit)



Core Operating Profit
¥ 114.0 billion

YoY +1.3
billion
(+1.2%)



Revenue ¥ 490.0 billion

YoY +3.1 billion (+0.6%)



R&D Expense ¥150.0 billion

YoY +6.7 billion (+4.7%)



SG&A Expense ¥120.0 billion

YoY -2.2 billion (-1.8%)

18/44

Next is the forecast for core operating profit.

Core operating profit is projected to increase JPY1.3 billion, or 1.7%, from the previous year to JPY114 billion. While R&D expenses are expected to increase by JPY6.7 billion from the previous year, revenue is expected to increase by JPY3.1 billion from the previous year, cost of sales is expected to decrease by JPY3.4 billion from the previous year, and SG&A expenses are expected to decrease by JPY2.2 billion from the previous year.

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



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

Breakdown

Cost of sales -¥3.4 billion (-3.1%)

Main reason

- Decrease in sales related to FORXIGA tablets and long-term listed products

R&D expenses +¥6.7 billion (+4.7%)

Main reasons

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

SG&A expenses -¥2.2 billion (-1.8%)

Main reasons

- Promotion of cost efficiency measures

* The exchange rate assumed in the financial forecast is ¥145 per US dollar.

19/44

The details are summarized in this table.

Cost of sales is expected to decrease by JPY3.4 billion from the previous year to JPY103.5 billion due to the decrease in sales of FORXIGA and long-term listed drugs.

R&D expenses are expected to increase by JPY6.7 billion from the previous fiscal year to JPY150 billion, due to the recording of 12 months of R&D expenses for Deciphera, compared to nine months in the previous fiscal year, in addition to development expenses related to Sapablursen introduced from Ionis in the US.

SG&A expenses are expected to decrease by JPY2.2 billion from the previous year to JPY120 billion due to the promotion of cost efficiency, while expenses related to Deciphera's business operations will increase due to the recording of 12 months' worth of expenses here as well.

Based on the above, we forecast core operating profit of JPY114 billion, up 1.2% or JPY1.3 billion from the previous year, and core profit for the period of JPY91 billion, up 0.7% or JPY0.6 billion from the previous year.

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



¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	<u>490.0</u>	3.1	0.6%
Cost of sales	147.9	<u>135.0</u>	(12.9)	(8.8%)
R&D expenses	149.9	<u>150.0</u>	0.1	0.1%
SG&A expenses	125.7	<u>120.0</u>	(5.7)	(4.5%)
Operating profit	59.7	<u>85.0</u>	25.3	42.3%
Profit before tax	59.3	<u>85.0</u>	25.7	43.3%
Income tax expense	9.2	<u>18.0</u>	8.8	96.5%
Profit for the year	50.0	<u>67.0</u>	17.0	33.9%

Breakdown

Cost of sales -¥12.9 billion (-8.8%)

Main reasons

- Decrease in sales related to FORXIGA tablets and long-term listed products
- Absence of sales milestone on FORXIGA recorded in the previous fiscal year

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 in the previous fiscal year

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

* The exchange rate assumed in the financial forecast is ¥145 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥1.3 billion in revenue and an increase of ¥0.3 billion in operating profit for every ¥1 depreciation of the yen.

20/44

This slide is for reference only, but it shows the consolidated financial forecast on a full basis.

Revenue is expected to be the same as the core basis, and operating profit is expected to increase by JPY25.3 billion from the previous year to JPY85 billion since the milestone of JPY13.6 billion for achieving sales of FORXIGA, impairment loss of JPY6 billion for intangible assets related to development compounds, and expenses related to the acquisition of Deciphera are not expected to occur in the next period.

Profit for the period is expected to increase by JPY17 billion from the previous year to JPY67 billion.

Deciphera Performance Trends



- Acquisition completed in June 2024 and P/L consolidation started in July 2024
- Sales of QINLOCK, already launched, are progressing steadily. Sales in the fiscal year ended in March 2025 were 25.5 billion yen. Sales in the fiscal year ending March 2026 are expected to be 34 billion yen.
- In February 2025, we launched ROMVIMZA, a drug for the treatment of tenosynovial giant cell tumors, in the United States.

Functions of ONO Pharma US will be integrated into Deciphera around July 2025.
Single-year profitability is expected in FY2027.



Forecast Annualized Exchange Rate of ¥145/USD

21/44

We have taken out and summarized here the trend of Deciphera, which will be fully booked for the full year starting this fiscal year.

First, QINLOCK has been performing well, and we expect an increase of more than 10% in volume for the period on a volume basis, but we anticipate a slight impact from the US Inflation-Reduction Act, or IRA, and we expect JPY34 billion.

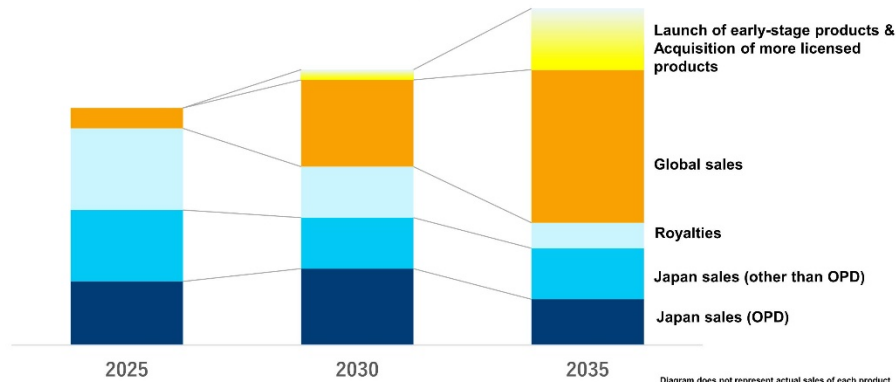
We have been selling ROMVIMZA in the US since February this year. Although it has only been on the market for a few months, it seems to be doing relatively well, so we would like to discuss the details at the R&D meeting scheduled for the 20th of this month.

So, for the current fiscal year, Deciphera is currently forecasting sales of about JPY40 billion for two drugs.

Projection for the Next 10 Years



- + Increase sales of global products (QINLOCK, ROMVIMZA, VELEXBRU, Sapablursen) ↗
- + Royalties for OPDIVO's subcutaneous formulations and compounds will continue after the expiration of the patent for the intravenous formulation expires ↗
- + Launch of ONO-2017 and Gel-One in Japan ↗
- + Launch of in-house products ↗
- During 2025 to 2026, patents for diabetes-related products (FORXIGA, GLACTIV) will expire ↘
- Patent expiration for OPDIVO (US 2028, Europe 2030, Japan 2031) ↘



22/44

This slide shows our sales growth image for the next 10 years.

Although we expect sales of diabetes-related products and OPDIVO to decrease due to patent expiration, we plan to increase sales of two products, QINLOCK and ROMVIMZA acquired through the Deciphera acquisition and other global products including Velexbu, and Sapablursen which we recently licensed from Ionis.

In addition, as for royalty income, since the subcutaneous formulation of OPDIVO has been launched in the US and Europe, we expect to receive the same royalty rate for the subcutaneous formulation as for the intravenous formulation for the first 10 years after its launch.

In addition, we are looking forward to domestic sales of products such as ONO-2017 (cenobamate), and Gel-One, which we recently announced our partnership with Seikagaku Corporation.

In addition, we have a number of exciting in-house products, including ONO-2020, ONO-1110, and ONO-4578, and we believe that by successfully developing these products in the future, we will be able to acquire additional licensed products and make a connection to the next growth phase.

Results of Reduction of Cross-Shareholdings



- Reduction plan (published on November 1, 2021)
 - Over the next 3 and a half years, the company will reduce its cross-shareholdings by about 30% as of the end of September 2021 (¥141.8 billion).
 - Under the medium-to long-term plan, we aim for the ratio of strategic shareholdings to net assets (on a balance sheet basis) to be less than 10%.

➤ Results of reduction

- Reduction (Market price at the end of September 2021 : ¥69.5bil (49.0%))
- The ratio of cross-shareholdings to net assets (on a balance sheet basis) : 9.4%

	End of September 2021	End of March 2025	Reduction*	Reduction rate
Market price at the end of September 2021	¥ 141.8 bil	¥ 72.3 bil	¥ 69.5 bil	49.0%

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of March 2025	Reduction	Reduction rate
Balance sheet accounting amount	¥ 141.8 bil	¥ 74.1 bil	¥ 67.7 bil	47.7%

※End of March 2025
Ratio of Cross-shareholdings to net assets : 9.4%

23/44

We will also report on the status of reduction of cross-shareholdings.

We have been working to achieve a reduction equivalent to 30% in three and a half years from November 2021, as well as to reduce the ratio to less than 10% of net assets as a mid- to long-term plan.

As a result, as shown in red, as of the end of March 2025, the reduction ratio was 49%, and the ratio of the bottom line and net assets, was 9.4%, which is less than 10%.

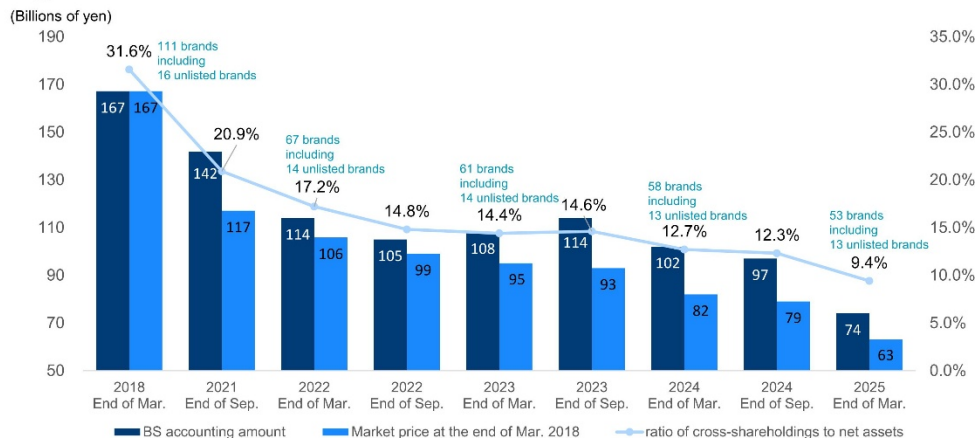
Status of reduction of Cross-shareholdings



➤ Reduction plan

We will continue to reduce our cross-shareholdings as part of our efforts to enhance corporate value.

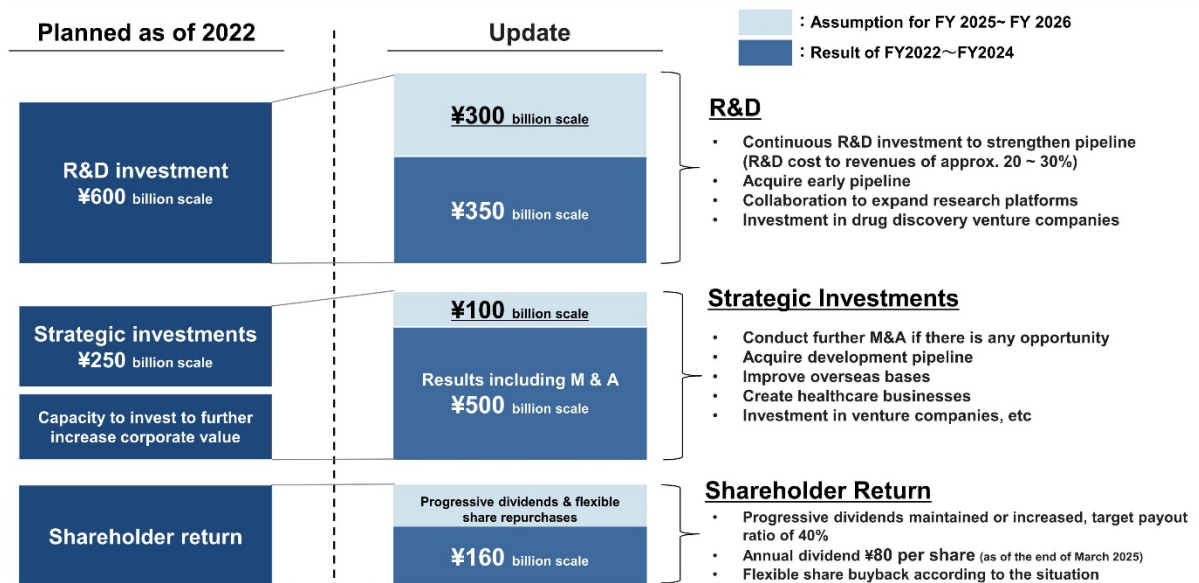
➤ Changes of reduction



24/44

This shows the situation since the beginning of the reduction of cross-shareholdings in 2018, and the percentage in the net assets has been steadily declining. Although we have achieved our initial target of less than 10%, we will continue our efforts to reduce the cross-shareholdings.

Update of Investment Allocation (FY 2022 to FY 2026)



25/44

Lastly, we have updated investment allocations for the period 2022 to 2026 and would like to present them to you. The right side is the update.

In the middle, we plan to file four applications in Japan and one in the US for approval in FY2025. The change from the previous issue is that we are planning to file for approval in the US for our own product ONO-4059, generic name tirabrutinib, marketed in Japan under the name Velexbu.

In FY2026, we plan to submit an application for approval of OPDIVO for the first-line treatment of gastric cancer based on the results of our ongoing Phase III trials in Japan, South Korea, and Taiwan. In this treatment, YERVOY will be added to the combination therapy of OPDIVO and chemotherapy, which has already been approved in Japan.

That concludes my report regarding the status and schedule of regulatory filing for approval.

Development status of OPDIVO

As of April 23, 2025



- Approval in FY2024 or filed/awaiting approval
- 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	Filed
Gastric cancer	1st	with Ipi/Chemo	III	III	III	—	—
Colorectal cancer	MSI-H/dMMR (1st)	with Ipi	Filed	—	—	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	Filed	III	III	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	III	III
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
Rhabdoid tumor	2nd	Monotherapy	II	—	—	—	—
Richter transformation	2nd	Monotherapy	II	—	—	—	—
Solid tumor	—	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	—	—	Approved	Filed

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

28/44

I would like to continue by explaining the changes in the main development status of OPDIVO. We have revised the table with the aim of clarifying the appeal points in introducing the development status.

Please note that we have decided to remove from the development status table the cancer tumors and treatment lines that have been approved in the past and to post them separately as approved results.

From this time onward, we will introduce the status of OPDIVO's development, including those that have been approved in the past year, those that have already been submitted for approval, and those that are in the process of major clinical trials for approval, in other words, those that have recent appeal points that we should share with you.

As in the past, changes from the previous time are shown in red and highlighted in yellow.

The third column from the top is an update on the approval in the US of combination therapy with ipilimumab for colorectal cancer with MSI-H in first-line treatment.

Continuing on, first-line treatment hepatocellular carcinoma. This is also a combination with ipilimumab, which has been approved in Europe and the US and has been updated.

These are the major development updates for OPDIVO.

Development pipeline (Oncology) ①



As of April 23, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
MEKTOVI Tablet (Binimetinib) MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	NCT04607421/JP, KR and others	1L BRAF-mutant colorectal cancer Combination with Cetuximab and FOLFOX						
QINLOCK (riporetinib) KIT inhibitor	NCT05734105/NA, SA, EU, AU, KR, TW	Gastrointestinal Stromal Tumor 2L KIT Exon 11+17/18						
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma						
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*						
	—/US	Colorectal cancer*						
	NCT06542731/JP	Non-small cell lung cancer*						
	NCT06570031/JP	Hormone receptor-positive, HER2-negative breast cancer						
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMPRSS6	NCT05143957/US, EU and others	Polycythemia Vera						
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT01968109/JP, US, EU	Melanoma*						
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*						
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor (with sotorasib)						
	NCT05957367/US	Advanced Malignancies (with ripretinib)						

NA : North America, SA : South America, AU : Australia, EU : European countries
 * : Combination with OPDIVO
 Estimated study completion date shown in jRCT or ClinicalTrials.gov

※Red: Update after announcement of FY 2023 financial result in May 2024
 ※Red: Update after Q3 FY2024 in February
 MOA : Mode of Action

29/44

Next, I would like to talk about the progress of our oncology development pipeline excluding OPDIVO.

The middle row, EP4 antagonist ONO-4578, based on the results of the Phase I study conducted in Japan for the first-line treatment of colorectal cancer in combination with OPDIVO and chemotherapy, we have started a new global Phase II study, PoC study, which has been updated.

In the US, we have already notified the FDA of the start of clinical trials, and we are preparing to start clinical trials in Japan and Europe as well, with plans to begin enrollment sequentially.

Next, ONO-0530, which was mentioned earlier, is a nucleic acid drug candidate, Sapablursen, for which we have obtained exclusive worldwide commercialization rights from Ionis Pharmaceuticals of the United States, and is code-named ONO-0530. We are developing this product for the treatment of true polycythemia vera and have added it to the list.

Please note that ONO-0530 will be outlined later.

Development pipeline (Oncology) ②



As of April 23, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Advanced Malignancies			FY2026 Primary Completion			
DCC-3009 Pan-KIT inhibitor	NCT06630234/US	Gastrointestinal Stromal Tumor			FY2028 Primary Completion			
ONO-7475 (tamnorratinib) Axl/Mer inhibitor	NCT06525246/JP	EGFR-mutated non-small cell lung cancer			FY2025 Primary Completion			
ONO-7913 (magrolimab) Anti CD47 antibody	NCT06532344/JP	Pancreatic cancer*			FY2026 Primary Completion			
	NCT06540261/JP	Colorectal cancer*			FY2027 Primary Completion			
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma			FY2025 Primary Completion			
	NCT06547528/JP				FY2028 Primary Completion			
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor			FY2029 Primary Completion			
ONO-7428 Anti-ONCOKINE-1 antibody	NCT06816108/JP	Solid tumor			FY2029 Primary Completion			

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

MOA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

30/44

Next is the area of oncology.

ONO-7428, an anti-ONCOKINE-1 antibody at the bottom. Information on the Phase I trial for this antibody in solid tumors is now available in the public database, so this is an update.

The development of ONO-7914, a STING agonist that was in Phase I trials in Japan for solid tumors, was discontinued for strategic reasons.

The development of ONO-7018, a MALT1 inhibitor for non-Hodgkin's lymphoma, which was in Phase I trials in Japan and the US, was also discontinued for strategic reasons.

In addition, we have deleted the Axl/Mer inhibitor, ONO-7475, from the Phase I study conducted in Japan for the first-line treatment of pancreatic cancer because the expected efficacy was unfortunately not observed in this indication. The development for the treatment of pancreatic cancer has been discontinued. Therefore, all three items have been deleted.

Development pipeline (Non-oncology)



As of April 23, 2025

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU	Tenosynovial Giant Cell Tumor				FY2024	FDA: Approval EMA: Filing accepted	
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	NCT06579573/JP	Primary generalized tonic-clonic seizures				FY2026	Primary Completion	
	NCT04557085/JP	Partial-onset seizures				FY2024	Primary Completion(Actual)	
VELEXBRU Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	NCT06696716/JP	Pemphigus				FY2027	Primary Completion	
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy				FY2025	Primary Completion	
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT06619561/US	chronic Graft Versus Host Disease				FY2029	Primary Completion	
ONO-1110 Endocannabinoid regulation	NCT06708416/JP	Postherpetic Neuralgia				FY2026	Primary Completion	
	NCT06752590/JP	Fibromyalgia				FY2026	Primary Completion	
	NCT06752603/JP	Hunner Type Interstitial Cystitis				FY2026	Primary Completion	
	NCT06792136/JP	Major Depressive Disorder				FY2026	Primary Completion	
	NCT06805565/JP	Social Anxiety Disorder				FY2026	Primary Completion	
ONO-2020 Epigenetic Regulation	NCT06881836/JP, US	Alzheimer's Disease				FY2026	Primary Completion	
	NCT06803823/JP	Agitation Associated with Dementia Due to Alzheimer's Disease				FY2026	Primary Completion	
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease				FY2024	Completion(jRCT)	
	NCT05332704/EU					FY2024	Primary Completion(Actual)	
ONO-4915 PD-1 x CD19 bispecific antibody	jRCT2071240056/JP	Autoimmune disease				FY2026	Completion(jRCT)	

NA : North America,
EU : European countries

Estimated study completion date shown in jRCT or ClinicalTrials.gov. Dashed lines indicate studies on healthy adults.

MOA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

31/44

The next section summarizes the development status in the non-oncology field. Here, both yellow highlights and red letters indicate only the release of trial information in public databases.

Sapablursen (ONO-0530)



- Anti-sense oligonucleotide targeting TMPRSS6¹⁾
- Ongoing Phase II study for adult polycythemia vera (PV) patients is expected to be completed in 2025

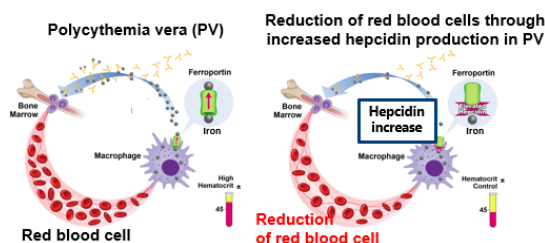
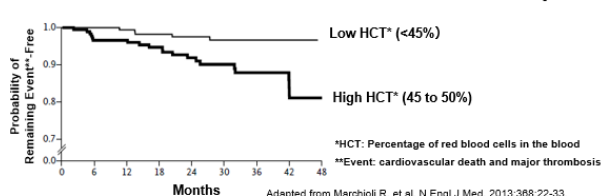
[Polycythemia vera (PV)]

- More than 95% PV patients have a JAK2 gene mutation, leading to the overproduction of red blood cells.
- PV is a rare and potentially life-threatening hematologic disease with an incidence rate of approximately 2 cases per 100,000 population²⁾ and a total of 75,000 patients on treatment in the US³⁾
- In the PV patients with high hematocrit (HCT) have a 3.91 times higher risk of cardiovascular death or thrombotic events compared to patients with low HCT.⁴⁾
- Quality of life (QOL) is impaired due to symptoms such as headaches, dizziness, and fatigue.
- Standard of care includes phlebotomy, low-dose aspirin and cytoreductive therapy (CRT) to maintain HCT <45% and prevent thrombotic events.
- Patients with high frequent phlebotomy present with iron deficiency. CRT increases the risks of infections and secondary cancers.

[Hypothetical Mechanism of Action]

- Hepcidin is the key regulator of iron homeostasis.
- Sapablursen (ONO-0530) increases hepcidin production through suppressing the TMPRSS6 gene expression, thereby reducing red blood cells in PV patients.

Increase in the risk of cardiovascular death and thrombotic events by PV



1) Ono Entered into License Agreement with Ionis Pharmaceuticals for Sapablursen for the Treatment of Polycythemia Vera in March 2025
2) Blood Cancer Journal (2020) 10:22, 3) Nat Rev Dis Primers. 2025 Apr 17;11(1):26. 4) N Engl J Med. 2013;368:22-33.

*HCT: Percentage of red blood cells in the blood

32/44

That is all for the progress of the pipeline, but as I mentioned earlier, let me briefly introduce ONO-0530 (Sapablursen).

ONO-0530 is a nucleic acid drug candidate for which we acquired exclusive worldwide development and commercialization rights from Ionis Pharmaceuticals in the US on March 12 of this year. Currently, a Phase II study in adult patients with true polycythemia vera is underway overseas and has received fast-track and orphan drug designation from the FDA.

The text on the right side explains that Polycythemia vera is a blood disorder characterized by an excessive increase in red blood cells. The risk of thrombosis increases as the blood becomes thicker, and the risk of myocardial infarction or stroke is said to increase.

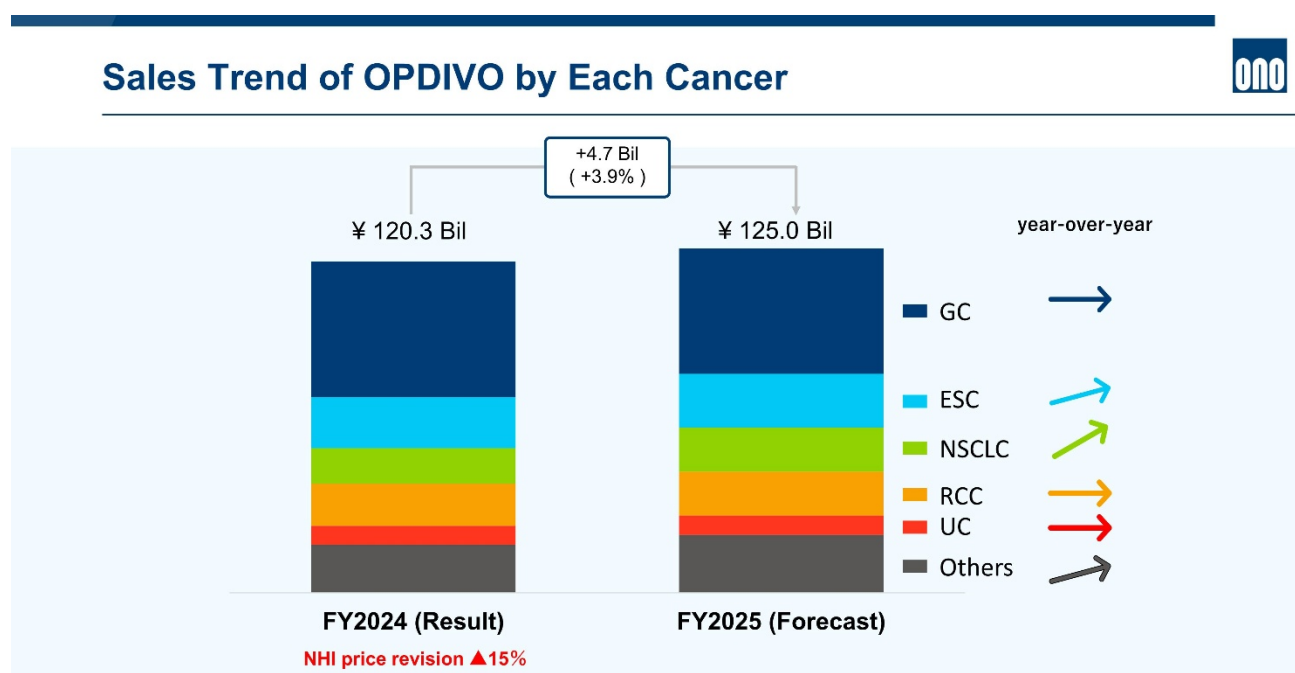
For this reason, phlebotomy is used as a treatment to keep hematocrit levels below a certain level, but if control is still poor, drug therapy to decrease red blood cells is used. However, in the drug therapies that reduce existing cells, a drug similar to anticancer drugs is used, which are said to have disadvantages, such as reducing cells other than red blood cells.

Despite these treatments, there are still patients who are poorly controlled and require frequent phlebotomy, and it is said that new treatment options are needed.

ONO-0530 is expected to be a new therapeutic agent that will satisfy unmet needs because it reduces red blood cells through a mechanism that is completely different from existing therapies that reduce cells, such as the so-called anticancer drugs I mentioned earlier.

The specific mechanism is to increase hepcidin, a peptide that inhibits the absorption and recycling of iron and is produced in the liver, thereby reducing the number of red blood cells. Suppressing iron utilization by increasing hepcidin. The mechanism of action of ONO-0530, Sapablursen, in the treatment of polycythemia vera is suppressing red blood cell production.

Imura: Kitada and Takahashi of the Sales and Marketing will give an overview of the OPDIVO trend.



Kitada: I would like to explain the OPDIVO trend.

OPDIVO has been on the market for 10 years and is still a growing mainstay product with additional indications, but we have reviewed the graph showing market share trends for each cancer type, and have narrowed down the number of cancer tumors to which we will explain.

First, we show OPDIVO sales trends by cancer type. As a result, profit for 2024 totaled JPY120.3 billion. In addition to the impact of NHI price revision, although sales volume for gastric cancer remained almost

unchanged YoY, growth stagnated in the urothelial carcinoma and esophageal cancer areas, where we had aimed for growth. Furthermore, we failed to achieve our target new prescription share for non-small cell lung cancer (hereinafter referred to as lung cancer), where we had aimed to recover the new prescription share. We believe these factors contributed to the decline in sales.

Currently, gastric cancer accounts for a large proportion in the OPDIVO sales, but a positive factor is that in January of this year, at a conference on gastrointestinal cancer hosted by the American Society of Clinical Oncology, five-year follow-up data from the CheckMate-649 trial was presented, reporting highly valuable data unique to OPDIVO.

In the 1990s, gastric cancer was recognized as a cancer with a very poor prognosis, with a five-year survival rate of only 2%, or one in 50 Japanese patients surviving five years. This OPDIVO report shows that one in eight patients in the overall population and one in six patients in the CPS 5 or higher patient population can achieve five-year survival.

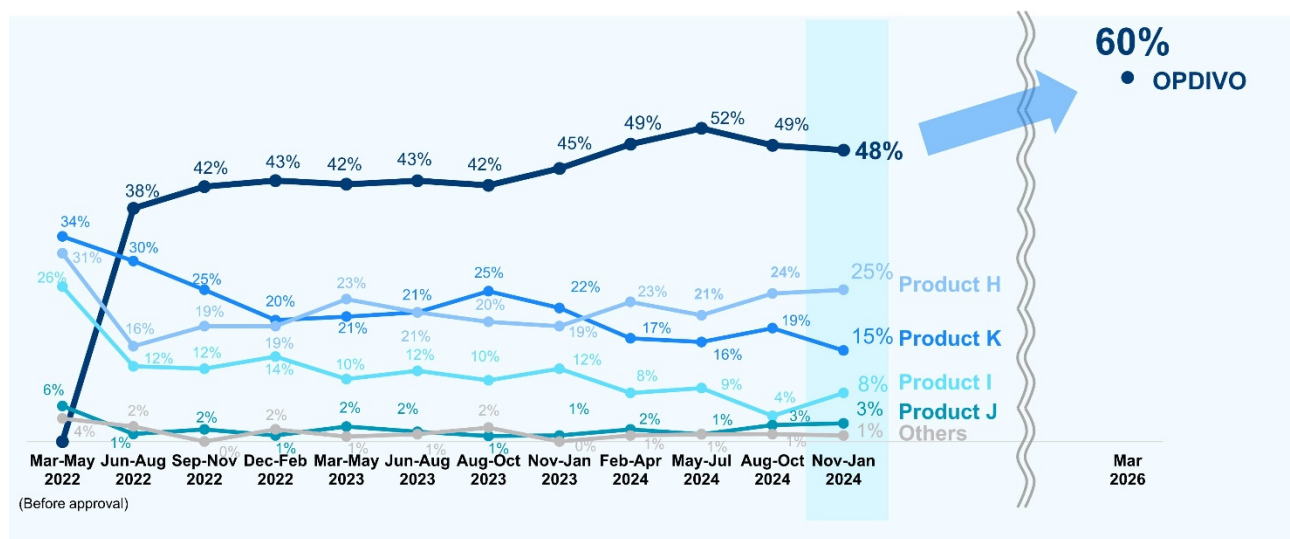
We will continue to promote the value of long-term survival widely in this oncology to minimize the impact of competing products and maintain a firm share of new patients.

In addition, we will focus on expanding prescriptions for esophageal cancer and lung cancer in particular this fiscal year. In addition, we plan to add new indications for the first-line treatment of hepatocellular carcinoma and the first-line treatment of MSI-H colorectal cancer, thereby maintaining our number one market share position in the gastrointestinal area.

We are in a competitive market, but we would like to bring our business to a growing stage this fiscal year by enhancing our reputation in areas where we are strong, where the market is large, and in new areas.

Takahashi, Director of Oncology Business Division, will now explain about the activities for esophageal cancer and lung cancer, which will be particularly focused on this fiscal year.

Prescription Ratio in Patients Newly Treated* for 1L ESC(Squamous Cell Carcinoma)



*Patients starting treatment within the last 3 month

Source: External data (May 2022~Jan 2025: n=150~155)

35/44

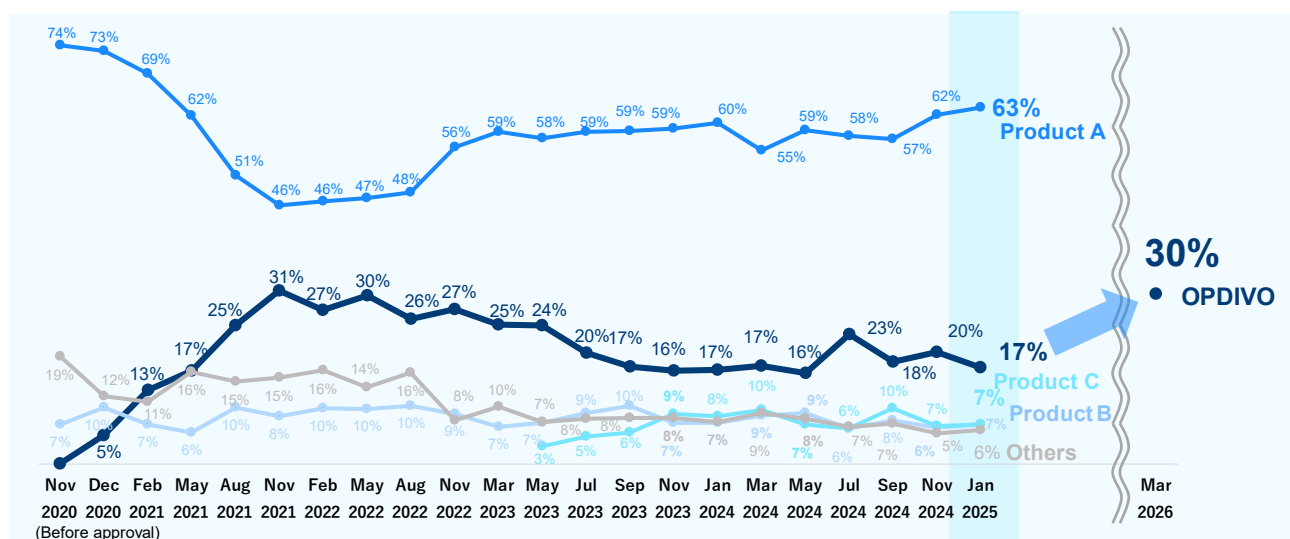
Takahashi: I would like to explain about the first-line treatment for esophageal cancer and first-line treatment for lung cancer, which will be our particular focus in FY2025.

First, esophageal cancer, here is the prescription ratio in patients newly treated for first-line treatment of esophageal cancer. For the first-line treatment of esophageal cancer, we believe that our greatest strength lies in our ability to propose prescriptions for each patient based on the characteristics of the two regimens: OPDIVO plus chemotherapy and OPDIVO plus YERVOY.

Although it entered the market six months after its predecessor, OPDIVO has been able to maintain a high share of 48% in new prescriptions, compared to 25% for Product H.

In FY2025, we hope to achieve a 60% share in the new prescriptions by increasing the evaluation of the two regimens through lectures, webinars, and other doctor to doctor activities.

Prescription Ratio in Patients Newly Treated* for 1L NSCLC



*Patients starting 1L treatment within the last 1 month (Except Driver Mutation)

Source: External data (Nov 2020~Jan 2025: n=167~245)

36/44

Next, I would like to explain about lung cancer. This chart shows the prescription ratio in patients newly treated for first-line treatment of lung cancer. As you are aware, the OPDIVO, YERVOY, and chemotherapy regimen, 9LA regimen, raised safety concerns based on the results of an investigator-initiated clinical trial conducted by the Japanese Clinical Oncology Research Group (hereafter referred to as JCOG), and in April 2023, the decision to discontinue the study was made and the announcement was released. This has led to a significant decrease in the use of OPDIVO with YERVOY or chemotherapy regimen prescriptions.

The latest ratio in the new prescriptions for OPTIVO has been 17%, but as a result of the extensive provision of safety information over the past two years, the number of new prescriptions has been gradually recovering after bottoming out in May last year, according to the internal data.

As of March 2026, we hope to increase the new prescription ratio to 30% and contribute to the long-term survival of lung cancer patients.

Question & Answer

Imura: Mr. Yamaguchi from Citigroup, please go ahead.

Yamaguchi: In the OPDIVO market, the competition, especially VYLOY against Claudin, seems to be doing very well, but what is the difference from your expectation or what measures will you take this fiscal year?

Also, in the last fiscal year, the results were a little lower, but as you mentioned earlier, could this be due to the fact that the lung market share did not increase or something like that? Please confirm that first.

Takahashi: The second point, that we did not reach our target of 25% of new prescriptions for lung cancer, is true. We had a plan of 25% but failed to reach it. The reason for this is that we are at the stage where prescriptions for negative cases, which have shown efficacy, have finally begun to increase, and we believe that the expanding the share in negative cases will eventually lead to an overall share of the new prescriptions in first-line of 30% in FY2025. Therefore, we would like to widely disseminate the data on the usefulness of the drug through the activities of doctor to doctor.

Yamaguchi: I was wondering if VYLOY has a remarkable share against Claudin resulting in an impact, and I was wondering if you have any comments on how it was affected last quarter, and how you see it this quarter.

Takahashi: We were able to maintain our target rate of new prescriptions at less than 70% for the entire year. However, in Q4, the new prescription rate was also affected by VYLOY. VYLOY grew by about 20%, and we struggled a bit.

However, as we look at VYLOY's figures and sales, they peaked in January and have settled down to a flat level. One thing we are considering is that the period during which doctors were very interested in the prescriptions for this drug, as it was a new mechanism of action, may have come to an end.

In addition, in January this year, at the ASCO GI, a gastroenterology conference, the results of the CheckMate-649 trial, which showed a five-year survival rate for OPDIVO, were presented. Looking at the five-year survival rate results, the five-year survival rate was 6% for chemotherapy alone, compared to 12% for the OPDIVO and chemotherapy group. In the CPS 5 or higher subgroup, the five-year survival rate was 6% for chemotherapy alone compared to 16% for the OPDIVO and chemotherapy group, according to the reported data.

Since this is based on the report at the conference, we have been able to disseminate this data to a wide range of doctors through webinars. We are also planning to publish a paper on this topic this year. We believe that once the paper is published, we will be able to firmly develop MR to doctor dissemination, and we would like to differentiate ourselves from our competitors in this area.

Yamaguchi: I don't think tariffs are included in the performance forecast for the business, but I am wondering whether Deciphera products are manufactured in the US or not and whether they will have any impact. As for existing businesses, I believe there will be no impact as you apply the royalty.

This is just a hypothesis, but I think there are many things that cannot be said, such as how to think about it or where products are made. However, I would appreciate it if you could say a word or two.

Itoh: Regarding the forecast for the current fiscal year ending March 2026, the impact of tariffs has not actually been factored in. Basically, most of their products are manufactured in the US, so we believe that tariffs will have a minimal impact for now. It is difficult to simulate the actual impact of tariffs until we see how they will be implemented in practice.

Imura: Next, Mr. Wakao from JPMorgan Securities, please go ahead.

Wakao: The first question is SG&A expenses for this fiscal year, which I thought were more restrained than expected. I would like to know more details. The term that ended was JPY125.6 billion, and the current term is JPY120 billion.

While the SG&A expenses of Deciphera will increase by about JPY3 billion, the profit-sharing portion of FORXIGA will also decrease, but I believe SG&A expenses will be reduced by several billion yen, or about JPY5 billion or less. Please tell me about more details.

Itoh: The decrease of SG&A expenses in core basis is something like JPY2.2 billion. (While there is an increase in Deciphera) FORXIGA sales will decrease, so naturally co-professional fees will also decrease. Since this is a core area, M&A-related expenses are excluded from the original, so the actual decrease in SG&A expenses and in the ONO Group is the result of the promotion of cost efficiency.

In the area of R&D expenses, both Deciphera and the ONO Group will make solid investments. In the area of SG&A expenses, we are looking for ways to save money, or in other words, to see if there are any non-essential expenses or areas where we can improve cost efficiency. We are making solid efforts in these areas this year.

Wakao: After next term, is it correct to assume that the JPY120 billion level of SG&A expenses for the current term will continue for some time?

Itoh: (Level of SG&A expenses) It depends on the state of the overall company, but the JPY120 billion includes co-promotion fees on FORXIGA sales, so I think we can assume that co-promotion fees will decrease from FY2026 onward.

Wakao: Am I correct in understanding that, with the exception of co-promotion fees, we will generally maintain the current level?

Itoh : Yes, that's right. We hope to maintain this level of expenses in the future.

Wakao: Thank you very much. The second question is about the 22nd slide, which is the slide about the growth image for the next 10 years. Regarding global sales, is it correct to consider QINLOCK, ROMVIMZA, and VELEXBRU in 2030, Sapablursen in 2035 as the products that will further increase sales? Can you tell us a little more about the breakdown? In particular, I am talking about global sales.

Takino: We have refrained from disclosing the details, but I think that 2030 is about the time when Sapablursen's contribution to the market will begin. Basically, I think the understanding of Mr. Wakao is fine.

Wakao: I understand. OPDIVO is also growing in Japan, and is my understanding correct that you are expecting the first-line treatment for hepatocellular carcinoma?

Takino: Yes. As the sales representative mentioned earlier, we understand that there is room for growth to recover and grow from this point forward.

Wakao: Finally, regarding Sapablursen, I thought it was similar to Takeda's rusfertide on the ultimate treatment mechanism. Is that understanding, correct?

Also, if they are the same, I think they are similar, maybe similar in hepcidin, but if they are the same, what is the point of differentiation?

Okamoto: First of all, we plan not to cover Sapablursen at the R&D meeting.

Regarding your question about rusfertide, hepcidin, which was mentioned earlier, is a peptide that plays an important role in terms of increasing red blood cell production. rusfertide is a hepcidin mimetic or a substance that mimics or resembles hepcidin.

On the other hand, ONO-0530, Sapablursen, increases hepcidin, but the mechanism of increasing hepcidin is by inhibiting the production of a serine protease called matriptase-2 (TMPRSS6). The common point of action is to increase hepcidin and inhibit the production of red blood cells, but the direct point of action is different.

Currently, both are in clinical trials as subcutaneous formulations, and rusfertide has successfully completed Phase III trials. As the dosing frequency of ONO-0530 is once every four weeks, we believe that our dosing frequency, which requires fewer administrations, is a clear point of differentiation.

Wakao: It is correct to understand that they are competing with each other, since both of them end up increasing hepcidin, is that correct?

Okamoto: Yes, that's right. Regarding ONO-0530, the data for Phase II itself is not yet available, and Phase III is yet to come, so it is hard to say from the perspective of data, but I think the current situation is as you understand it.

Imura: Now, Mr. Sakai from UBS Securities, please go ahead.

Sakai: I would like to ask you a question, Mr. Takino.

If they had announced the earnings in the middle of the market and I had not been prepared and saw these numbers, it would have seemed to me that it would cause a very surprising reaction both in terms of the stock price and investors. So far, your company's stock price has been relatively stable.

What I want to ask you is, after all, this fiscal year, the current forecast for core operating profit is JPY114 billion. I am wondering if this is the bottom or the base considering the immediate transient cost of the Deciphera and considering the cost from the Deciphera and if this is the lowest.

In 2028, the first cliff of OPDIVO will come in, and the table in page 22 could be realized when you successfully maintain this level until then, right? In 2030, I believe the European patent expires in 2030, but if you survive that period and when the OPDIVO patent in Japan expires in 2031, do you envision a scenario in which some level can already be maintained at that point? As a way of thinking about this time when the image of this decade was put forth, please tell us a little bit about that.

Takino: The message is that we envision significant growth every five years. As you can see below, this is not a detailed representation of actual sales, which I believe you already understand.

We assume that, largely, from 2025 to 2030, or especially in the first half of that period, we expect that generics of diabetes in the exclusive period will enter the market, so there will be a certain amount of negative impact on that area.

On the other hand, in the short term, it is difficult to predict how much growth will be achieved in the short term for ONO-2017, cenobamate, which is expected to be launched next year, or QINLOCK, especially ROMVIMZA, which has just been launched, this year or next year. We would like to disclose this information to the public as carefully as possible. We are considering how the offsetting relationship between them will work.

However, considering the timing of 2030, there is also the possibility that products such as Velembro and Gel-One will emerge, so we are imagining this kind of significant growth.

Of course, with regard to the 2035 target and the 2030 target, we recognize that we need to make further efforts in business development and licensing at both points in time. Although we have not made any announcements yet, we will continue to actively pursue business development and licensing as before while striving to send signals from within our company.

Sakai: In other words, I wonder how much profit can be maintained in 2025, 2026, and 2027. I think it would be a little bit difficult to just say we will do our best, but what kind of image do you have in mind?

Takino: We have not disclosed specific figures, but as I mentioned earlier, we will first see a decrease in two diabetes products. In contrast, we expect that the offsetting effects of QINLOCK, ROMVIMZA, and cenobamate, which are materials that will drive growth in the short term, will be roughly balanced. We hope that the overall result will be more or less even.

Sakai: I see. Is it correct that that is the assumption up to 2028?

Takino: Yes. That is the point you mentioned, isn't it?

Sakai: Yes. Thank you very much. One more thing, OPDIVO, SC, which Bristol also launched, and I think it was mentioned that the replacement rate is roughly 30 to 40% from intravenous to SC. Plus, it is not clear when your company will apply in Japan, but am I correct in understanding that the data is already in place? Could you please confirm these two points? I assume that this is naturally taken into account in the royalty income in this figure. How about it?

Okamoto: First of all, as you mentioned, BMS, in their territory, which is currently the US, estimates that the rate of switchover from intravenous to subcutaneous formulations is about 30%.

In Japan, although we did not mention it in the pipeline progress status in today's meeting, Phase I is still underway, and the trial is progressing smoothly with no particular problems.

As we have been saying for some time, we would like to file an application at an appropriate time, taking into consideration the status of development of competing subcutaneous injections.

As for whether the data is ready, although Japan did not participate in the main evaluation material, we believe that the Phase III study approved by BMS can be used in the domestic application, so we do not think there is any particular problem.

Sakai: I see. The domestic PI is only to confirm bioavailability, is that what you are saying, then?

Okamoto: Since ongoing trial is PI, we are checking pharmacokinetics, and whether there are any specific safety issues in the Japanese population.

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

Muraoka: I would like to know about ROMVIMZA. I think that if you grow 5, 10, 15, and 20 by quarter roughly, you will reach JPY5 billion of your plan this year. What kind of image should I think of, whether I should think of it that way, whether I should move forward a little more, or whether I should extend it much further in the second half of the year?

Takino: We have not been able to disclose the details about your current question, but we are hoping that the person in charge will be able to give you some sense of the current initial uptake at the R&D meeting the week after next.

Muraoka: I understood. By the way, from January to March, although it is not disclosed, was there JPY100 million to JPY200 million, or at least USD1 million to USD2 million, or was the level a bit out of reach there?

Takino: I think you can make an assumption like that. However, since it was really approved in mid-February, it is certain that we have not really gone to the point where we can say how it is as a number anymore.

Muraoka: On the last page of the attached document, about the depreciation and capital expenditures. The investment in intangible assets for the current fiscal year is JPY45.2 billion, which is a very large number, please explain.

Itoh: This is because the contract signing fee with Ionis is classified as an intangible asset investment.

Imura: Next, Mr. Yoshimizu of Pharmaceutical Economics, please go ahead.

Yoshimizu: There are two questions, one is the 10-year growth image on page 22, which has been discussed earlier. The image shows that global sales will roughly be more than half of the total by 2035.

First of all, I would like to know your thoughts on whether these four global products are sufficient. Also, what kind of image should we take of sales and the overall picture in 2035, whether it will reach JPY1 trillion or not?

Takino: In terms of the main products that will make up our top line in 2035, with regard to global products, in addition to two products following QINLOCK and ROMVIMZA, namely, Velexbu and Sapablursen, we anticipate that some of our own products will also be launched by 2035, and that we will acquire additional licensed products globally.

Yoshimizu: What is the overall feeling, whether it goes to JPY1 trillion or not?

Takino: At the moment, we would like to aim for JPY1 trillion, but we may consider stretching ourselves at some point in the future.

As an innovative new drug manufacturer that has always created innovative and exclusive products such as OPDIVO, we will continue to strive to expand globally rather than remaining domestic with the aim of becoming a Global Specialty Pharma.

In this context, we have not changed our goal of becoming a company that is capable of spending JPY200 billion for R&D cost.

Yoshimizu: I understand very well. One more question from me, and this is the last one. Yesterday, Shionogi, also in Osaka, bought Torii, and I read in this morning's Nikkei newspaper that there is a growing momentum for the reorganization of mid-sized pharmaceutical companies. Please let us know your thoughts on domestic reorganization and your stance on the matter.

Takino: As for the announcements made by another company yesterday, it is not our place to say anything, and we are of course aware that there are signs of a trend toward restructuring, as reported in the newspapers.

However, as for how it will spread in the future, or how our company views the situation, I honestly do not know how the overall situation will develop.

However, while other companies are pursuing various management policies, we are focusing on aiming to a Global Specialty Pharma by leveraging our unique research and development capabilities and financial strength, as I mentioned earlier, and developing products with a high degree of originality for the global market. Therefore, we are not particularly concerned about domestic restructuring.

Yoshimizu: I understand. I understand your thoughts very well. Thank you very much.

Imura: Mr. Ishii of the Iyaku Tshinsha. Please, go ahead.

Ishii: Though overlaps with what was mentioned earlier, I would like to hear a little more about the future scenarios for QINLOCK, ROMVIMZA, and Velexbu and also your impressions after one year taking the position as the president. These are my two questions.

Takino: I have the impression that QINLOCK and ROMVIMZA, these two products acquired through the Deciphera acquisition, are performing relatively as initially expected and are making a solid pitch.

Ultimately, with regard to QINLOCK, if we maintain the current indication label and achieve annual sales of around JPY40 billion and if we are able to secure the additional indication and expanded use for second-line treatment that we are currently working on, there is potential for an additional JPY20 billion to be added.

With regard to ROMVIMZA, we are currently conducting a treatment for tenosynovial giant cell tumors (TGCT), and we expect that this product will be successful, with sales reaching JPY40 billion or JPY60 billion.

In addition, we expect that the number of transplant-related indications will be expanded and that the number of patients who can use the drug will also increase. In that sense, I would say that these two products have started off relatively well over the past year.

In addition, as for Velexbu. It has been several years since the product was launched in Japan, and it has been progressing relatively well. We have high expectations that the product will contribute to our growth when we bring it to the US and European markets. That is the answer to the first question.

As for the second question, I believe that this has been a year of tremendous change. Amid such circumstances, I feel that we must continue to work even harder to become a company that can give everyone a clear sense of and expectations for the next phase of cliff and growth of OPDIVO and the Company as a whole. With this in mind, I am determined to continue my efforts. We hope you will give us your warm support.

Imura: Ms. Kimura of Nikkei Biotech, please go ahead.

Kimura: I would like to ask you about the part about the discontinuation of development of ONO-7018 and ONO-7914. Regarding the reason why the development of these products was discontinued, were there major safety issues or were there many efficacy issues? If there were no particular concerns regarding safety or efficacy and there were other reasons, could you please tell me which is applied to the withdrawal?

Okamoto: In my earlier explanation, for example, I said that ONO-7475 was not expected to have enough efficacy, but the development discontinuation with the strategic reason I said was discontinued in terms of portfolio management. In other words, that it was not discontinued based on clinical data. It is only from the perspective of portfolio management of the entire pipeline.

Kimura: Thank you very much. I understood that both were discontinued from a portfolio management perspective.

Imura: Thank you. Now, we will conclude the meeting.

Finally, we would like to introduce our upcoming events. As President Takino mentioned during the meeting, we are planning to hold an R&D Day on May 20 for institutional investors and analysts to introduce ROMVIMZA.

Also, on June 4, there will be an R&D meeting on the data regarding tirabrutinib, which is scheduled to be presented at ASCO. We will send you another invitation and would appreciate your attendance.

This is the end of the meeting. Thank you for attending today's meeting.