



ONO PHARMACEUTICAL CO., LTD.

FY2024 2Q Financial Results Meeting

November 1, 2024

[Number of Speakers]

6

Toichi Takino
Satoshi Takahagi

Representative Director, President and COO
Corporate Executive Officer / Executive
Director, Sales and Marketing

Masaki Ito

Corporate Officer / Division Director,
Corporate Strategy & Planning

Tatsuya Okamoto

Corporate Officer / Executive Director,
Clinical Development

Masayuki Tanigawa

Corporate Officer / Executive Director,
Corporate Development & Strategy

Ryuta Imura

Senior Director, Corporate Communications

Presentation

Imura: We would like to begin the ONO PHARMACEUTICAL CO., LTD. financial results meeting for Q2 of the fiscal year ending March 31, 2025.

Today, we are holding the event in a hybrid format, both at the venue and online.

Today's Attendees



代表取締役 社長 COO

Representative Director, President and Chief Operating Officer

滝野 十一

Toichi Takino

常務執行役員 営業本部長

Corporate Executive Officer / Executive Director, Sales and Marketing

高萩 聡

Satoshi Takahagi

執行役員 経営戦略本部 経営管理統括部長

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

伊藤 雅樹

Masaki Itoh

執行役員 開発本部長

Corporate Officer / Executive Director, Clinical Development

岡本 達也

Tatsuya Okamoto

執行役員 事業戦略本部長

Corporate Officer / Executive Director, Corporate Development & Strategy

谷川 雅之

Masayuki Tanigawa

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Agenda



2025年3月期第2四半期 決算概要 / 政策保有株式の縮減について

Material for Financial Announcement FY 2024 Q2 /

Status of Cross-shareholdings

(10:00-10:25)

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 (10:25-10:35)

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 (10:35-10:45)

常務執行役員 営業本部長

Corporate Executive Officer / Executive Director, Sales and Marketing

高萩 聡

Satoshi Takahagi

質疑応答

Q&A Session (10:45-11:00)

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First, President Takino would like to provide an overview of the financial results for Q2 of the fiscal year ending March 31, 2025, and explain the status of reduction of cross-shareholdings. Then, Mr. Okamoto, Executive Director of the Clinical Development, will give an update on the progress of development pipeline, and Mr. Takahagi, Executive Director of the Sales and Marketing, will conclude the presentation with an update on Opdivo.

And as for today's materials, they have already been posted on our website, so please refer to them. Now, President Takino would like to begin with an overview of the financial results.

Highlights of Financial Results for FY2024 Q2



- Starting from the second quarter, the profit and loss (including sales, cost of sales, research and development expenses, and selling, general, and administrative expenses) of Deciphera Pharmaceuticals, Inc. for the three months from July to September will be included in our consolidated financial statements.
- In the second quarter, as a provisional accounting treatment, the entire difference between the acquisition cost and the net assets has been recorded as goodwill. In the third quarter financial statements, we plan to record intangible assets and other items as of the acquisition date through a fair value assessment. (In other words, the amortization expenses for intangible assets recognized through the acquisition are not included in this second quarter.)
- Starting from the fiscal year 2024, we will disclose core-basis financial results to present our performance in our core business. In the second quarter, we will present the full-year consolidated financial forecast on a core basis. (The full-year core-basis financial forecast for the fiscal year ending March 2025 is calculated by deducting provisional amortization expenses for intangible assets related to acquisitions from the full-basis financial forecast for the same period.)
- Regarding the exclusive option and asset purchase agreement for "itolizumab" signed with Equillum, Inc. in the United States in December 2022, we decided not to exercise the option for strategic reasons in October 2024.

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Takino: Thank you very much for your continued support. Let me get started by first explaining some of the financial results topics for Q2. First from Q2 of this fiscal year, the profit and loss for three months from July to September of Deciphera, which was acquired in June, will be included. In other words, three months of Deciphera's sales and three months of its expenses will be included in the consolidated financial statements.

In Q2, since the fair value evaluation of intangible assets, called PPA, has not been completed, the entire difference between the acquisition cost and the net assets has been recorded as goodwill, as a provisional accounting treatment. The PPA is expected to be completed in Q3, and Q2 results do not include amortization of intangible assets related to the acquisition.

In addition, starting from the fiscal year ending March 31, 2025, we have decided to disclose our core financial indicators to present our performance. In Q2, we will present our full year consolidated financial forecast on a core basis in addition to the previous full basis. However, as I mentioned earlier, the PPA has not been completed, so please keep in mind that the core-based forecast we are presenting today is only a provisional figure.

Regarding the asset acquisition agreement with Equillum of the United States, which includes an exclusive option to acquire itolizumab, which we concluded in December 2022, I would like to first report that in October of this year, for strategic reasons, we decided not to exercise the option.



Revenue
¥240.3 billion
 YoY -18.4 billion
 (-7.1%)



Goods and Products Sales
¥163.3 billion
 YoY +3.4billion (+2.1%)



Royalty and Others
¥77.0 billion
 YoY -21.8 billion (-22.0%)

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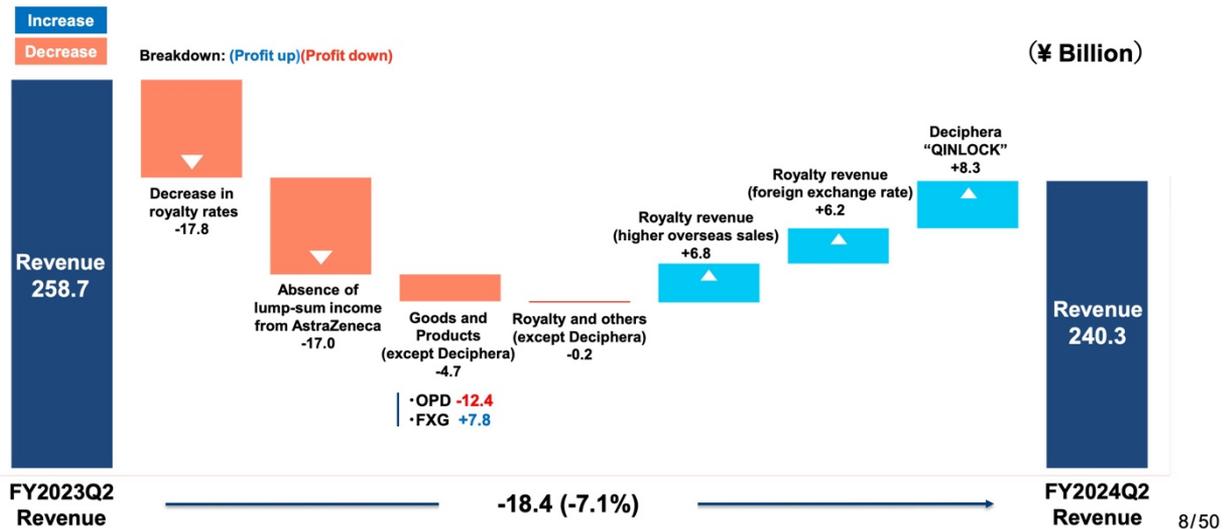
I will now explain the financial results for Q2 of the current fiscal year. First is revenue. Revenue for Q2 decreased by JPY18.4 billion or 7.1% YoY to JPY240.3 billion. Product sales were significantly affected by the NHI price revision of OPDIVO, resulting in a decrease in domestic sales. However, due to the addition of sales of QINLOCK, a treatment for gastrointestinal stromal tumor, GIST, which we acquired through the acquisition of Deciphera, sales increased by JPY3.4 billion, or 2.1%, YoY to JPY163.3 billion.

On the other hand, royalties and others, lower section, were affected by lower royalty rates from Merck of the United States and other companies, resulting in a decrease of JPY21.8 billion, or 22%, YoY to JPY77 billion.

FY2024 Q2 : 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.



This is the breakdown of the increase or decrease in revenue. The first item on the left is a decrease in royalty income of JPY17.8 billion due to lower royalty rates from Merck of the United States and other companies. This was followed by a decrease of JPY17 billion due to the absence of income from the settlement of a patent-related lawsuit with AstraZeneca in the previous year.

As for product sales, while sales of FORXIGA increased significantly, the impact of the NHI price reduction of OPDIVO on sales declined by JPY4.7 billion. There were several factors that caused sales to decrease significantly compared to the previous fiscal year.

On the other hand, an increase in royalty income from OPDIVO from Bristol-Myers Squibb, the positive impact of the weak yen, and sales of QINLOCK acquired through the acquisition of Deciphera were enough to cover several negative factors, limiting the decrease to JPY18.4 billion YoY, to JPY240.3 billion.

FY2024 Q2 : Sales Revenue by Product (Domestic)



¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	240.3	(18.4)	(7.1%)	450.0
Goods and products	159.9	163.3	3.4	2.1%	304.0
Royalty and others	98.8	77.0	(21.8)	(22.0%)	146.0

Goods and Products (Domestic)	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Opdivo Intravenous Infusion	75.0	62.6	(12.4)	(16.5%)	125.0
Forxiga Tablets	35.9	43.7	7.8	21.7%	83.0
Orencia for Subcutaneous Injection	13.0	13.5	0.5	3.5%	27.0
Glactiv Tablets	10.8	9.6	(1.2)	(11.2%)	18.5
Velexbru Tablets	5.0	5.2	0.2	3.7%	10.0
Kyprolis for Intravenous Infusion	4.6	4.6	(0.0)	(1.0%)	9.5
Parsabiv Intravenous Injection	4.1	4.2	0.0	0.7%	8.5
Ongentys Tablets	3.1	3.8	0.7	21.4%	7.5

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 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.

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Next, I will move on to the slide explaining sales revenue by product. First, sales of OPDIVO decreased by JPY12.4 billion YoY to JPY62.6 billion due to the impact of the 15% NHI price reduction. As for FORXIGA, sales increased more than expected to JPY43.7 billion, up JPY7.8 billion or 21.7% YoY, due to its expanded use in chronic kidney disease.

As for other major products, ORENCIA sales increased by JPY500 million YoY to JPY13.5 billion, and VELEXBRU sales increased by JPY200 million YoY to JPY5.2 billion, despite a 15% NHI price reduction. ONGENTYS sales increased by JPY0.7 billion YoY to JPY3.8 billion.

On the other hand, GLACTIV sales decreased JPY1.2 billion YoY to JPY9.6 billion, KYPROLIS was almost the same YoY at JPY4.6 billion, and PARSABIV was also almost the same YoY at JPY4.2 billion.

FY2024 Q2 : Sales Revenue by Product (Overseas) / Royalty



¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	240.3	(18.4)	(7.1%)	450.0
Goods and products	159.9	163.3	3.4	2.1%	304.0
Royalty and others	98.8	77.0	(21.8)	(22.0%)	146.0

Goods and Product (Overseas)	FY2023Q2	FY2024Q2	YoY	
			Change	Change (%)
OPDIVO	6.1	6.5	0.4	6.9%
QINLOCK	–	8.1	–	–

Royalty and others	FY2023Q2	FY2024Q2	YoY	
			Change	Change (%)
OPDIVO	47.4	56.4	9.0	19.1%
KEYTRUDA®	25.6	12.8	(12.8)	(50.0%)

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 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.

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We have also decided to disclose overseas sales by product from this fiscal year. As for OPDIVO, in the middle section, sales in South Korea and Taiwan increased by JPY400 million YoY to JPY6.5 billion. Sales of QINLOCK, which we acquired through the acquisition of Deciphera, totaled JPY8.1 billion for the three months from July to September.

Regarding royalties and others, in the lower section, royalty income from Bristol-Myers Squibb for OPDIVO increased by JPY9 billion YoY to JPY56.4 billion, while royalties from Merck US for KEYTRUDA decreased by JPY12.8 billion, or 50%, due to a decrease in the royalty rate.

FY2024 Q2 : Operating Profit



Operating Profit
¥55.9 billion

YoY -41.2 billion
(-42.4%)



Revenue ¥240.3 billion
YoY -18.4 billion (-7.1%)



R&D Expense ¥68.8 billion
YoY +19.4 billion (+39.4%)



SG&A Expense ¥58.4 billion
YoY +10.8 billion (+22.7%)

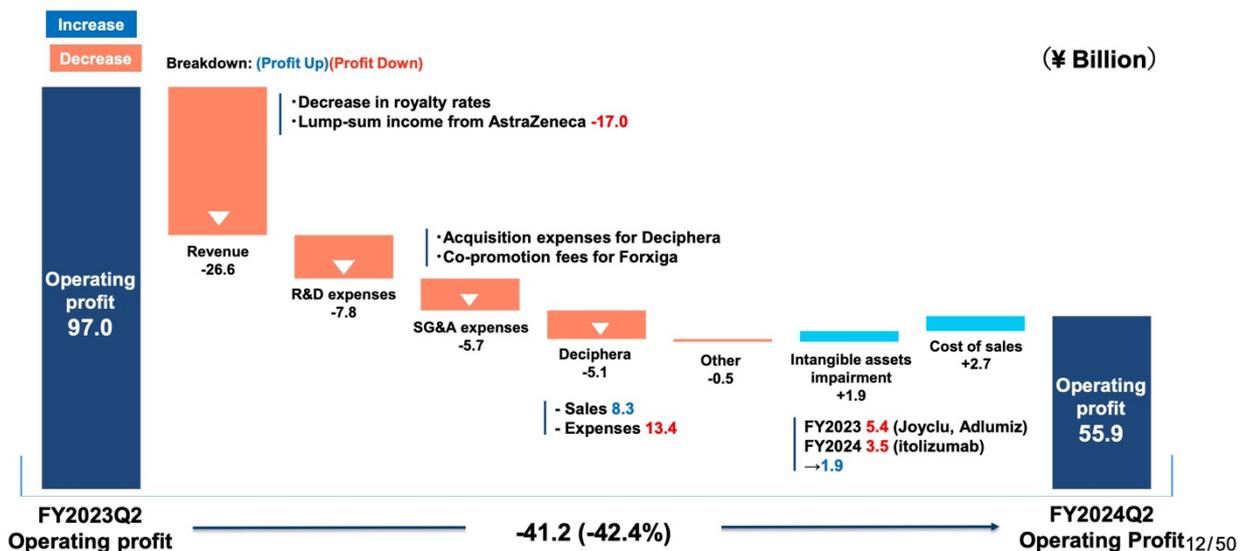
11/50

Next is operating profit. Operating profit decreased by JPY41.2 billion, or 42.4% YoY to JPY55.9 billion. On the right side in the slide, revenue decreased by JPY18.4 billion YoY, R&D expenses increased by JPY19.4 billion YoY, and SG&A expenses increased by JPY10.8 billion YoY.

FY2024 Q2 : Operating Profit (Breakdown)



• Operating profit was decreased by 41.2 billion to 55.9 billion mainly due to increases in R&D and SG&A expenses, despite a decrease in cost of sales.



Similarly, this shows the breakdown of the increase or decrease in operating profit. The main reasons for the decrease were lower sales revenue, higher R&D expenses, and higher SG&A expenses, as well as an operating loss of JPY5.1 billion for the period from July to September for the acquired Deciphera, with sales of JPY8.3 billion and expenses of JPY13.4 billion.

FY2024 Q2 : Financial Overview



¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	<u>240.3</u>	(18.4)	(7.1%)	450.0
Cost of sales	64.8	<u>56.9</u>	(7.9)	(12.2%)	113.0
R&D expenses	49.4	<u>68.8</u>	19.4	39.4%	112.0
SG&A expenses	47.6	<u>58.4</u>	10.8	22.7%	100.0
Other income	0.9	<u>0.6</u>	(0.3)	(36.0%)	0.5
Other expenses	0.8	<u>0.9</u>	0.1	10.2%	3.5
Operating profit	97.0	<u>55.9</u>	(41.2)	(42.4%)	122.0
Profit before tax	99.3	<u>54.6</u>	(44.7)	(45.0%)	123.0
Profit for the period (attributable to owners of the Company)	74.5	<u>41.6</u>	(32.9)	(44.1%)	91.0

YoY Breakdown

Cost of sales -¥7.9 billion

Main reasons

- Absence of impairment losses on sales licenses recorded in the previous fiscal year -5.4 billion

R&D expenses +¥19.4 billion R&D ratio : 28.6%

Main reasons

- Research costs and development costs for clinical trials
- R&D expenses from Deciphera
- Impairment loss for itolizumab +3.5 billion

SG&A expenses +¥10.8 billion

Main reasons

- Co-promotion fees for Forxiga Tablets
- SG&A expenses from Deciphera
- Expenses associated with the acquisition of Deciphera

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 2024, is provided.

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The table shows the financial overview. The cost of sales decreased by JPY7.9 billion YoY to JPY56.9 billion, mainly due to a reactionary decrease from the impairment loss of JPY5.4 billion on sales rights recorded in the same period last year.

R&D expenses increased by JPY19.4 billion YoY to JPY68.8 billion, due to an increase in R&D expenses, the recognition of research and development R&D expenses for Deciphera, and, as I mentioned at the beginning, the recognition of an impairment loss of JPY3.5 billion for itolizumab, for which option rights were not exercised.

SG&A expenses amounted to JPY58.4 billion, JPY10.8 billion higher YoY, due to an increase in co-promotion fees in line with FORXIGA's sales expansion, as well as the recording of SG&A expenses for Deciphera and acquisition-related expenses related to the acquisition.

As a result, operating profit decreased by JPY41.2 billion, or 42.2% YoY to JPY55.9 billion. Interim income attributable to owners of the Company decreased by JPY32.9 billion, or 44.1%, YoY to JPY41.6 billion.

Introduction of a Core-Basis Result



< Background for Introducing a Core-Basis Result >

Previously, IFRS full-basis results have included the impact of transactions that are not related to our core business or are temporary in nature. Additionally, due to the acquisition of Deciphera Pharmaceuticals, Inc., we anticipate amortization expenses for intangible assets acquired through the acquisition in the future. Therefore, starting from the FY 2024, we will disclose the core-basis result to present our performance in our core business.

< Definition of a Core-Basis Result >

Core-basis results are calculated by adjusting items not related to the essential performance of our business and temporary items such as those occurring in a single fiscal year from the IFRS full-basis results.

Examples of specific adjustment items include amortization expenses arising from intangible assets acquired through acquisitions or in-licensing, impairment losses, and compensation or settlement from litigation, losses due to disasters, etc.

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Next, I would like to report on our full-year performance forecast for the fiscal year ending March 31, 2025. As I mentioned at the beginning, we will introduce core basis in financial results from FY2024, that is, the fiscal year ending March 31, 2025.

The background to this is that our full-basis IFRS results included the impact of transactions that were not part of our core business or were one-off transactions. In addition, with the acquisition of Deciphera, the Company expects to incur amortization expenses for intangible assets associated with the acquisition. For this reason, going forward, we will disclose our performance on a core basis to show you our performance in our core business. The definition of core basis in financial results is described here and is common in the industry.



Goods and Products Sales
¥333.0 billion
YoY +16.0 billion (+5.1%)



Royalty and Others
¥152.0 billion
YoY -33.7 billion (-18.1%)

* The forecast of consolidated financial results for the fiscal year ending March 31, 2025, as announced on May 9, 2024, has been revised.

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Regarding the consolidated earnings forecast for the fiscal year ending March 31, 2025, we have revised the consolidated earnings forecast for the full year announced on May 9, 2024, at the beginning of the period.

Revenues are expected to decrease by JPY17.7 billion YoY, but are projected to be JPY485 billion, JPY35 billion higher than the forecast at the beginning of the period. Breaking this down, product sales are expected to increase by JPY16 billion YoY to JPY333 billion, as shown on the right, and royalties and others, shown in the lower section, are expected to decrease by JPY33.7 billion YoY to JPY152 billion.

FY2024 : Financial Forecast (Sales by Product)



Goods and Products (Domestic)	FY2023	FY2024 Forecast	YoY	
			Change	Change (%)
Opdivo Intravenous Infusion	145.5	<u>125.0</u>	(20.5)	(14.1%)
Forxiga Tablets	76.1	<u>89.0</u>	12.9	16.9%
Orencia for Subcutaneous Injection	25.8	<u>27.0</u>	1.2	4.5%
Glactiv Tablets	21.2	<u>18.5</u>	(2.7)	(12.7%)
Velexbru Tablets	10.2	<u>10.0</u>	(0.2)	(2.1%)
Kyprolis for Intravenous Infusion	9.1	<u>9.5</u>	0.4	3.9%
Parsabiv Intravenous Injection	8.2	<u>8.5</u>	0.3	3.3%
Ongentys Tablets	6.3	<u>7.5</u>	1.2	18.8%

*Sales of Forxiga Tablets are forecasted to be ¥89.0 billion, an upward revision of ¥6.0 billion from the previous forecast announced on May 5th, 2024.

Goods and Product (Overseas)	FY2023	FY2024 Forecast	YoY	
			Change	Change (%)
OPDIVO	12.0	<u>13.5</u>	1.5	12.5%
QINLOCK	–	<u>23.5</u>	–	–

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

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

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This slide shows domestic sales forecast by product. For FORXIGA, we expect JPY89 billion, an increase of JPY6 billion from the previously announced forecast. For other products, there is no change from the figures in the initial forecast, and the situation is proceeding as planned.

The total sales of OPDIVO in South Korea and Taiwan are expected to increase by JPY1.5 billion YoY to JPY13.5 billion, and the sales of QINLOCK, which was acquired through the acquisition of Deciphera, are expected to be JPY23.5 billion for the nine-month period from July to March of the following year.

FY2024 : Financial Forecast (Operating Profit)



Operating Profit
¥82.0 billion

YoY -77.9 billion
(-48.7%)

Core Operating Profit
¥110.0 billion



Revenue **¥485.0 billion**

YoY -17.7 billion (-3.5%)



R&D Expense **¥147.0 billion**

YoY +34.8 billion (+31.0%)



SG&A Expense **¥123.0 billion**

YoY +22.7 billion (+22.7%)

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Next is the operating profit forecast. This is expected to decrease by JPY77.9 billion YoY to JPY82 billion. This is due to an expected decrease in sales revenue of JPY17.7 billion YoY, an increase in R&D expenses of JPY34.8 billion YoY, and an increase in SG&A expenses of JPY22.7 billion YoY.

The core operating profit shown from this time onwards is expected to be JPY110 billion.

FY2024 : Financial Forecast (Changes vs. FY2023)



¥ Billion	FY2023 Actual	FY2024 Revised forecast	Change	Change (%)	Changes (vs. FY2023)
Revenue	502.7	485.0	(17.7)	(3.5%)	Changes (vs. FY2023) Cost of sales +¥2.9 billion (2.3%) Main reason - Absence of impairment losses on sales licenses recorded in the previous fiscal year. - Amortization expenses associated with QINLOCK, etc. ¥15.0 billion
Cost of sales	127.1	130.0	+2.9	+2.3%	
R&D expenses	112.2	147.0	+34.8	+31.0%	R&D expenses +¥34.8 billion (+31.0%) Main reasons - R&D expenses from Deciphera +¥26.0 billion - License agreement with LigaChem BioScience, Inc.
SG&A expenses	100.3	123.0	+22.7	+22.7%	SG&A expenses +¥22.7 billion (+22.7%) Main reasons - SG&A expenses from Deciphera +¥15.0 billion - Expenses associated with the acquisition of Deciphera - Co-promotion fees for Forxiga Tablets
Operating profit	159.9	82.0	(77.9)	(48.7%)	Adjustment for a core-basis result Main items - Amortization expenses associated with QINLOCK and development compounds - Impairment loss for itolizumab ¥3.5 billion
Adjustments	—	28.0	—	—	
Core operating profit	—	110.0	—	—	
Profit before tax	163.7	81.5	(82.2)	(50.2%)	
Profit for the year (attributable to owners of the Company)	128.0	58.0	(70.0)	(54.7%)	
Core profit for the year	—	81.0	—	—	

*The exchange rate assumed for the second half of the fiscal year in the financial forecast is ¥145 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥0.4 billion in revenue and a decrease of ¥0.2 billion in operating profit for every ¥1 depreciation of the yen.

18/50

This slide shows the breakdown of the forecast. In terms of cost of sales, while there will be a rebound from the impairment loss on sales rights recorded in the previous period, we expect it to increase by JPY2.9 billion YoY to JPY130 billion, due to factors including approximately JPY15 billion in amortization expenses for the provisional QINLOCK intangible assets.

Regarding R&D expenses, in addition to the increase in R&D costs, we expect that the total will increase by JPY34.8 billion YoY to JPY147 billion due to the nine-month R&D costs of JPY26 billion for Deciphera, as well as the upfront and milestone payments associated with the license agreement with LigaChem BioSciences.

SG&A expenses are expected to increase by JPY22.7 billion YoY to JPY123 billion, due to an increase in co-promotion expenses accompanying the expansion of FORXIGA sales, as well as JPY15 billion in SG&A expenses for the nine months of Deciphera and acquisition-related expenses related to the acquisition.

Core operating profit is expected to be JPY110 billion, calculated by deducting the amortization expenses for intangible assets related to QINLOCK and in-licensed products, and the impairment loss of JPY3.5 billion related to itolizumab from the full-base operating profit.

Net income attributable to owners of the Company is projected at JPY58 billion, a decrease of JPY70 billion, or 54.6% YoY, due to a decrease in income before income taxes. Core profit is expected to be JPY81 billion.

FY2024 : Financial Forecast (Changes vs. Previous Forecast)



The ¥40.0 billion decrease in operating profit compared to the initial forecast is primarily due to significant investments aimed at overcoming the patent expiration of Opdivo and growing into a global specialty pharma company. These investments include costs arising from the acquisition of Deciphera Pharmaceuticals, Inc., which were not factored into the initial forecast, and the license agreement with LigaChem BioScience, Inc. Excluding these factors, we expect to secure profit levels comparable to the initial forecast.

¥ Billion	FY2024 Previous forecast	FY2024 Revised forecast	Change	Change (%)	
Revenue	450.0	485.0	(35.0)	+7.8%	Breakdown of ¥40.0 billion decrease in operating profit
Cost of sales	113.0	130.0	+17.0	+15.0%	Revenue +¥35.0 billion
R&D expenses	112.0	147.0	+35.0	+31.3%	Main reason - QINLOCK +¥23.5 billion
SG&A expenses	100.0	123.0	+23.0	+23.0%	Cost of sales +¥17.0 billion
Operating profit	122.0	82.0	(40.0)	(32.8%)	Main reasons - Amortization expenses associated with QINLOCK, etc. +¥15.0 billion
Adjustments	—	28.0	—	—	R&D expenses +¥35.0 billion
Core operating profit	—	110.0	—	—	Main reasons - R&D expenses from Deciphera +¥26.0 billion - License agreement with LigaChem BioScience, Inc.
Profit before tax	123.0	81.5	(41.5)	(33.7%)	SG&A expenses +¥23.0 billion
Profit for the year (attributable to owners of the Company)	91.0	58.0	(33.0)	(36.3%)	Main items - SG&A expenses from Deciphera +¥15.0 billion - Expenses associated with the acquisition of Deciphera
Core profit for the year	—	81.0	—	—	

19/50

Finally, we have presented a table comparing our revised forecast with the forecast we made at the beginning of the fiscal year. The gains related to the Deciphera acquisition, and the costs relating to the license agreement with LigaChem contract were not factored into the forecast at the beginning of the fiscal year. Therefore, excluding these factors, we are proceeding almost exactly as planned at the beginning of the fiscal year.

The acquisition of Deciphera is a major investment to overcome the patent expiration of OPDIVO and to grow the Company into a Global Specialty Pharma, and the license agreement with LigaChem is an aggressive investment in a promising ADC. We appreciate your understanding.

Reduction plan of Cross-shareholdings (published on November 1, 2021)



➤ Reduction plan

- Period: October 2021 to March 2025 (3 and a half years)
- Details of reduction plan:
 - 30% reduction from the end of September 2021 (141.8 billion yen)
 - ※The company plans to reduce its cross-shareholdings to less than 20% of its net assets by the end of March 2022.

	End of September 2021	Expected at the end of March 2025	Plan	
			Reduction	Reduction rate
Market price at the end of September 2021	¥ 141.8 bil	¥ 99.3 bil	¥ 42.5 bil	30.0%

➤ 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%.

21/50

Next, I will report on the status of reduction in cross-shareholdings. There were three items that we presented at the Q2 financial results meeting in November 2021 as part of our plan to reduce our cross-shareholdings.

To implement a reduction equivalent to 30% of the JPY141.8 billion based on market value as of the end of September 2021, over 3.5 years starting in October 2021. And by the end of March 2022, the ratio of cross-shareholdings to net assets must be reduced to less than 20%. And in the medium to long term, we will aim to achieve a ratio of cross-shareholdings of less than 10% on a balance sheet basis as a percentage of net assets. We have explained these three points to you.

Status of reduction of Cross-shareholdings



	End of September 2021	End of September 2024	Reduction*	Reduction rate
Market price at the end of September 2021	¥ 141.8 bil	¥ 92.4 bil	¥ 49.4 bil	34.9%

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of September 2024	Reduction	Reduction rate
Balance sheet accounting amount	¥ 141.8 bil	¥ 97.3 bil	¥ 44.5 bil	31.4%

※End of September 2024
Ratio of Cross-shareholdings to net assets : 12.3%

22/50

And this is the result at the end of September 2024. The amount has been reduced by JPY49.4 billion on a market value basis as of September 30, 2021. The reduction rate is 34.9%, exceeding the target of 30%.

The amount on the balance sheet was also reduced by JPY44.5 billion, or 31.4%, amid the rise in the Nikkei Stock Price Average, and the ratio of cross-shareholdings to consolidated net assets was reduced to 12.3%, as shown on the lower right.

Status of reduction of Cross-shareholdings



➤ Reduction plan

- 30% reduction by the end of September 2021 as of the end of March 2018 (111 brands, 167.1 billion yen)
- 30% reduction by the end of March 2025 as of the end of September 2021 (141.8 billion yen)

➤ Changes of reduction



23/50

This shows a slightly longer-term trend in the proportion of cross-shareholdings in net assets since the end of the fiscal year ended March 2018. It has been six and a half years since the end of the fiscal year ended March 2018, when it was 31.6%, but the ratio has now fallen by just under 20 points, or around 19 points, to 12.3%.

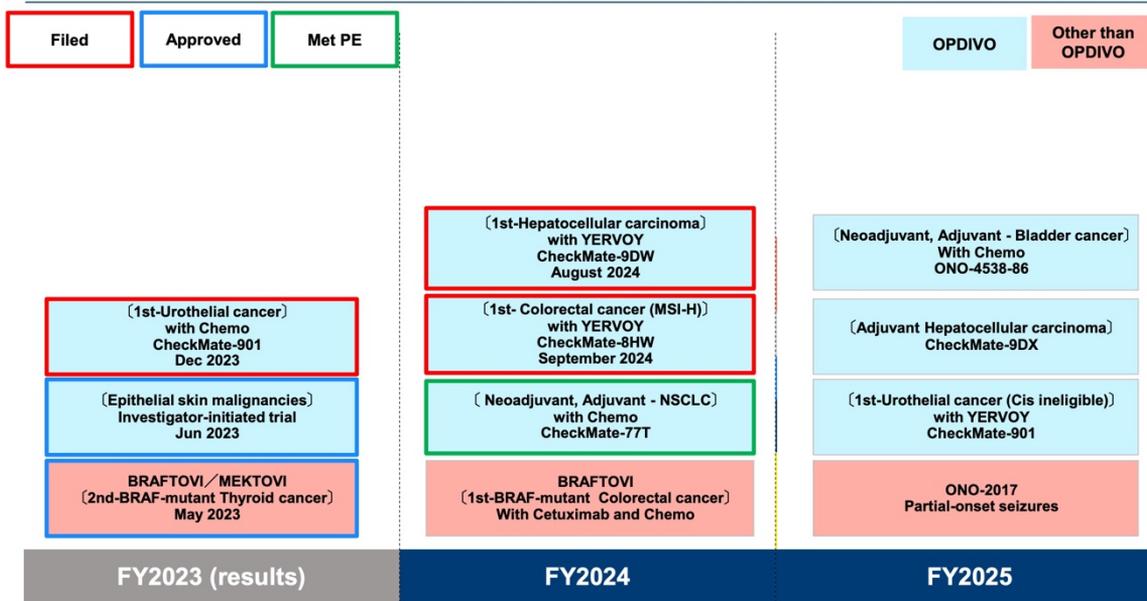
We will continue to reduce the ratio to less than 10% of net assets, and we will continue to engage in dialogue with our portfolio companies to further reduce the ratio.

Imura: Next, Mr. Okamoto, Executive Director of Clinical Development, will give an update on the progress of the development pipeline.

Status of regulatory filing for approval in Japan



As of October 24, 2024



PE : Primary endpoint

25/50

Okamoto: I would like to explain the progress of our development pipeline. I would like to mainly explain the changes since July 22 of this year, using the development pipeline progress materials posted on our website. First, I would like to explain the status of regulatory filing for approval in Japan. The middle column shows the status in FY2024, and there are two changes from the previous year.

First, based on the results of the CheckMate-9DW global multi-center Phase III study of OPDIVO for first-line treatment of hepatocellular carcinoma, we applied for domestic approval on August 9 of this year. This is YERVOY combination therapy. In addition, based on the results of the CheckMate-8HW global multi-center Phase III study of OPDIVO targeting first-line treatment of MSI-H colorectal cancer, we applied for approval in Japan on September 12 of this year. This will also be used in combination with Yervoy.

As announced by BMS on October 31 US time, the CheckMate-8HW study not only compared with chemotherapy, but also compared with pembrolizumab. Currently, the first-line treatment for MSI-H colorectal cancer is pembrolizumab, but in this study, we are also comparing what we call a hypothetical pembrolizumab with OPDIVO alone, and a statistically significant extension of PFS was also observed with OPDIVO alone compared to the hypothetical pembrolizumab.

Then the bottom part for FY2024. As I explained last time, regarding the application for domestic approval based on the global multi-center Phase III study, CheckMate-77T, targeting neoadjuvant and adjuvant therapy of non-small cell lung cancer, the trial has already produced successful results. However, there are still some differences of opinion between us and the authorities, and to date, these differences have not yet been resolved. We would like to apply as soon as the issues are resolved, and at this time, we continue to plan to apply in FY2024.

Next, regarding FY2025, the press release from BMS I mentioned earlier was released yesterday in the U.S. Unfortunately, the YERVOY combination part of the CheckMate-901 study, a global multi-center Phase III study in first-line urothelial carcinoma, in patients who were not eligible for cisplatin, did not meet its primary endpoint. Therefore, we will remove it from this table next time. That concludes my report regarding the status of regulatory filing for approval in Japan.

Development status of OPDIVO (1)



As of October 24, 2024

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug* (relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	Approved	Filed
	1st	with Ipi	Approved	Approved	Approved	Approved	–
		with Ipi/Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	–	–	–	–
	2nd	with Chemo (NSQ)	Revision of labeling	Approved	Approved	–	–
2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved	
Hodgkin's lymphoma	Relapsed /Refractory	with Brentuximab	III	–	–	III	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	Standard of care refractory	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July 26/50

I will continue with an explanation of the major changes in the development status of OPDIVO. As in the past, changes from the previous time are shown in red and highlighted in yellow.

As I mentioned earlier, this table is based on the results of CheckMate-77T, a neoadjuvant/adjuvant treatment for non-small cell lung cancer. This has been updated since BMS received approval in the United States on October 3.

Development status of OPDIVO (2)

As of October 24, 2024



Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
		with Ipi/Chemo	III	III	III	–	–
	3rd	Monotherapy	Approved	Approved	Approved	–	–
Esophageal cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Colorectal cancer	MSI-H/dMMR (1st)	with Ipi	Filed	–	–	III	Filed
	MSI-H/dMMR (3rd)	Monotherapy	Approved	–	Approved	Approved	-
		with Ipi	Approved	Approved	Approved	Approved	Approved**
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	Filed	III	III	Filed	Filed
	2nd	with Ipi	II	II	Approved	Approved	II

★★2nd Line

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July 27/50

As I mentioned earlier in the section on domestic applications, we have submitted a domestic application for combination therapy with ipilimumab for first-line treatment of MSI-H colorectal cancer, so we have updated it as filed.

The application for the combination therapy with ipilimumab for the first-line treatment of hepatocellular carcinoma was submitted by BMS overseas on August 21 in the US and July 19 in Europe, and both applications were accepted by the local regulatory authorities, so we have updated as filed. As for Japan, as I mentioned earlier, the application was filed on August 9.

Development status of OPDIVO (3)

As of October 24, 2024



Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		with Ipi/TKI	–	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Filed	Approved	Approved	Approved	Approved
		with Ipi	III	III	III	III	III
2nd	Monotherapy	II	Approved	Approved	Approved	Approved	
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Rhabdoid tumor	2nd	Monotherapy	II	–	–	–	–
Flat dose	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved
Solid tumor	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	–	–	Filed	Filed

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

28/50

We have updated the chemotherapy combination part of the CheckMate-901 study targeting first-line treatment of urothelial carcinoma, as this received approval in Taiwan on October 9. On the other hand, as I mentioned earlier, the ipilimumab combination part, which is aimed at patients who are not suitable for cisplatin, did not achieve its primary endpoint, so it will be removed from the table next time.

In Japan, we have started a Phase II study for a very rare cancer called rhabdoid tumor, and we are updating the status. This Phase II study targets rare cancers, and once results are obtained, we would like to apply for approval.

Let me briefly explain the rhabdoid tumor. Rhabdoid tumor is a malignant tumor that most commonly occurs between 12 and 35 months of age, and is an extremely rare disease, with approximately 20 cases in Japan and approximately 20 new cases per year.

Given that clinical trials of PD-1 antibodies and PD-L1 antibodies, which are similar drugs, have been conducted overseas, and have shown a certain degree of therapeutic efficacy, we have begun study of nivolumab alone to address unmet needs in Japan.

Regarding the bottom point, this is a question that is often asked at these types of meetings, we are already conducting a Phase I study of nivolumab subcutaneous injection in Japan, and I would like to add that patient enrollment in the Phase I study and the study itself are progressing very well.

Development pipeline (Oncology)



As of October 24, 2024

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						FY2024.5 Approval
Mektovi Tablet (Binimetinib) MEK inhibitor	JRCT2011200018/JP	BRAF-mutant thyroid cancer						FY2024.5 Approval
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma						FY2025 Primary Completion (Part A)
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*						FY2024 Primary Completion
	NCT01968109/JP, US, EU	Melanoma*						FY2024 Primary Completion (Actual)
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*						FY2025 Primary Completion
	NCT06256328/JP, KR, TW	Gastric cancer*						FY2025 Primary Completion
ONO-4578 PG receptor (EP4) antagonist	NCT06547385/JP	Colorectal cancer*						FY2027 Primary Completion
	NCT06538207/JP	Pancreatic cancer*						FY2024 Primary Completion
	NCT06542731/JP	Non-small cell lung cancer*						FY2026 Primary Completion
	NCT06570031/JP	Hormone receptor-positive, HER2-negative breast cancer						FY2025 Primary Completion
ONO-7475 (tamnorzinib) Axl/Mer inhibitor	NCT06532331/JP	Pancreatic cancer*						FY2027 Primary Completion
	NCT06525246/JP	EGFR-mutated non-small cell lung cancer						FY2025 Primary Completion
ONO-7913 (magrolimab) Anti-CD47 antibody	NCT06532344/JP	Pancreatic cancer*						FY2025 Primary Completion
	NCT06540261/JP	Colorectal cancer*						FY2024 Primary Completion
ONO-7914 STING agonist	NCT06535009/JP	Solid tumor						FY2026 Primary Completion
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma						FY2025 Primary Completion
	NCT06547528/JP							FY2028 Primary Completion
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia						FY2027 Primary Completion
	NCT06622226/JP							FY2027 Primary Completion
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing 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 Q1 FY2024 in July

29/50

Next, I would like to talk about the progress of our oncology development pipeline excluding OPDIVO. First, there are a lot of yellow and red letters in the study number section. This section used to show jRCT study IDs, but we have newly obtained ClinicalTrials.gov study IDs for several studies, so we have updated the information to those IDs. The status information of the trials has also been updated accordingly.

Going further down, we have ONO-7018, a MALT1 inhibitor. It is currently undergoing clinical trials on patients in the United States, but we have also started a new Phase I trial in Japan, so we have updated the information here.

As for ONO-8250, a CAR-T cell therapy targeting HER2 derived from iPSC cells, as announced by Fate in August in the US, the first patient has already been enrolled in this Phase I trial in the US, and the enrollment of patients is also progressing smoothly.

Development pipeline (Non-oncology)



As of October 24, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	NCT06579573/JP	Primary generalized tonic-clonic seizures						
	NCT04557085/JP	Partial-onset seizures						
Velexbru Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	jRCT2031220043/JP	Pemphigus						
ONO-2910 Enhancement of Schwann cell differentiation	NCT06538272/JP	Chemotherapy-Induced Peripheral Neuropathy						
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy						
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease						
	NCT05332704/EU							
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease						
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain						
ONO-4915 PD-1 x CD19 bispecific antibody	jRCT2071240056/JP	Autoimmune disease						

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 Q1 FY2024 in July

30/50

Next, here is a summary of the development status of the non-oncology field. As with the oncology mentioned earlier, we are also updating this page as we have obtained ClinicalTrials.gov trial IDs for some of our trials.

On the other hand, the middle row, ONO-2910, a Schwann cell differentiation enhancer, was being tested in Japan in a Phase II, PoC study for patients with diabetic polyneuropathy, but unfortunately the expected efficacy was not confirmed, so it was removed from the table.

On the other hand, this does not mean that we have stopped development of the compound itself, and PoC studies for chemotherapy-induced peripheral neuropathy are progressing well.

Then at the bottom, we have ONO-4915, which has recently entered the clinical stage. This is a bispecific antibody targeting PD-1 and CD19. Clinical trials have been initiated in Japan for this compound. As for ONO-4915, we will give a brief explanation of the compound later.

For ONO-2020 and ONO-1110, the trial status states, for example, that FY2023 Primary completion and that FY2024 Completion. We are now preparing to proceed with the next Phase II studies for these that were in Phase I studies in Japan and overseas.

Development pipeline - Deciphera



As of October 24, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
QINLOCK (ripretinib) KIT inhibitor	NCT03353753/NA, EU, AU, SG	GIST ≥4 th Line						FY2020 Approval
	NCT05734105/NA, SA, EU, AU, KR, TW	GIST 2nd KIT Exon 11+17/18						FY2025 Primary Completion
DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU, AU, HK	TGCT						FY2024 FDA: Filing accepted EMA: Filing accepted
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor (with sotorasib)						FY2027 Study completion
	NCT05957367/US	Solid tumor (with ripretinib)						FY2026 Study completion
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Solid tumor						FY2026 Study completion

NA : North America, SA : South America, AU : Australia, SG : Singapore, HK : Hong Kong, KR : Korea, TW : Taiwan, JP : Japan

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 Q1 FY2024 in July 31/50

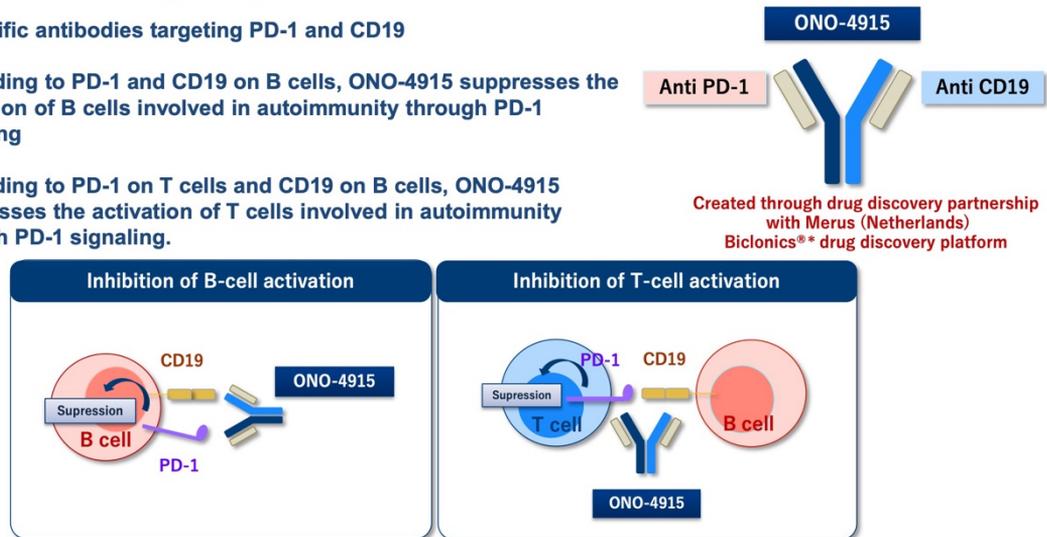
Here we show the pipeline of Deciphera. We have updated the information regarding vimseltinib, a CSF-1R inhibitor, as the US FDA has accepted an application for approval to treat a benign tumor called tenosynovial giant cell carcinoma. There are no other updates.

ONO-4915



Initiated Phase I study in Japan for the treatment of autoimmune disease

- Bispecific antibodies targeting PD-1 and CD19
- By binding to PD-1 and CD19 on B cells, ONO-4915 suppresses the activation of B cells involved in autoimmunity through PD-1 signaling
- By binding to PD-1 on T cells and CD19 on B cells, ONO-4915 suppresses the activation of T cells involved in autoimmunity through PD-1 signaling.



Bionics** : Bispecific antibody that binds simultaneously to two different antigens

32/50

This was the status of our development pipeline so far. As I mentioned earlier, I would like to briefly explain ONO-4915, which has recently entered the clinical stage. ONO-4915, as you can see in the picture of the Y-shaped antibody on the right, is an antibody that targets both PD-1 and CD19, making it a bispecific antibody.

By binding to PD-1 on B cells and CD19 on B cells, it is expected to suppress activated B cells that are involved in the onset and exacerbation of autoimmune diseases.

Also, on the right side, it is thought that it may bind to CD19 on B cells and PD-1 on T cells, and when it does so, it is believed to have the effect of suppressing activated T cells involved in autoimmune diseases.

The most well-known B cell-targeting agent for autoimmune diseases is rituximab, an anti-CD20 antibody, but ONO-4915 can control not only B cells but also T cells, so we are developing ONO-4915 with the expectation that it will be a new therapeutic agent in the therapeutic areas where unmet needs still remain.

Key milestones in FY2024 Q2 (FY ending March 2025)

As of October 24, 2024



(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Urothelial cancer (1L with Chemo) /CheckMate-901	Approved (Oct.2024) in TW
		NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T	Approved (Oct.2024) in US
		Hepatocellular carcinoma (1st with Ipi) /CheckMate-9DW	Filed in US, EU (Aug.2024) in JP (Sep.2024)
		MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Filed in JP (Sep.2024)
	Vimseltinib (DCC-3014)	TGCT	Filing accepted in EU (Jul.2024) in US (Aug.2024)
P2	OPDIVO	Rhabdoid tumor	Started in JP (Sep.2024)
	ONO-2910	Diabetic polyneuropathy	Discontinued (Sep.2024)
P1	ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	Started in JP (Oct.2024)
	ONO-4915	Autoimmune disease	Started in JP (Sep.2024)

33/50

This is an update to the discontinued development of ONO-2910 that I mentioned earlier.

Key milestones in FY2024 Q2 (FY ending March 2025)

As of October 24, 2024



(Drug discovery partnerships & Research collaborations/Licensing & Co-promotion)

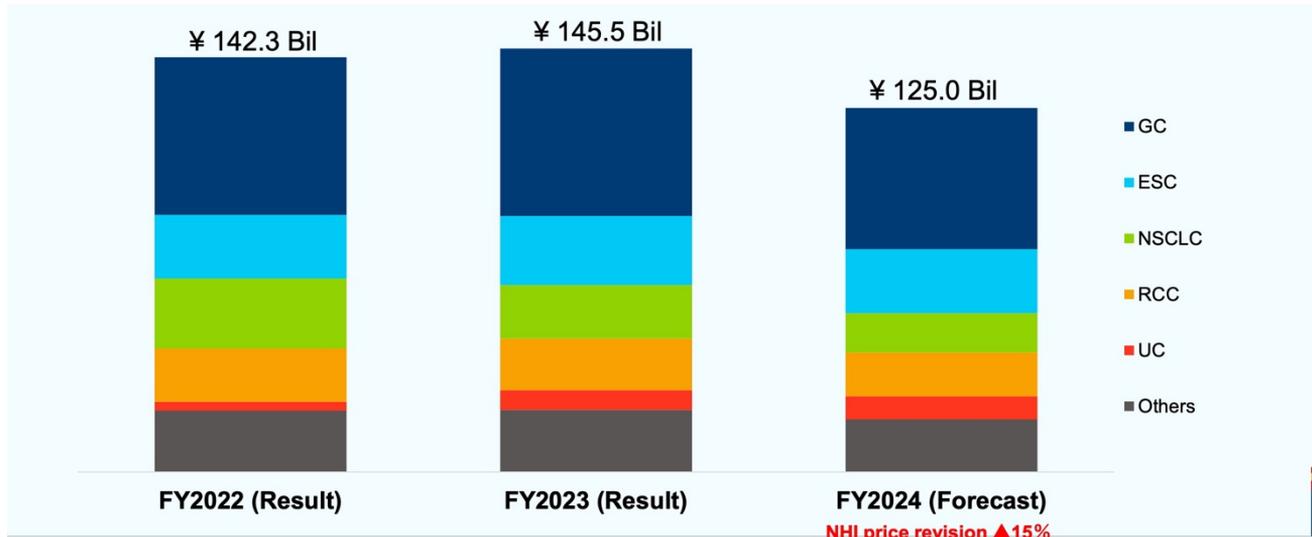
Title	Progress
Ono Enters into a New Option and Research Collaboration Agreement with Monash University to Discover and Create New Anti-GPCR Antibodies in the Autoimmune and Inflammatory Diseases	Started (Aug.2024)
Ono Enters into License Agreement for LCB97, an Antibody-Drug Conjugate, and Research Collaboration and License Agreement to generate novel ADC candidates by leveraging ConjuAll™ ADC platform with LigaChem Biosciences	Started (Oct.2024)
Ono Enters into a Drug Discovery Collaboration and Option Agreement with Shattuck Labs to Generate Bifunctional Fusion Proteins	Discontinued
Ono Enters into Collaboration Agreement with Domain Therapeutics and Université de Montréal for GPCR-Targeted Drug Discovery	
Ono and Equillium Announce Exclusive Option and Asset Purchase Agreement for the Development and Commercialization of Itolizumab	Not exercising option

34/50

As President Takino mentioned at the beginning of this presentation, we have decided not to exercise the option right for itolizumab, an anti-CD6 antibody, for strategic reasons. That is all from me.

Imura: That is all for the development part. Next, Mr. Takahagi, Executive Director of Sales and Marketing, will give an overview of OPDIVO trends.

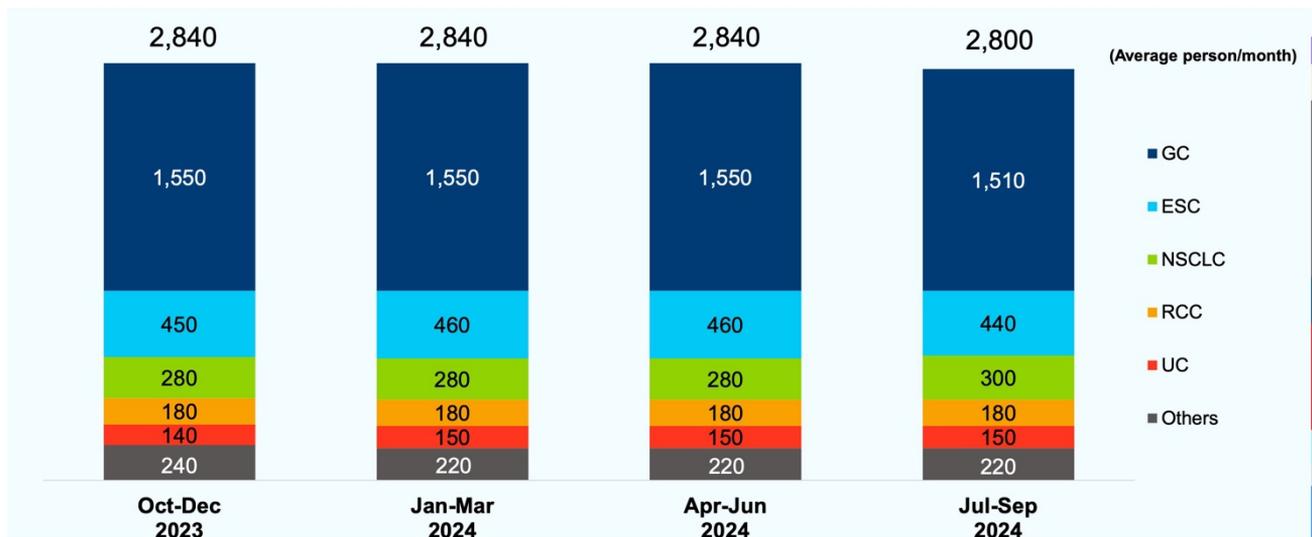
Sales Trend of OPDIVO by Each Cancer



Source: Estimation from external and internal data 36/50

Takahagi: As for sales, we believe that in FY2024 we are currently making progress as planned. As I will show later, the share of new prescriptions for lung cancer is on the rise, and we will continue to secure our share in gastric cancer. This is expected to amount to JPY125 billion for this fiscal year.

Number of Patients Newly Prescribed with OPDIVO by Each Cancer (Estimation)



Source: Estimation from external and internal data 37/50

This is the trend of the number of patients newly prescribed with OPDIVO. First, the number of gastric cancer cases decreased by about 40 cases compared to April to June. As you may have already noticed, there has been a decrease in first-line treatment for gastric cancer and a decrease of about 20 cases for esophageal cancer. This is part of the second-line treatment, and the amount of the second-line treatment has been decreasing due to the spread of IO, including the OPDIVO regimen, in the first-line treatment. On the other

hand, the first-line treatment of non-small cell lung cancer has increased by about 20 cases. We are in the process of expanding prescriptions here.

Trend of total sales of ICPIs and OPDIVO share

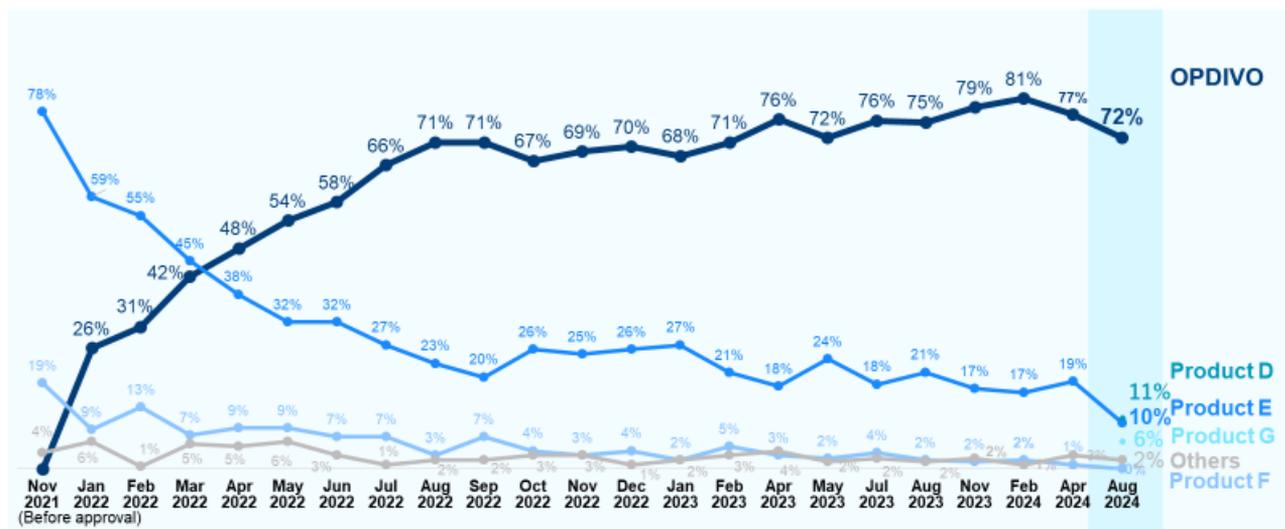


Source: External data

38/50

As for OPDIVO's market share, the result of the July to September period was 26%.

Prescription Ratio in Patients Newly Treated* for 1L GC



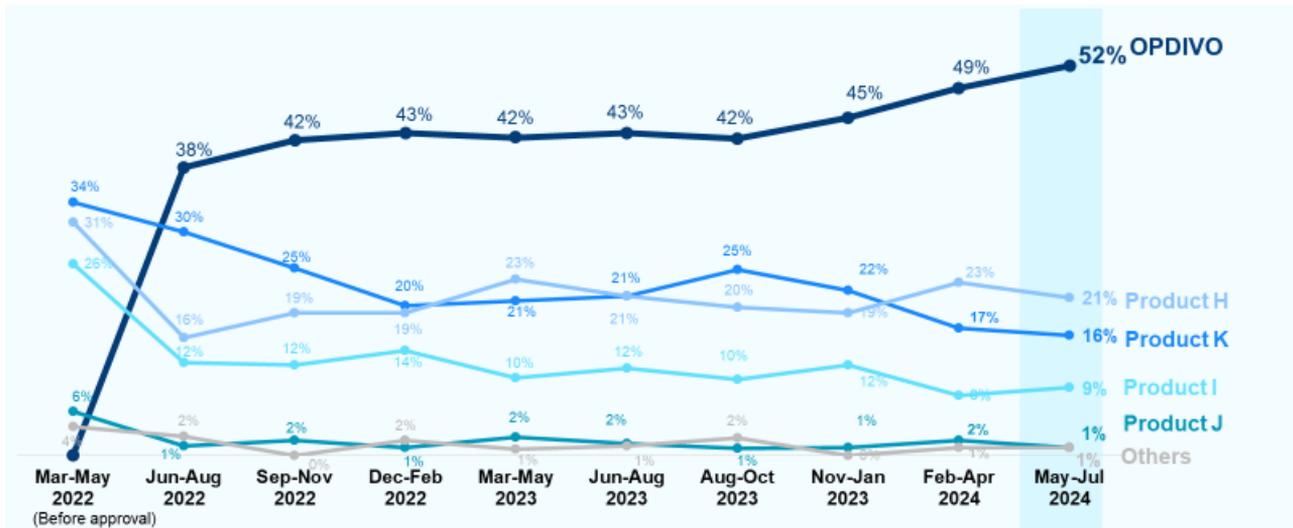
*: Patients starting 1L treatment within the last 3 months

Source: External data (Nov 2021~Aug 2024: n=200~204)

40/50

Gastric cancer. The share of new prescriptions in first-line treatment was 72%, and we believe that erosion by competing products is as expected. Regarding the positive Claudin antibody test results in particular, we do not believe that the drug to be used should be determined based on this positive test result alone, and we would like to continue our activities in this regard.

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



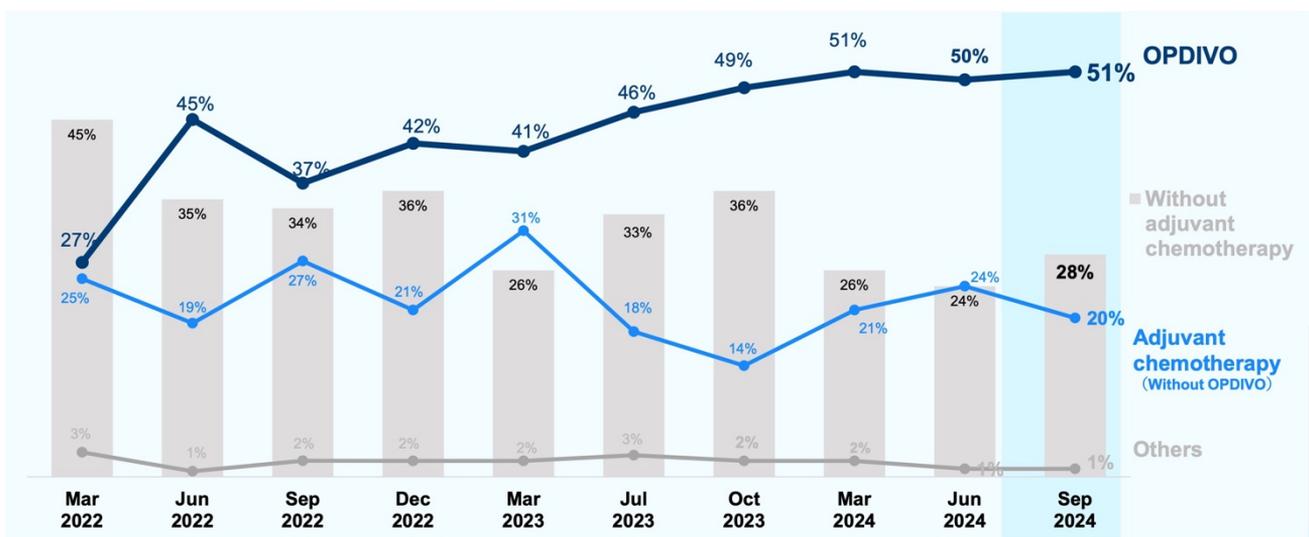
*Patients starting treatment within the last 3 month

Source: External data (May 2022~Jul 2024; n=150~155)

42/50

Esophageal cancer. The prescription ratio in patients newly treated for the first-line esophageal cancer is 52, and the upward trend continues, so we would like to maintain this trend.

Prescription Ratio in Patients Newly Treated* for ESC(adjuvant chemotherapy)



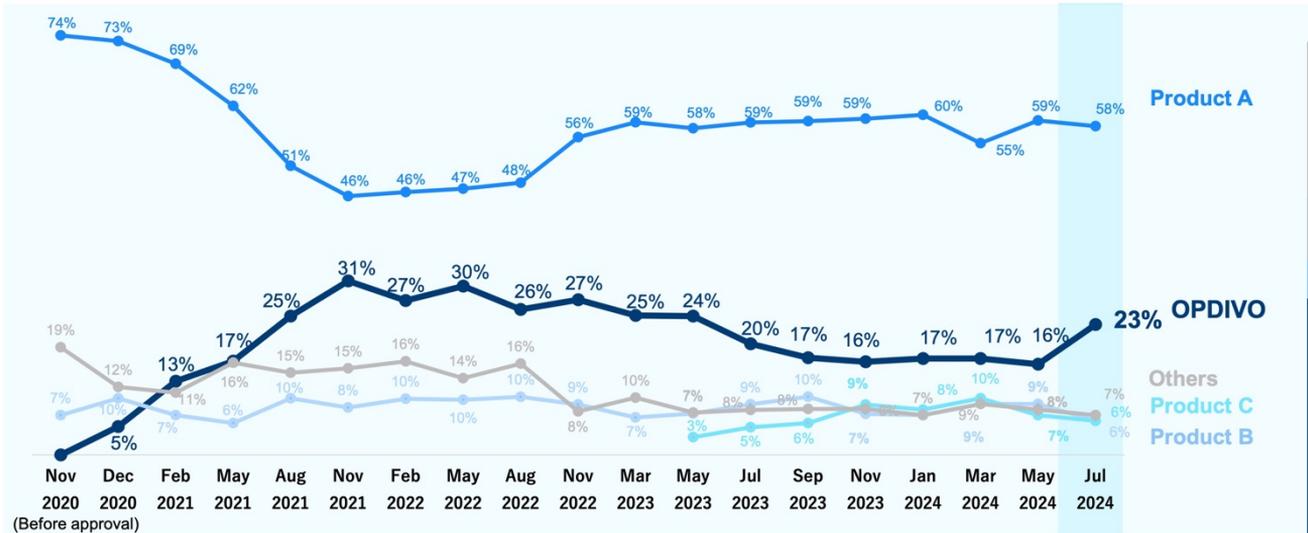
*Patients starting treatment within the last 3 months

Source: External data (Mar 2022~Sep 2024 n=130~152)

44/50

For adjuvant therapy, the figure was 51%, and we are also aware of this as an issue, as there are still many people who are not interested in adjuvant therapy or chemotherapy. Therefore, if we continue to raise awareness in this area, we can expect to see further growth.

Prescription Ratio in Patients Newly Treated* for 1L NSCLC



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

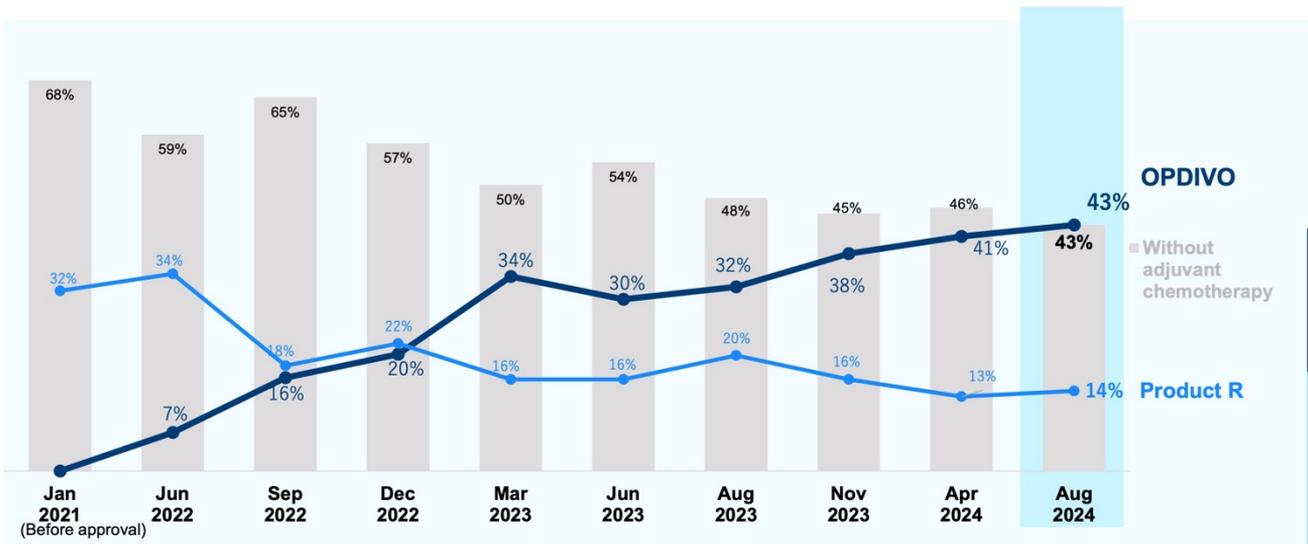
Source: External data (Nov 2020–Sep 2024: n=167–245)

46/50

Lung cancer. The prescription ratio in patients newly treated for the first-line lung cancer has recovered to 23%. We believe that follow-up data for both CheckMate-227 and CheckMate-9LA, and countermeasures against side effects, are beginning to permeate the market.

Although we believe that the bottom has been reached in the share of new patient prescriptions, we believe that further recovery is an initiative for H2 of this fiscal year.

Prescription Ratio in Patients Newly Treated* for Bladder Cancer (adjuvant chemotherapy)



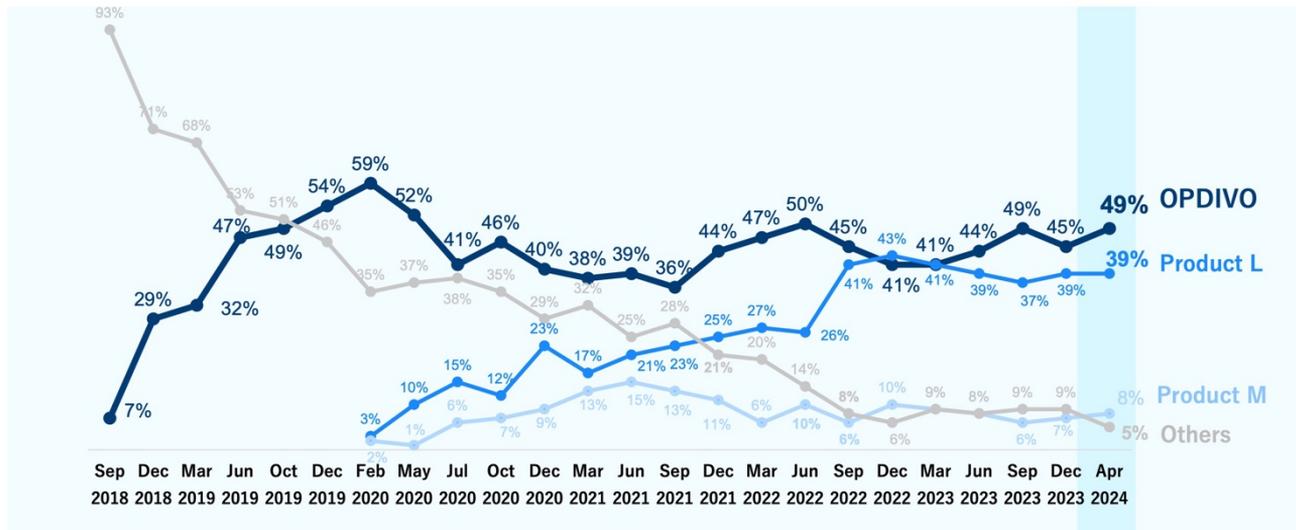
*Patients starting treatment within the last 3 months

Source: External data (Jan 2022–Aug 2024: n=200)

48/50

Urothelial carcinoma. The prescription ratio in patients newly treated for urothelial carcinoma is 43% and is gradually increasing, but we still need to speed up the process.

Prescription Ratio in Patients Newly Treated* for 1L RCC



*Patients starting treatment within the last 3 months

Source: External data (Sep 2018~Apr 2024: n=46~150)

50/50

Lastly, I will explain the renal cell carcinoma. We have not been able to update the figure since the last time, so the current figure is 49%, the same as last time. Urothelial carcinoma and renal cell carcinoma are in the urological field, so we will continue to work to maintain and further expand our presence here.

As I mentioned earlier, our sales plan for FY2024 is progressing as planned. However, in this context, we must secure a firm share of the gastric cancer market, and since there are lots of patients with non-small cell lung cancer, we must further increase our share of newly prescribed patients in this area. In addition, from next year onwards, we will be able to start activities in the areas of liver cancer, etc., so we would like to use this as a solid growth driver and enter a growth phase from fiscal 2025 onwards.

That is all from me.

Imura: Thank you very much. That concludes our presentation.

Question & Answer

Imura : Now, we would like to answer your questions. Mr. Hashiguchi from Daiwa Securities, please go ahead.

Hashiguchi : In the explanation of the full year forecast on page 19, I believe you explained that excluding acquisitions and license agreements, the results would be at the same level as the initial forecast. However, FORXIGA has been revised upward by JPY6 billion, but in the end, it is at the same level. Are there any other negative factors? You have not changed your sales forecast except for FORXIGA, but does this mean that the actual situation is slightly weaker? Could you elaborate on this?

Itoh : I understand that your question is that the expenses are a bit under-explained.

Hashiguchi : I'm not sure if it's an expense or what, but as far as sales for FORXIGA are concerned, it's strong, compared to the initial forecast.

Itoh : Yes, exactly.

Hashiguchi : Despite this, is there any other negative factor that would cause profits, excluding acquisitions and license agreements, to remain at the same level as the initial forecast?

Itoh : Regarding the increase in sales by product, FORXIGA, you are correct on that. We have also revised upward our initial forecast for royalties. When compared to the full basis, the core and operating profit of FY2024 previous forecasts seem a little weak. That's your question, am I correct?

We announced this part last month. As for the expenses for license agreement with LigaChem Biosciences, and we expect to pay the upfront and the first milestone payment within this fiscal year, so this portion was not included in our initial earnings forecast.

In addition, since we have recorded an impairment loss this time, the cost of the impairment has not been included in the initial forecast. However, the impairment is not a cash outflow, but a part that has already been paid, and as for LigaChem, it is a growth investment, so if this were a little later in phase, it would not affect the full base profit and loss.

When these factors are taken into account, it appears to be slightly negative on a full basis, however, this has been deducted from the core portion and not from the LigaChem portion, so I think that this explains it for the most part.

Hashiguchi : Just one more point, I understand that the development of GVHD for vimseltinib is coming up in the future, and in that context, the option right for itolizumab, this time, will not be exercised for strategic reasons. When you announced the acquisition of Deciphera, I believe you mentioned your expectations for itolizumab's effectiveness in treating GVHD as a significance of the acquisition.

It would be much easier to understand if you said that the data that came out was disappointing, but I'm not sure I understand what you are explaining as strategic reasons, so I was wondering if you could comment a little more on this GVHD area and how you intend to utilize the assets acquired through the Deciphera acquisition.

Takino : I hope you will understand that I am refraining from explaining too much in detail as it involves our partner. One of the reasons why I explained that it was a strategic decision is that we were making a comprehensive judgment on whether to acquire Deciphera at this time and then exercise the option

opportunity for itolizumab, taking into account the market landscape for acute GVHD and the competitiveness of drugs for lupus nephritis. I hope I can refrain from going into further detail, as I don't want to cause trouble for the partner.

Imura : Mr. Ueda from Goldman Sachs, please.

Ueda : First, I would like to know about your current approach to business development. In H1 of this fiscal year, there was progress in various areas, such as acquisition of Deciphera and partnership with LigaChem, but to what extent has this been able to address the cliff of OPDIVO? Also, if business development is necessary in the future, what areas do you intend to reinforce, domestic or overseas, in the early or late phases?

Takino : The Deciphera opportunity is a very big opportunity, but the OPDIVO product is also very big. I don't necessarily think that the arrival of Deciphera products is sufficient to cover the cliff. Therefore, we believe that there is every possibility for future business development to be compound-based, product-based, or through M&A, and we intend to actively pursue these areas.

Regarding what kind of direction that we are looking for, of course we would like to see high business efficiency, but it depends on drug candidates. It could be possible whether it's early or late phase, but I think that's the best if we utilize our rich domestic capabilities.

Currently, we are in a situation where we have a global footprint, and we are more interested than ever in leveraging and developing that footprint. Overall, I would say that everything you expressed falls into the category, but to be honest, of course I would appreciate it if you could understand it's in the late phase.

Ueda : Thank you. Just one follow-up question, regarding the scale of your investment in business development. I assume that you are utilizing the cash you currently have on hand and the repayment of fixed term deposit of Deciphera, but you also mentioned borrowing money and the sale of cross-shareholdings. Including these, how much money do you think you can currently spend on business development?

Takino : I would like to refrain from giving a quantitative answer, because I don't want to create misunderstandings, but it depends on the case. Even if this is a slightly larger initiative, we will do it if there is an opportunity to do it, and I hope you understand that the answer will not change much, whether it is after or before Deciphera acquisition.

Ueda : I understand. Thank you. That is all.

Imura : Mr. Akahane from Tokai Tokyo Intelligence lab., please go ahead.

Akahane : I would like to ask three questions. First, as mentioned in the opening question, FORXIGA is doing well in this financial statement and royalties are also up due to revenue and exchange rates. You said it is almost in line with your forecast, but core operating profit is JPY110 billion for the current fiscal year. This was neither in the last fiscal nor at the beginning of the term, so what does it mean when you look at it here? It doesn't have to be quantitative, so what is your qualitative impression? This is my first question.

Itoh : We are not able to provide a comparison with the previous period, but if we assume that the core operating profit of JPY110 billion represents the profit from our main business, then I believe that the fact that it exceeds JPY100 billion indicates to a certain extent the scale of our profitability.

Akahane : Is it correct that not much has changed? Is it correct to assume that since there was no change, there will be no change?

Itoh : Yes, exactly.

Akahane : I see. The second point is slightly related to this, but the H1 royalties were JPY77 billion, and if we simply subtract the royalties, you have a deficit of JPY21.2 billion, excluding royalties, but in H2 you have a deficit of JPY42.8 billion, excluding royalties. The full-year core operating profit is JPY110 billion, and if we subtract the annual royalties of JPY152 billion, we get a deficit of JPY42.8 billion, excluding royalties. Is it correct to say that this is almost entirely due to the irregular factors related to the Deciphera acquisition? Can we assume that earnings excluding acquisitions will improve?

Itoh : Are you talking about operating profit excluding royalties?

Akahane : Yes, that's right. Looking at operating profit, if we subtract royalties, which are planned to be JPY140 billion, for the full year it would be JPY64 billion, which would result in a deficit of JPY42.8 billion in H2. Does this mean that this is mostly explained by acquisitions?

Itoh : The impact of this acquisition on Deciphera's performance includes not only Deciphera's standalone performance but also the amortization of intangible assets related to the M&A related to the PPA. Since the integration period is three months in H1 and six months in H2, the impact will naturally become more significant in H2.

Akahane : I see. Lastly, as you explained at the beginning of this presentation, you simply subtracted the assets from the acquisition funds, and this time you will record that as goodwill, and the goodwill will be JPY315.1 billion. I assume there will likely be further revisions in the future. I imagine that it was difficult to analyze this at the time of the acquisition, but can we say that the goodwill of JPY310 billion is reasonably appropriate at this time? The world is in an inflationary phase, and new drug seeds are inevitably causing inflation right now. As for your company's current assessment, would you say that this goodwill is as expected?

Takino : As expected or within the expected range.

Akahane : I see.

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

Sakai : The table on page 39 shows the share of new first-line prescriptions in gastric cancer, and I assume the product G here is probably a new product launched by another company. I understand well what Mr. Takahagi explained and I understand that OPDIVO has a good share on the market overall, including Japanese data, but G has 6%. I think this is quite a rocket start. The company that launched the product also explained that it got off to a good start, but what happened in the market now, over the course of the launch? I am sure there are doctors who are using the product, and I would like to know how your company is responding to the competition, including how it is feeling. Could you elaborate on this?

Takahagi : First, the competitor is a new molecular-targeted drug, so I think this is really what we expected to see in terms of early adopters and adoption. One reason is that it is a new drug that has never existed before. Perhaps the doctors who are using it wanted to try it out a bit now. After all, it is a new drug. We have heard many such comments, so we are almost in line with our estimates in that area as well.

We believe that from this point on, evaluation and clinical issues, good points and bad points, will probably emerge, so we will carefully and thoroughly grasp the situation, but we do not think it is necessary to make major changes to our strategy. We have been grateful for the lead we have built up so far, and the doctors who use OPDIVO are reevaluating various regimens, including OPDIVO.

In the process, they have a deeper understanding of what OPDIVO is good at, so I think that the data I showed you earlier will help deepen their understanding. Taking these factors into consideration, we believe that we will be able to secure a firm share of the market, and we believe that we can do so.

Sakai : Just to follow up, regarding the biomarker, the Claudin 18.2 antibody, it is still unclear whether this will be an advantage or a disadvantage, but is it correct to understand that essentially this test is not an obstacle to prescribing the drug?

Takahagi : Yes. We think they do not choose a treatment based on that. Each patient is completely different in terms of tumor size, age, PS, and so on, and when you listen to the doctors' stories about each patient, you realize that they are all completely different. The doctors will decide on the treatment drug based on their lifestyle and what kind of goal they want to achieve. We do not believe that doctors will choose a certain treatment simply because there is a certain condition.

Sakai : I understand. Also, briefly, the table on page 18, I think someone asked about core and non-core, but the core adjustment amount for the full year is JPY28 billion. As explained here, the impairment of itolizumab is JPY3.5 billion, so the balance will be JPY24.5 billion? Am I calculating this correctly? Am I correct in understanding that the difference in these numbers, the JPY24.5 billion, is the amortization of the intangible related to Deciphera and QINLOCK, which will appear in H2 of this fiscal year? Is this amount for nine months?

Itoh : On page 18.

Sakai : There is a core adjustment amount. JPY28 billion.

Itoh : In the explanation of cost on page 19, I believe it is stated that the amortization expense for intangible assets related to Qinlock is JPY15 billion, and this amount is included as a deduction item. Also, as shown in the Q1 financial results summary, I believe we recorded JPY3 billion in M&A expenses that we paid this time, and this amount has been deducted from the core amount this time. The other part is the amortization of in-licensed- products. If we adjust the core when there is an impairment loss, we have to exclude the recurring portion as well, otherwise the results will be uneven. That is a breakdown of JPY28 billion.

Sakai : I see. So, JPY15 billion plus JPY3.5 billion, and the rest is the amount you just mentioned.

Itoh : Yes.

Sakai : However, this is not yet a definite number, is it? This could change after the PPA is set.

Itoh : There is a possibility that JPY15 billion for QINLOCK could be changed a little.

Sakai : Is this for nine months?

Itoh : It is for nine months.

Sakai : I understand. Thank you.

Imura : Mr. Matsubara from Nomura Securities, please ask your questions.

Matsubara : Thank you. I have two questions. The first question is about FORXIGA. Since the forecast has been revised upwards, can you tell us about the share of new patients with kidney disease in clinical practice, how it compares with competitors, and will we see similar growth next fiscal year? Can you tell us about these areas?

Takahagi : First, regarding FORXIGA, it is difficult to gain the new patient share, and I cannot truly state it clearly. This is because, although there are probably 1.2 million patients who have been diagnosed with chronic kidney disease and are receiving treatment, the current number of potential patients in Japan is said to be 20 million. Since these patients are untreated or undiagnosed, the share of new patients will vary depending on the population size. Currently, the number of new patients receiving FORXIGA for chronic

kidney disease, diabetes, and chronic heart failure is steadily increasing. As a result, our products have remained at a level that is almost on par with our competitors' products.

As for our outlook for the future, as I mentioned earlier, there is still a very large number of s 1.2 million of chronic kidney disease patients , and when you consider that there are 20 million potential patients, I believe there is still plenty of potential for growth. We are also seeing this as an opportunity, including in the case of competing products. As both companies are expanding promotion, the number of patients using the drug is increasing steadily, and we believe that further expansion can be expected from next fiscal year onwards.

Matsubara : Thank you very much. Next question is about QINLOCK. According to the literature, approximately 80% of GIST patients have mutations in EXON 11, 17, and 18. Comparative studies with sunitinib have shown efficacy, so will you be able to capture 80% of these patients with sunitinib in the second line? Or how much upside do you think will be? Can you tell us more about the situation here?

Tanigawa : QINLOCK is currently undergoing Phase III studies with additional indications for a special genetic mutation. Although we do not know where you got the 80%, based on past Phase III analysis, 14% of patients will be our target.t We do not yet have any information as to what percentage this will actually be in actual clinical practice.

Matsubara : So, does the current 14% figure mean that the upside is limited?

Tanigawa : I don't know the information right now, but are you asking if the percentage will be higher than 14%?

Matsubara : Yes.

Tanigawa : We don't have enough information on that point yet, so the information we have now is the percentage of 14% that was implemented in P3.

Matsubara : I understand. Thank you.

Imura : Mr. Muraoka from Morgan Stanley MUFG Secretaries, please go ahead.

Muraoka : Regarding the outlook for next fiscal year, I understand what Mr. Takahagi said earlier about the expectation that FORXIGA will continue to grow, but I don't think there will be a generic version of FORXIGA next fiscal year yet, but will a genetic of GLACTIV be available around next fiscal year? Or is it not until 2026? Including that, I would like you to organize the incoming and outgoing factors for the next fiscal year.

Will there be no generic entries in Japan? Will there be any preparation costs for an application for VELEXBRU in the US in the next fiscal year? Also, on a 12-month basis, will Deciphera's losses increase compared to a 9-month basis, or will they break even? Please tell me how I should understand the next fiscal year in this area.

Takahagi : First, speaking about domestic products, we expect generic versions of GLACTIV to be introduced in 2026, so we do not expect this to have any impact on GLACTIV next fiscal year. FORXIGA is still on an upward trend, and as I mentioned earlier, we will continue to try to expand prescriptions of OPDIVO for lung cancer, and we will also secure a firm share of the gastric cancer market. In terms of potential for growth, we are planning to enter the liver cancer market, and we would like to make this our growth driver. This is the current status of our main products. That is all.

Takino : Regarding the question about the QINLOCK, our current expectation is that it will be profitable on a single-year basis in about three years. In that sense, we have not yet been able to fully examine the situation to the extent that we are able to comment on the direction that QINLOCK's or Deciphera's figures will be next fiscal year.

Muraoka : Thank you. Three years from now means you will break even in FY2027, right?

Takino : That's about the extent of what we're aiming for at the moment.

Muraoka : I understood. In that sense, it sounds like if you were to look at the three-year period in a straight line, the nine-month deficit and the 12-month deficit would be roughly balanced. So, from there onwards, shall I think about it by my own?

Takino : Yes. We would like to make some comments, but we do not have enough information, and we cannot mislead you.

Muraoka : I understand. Thank you.

Imura : That concludes the question-and-answer session. We are pleased to present our current year's events. At the end of this fiscal year, we are currently planning to hold an R&D Day and ESG Meeting in March.

As I mentioned earlier today, on March 5, Deciphera employees and executives will be holding an R&D day where we will provide you with more details about vimseltinib, which is expected to be approved in the United States in February.

We are planning to have an ESG Meeting on March 27. We know you are busy, but we would be delighted if you could join us again. This concludes the financial results meeting for Q2 of the fiscal year ending March 31, 2025. Thank you very much for your time today.