# ONO PHARMACEUTICAL CO., LTD.

FY2026 Q2 Financial Results Earnings Call

October 29, 2026

**[Number of Speakers]** 5

| | |
|---|---|
| Toichi Takino | Representative Director, President and Chief Operating Officer |
| Masaki Itoh | Corporate Executive Officer/Chief Officer of Finance & Accounting Division |
| Tatsuya Okamoto | Corporate Officer/Executive Vice President, Clinical Department |
| Hirokazu Kitada | Corporate Officer, Executive Vice President, Sales & Marketing |
| Ryuta Imura | Vice President, Corporate Communications |

## Presentation

**Imura**: Thank you very much for joining us today at Ono Pharmaceutical's financial results meeting for Q2 of the fiscal year ending March 2027.

First, I would like to introduce the attendees. Takino, Representative Director, President and COO.

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

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

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

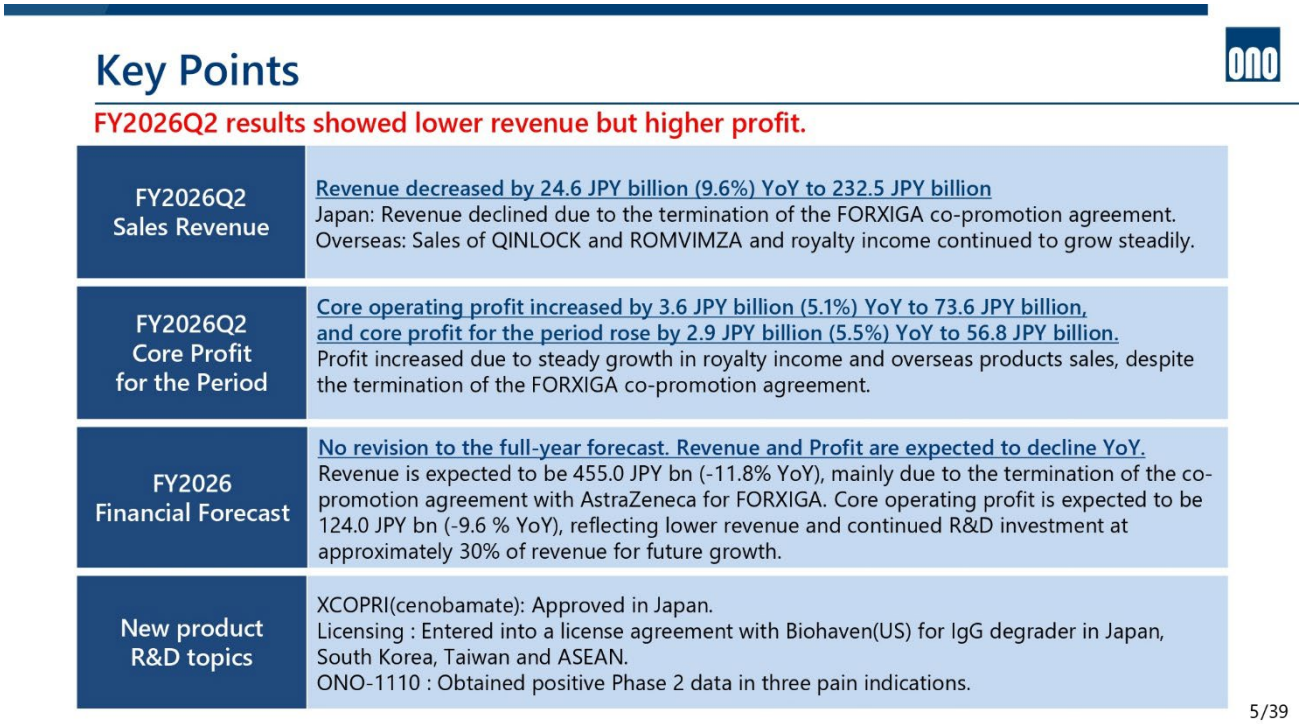
That is all.




First, President Takino will provide an overview of the financial results for Q2 of the fiscal year ending March 2027, followed by Mr. Okamoto, Executive Vice President, Clinical Department, who will explain the progress of our development pipeline.

There will also be time for questions and answers after the Company's presentation. As you are likely already aware, the materials are available on our website, so please feel free to refer to them.

Now, President Takino will begin by presenting an overview of our financial results for Q2 of the fiscal year ending March 2027.




**Takino**: Now, let's move right on to the financial highlights for Q2 of the fiscal year ending March 2027. First, let's start with the key points of today's overview. As indicated in red, our financial results for H1 showed a decline in revenue but an increase in profit.

In terms of revenue, while domestic sales declined following the termination of the co-marketing agreement for FORXIGA, overseas sales increased steadily due to strong growth in QINLOCK and ROMVIMZA, and royalty income also rose. As a result, revenue totaled JPY232.5 billion, a 9.6% decrease from the same period last year.

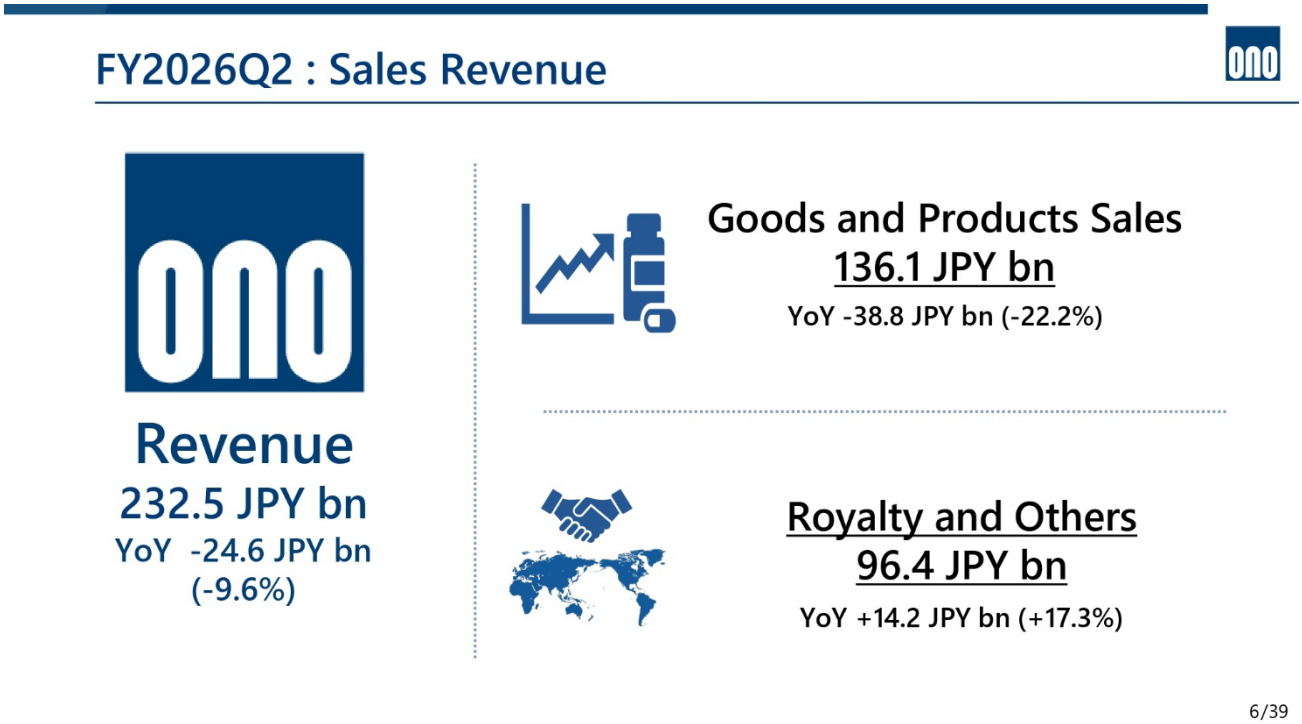
Core operating income increased 5.1% YoY to JPY73.6 billion, while core interim income rose 5.5% YoY to JPY56.8 billion.

There are no revisions to our full-year earnings forecast from what was announced in May of this year, and we currently expect both revenue and profit to decline compared to the previous fiscal year. Regarding revenue, we expect it to reach JPY455 billion due to factors such as the end of the co-marketing agreement for FORXIGA; however, with an eye toward future growth, we will continue to maintain our R&D investment at a level of approximately 30% of revenue. As a result, due to factors such as proactive investments and a decline in revenue, we currently expect core operating income to be JPY124 billion.

Finally, we have a few topics related to research and development of new products. First, XCOPRI was approved in Japan, and we acquired the development and marketing rights for BHV-1300—a Phase 3 treatment for Graves' disease—from the US-based company Biohaven for Japan, South Korea, Taiwan, and ASEAN countries. I'd like to briefly touch on these points later.

In addition, as we announced in a press release today, we have been conducting five proof-of-concept (PoC) trials related to pain and mental disorders. It's an endocannabinoid modulator. Regarding ONO-1110, positive signals were received for three pain-related indications.

Although our development team will provide further details on this later, given the very favorable safety profile observed in the clinical trial, we have high hopes that this will become a major growth driver going forward.

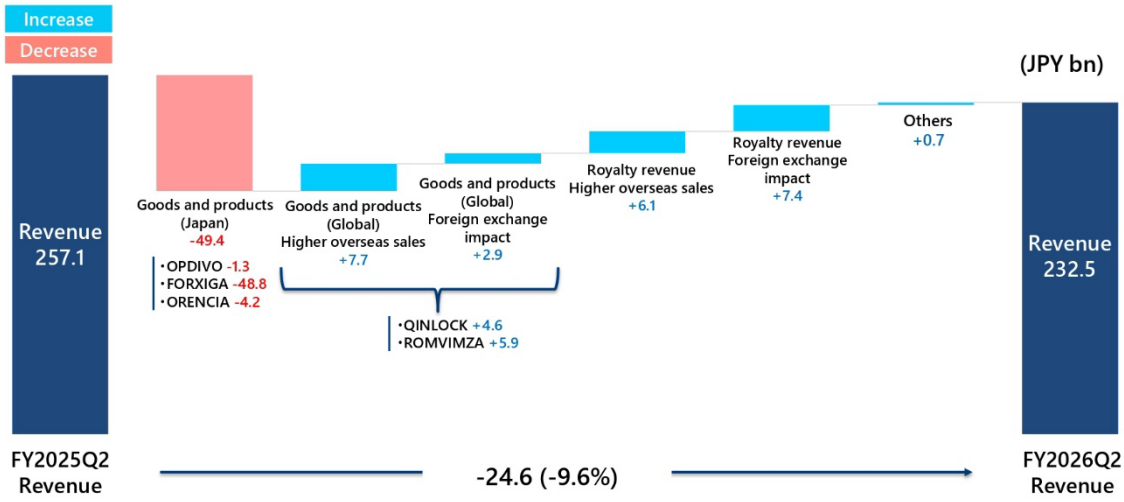



Here are the revenue figures for Q2.

As shown in the breakdown on the right, sales of products and merchandise decreased by JPY38.8 billion, or 22.2%, YoY to JPY136.1 billion, while royalties and other revenue increased by JPY14.2 billion, or 17.3%, YoY, totaling JPY96.4 billion. Consequently, total revenue decreased by JPY24.6 billion, or 9.6%, YoY to JPY232.5 billion.

# FY2026Q2 : Sales Revenue (Breakdown)

Revenue declined by 24.6 JPY billion to 232.5 JPY billion YoY, primarily due to the loss of FORXIGA sales after the co-promotion agreement terminated, despite growth in OPDIVO royalties and Deciphera-related revenue.




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Here is the breakdown of the increase or decrease in sales revenue figures for Q2.

As shown here, domestic product sales decreased by JPY49.4 billion, driven by a JPY48.8 billion decline in sales of FORXIGA, as well as declines in sales of OPDIVO, ORENCIA, and other products.

On the other hand, overseas product sales—shown in blue—increased by JPY10.7 billion, driven by higher sales of QINLOCK and ROMVIMZA, among other factors. Additionally, regarding royalties for OPDIVO, local sales amounted to JPY6.1 billion, and due to exchange rate fluctuations, this figure increased by JPY7.4 billion. As a result, revenue totaled JPY232.5 billion, a decrease of JPY24.6 billion from the JPY257.1 billion recorded in the same period of the previous fiscal year.

# FY2026Q2: Sales Revenue by Product / Japan

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Goods and products | 175.0 | 136.1 | -38.8 | -22.2% | 270.0 |
| Royalty and others | 82.2 | 96.4 | 14.2 | 17.3% | 185.0 |

| Goods and Products (Japan) | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| OPDIVO Intravenous Infusion | 58.5 | 57.2 | -1.3 | -2.3% | 120.0 |
| ORENCIA for Subcutaneous Injection | 13.8 | 9.6 | -4.2 | -30.5% | 19.0 |
| VELEXBRU Tablets | 6.0 | 6.1 | 0.1 | 1.6% | 12.0 |
| PARSABIV Intravenous Injection | 4.5 | 5.0 | 0.5 | 11.3% | 10.0 |
| ONGENTYS Tablets | 4.5 | 5.2 | 0.8 | 17.0% | 10.0 |
| GLACTIV Tablets | 6.9 | 6.2 | -0.7 | -10.1% | 9.5 |
| BRAFTOVI Capsules | 2.7 | 4.0 | 1.3 | 50.1% | 8.5 |
| KYPROLIS for Intravenous Infusion | 4.0 | 3.5 | -0.5 | -12.3% | 7.0 |

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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Next, we will move on to an overview of domestic sales by product.

First, regarding OPDIVO, sales decreased by 2.3% YoY to JPY57.2 billion due to intensifying competition. Sales of ORENCIA, a treatment for rheumatoid arthritis, decreased by 30.5% YoY to JPY9.6 billion due to the impact of the NHI price revision in April of this year.

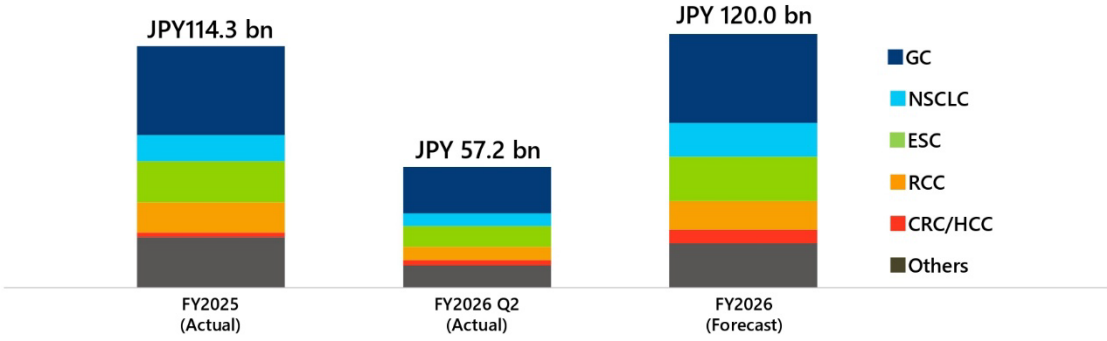
In addition, sales of GLACTIV, a drug for diabetes treatment, decreased 10% to JPY6.2 billion. Furthermore, sales of KYPROLIS, a drug for multiple myeloma treatment, decreased 12% to JPY3.5 billion due to the impact of competitive products. On the other hand, VELEXBRU increased 1.6% to JPY6.1 billion, PARSABIV increased 11% to JPY5 billion, and ONGENTYS, a drug for Parkinson's disease treatment, increased 17% to JPY5.2 billion, continuing to show steady growth.

BRAFTOVI saw significant growth in first-line treatment for BRAF-mutated colorectal cancer—an indication added last fiscal year—with sales reaching JPY4 billion, a 50% YoY.

# OPDIVO Sales Trend by Each Cancer

**Progress Status of Key Indications**

| | |
|---|---|
| GC | : Progressed in line with plan despite impact of competing products. |
| NSCLC | : Remains below plan; commercial activities are being reinforced. |
| ESC | : Progressed in line with plan despite the entry of a competing product. |
| CRC | : Remains slightly below plan; further growth in new prescriptions is expected following guideline revisions. |
| HCC | : Remains slightly below plan; further growth in new prescriptions is expected as AE management practices become more widely adopted. |




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I'd like to add just one more point regarding OPDIVO.

As of the end of H1 of this fiscal year, we are slightly behind our targets. By cancer type, while there are competing products for gastric cancer and esophageal cancer, progress is proceeding largely as planned.

On the other hand, while we are beginning to see some growth in non-small cell lung cancer cases, we are still falling short of our targets when compared to our plan. In addition, while we are seeing steady growth in the areas of hepatocellular carcinoma and colorectal cancer—which were added to the coverage last year—we are currently running slightly behind schedule.

In H2 of the fiscal year, we intend to achieve solid growth and aim for JPY120 billion.

## FY2026Q2 : Sales Revenue by Product / Overseas / Royalty

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Goods and products | 175.0 | 136.1 | -38.8 | -22.2% | 270.0 |
| Royalty and others | 82.2 | 96.4 | 14.2 | 17.3% | 185.0 |

| Goods and Products (Overseas) | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| QINLOCK® | 18.1 | 22.8 | 4.6 | 25.6% | 43.0 |
| ROMVIMZA® | 2.8 | 8.7 | 5.9 | 215.8% | 19.0 |
| OPDIVO® | 7.2 | 7.2 | -0.0 | -0.3% | 13.0 |

| Royalty and others | FY2025Q2 | FY2026Q2 | YoY | | |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| OPDIVO® | 59.4 | 69.1 | 9.7 | 16.3% | |
| KEYTRUDA® | 13.8 | 16.1 | 2.3 | 16.8% | |

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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Next, we'll look at overseas sales by product.

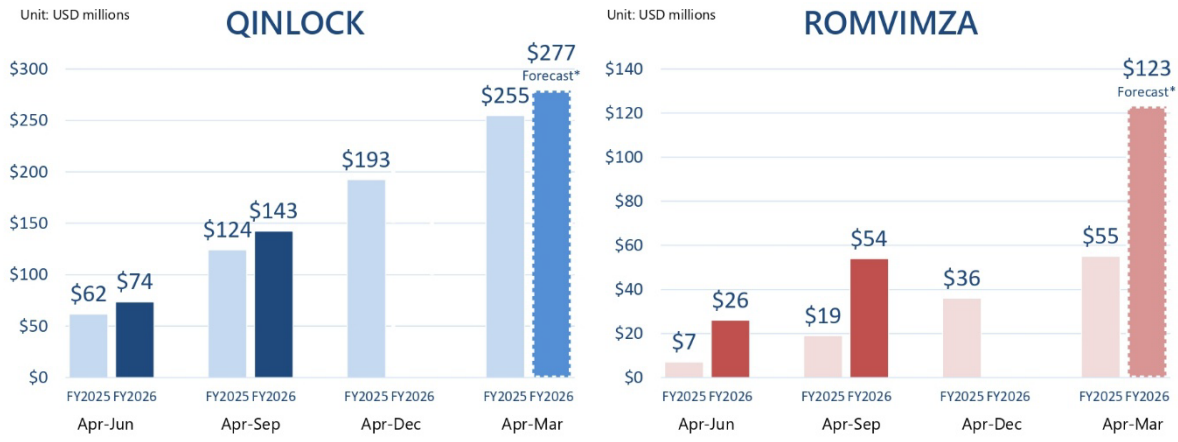
Sales of QINLOCK, a drug for gastrointestinal stromal tumors (GIST) treatment, have been performing strongly, rising 25.6% YoY to JPY22.8 billion, driven by expanded use not only in the US but also in Europe and other regions.

Furthermore, regarding ROMVIMZA, the results indicate that it is steadily gaining recognition as the first-line treatment for patients with tenosynovial giant cell tumor (TGCT). Sales have also been performing well, reaching JPY8.7 billion—a 215.8% increase YoY.

Regarding OPDIVO, the figures shown here represent the combined total for South Korea and Taiwan, which amounted to JPY7.2 billion, a 0.3% decrease YoY. Meanwhile, regarding OPDIVO royalties, driven by increased local sales of OPDIVO and foreign exchange effects, they increased 16.3% YoY to JPY69.1 billion, while royalties from KEYTRUDA increased 16.8% to JPY16.1 billion.

## Sales Progress of QINLOCK and ROMVIMZA (USD Basis)

Both products grew compared to the last year and progressed as scheduled compared to the initial announcement.




*FY2026 Full-year forecast converted at an exchange rate of JPY 155/USD: Qinlock JPY43.0 billion and ROMVIMZA JPY19.0 billion

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For your reference, this chart shows the quarterly sales trends for QINLOCK and ROMVIMZA for the previous and current fiscal years, with figures in US dollars to illustrate local sales.

Even when excluding the impact of exchange rates, I believe you can see that we are achieving steady growth quarter by quarter, and both products are on track to meet the full-year targets for this fiscal year shown on the far right.

## FY2026Q2 : Core Operating Profit

**Core Operating Profit**
**73.6 JPY bn**
YoY +3.6 JPY bn
(+5.1%)

**Revenue 232.5 JPY bn**
YoY -24.6 JPY bn (-9.6%)

**Cost of Sales 41.7 JPY bn**
YoY -13.1 JPY bn (-23.8%)

**R&D Expense 69.1 JPY bn**
YoY -1.9 JPY bn (-2.7%)

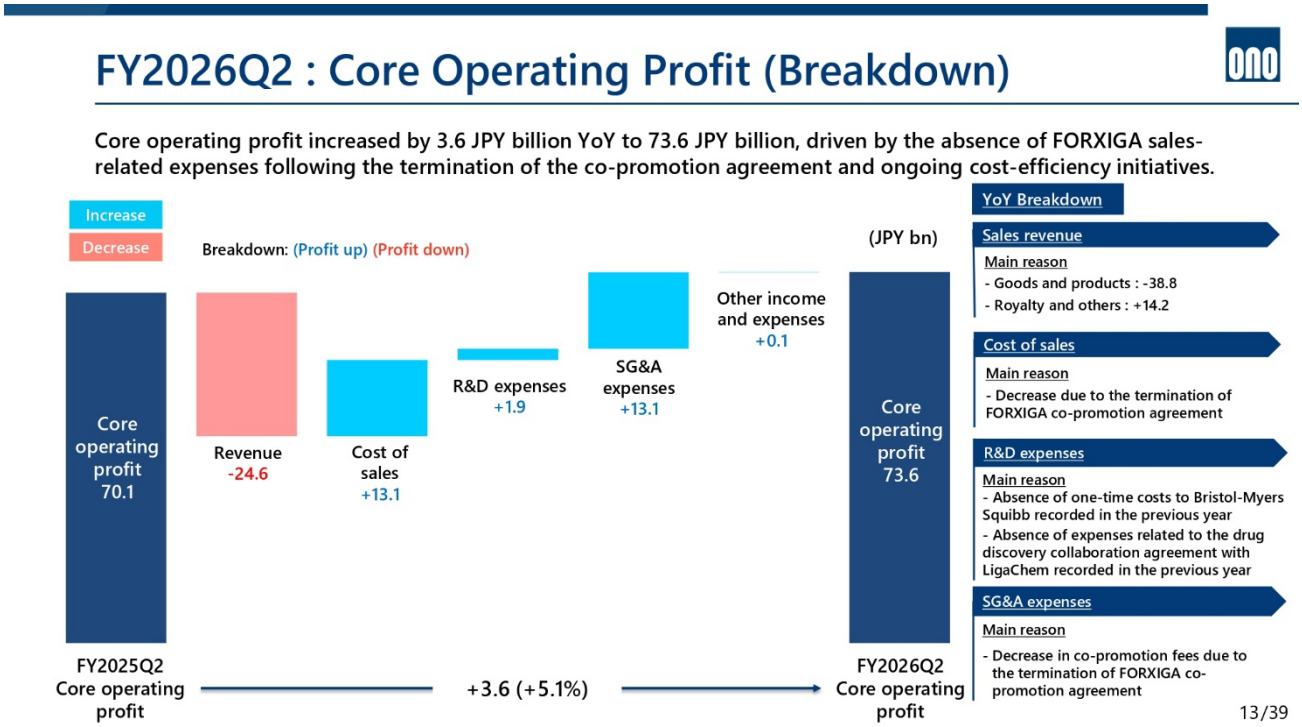
**SG&A Expense 47.9 JPY bn**
YoY -13.1 JPY bn (-21.5%)

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Next, let’s move on to core operating income.

Net income rose by JPY3.6 billion, or 5.1%, from the previous quarter to JPY73.6 billion.

As for the factors behind this, while revenue decreased by JPY24.6 billion YoY to JPY232.5 billion, on the expense side, costs related to FORXIGA and other items decreased by JPY13.1 billion, research and development expenses decreased by JPY1.9 billion YoY, and selling, general, and administrative expenses decreased by JPY13.1 billion YoY.




We have illustrated the breakdown of these increases and decreases in the chart below.

While revenue decreased by JPY38.8 billion due to the termination of the co-marketing agreement, which resulted in the discontinuation of revenue recognition for FORXIGA, the net decrease in revenue was JPY24.6 billion due to an increase in royalty income.

Costs of sales decreased by JPY13.1 billion, primarily due to a reduction in expenses related to FORXIGA. Research and development expenses decreased by JPY1.9 billion compared to the same period last year, due to a decline in one-time development expenses paid to Bristol-Myers Squibb and a decline in expenses related to the drug discovery partnership with LigaChem.

As for selling, general, and administrative expenses, they decreased by JPY13.1 billion—primarily due to a reduction in co-promotion expenses following the end of the co-marketing arrangement for FORXIGA—resulting in a JPY3.6 billion YoY increase in core operating income to JPY73.6 billion.

## FY2026Q2 : Financial Overview (Core)

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Cost of sales | 54.8 | 41.7 | -13.1 | -23.8% | 84.0 |
| R&D expenses | 71.0 | 69.1 | -1.9 | -2.7% | 143.0 |
| SG&A expenses | 61.1 | 47.9 | -13.1 | -21.5% | 101.0 |
| Core operating profit | 70.1 | 73.6 | 3.6 | 5.1% | 124.0 |
| Core profit before tax | 70.7 | 74.1 | 3.4 | 4.9% | 124.0 |
| Core profit for the period (attributable to owners of the Company) | 53.8 | 56.8 | 2.9 | 5.5% | 93.0 |

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

YoY Breakdown

Cost of sales -13.1 JPY bn (-23.8%)

COGS ratio : 17.9%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -1.9 JPY bn (-2.7%)

R&D ratio : 29.7%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -13.1 JPY bn (-21.5%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Core operating profit ratio : 31.7%

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Here is the overall income statement on a core basis.

Although revenue decreased by 9.6% YoY to JPY232.5 billion, core operating profit increased by 5.1% YoY to JPY73.6 billion, and core profit for the period increased by 5.5% YoY to JPY56.8 billion.

## (Ref) FY2026Q2 : Financial Overview (Full Basis)

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Cost of sales | 72.0 | 57.4 | -14.5 | -20.2% | 114.0 |
| R&D expenses | 71.0 | 69.1 | -1.9 | -2.7% | 143.0 |
| SG&A expenses | 61.2 | 47.9 | -13.2 | -21.7% | 101.0 |
| Operating profit | 52.1 | 57.9 | 5.8 | 11.2% | 94.0 |
| Profit before tax | 52.2 | 58.4 | 6.2 | 12.0% | 94.0 |
| Profit for the period (attributable to owners of the Company) | 40.1 | 44.9 | 4.8 | 12.1% | 71.0 |

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

YoY Breakdown

Cost of sales -14.5JPY bn (-20.2%)

COGS ratio : 24.7%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -1.9 JPY bn (-2.7%)

R&D ratio : 29.7%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -13.2 JPY bn (-21.7%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Operating profit ratio : 24.9%

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For your reference, these are the consolidated financial results on a full-basis.

While revenue was the same as core revenue, operating profit increased 11.2% YoY to JPY57.9 billion, and profit for the period attributable to owners of the parent company increased 12.1% YoY to JPY44.9 billion. On a full-year basis as well, the financial results show a decline in revenue but an increase in profit.

## (Ref) FY2026Q2 : Reconciliation from Full to Core Basis

| JPY bn | IFRS (Full) basis | Adjustment | | | | Core basis |
|---|---|---|---|---|---|---|
| | | Amortization | Impairment loss | Others | Total | |
| Revenue | 232.5 | | | | | 232.5 |
| Cost of sales | 57.4 | -12.0 | | -3.7 | -15.7 | 41.7 |
| Gross profit | 175.1 | +12.0 | – | +3.7 | +15.7 | 190.8 |
| R&D expenses | 69.1 | | | | – | 69.1 |
| SG&A expenses | 47.9 | | | | – | 47.9 |
| Other income /expenses (- Exp) | -0.1 | | | | – | -0.1 |
| Operating profit | 57.9 | +12.0 | – | +3.7 | +15.7 | 73.6 |
| Operating profit ratio | 24.9% | | | | – | 31.7% |
| Finance income / Finance cost (- Exp) | 0.5 | | | -0.0 | -0.0 | 0.5 |
| Profit before tax | 58.4 | +12.0 | – | +3.7 | +15.7 | 74.1 |
| Income tax expense | 13.4 | +3.0 | | +0.9 | +3.9 | 17.2 |
| Profit for the period | 44.9 | +9.1 | – | +2.8 | +11.8 | 56.8 |

**Breakdown**

**Cost of sales**

Main reason

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

**R&D expenses**

Main reason

- None

**SG&A expenses and Other income&expense**

Main reason

- None

*PPA : Purchase Price Allocation

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Here is the full base to core base adjustment table.

The adjustments primarily relate to cost of goods sold and include JPY12 billion in amortization of intangible assets associated with acquisitions and system implementations, as well as a JPY3.7 billion adjustment to inventory valued at fair value.

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

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

| JPY bn | FY2025 Actual | FY2026 Forecast | Change | Change (%) |
|---|---|---|---|---|
| Revenue | 515.8 | 455.0 | -60.8 | -11.8% |
| Cost of sales | 107.0 | 84.0 | -23.0 | -21.5% |
| R&D expenses | 145.1 | 143.0 | -2.1 | -1.5% |
| SG&A expenses | 123.6 | 101.0 | -22.6 | -18.3% |
| Core operating profit | 137.1 | 124.0 | -13.1 | -9.6% |
| Core profit before tax | 138.3 | 124.0 | -14.3 | -10.3% |
| Income tax expense | 34.6 | 31.0 | -3.6 | -10.5% |
| Core profit for the year (attributable to owners of the Company) | 103.5 | 93.0 | -10.5 | -10.1% |

Breakdown

Cost of sales -23.0 JPY bn (-21.5%)

COGS ratio : 18.5%
Main reason
- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

R&D expenses -2.1 JPY bn (-1.5%)

R&D ratio: 31.4%
Main reason
- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

SG&A expenses -22.6 JPY bn (-18.3%)

SG&A ratio : 22.2%
Main reason
- The termination of co-promotion agreement for FORXIGA Tablets

Core operating profit ratio : 27.3%

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

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Next, here are our core-based earnings forecasts for this fiscal year. There are no changes to the earnings forecast we announced on May 8 of this year.

We expect revenue to decrease by 11.8% YoY to JPY455 billion, primarily due to the termination of the co-marketing agreement for FORXIGA. In terms of expenses, we will continue to allocate approximately 30% of our revenue to research and development as an investment in future growth.

While we are striving to streamline other expenses, due to the impact of aggressive investments and a decline in revenue, we expect core operating income to decrease by 9.6% YoY to JPY124 billion, and core net income to decrease by 10.1% to JPY93 billion.

Although we are forecasting a decline in profits, we are making every effort to maintain our profit levels as much as possible.

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

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

| JPY bn | FY2025 Actual | FY2026 Forecast | Change | Change (%) |
|---|---|---|---|---|
| Revenue | 515.8 | 455.0 | -60.8 | -11.8% |
| Cost of sales | 141.7 | 114.0 | -27.7 | -19.6% |
| R&D expenses | 147.0 | 143.0 | -4.0 | -2.7% |
| SG&A expenses | 123.7 | 101.0 | -22.7 | -18.3% |
| Operating profit | 92.2 | 94.0 | 1.8 | 1.9% |
| Profit before tax | 92.7 | 94.0 | 1.3 | 1.5% |
| Income tax expense | 22.7 | 23.0 | 0.3 | 1.1% |
| Profit for the year (attributable to owners of the Company) | 69.8 | 71.0 | 1.2 | 1.8% |

**Breakdown**

**Cost of sales -27.7 JPY bn (-19.6%)**
COGS ratio : 25.1%
Main reason
- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

**R&D expenses -4.0 JPY bn (-2.7%)**
R&D ratio: 31.4%
Main reason
- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

**SG&A expenses -22.7 JPY bn (-18.3%)**
SG&A ratio : 22.2%
Main reason
- The termination of co-promotion agreement for FORXIGA Tablets

**Operating profit ratio : 20.7%**

* The exchange rate assumed in the financial forecast is 155 yen per US dollar.
For the second half of the fiscal year, the sensitivity to exchange rates is assumed to be an increase of 0.8 billion yen in revenue and an increase of 0.2 billion yen in operating profit for every 1-yen depreciation of the yen.

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Here's for your reference. There are also no changes to the full-year forecast on a full-basis from the forecast announced on May 8 of this year.

That concludes our report on financial results. As I mentioned at the beginning, I would now like to discuss several topics related to new products and research and development that are unrelated to our financial performance.

## Unmet Needs in Epilepsy Care and the Mechanism of Action of Xcopri®

◆ Patients with persistent seizures despite current therapy need a new option that offers the potential for seizure freedom

**Current Landscape and Unmet Needs in Epilepsy Care**

People with Epilepsy in Japan ~1 Million

Patients with Uncontrolled Seizures ~30%

Adapted from Chen Z et al. JAMA Neurol. 2018;75(3):279-286

**Patient Perspectives and Concerns**

Patients Who Consider Seizure Freedom Essential for Good Quality of Life

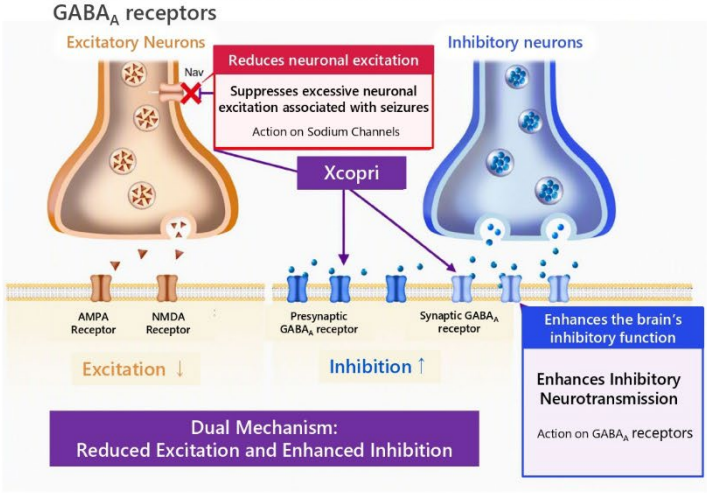
**75.7%**

Anxiety, Fear, and Limitations on Daily Life Due to Persistent Seizures




Adapted from Mecarelli O et al. Epilepsy Behav. 2022;137(Pt A):108950
Adapted from Penovich PE et al. Neurol Clin Pract. 2021;11(5):377-384

◆ Suppresses neuronal hyperexcitability through voltage-gated sodium channel inhibition and positive allosteric modulation of $GABA_A$ receptors




Adapted from Ono Pharmaceutical internal data (Action on Sodium Channels), review data for regulatory approval
Adapted from Ono Pharmaceutical internal data (Action on GABAA Receptors), review data for regulatory approval
Adapted from Sharma R et al. Eur J Pharmacol., 2020; 879. 173117

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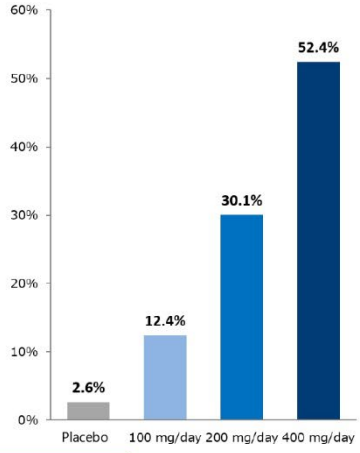
First, I'd like to introduce XCOPRI, a new epilepsy treatment that was approved in Japan on September 16 of last month.

It is estimated that there are approximately 1 million people with epilepsy in Japan, and 30 percent of them still experience seizures. XCOPRI, which has now been approved, is a medication that suppresses seizures through two mechanisms of action: sodium channels and GABA receptors. It was already approved in the US in 2019 and is now widely used there.

We, too, are very much looking forward to this new medication for the neurological field, as it will be the first new drug we've been able to bring to Japan in quite some time.

## Xcopri® Global Phase 3 Study Results: Efficacy and Safety

**Efficacy (Seizure Freedom Rate)**




**Safety (Major Adverse Drug Reactions)**

| | Placebo | Cenobamate 100 mg/day | Cenobamate 200 mg/day | Cenobamate 400 mg/day |
|---|---|---|---|---|
| **Eye disorders** | | | | |
| Diplopia | 1.5 | 2.3 | 3.1 | 13.3 |
| **Gastrointestinal disorders** | | | | |
| Nausea | 2.3 | 2.3 | 1.5 | 8.6 |
| Vomiting | 0.8 | 2.3 | 0 | 10.2 |
| **Injury, poisoning, and procedural complications** | | | | |
| Fall | 0.8 | 0 | 5.4 | 3.1 |
| **Laboratory tests** | | | | |
| γ-glutamyl transferase increased | 6.2 | 7.0 | 13.1 | 16.4 |
| White blood cell count decreased | 2.3 | 1.6 | 6.9 | 2.3 |
| **Metabolism and nutrition disorders** | | | | |
| Decreased appetite | 0.8 | 1.6 | 3.1 | 7.0 |
| **Nervous system disorders** | | | | |
| Dizziness | 10.8 | 19.5 | 36.9 | 64.8 |
| Somnolence | 14.6 | 21.1 | 26.9 | 45.3 |
| Ataxia | 0 | 1.6 | 3.1 | 10.2 |
| Headache | 2.3 | 3.1 | 1.5 | 6.3 |

Ono Pharmaceutical internal data (Asian Phase 3 Study: YKP3089C035 [Double-Blind Period]), review data for regulatory approval

**Key Value Propositions**

**Patient Value**
Toward a Seizure-Free Daily Life

**Clinical Value**
Shifting the Treatment Goal Toward Seizure Freedom

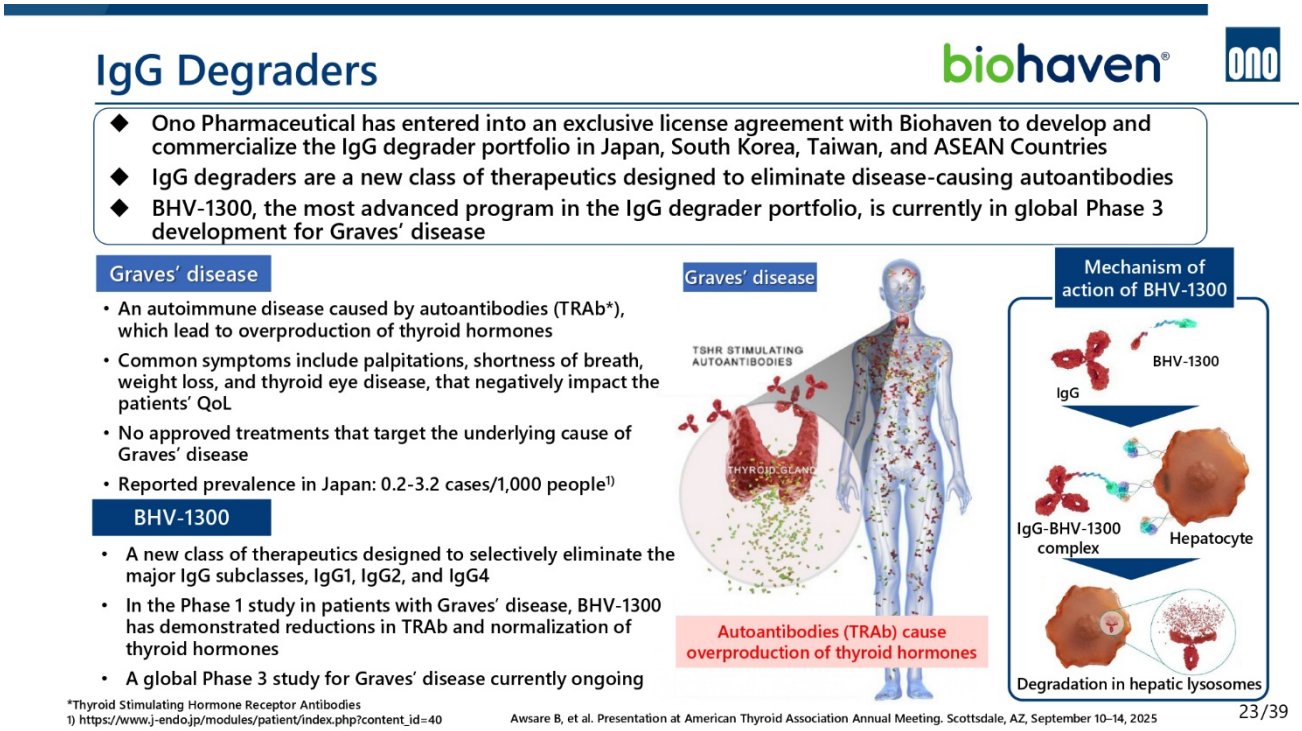
**Business Value**
Providing a New Treatment Option to the Market

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I'd like to briefly explain some of its features.

These are the results of an international Phase 3 clinical trial conducted in Asian patients. As shown in the graph on the left, the seizure freedom rates were 30.1% for the 200 mg dose and just over 52% for the 400 mg dose. These figures represent seizure freedom rates that cannot be achieved with existing antiepileptic drugs.

On the other hand, since the frequency of side effects tends to increase with higher doses, we expect that careful dose adjustment during treatment will help control seizures in patients with epilepsy and, in particular, contribute to achieving a seizure-free state.

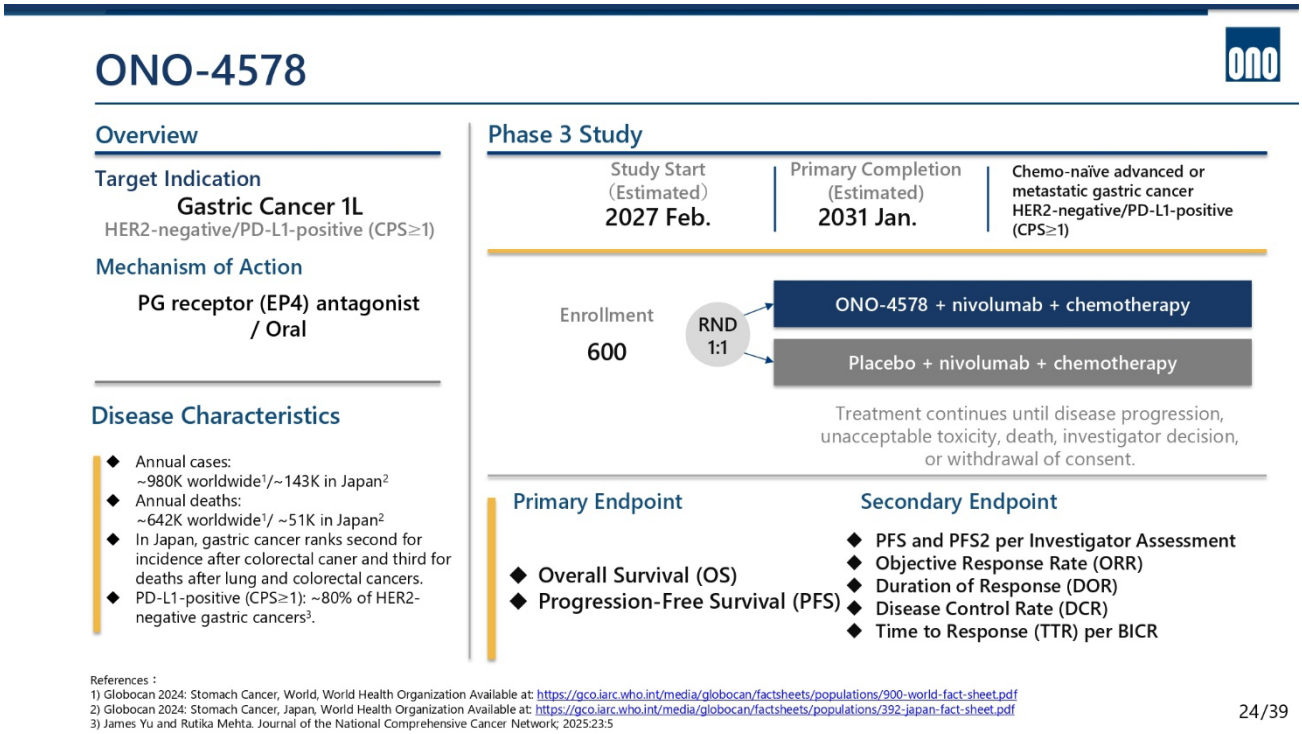



I'd also like to introduce the topic of licensing partnerships.

As announced in our press release on October 8 of this year, we have entered into an exclusive licensing agreement with the US-based company Biohaven for its IgG degrader, and have secured the rights to develop and commercialize the product in Japan, South Korea, Taiwan, and the ASEAN countries.

We expect this IgG-degrading agent to become a new class of therapeutic drug that eliminates the autoantibodies responsible for autoimmune diseases. I invite you to review the details, but among the assets for which we have acquired rights this time, BHV-1300—which is the most advanced in development—has already demonstrated in Phase 1 trials that it reduces levels of thyroid-stimulating hormone (TSH) receptor antibodies, known as TRAb, and normalizes thyroid hormone levels accordingly.

An international Phase 3 clinical trial for Graves' disease is currently underway, and results are expected in January 2028. Although these rights are primarily focused on Asia, we view them as assets aimed at bringing the product to market by 2030—and, particularly in Japan, as a product that will allow us to fully leverage our capabilities—and we have high hopes for them.



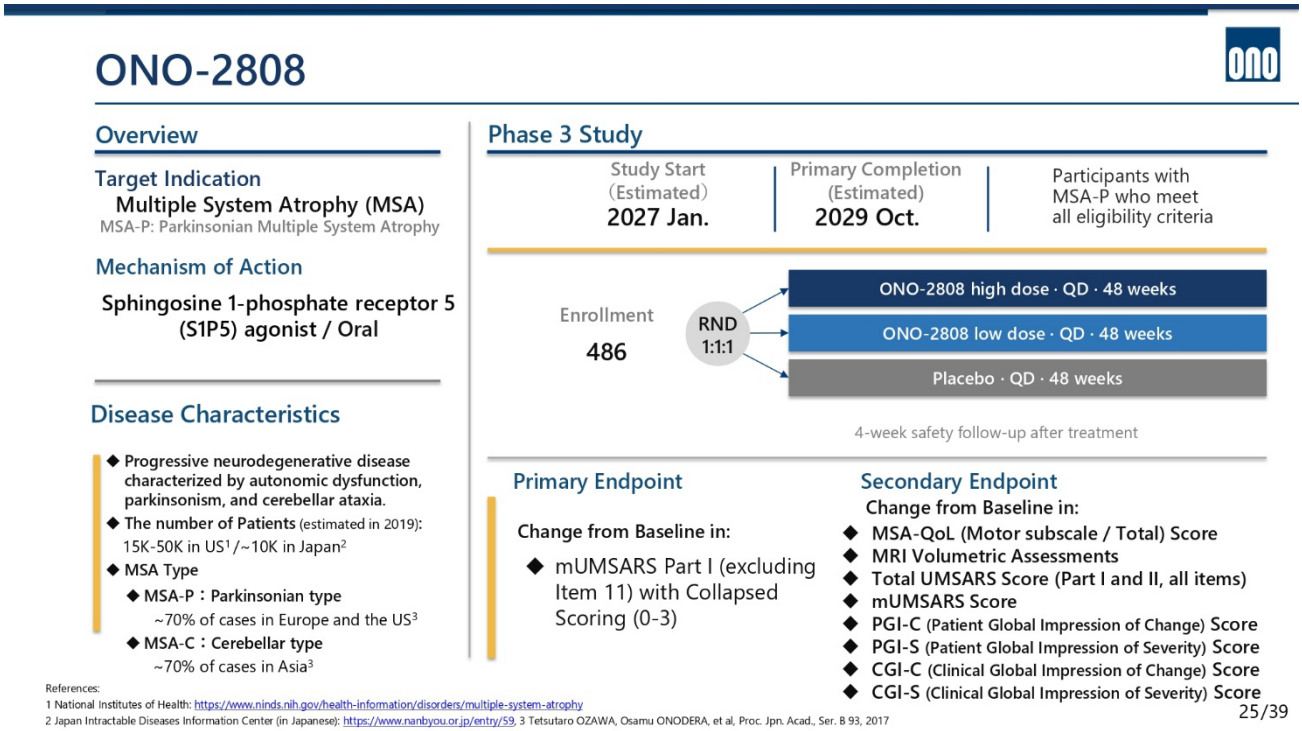

This is an update on ONO-4578, a project currently in our pipeline.

This information has already been published on the clinical trial information website, ClinicalTrials.gov. Here is the study design for the Phase 3 trial.

This will be a global, double-blind, controlled clinical trial. This trial is designed for patients with advanced or metastatic gastric cancer who have not previously received chemotherapy, are HER2-negative, and are PD-L1-positive—specifically, those with a CPS score of 1 or higher.

Regarding the target number of cases, this is a trial involving 300 cases in each group, for a total of 600 cases. As stated, the primary endpoints are OS and PFS; as for the secondary endpoints, I will omit them here as they are already listed.

Globally, approximately 1 million patients are newly diagnosed with gastric cancer each year, and in Japan, 140,000 people are diagnosed annually; it is said to be the third leading cause of cancer-related deaths in Japan. Furthermore, it is said that patients with a CPS score of 1 or higher—who are the focus of this study—account for 80% of patients with HER2-negative gastric cancer. We plan to begin collecting tumor data in January 2031, but we intend to move forward with the process so that we can complete it as quickly as possible and bring the product to market.

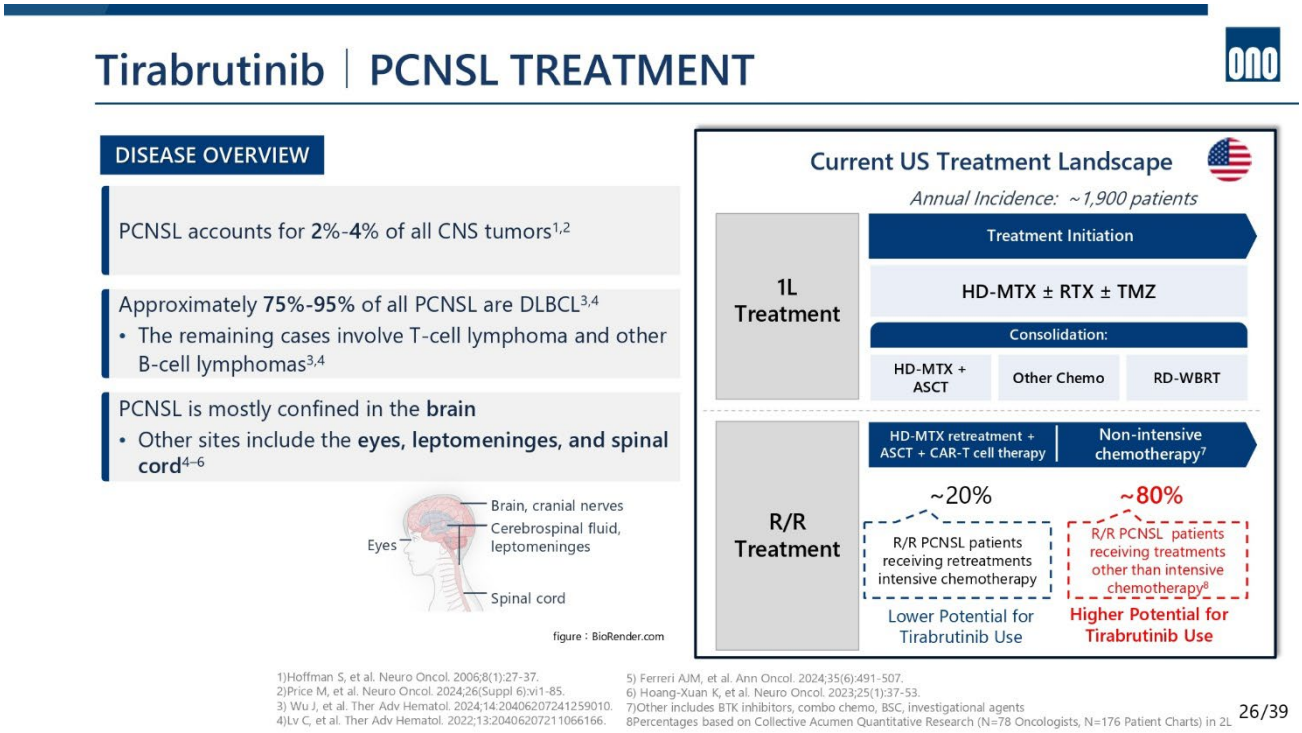



Next, here is an update on the ONO-2808, which, like the ONO-4578, is scheduled to begin testing this fiscal year. This information is also taken from the publicly available data on ClinicalTrials.gov.

As with ONO-4578, Phase 3 will be a global, double-blind, controlled trial, and the target patient population will consist of patients with MSA-P, a Parkinsonism-predominant form of multiple system atrophy. The study consists of three groups—high-dose, low-dose, and placebo—with a target sample size of 486 patients.

The primary endpoint was assessed based on 11 of the 12 items in Part 1 of the Modified UMSARS (mUMSARS)—a globally recognized symptom score for patients with MSA—excluding the 11th item. The secondary endpoints are as described here.

We plan to collect the primary data for these trials in 2029, and we hope to make this treatment available as soon as possible to patients suffering from MSA.




This is the last page for my presentation.

Regarding tirabrutinib, which is currently under review for approval in the US, the PDUFA target date for the completion of the review is December 18 of this year.

With regard to PCNSL (primary central nervous system lymphoma), the target indication for tirabrutinib, this is a disease primarily confined to the brain. In the US, treatment typically begins with the three drugs shown on the right—high-dose methotrexate, rituximab, and temozolomide—as shown on the right—but for recurrent or refractory(R/R) PCNSL, approximately 80 percent of patients receive treatments other than high-intensity chemotherapy. We expect tirabrutinib to be approved as one of the treatment options in this setting.

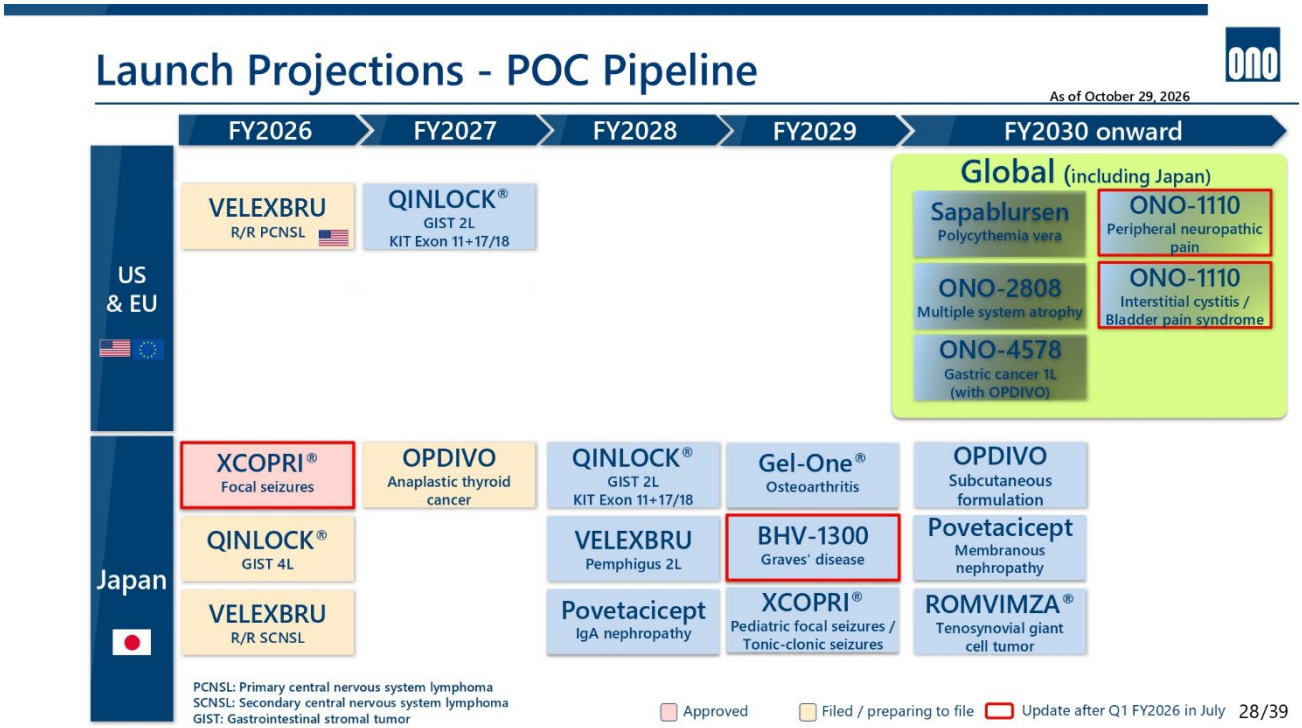
Currently, there are no drugs approved in the US for the treatment of R/R PCNSL; therefore, we believe that, if approved, this drug will benefit PCNSL patients by providing a new treatment option.

Furthermore, here at Ono Pharmaceutical, following the acquisition of Deciphera two years ago—which led to the acquisition of QINLOCK—and the launch of ROMVIMZA last year, we are hopeful that this will mark our third new global product in three consecutive years.

Later on, we will hear a detailed update on the development status directly from the development team, but first and foremost, I would like to clearly convey today that we are making steady progress in strengthening our development pipeline. We are committed to continuing to invest heavily in research and development while striving to further increase our global product sales and market presence.

That concludes my presentation.

**Imura**: Next, Mr. Okamoto, Executive Vice President of Clinical Department, will discuss the progress of our development pipeline.




**Okamoto**: I will use the progress report on our development pipeline—which is available on our website—to explain the changes that have occurred since July 31 of this year.

Here are the current status and schedule for obtaining approvals.

First, regarding the status of approvals for FY2026—this current fiscal year—as President Takino mentioned earlier, we have successfully updated the approval for XCOPRI (generic name: cenobamate), which was granted in Japan this past September.

Next, regarding our future plans: We had planned to seek approval for OPDIVO for the treatment of hepatocellular carcinoma following surgery in FY2027; however, since we unfortunately did not achieve the expected efficacy or results, we have removed this from our plans.

Next, as President Takino mentioned to you individually a moment ago, we have the BHV-1300. This compound was licensed from Biohaven in the US. We are currently projecting that it will receive approval in Japan in FY2029 for the treatment of Graves' disease, so we have added this information.

Next, in the upper right corner, the area outlined in green represents a group of compounds that we plan to roll out globally—including Europe, the US, and Japan. As announced in today's press release, regarding ONO-1110, we have established proof of concept (PoC) for peripheral neuropathic pain and interstitial cystitis, and we have determined that we have established proof of concept (PoC) for these indications, so we are adding them to this list.

Regarding the ONO-1110, I will provide an overview—including our future development plans—at the end of my presentation.

That concludes our report on the status and schedule regarding the acquisition of approvals.

# Development pipeline (Oncology) ①

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| ONO-4059 (tirabrutinib)<br>BTK inhibitor | PCNSL 1L, ≥2L | | | | | | | 2026.2 US : Filed (Part A) | US | NCT04947319 |
| | SCNSL | | | | | | | 2026.6 JP : Filed | JP | jRCT2031220529 |
| | PCNSL ≥2L (confirmatory Study) | | | | | | | FY2027<br>Primary Completion | US | NCT07104032 |
| QINLOCK<br>DCC-2618 (ripretinib) KIT inhibitor | GIST 2L KIT Exon 11+17/18 | | | | | | | FY2027<br>Primary Completion | US, EU, KR, TW and others | NCT05734105 |
| | GIST 4L | | | | | | | FY2027<br>Primary Completion | JP | NCT07618377 |
| ONO-0530 (sapablursen)<br>Antisense oligonucleotide targeting TMPRSS6 | Polycythemia vera (PV) | | | | | | | FY2028<br>Primary Completion | JP, US, EU, KR, TW and others | NCT07429266 |
| ONO-4578 PG receptor (EP4) antagonist | Gastric cancer* | | | | | | | FY2030<br>Primary Completion | JP, US, EU, KR, TW and others | NCT07818070 |
| | Colorectal cancer* | | | | | | | FY2027<br>Primary Completion | JP, US, EU and others | NCT06948448 |
| ONO-4482 (relatlimab) Anti-LAG-3 antibody | Melanoma* | | | | | | | FY2024<br>Primary Completion (Actual) | JP, US, EU and others | NCT01968109 |
| ONO-7427 Anti-CCR8 antibody | Solid tumor* | | | | | | | FY2031<br>Primary Completion | JP, US, EU and others*1 | NCT04895709 |
| DCC-3116 (inlexisertib) ULK inhibitor | Advanced malignancies (with ripretinib) | | | | | | | FY2026<br>Primary Completion | US, EU | NCT05957367 |

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

MOA : Mode of Action
* : Combination with OPDIVO

*1 : Development right country: JP
Estimated study completion date shown in jRCT or ClinicalTrials.gov

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

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Next, we will present the progress of our development pipeline in the field of oncology.

As for ONO-4578 phase 3 clinical trial, since Mr. Takino already discussed this earlier, I'll skip over it.

Meanwhile, regarding ONO-4578, we had been conducting development and exploratory trials in Japan for its use as a second-line treatment for non-small cell lung cancer; however, we have decided to discontinue these trials for strategic reasons and have therefore removed this item from this report.

While first-line treatment for non-small cell lung cancer—regardless of whether the patient is in Japan or abroad—typically involves regimens that include immunotherapy (IO) unless a specific genetic mutation is present, we have conducted an exploratory trial to evaluate the efficacy of ONO-4578 with OPDIVO in combination with standard chemotherapy patients who had previously received first-line treatment and were now eligible for second-line therapy.

I'm sure you are all aware that, fundamentally speaking, competition in the development of first-line treatments for non-small cell lung cancer has become extremely intense. Specifically, given that it has become increasingly difficult to envision conventional immunotherapy—particularly bispecific antibodies—remaining the standard of care indefinitely, we have decided, as part of our portfolio management strategy, to discontinue development for second-line treatment of non-small cell lung cancer.

# Development pipeline (Oncology) ②

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| DCC-3009 Pan-KIT inhibitor | Gastrointestinal Stromal Tumor (GIST) | | | | | | | FY2028 Primary Completion | US | NCT06630234 |
| ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody | T-cell lymphoma | | | | | | | FY2027 Primary Completion | US | NCT05079282 |
| | | | | | | | | FY2028 Primary Completion | JP | NCT06547528 |
| ONO-8250 iPSC-derived HER2 CAR T-cell therapy | HER2-expressing solid tumor | | | | | | | FY2029 Primary Completion | US | NCT06241456 |
| ONO-7428 Anti-ONCOKINE-1 antibody | Solid tumor | | | | | | | FY2029 Primary Completion | JP | NCT06816108 |
| DCC-2812 GCN2 activator | Renal cell carcinoma, urothelial cancer, castration-resistant Prostate cancer | | | | | | | FY2028 Primary Completion | US | NCT06966024 |
| ONO-7429 Anti-L1CAM ADC | Solid tumor | | | | | | | FY2028 Primary Completion | JP | NCT07787208 |

MOA : Mode of Action
* : Combination with OPDIVO
Estimated study completion date shown in jRCT or ClinicalTrials.gov
F : Filed, A : Approval
※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July



Staying with the field of oncology, this concerns the Phase 1 trial of ONO-7429, the anti-L1CAM ADC shown below. While this trial has already been conducted in Japan, we are currently updating the information now that the database data has been made public.

# Development pipeline (Non-oncology) ①

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| XCOPRI ONO-2017 (cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel | Partial-onset seizures | | | | | | | FY2026.9 JP : Approval | JP, KR and others*1 | NCT04557085 |
| | Partial-onset seizures (pediatric) | | | | | | | FY2027 Primary Completion | JP | NCT07594158 |
| | Primary generalized tonic-clonic seizures | | | | | | | FY2026 Primary Completion | JP | NCT06579573 |
| VELEXBRU Tablet (ONO-4059: tirabrutinib) BTK inhibitor | Pemphigus | | | | | | | FY2027 Primary Completion | JP | NCT06696716 |
| ONO-8531 (povetacicept) BAFF/APRIL dual antagonist | IgA nephropathy | | | | | | | FY2027 Primary Completion | JP, US, EU, KR, TW and others*2 | NCT06564142 |
| | Primary membranous nephropathy | | | | ★3 | | | FY2028 Primary Completion | US, EU, KR and others*2 | NCT07204275 |
| ONO-5532 (Gel-One) Cross-linked hyaluronate | Knee osteoarthritis | | | | | | | FY2027 Completion | JP | jRCT2031240621 |
| | Hip osteoarthritis | | | | | | | FY2027 Completion | JP | jRCT2061240110 |
| ONO-2808 S1P5 receptor agonist | Multiple system atrophy (MSA) | | | | | | | FY2029 Primary Completion | JP, US, EU and others | NCT07825402 |
| BHV-1300 IgG Degrader | Graves' disease | | | | | | | FY2027 Primary Completion | US and others*4 | NCT07661056 |
| ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor | Tenosynovial giant cell tumor (TGCT) | | | | | | | FY2028 Primary Completion | JP | NCT07832747 |
| | Chronic graft versus host disease (cGVHD) | | | | | | | FY2029 Primary Completion | US | NCT06619561 |

F : Filed, A : Approval EU : European countries

*1 : Development right country: JP, *2 : Development rights countries: JP, KR *3 : P IIb/III, *4 : Development rights countries: JP, KR, TW, ASEAN
MOA : Mode of Action Estimated study completion date shown in jRCT or ClinicalTrials.gov
※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July



Next, here is the status of development in the non-cancer field.

As for cenobamate, XCOPRI tablets, since this information overlaps with what I mentioned earlier, I will omit it.

Next, we have Item ONO-2808, located slightly below the middle section. Since Mr. Takino has already provided an overview of the exam for this item, I will skip the details here.

Next is the BHV-1300, right below that. As I mentioned at the beginning, regarding this matter as well, we plan to obtain domestic approval during FY2029, following the collection of key data in FY2027.

Moving on to ROMVIMZA below, while we are conducting a Phase 2 clinical trial in Japan for the same indications as those in the US and Europe, this update is solely due to changes in the disclosure of database information.

## Development pipeline (Non-oncology) ②

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| ONO-1110 Endocannabinoid regulation | Postherpetic neuralgia | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06708416 |
| | Fibromyalgia | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06752590 |
| | Hunner type interstitial cystitis | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06752603 |
| ONO-2020 Epigenetic Regulation | Alzheimer's disease | | | | | | | FY2026 Primary Completion | JP, US | NCT06881836 |
| | Agitation associated with dementia due to Alzheimer's disease | | | | | | | FY2026 Primary Completion | JP | NCT06803823 |
| ONO-4915 PD-1 x CD19 bispecific antibody | Sjögren's disease | | | | | | | FY2028 Primary Completion | JP | NCT07823790 |
| ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody | Autoimmune disease | | | | | | | FY2024 Completion | JP | jRCT2071220081 |
| | | | | | | | | FY2024 Primary Completion (Actual) | EU | NCT05332704 |
| ONO-2416 | Psychiatric disease | | | | | | | FY2027 Completion | JP | jRCT2071250147 |
| ONO-3310 | Kidney disease | | | | | | | FY2027 Primary Completion | JP | NCT07619157 |
| ONO-6414 | Autoimmune disease | | | | | | | FY2027 Primary Completion | US | NCT07749768 |
| ONO-3401 | Neurological disease | | | | | | | FY2027 Completion | JP | jRCT2071260067 |

MOA : Mode of Action

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

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

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Next up is the ONO-1110, which I mentioned briefly at the beginning.

As I mentioned earlier, I will discuss the trial overview and the next steps at the end of this presentation. However, based on this pipeline list, we have discontinued development related to mental disorders—specifically, depression and social anxiety disorder—as we were unfortunately unable to confirm their efficacy, and have therefore removed them from the list.

Next, regarding ONO-4915, we have updated this entry because we have initiated a Phase 2 clinical trial in Japan for Sjögren's syndrome.

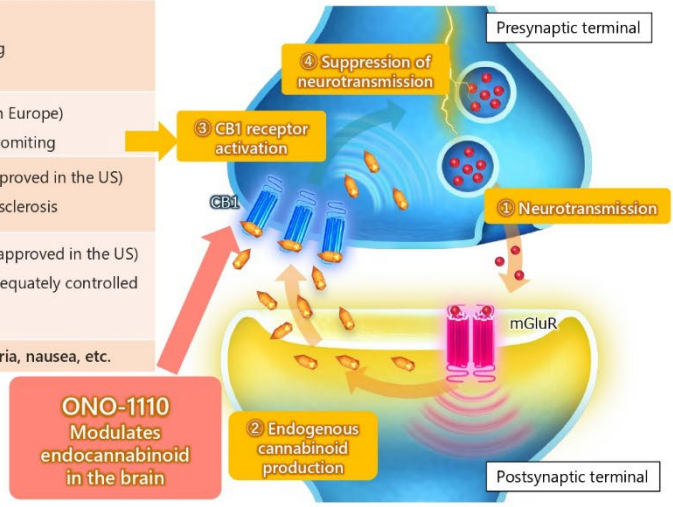
Although we are currently conducting Phase 1 trials for ONO-3310 and ONO-6414 below, we will only be disclosing information from the database regarding these as well.

That concludes with the update on the pipeline's progress.

## ONO-1110 MoA

| Approved drugs related to Δ9-THC | |
|---|---|
| Dronabinol (Synthesized Δ9-THC) | Marinol®/Syndros® (US Approved)<br>Refractory chemotherapy-induced nausea and vomiting<br>/ Loss of appetite with weight loss in AIDS patients |
| Nabilon (Δ9-THC analog) | Cesamet®/Canemes® (US, Canada, partially approved in Europe)<br>Refractory cancer chemotherapy-induced nausea and vomiting |
| Nabiximorus (Plant-derived Δ9-THC + CBD) | Sativex® (Canada, partially European, Australian, not approved in the US)<br>Moderate to severe spasticity associated with multiple sclerosis |
| VER-01 (Standardized cannabis flower extract, Main ingredient: Δ9-THC) | Exilby® (liquid) (approved in Germany and Austria, not approved in the US)<br>Chronic low back pain with a radicular component inadequately controlled by non-opioid analgesics |
| Side effects: dizziness, drowsiness, disorientation, depressive mood, euphoria, nausea, etc. | |

| Medical cannabis | |
|---|---|
| Country Region | US (some states), Canada, UK, Australia, and others |
| Main uses | Cancer chemotherapy-induced nausea and vomiting<br>Loss of appetite with weight loss in AIDS patients<br>Multiple sclerosis, chronic pain<br>Sleep disorders, anxiety disorders, depression, PTSD |




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I'd like to take a moment to once again provide an overview of the ONO-1110 PoC testing and related details.

First, regarding the mechanism of action: As we have previously stated, the mechanism of action of ONO-1110 involves the regulation of endocannabinoids. As shown in this figure, it can be described as a drug that regulates endocannabinoids in the brain.

As I'm sure you all know, cannabinoids are found in the plant known as hemp, or cannabis. It is considered a general term for a group of compounds containing 21 carbon atoms found in hemp, and it is said that there are as many as 104 different types.

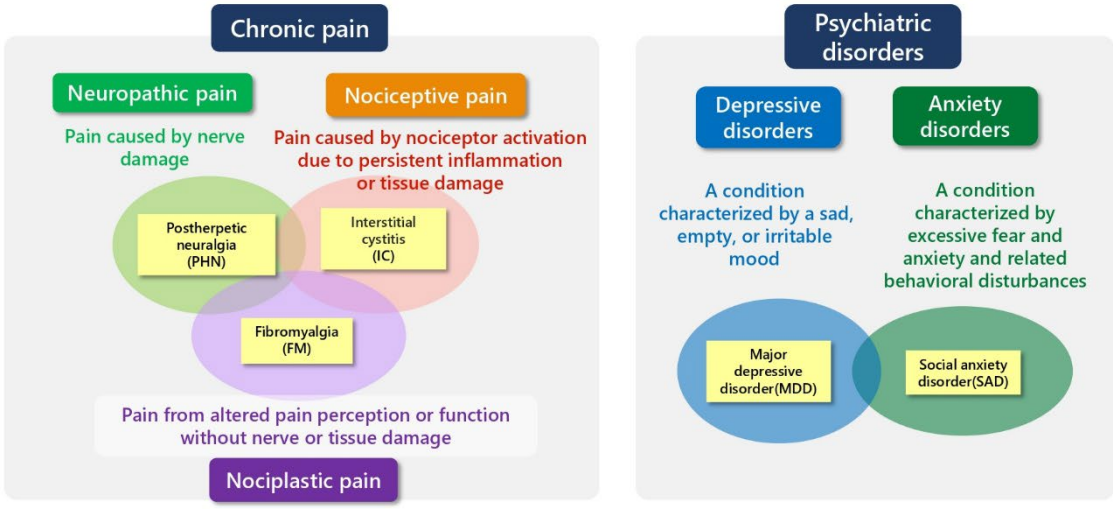
It has been reported that cannabinoids possess pharmacological effects beneficial to humans, such as analgesic, anticonvulsant, and anti-inflammatory effects. As shown on the left, in some countries, medical cannabis or cannabinoids—as I mentioned earlier, there are 104 types—including their derivatives, such as those shown here, have been approved as medications.

While the analgesic effects of these drugs and their effects on loss of appetite are thought to result from the activation of CB1 receptors on the right side, the occurrence of various side effects—including characteristic effects such as euphoria—is considered problematic.

On the other hand, the human body possesses what are known as endogenous cannabinoids—a natural defense mechanism that produces these substances in response to stimuli such as pain. Endogenous cannabinoids are believed to play a role in the body's defense mechanisms against pain and other conditions through the activation of CB1 receptors.

ONO-1110 is administered externally by regulating this endogenous cannabinoid. Unlike medical cannabis, as shown on the left, or substances similar to tetrahydrocannabinol, ONO-1110 is being developed with the aim of providing beneficial effects—such as pain relief—while avoiding problematic side effects.

# Target Indications for Phase 2 Trials in Japan




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This table lists the diseases included in the Phase 2 clinical trials conducted in Japan.

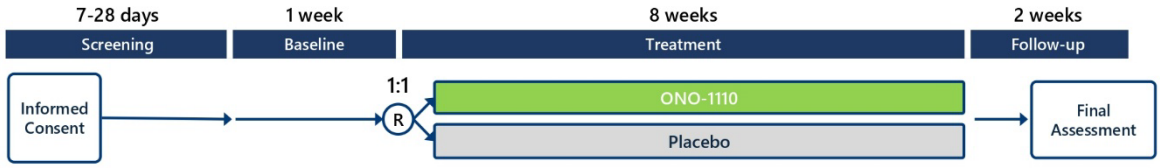
First, regarding chronic pain on the left side, it is generally accepted that there are three types of chronic pain with different mechanisms of onset: neuropathic pain, nociceptive pain, and nociplastic pain. From among these, we selected postherpetic neuralgia, interstitial cystitis, and fibromyalgia as representative conditions and conducted clinical trials in Japan. We have also selected depression and social anxiety disorder as the mental health conditions on which to focus our development efforts.

As for the results, as we have already announced in a press release and as I mentioned earlier, unfortunately, we were unable to identify any signs of efficacy for the mental disorder on the right.

On the other hand, regarding this pain disorder, while I mentioned that we were able to establish proof of concept (PoC), I believe we have obtained results that warrant moving forward to the next phase. From this point on, we will present an overview of the trials targeting three pain-related conditions, as well as an overview of the proof-of-concept (PoC) trials for which results have been obtained.

## Overview of ONO-1110-04 Study

| Phase 2a Trial of ONO-1110 in Patients with Postherpetic Neuralgia (ONO-1110-04 Study) | |
|---|---|
| Objective | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with postherpetic neuralgia |
| Study Design | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| Patients | Patients with moderate to severe postherpetic neuralgia |
| Primary Outcome Measures | Change in weekly mean of average pain score (NRS) from baseline to Week 8 of the treatment period |
| Secondary Outcome Measures | Changes from baseline in: weekly mean worst pain score (NRS), 30% and 50% responder rates, Brief Pain Inventory-Short Form (BPI-SF), Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2), Hospital Anxiety and Depression Scale (HADS), and Patient Global Impression of Change (PGIC); plasma ONO-1110 concentrations |
| Exploratory Outcome Measures | Quantitative sensory testing, frequency and amount of rescue medication use |
| Safety Assessments | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, Columbia-Suicide Severity Rating Scale (C-SSRS) |
| Dose Regimen | XXXXX |
| Treatment Groups / Sample Size | Total n=140 (ONO-1110: n=70; placebo: n=70) |
| Study Schema | Screening: 7-28 days; Baseline: 1 week; Treatment: 8 weeks; Follow-up: 2 weeks |
| Study Period | October 2024 - June 2026; 13-month enrollment period |



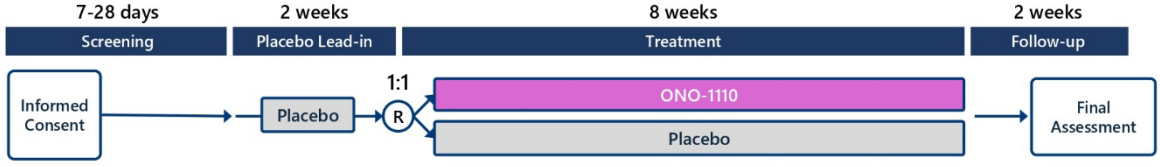

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First, here is an overview of the ONO-1110-04 trial, which focused on postherpetic neuralgia.

This study compared the placebo group with the 1110 treatment group in a cohort of 140 Japanese patients. The treatment period is eight weeks. Please note that, while this applies to all products, we are currently unable to disclose information regarding their usage and dosage. The primary endpoint was the weekly average of the mean pain score at eight weeks after the start of treatment. This was the change from the NRS baseline.

## Overview of ONO-1110-05 Study

| Phase 2a Trial of ONO-1110 in Patients with Fibromyalgia (ONO-1110-05 Study) | |
|---|---|
| Objective | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with fibromyalgia |
| Study Design | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| Patients | Patients with moderate to severe fibromyalgia |
| Primary Outcome Measures | Change in weekly mean of average pain score (NRS) from baseline to Week 8 of the treatment period |
| Secondary Outcome Measures | Changes from baseline in: weekly mean worst pain score (NRS), 30% and 50% responder rates, Widespread Pain Index (WPI), Symptom Severity Scale (SSS), Japanese version of the Revised Fibromyalgia Impact Questionnaire (JFIQR), PGIC, MOS Sleep Scale, and HADS; plasma ONO-1110 concentrations |
| Exploratory Outcome Measures | Quantitative sensory testing, tender point count, activity/sleep/pulse rate measurements, CVR-R, frequency and amount of rescue medication use |
| Safety Assessments | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, C-SSRS |
| Dose Regimen | XXXXX |
| Treatment Groups / Sample Size | Total n=160 (ONO-1110: n=80; placebo: n=80) |
| Study Schema | Screening: 7-28 days; Placebo lead-in: 2 weeks; Treatment: 8 weeks; Follow-up: 2 weeks |
| Study Period | November 2024 - May 2026; 13-month enrollment period |



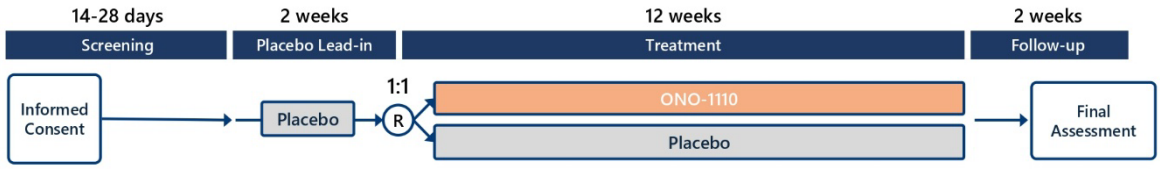

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Next, here is an overview of the ONO-1110-05 trial for fibromyalgia.

This study compared the placebo group with the ONO-1110 treatment group in a cohort of 160 Japanese patients. The treatment period for this study is also eight weeks, and the primary endpoint is the NRS, which is the same as in Study 04.

## Overview of ONO-1110-06 Study

| Phase 2a Trial of ONO-1110 in Patients with Hunner Type Interstitial Cystitis (ONO-1110-06 Study) | |
|---|---|
| Objective | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with Hunner type interstitial cystitis |
| Study Design | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| Patients | Patients with moderate to severe Hunner type interstitial cystitis |
| Primary Outcome Measures | Change in weekly mean of average pain score (NRS) from baseline to Week 12 of the treatment period |
| Secondary Outcome Measures | Changes from baseline in: Weekly mean worst pain score (NRS), 30% and 50% responder rates, Interstitial Cystitis Symptom Index (ICSI), Interstitial Cystitis Problem Index (ICPI), average daytime and nocturnal urinary frequency, mean and maximum voided volume per micturition, urgency episodes, SF-12v2 (health-related quality of life), PGIC, and HADS; plasma ONO-1110 concentrations |
| Exploratory Outcome Measures | Frequency and amount of rescue medication use |
| Safety Assessments | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, C-SSRS |
| Dose Regimen | XXXXX |
| Treatment Groups / Sample Size | Total n=50 (ONO-1110: n=25; placebo: n=25) |
| Study Schema | Screening: 14-28 days; Placebo lead-in: 2 weeks; Treatment: 12 weeks; Follow-up: 2 weeks |
| Study Period | January 2025- June 2026; 15-month enrollment period |




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This is an overview of the ONO-1110-06 trial for Hanner-type interstitial cystitis.

This study was on a slightly smaller scale; we compared the treatment to a placebo in 50 Japanese patients. In this study, the drug was administered for 12 weeks. As in ONO-1110-04 and ONO-1110-05 trial, the primary endpoint is the NRS.

I would like to explain the key evaluation criteria—please consider this strictly as a reference for today.

As I'm sure many of you have seen in comparisons of other trials—and we set the intergroup difference between the active-treatment and placebo groups over time as the primary endpoint common to all three pain conditions.

Though I can't disclose the data of the clinical trial result today, I'd like to briefly explain the basis for our statement that, based on the results of this test, we have successfully established a PoC and obtained results that support moving forward to the next phase.

As mentioned earlier, in this PoC trial, the primary endpoint for each trial was the change from the NRS baseline. With regard to the between-group difference between the ONO-1110 group and the placebo group, we have compared it to an already approved drug, we have predefined an ideal efficacy value, the TV (Target Value), as well as a threshold for unacceptable efficacy.

For example, the range defined as "effective." Specifically, we have established a rule whereby results that significantly exceed the target value—or that fall just above the target value but do not reach the unacceptable efficacy threshold—are considered valid, while results that fall short of the target value are deemed invalid. We interpret the results once all three tests have been completed.

I explain the summary of the results.

Regarding postherpetic neuralgia, while the primary endpoint in the overall population did not exceed the target value, there were several subgroup analyses that we had specified in advance, and based on the results of those analyses, we have concluded that the treatment is effective.

As for the secondary endpoints, we also conducted several different efficacy assessments that were independent of the primary endpoints, and we obtained consistent results—that is results that were consistent with those from the subgroup analyses. Therefore, we have determined that proof of concept (PoC) for postherpetic neuralgia was established in this Phase 2 trial.

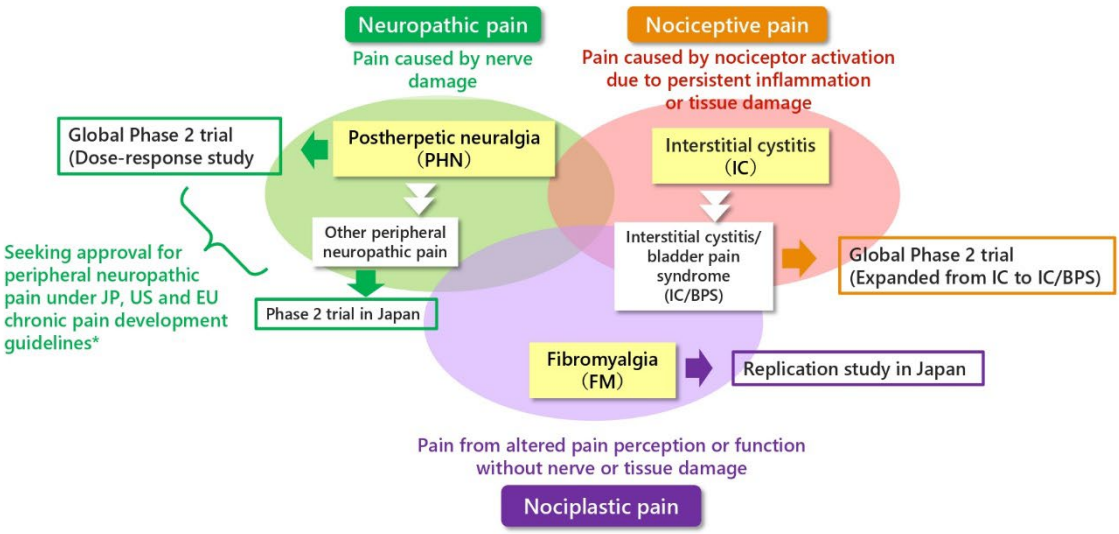
Similarly, regarding interstitial cystitis, the interpretation of the results is similar to that for postherpetic neuralgia. Although the primary endpoint for the overall population unfortunately showed no efficacy, we have concluded that the pre-specified subgroup analysis provides confirmation that ONO-1110 has the potential to be a treatment for interstitial cystitis.

Turning to the secondary endpoints—which are symptoms specific to interstitial cystitis and constitute a separate assessment criterion from the NRS mentioned earlier—we can say that consistent results were obtained for these symptoms as well; specifically, the results suggest the efficacy of ONO-1110.

On the other hand, regarding fibromyalgia, it is well known that evaluating the efficacy of treatments for this condition is inherently difficult. This case is slightly different from the previous two. While the results of the pre-specified subgroup analysis did not lead us to conclude that the treatment was effective, we conducted a post-hoc analysis and were able to identify a subgroup in which the drug's efficacy could be sufficiently confirmed. That is the summary of our findings.

Furthermore, overall—whether considering the three trials or the five trials that included patients with psychiatric disorders—the data demonstrates a favorable safety profile. Specifically, the drug demonstrated a favorable safety profile even with regard to side effects of concern that are specific to centrally acting medications, such as drowsiness—as observed with gabapentinoids—and unsteadiness.

## ONO-1110 Development Plan




* Guidelines for the Clinical Evaluation of Drugs for Neuropathic Pain (PMDA, 2020)
Guideline on the clinical development of medicinal products intended for the treatment of pain (EMA, 2017)
Development of Non-Opioid Analgesics for Chronic Pain: Guidance for Industry, Draft Guidance (FDA, May 2026)

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This outlines the direction of future development.

As I mentioned earlier regarding postherpetic neuralgia, we have determined that we have established proof of concept (PoC), and we plan to conduct a global dose-response study—commonly referred to as a late Phase 2 study or P2b—next.

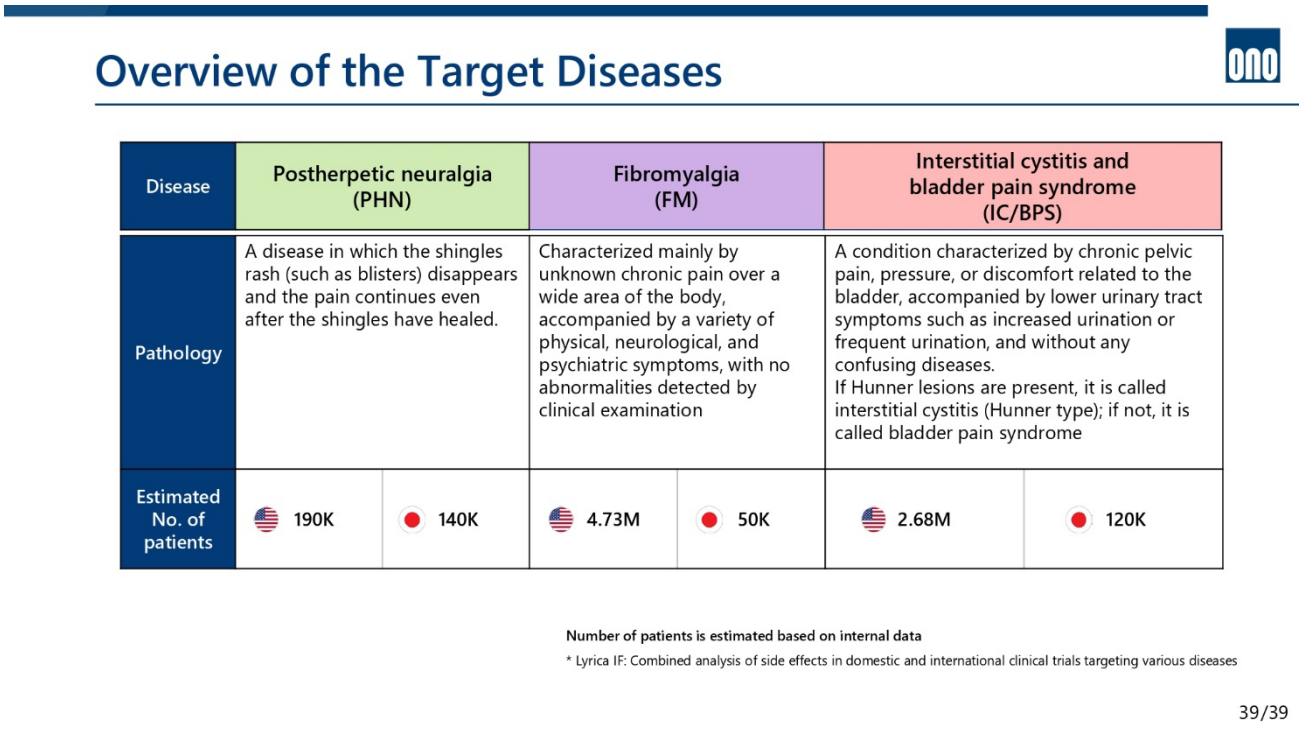
In addition, regarding peripheral neuropathic pain other than postherpetic neuralgia—I will refrain from specifying the target conditions today—but generally speaking, these include diabetic peripheral neuropathy and radiculopathy, such as sciatica. We plan to conduct a Phase 2 clinical trial in Japan for these indications.

As for why we are studying another condition, the reason is that, with regard to neuropathic pain, if we can demonstrate efficacy in two or more different conditions, we can obtain approval for a comprehensive indication that includes other types of neuropathic pain.

Specifically, this is possible in Japan and Europe. Furthermore, regarding the draft guidance recently issued in the US, we believe that, based on this guidance, it will be possible to obtain comprehensive indications in a manner similar to that in Japan and Europe; therefore, we intend to proceed with late-stage development with that goal in mind.

As for interstitial cystitis, which is shown on the right, our development efforts to date have focused exclusively on the type known as the Hunner type. This is known as a “Hunner lesion.” We developed this treatment specifically for cases in which a cystoscope examination of the bladder revealed the presence of lesions known as Hunner lesions; however, it is said that there are patients worldwide who, although they exhibit similar symptoms, are not classified as having Hunner-type interstitial cystitis because they do not have Hunner lesions; yet their condition is considered to be equivalent to Hunner-type interstitial cystitis. We plan to conduct a global Phase 2 clinical trial targeting this comprehensive disease concept as well.

Finally, regarding fibromyalgia—as I mentioned earlier, it differs somewhat from the previous two pain conditions. Rather than conducting a late-phase Phase 2 trial, we believe the patient population we have identified requires a reproducibility study to determine whether ONO-1110 is truly effective for fibromyalgia, and we plan to conduct that study in Japan.




Finally, we have provided an overview of the target diseases I mentioned earlier.

As you may already be aware, there is a very high unmet need for all of these disease groups. In fact, the approved treatments are used to treat these pain disorders, I believe this is a group of conditions where many unmet needs remain in various respects—such as the characteristic side effects resulting from their central nervous system effects, as I mentioned earlier; the need for dose escalation during the initiation phase; and the inability to drive.

Since we conducted this Phase 2 trial simultaneously across five disease areas, we are quite confident—at least regarding safety—that this will be successful. As for efficacy, while unfortunately the results for the two psychiatric disorders were negative, all the pain-related conditions showed results pointing in the same direction. Although the stratified analysis based on the predefined criteria used similar stratification factors, when we analyzed the data by each stratum, the results did not show inconsistent trends—with some trials pointing in one direction and others in the opposite—but rather all pointed in the same direction. Given this, even though the trial was not large in scale, I believe we were able to sufficiently confirm the therapeutic efficacy of ONO-1110. Although the next step is not a Phase 3 trial, I am confident that we can proceed to a late-Phase 2 trial.

Although this is not a Phase 3 trial, I would like to add one more point: From a mechanism-of-action perspective, we had high hopes that Compound ONO-1110 would show significant scaling up. However, as has been widely noted, it is well known that it is extremely difficult to demonstrate efficacy with drugs based on novel mechanisms of action for pain disorders.

Given these circumstances, we formulated a development plan that prioritized confirming, first and foremost, that this 1110 works as our hypothesis suggests and demonstrates efficacy in humans. Consequently, we conducted five trials for five different diseases using a single fixed dose—the one we believed would be effective.

On the other hand, when submitting an application for approval, we are inevitably required to provide an explanation regarding the dose-response relationship. Since we have not yet confirmed the dose-response relationship at this point, we are unable to proceed directly to Phase 3 at this time.

That concludes my presentation on the progress of the pipeline and an overview of ONO-1110. Thank you.

## Question & Answer

**Imura :** Now, I'd like to take questions from the audience.

Mr. Yamaguchi from Citigroup Securities, please.

**Yamaguchi :** I'd like to ask a few questions about the ONO-1110 you just explained.

The first point is the mechanism. You mentioned "control"—does this mean it stimulates that area in the same way as exogenous cannabinoids? I'm having a little trouble fully understanding the concept of "control," so I'd like you to explain that to me first.

One more thing: although the primary endpoint was not met, a subgroup analysis was conducted. Specifically, what do you mean by "stratified analysis"? And ultimately, will the number of eligible patients decrease as a result of the stratified analysis, or will that not be the case? Could you please explain these two points?

**Okamoto :** First of all, I apologize, but as has been our policy, we are unable to disclose any further details regarding the mechanism, so I would like to refrain from providing a detailed explanation of the specific points of action today.

Next, regarding stratified analysis—to give you a general idea of what stratified analysis entails, based on the question you asked earlier— We've conducted numerous trials with PD-L1 antibodies as well. However, since some studies treat PD-L1-positive patients as an "all-comer" group—using PD-L1 as a stratification factor and, once patients group is achieved based on PD-L1 status, moving them to the "all-comer" group in the next stratification level—I think the overall patient population would likely be smaller in such cases.

Please bear with us this time—we won't go into the finer details of this stratified analysis. We do not believe that the results of this stratified analysis will narrow down the target population. Stratified analysis—again, speaking in general terms—essentially refers to factors that are likely to influence drug efficacy. For example, while there are cases involving prognostic factors, and in the case of pain disorders, there may be areas where the so-called placebo effect is particularly pronounced, in any case, although the results were favorable in the pre-specified subgroup analyses, we do not believe that this means the findings are limited to a specific subgroup.

**Yamaguchi :** I understood. Also, I believe ONO-2020 data hasn't been released yet, but there seems to be a note on ClinicalTrials.gov suggesting that it has already been completed. When do you think this information will be announced?

**Okamoto :** As for ONO-2020, it will be within this year. We expect to be able to provide you with an update by the end of December 2026.

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

**Seki :** I'd like to ask about ONO-1110. So, when you performed stratified analysis, were the point estimates exceeding from the target value of -1.0? When we perform a stratified analysis, the number of patients decreases, so I feel that this causes the confidence interval to widen, making it more likely to fall outside the

-1.0 range. However, to rule out that possibility, one thing to check is whether the point estimate of -1.0 was exceeded.

One more thing: Is the stratified analysis you're referring to here just one? Or, was it more than one? If all of the stratified analyses specified in advance were valid, I think that would be very positive because it would mean there was no selection bias. However, are you saying that some of the stratified analyses—out of the several that existed—were valid because they were chosen arbitrarily? Which is it? This is my second question.

**Okamoto :** First, regarding your question about point estimates—specifically, whether the LS mean exceeded the so-called target value or not—I would like to refrain from answering that at this time, as there will be academic conferences on this topic in the near future.

Since you also mentioned confidence intervals, it goes without saying that as the sample number decreases, the confidence interval widens. Conversely, as the confidence interval widens, the probability of falling within this “valid” range becomes very low.

To be specific, I think the general idea is that it would tend to fall toward the “Invalid” end of the spectrum or be classified as “inconclusive” I would like to state that, at least for postherpetic neuralgia and interstitial cystitis, the results fell within the “effective” range rather than being classified as “inconclusive.”

In addition, we plan to present the data at an academic conference sometime next spring. I can’t really go into detail on that just yet, but I would like to note that the stratified analysis clearly showed this—and it wasn’t just a very small number of cases.

One more thing— regarding the stratified analysis. It’s not as if this is the result of breaking down the stratified analysis into many smaller parts. The reason is—as we’ve clearly shown here—that, as researchers who conduct clinical trials and interpret the results, we do not arrive at conclusions by analyzing the data from various angles and saying, “It turned out this way.” In that case, while I did mention that fibromyalgia was identified through post-hoc analysis, regarding the subgroup analysis, I hope you’ll understand that when we segmented the data based on a common subgrouping factor, the results moved in the same direction.

**Seki :** My second point is regarding the PDUFA review of tirabrutinib on December 18—is that proceeding smoothly? And also, regarding Povetacicept for IgA nephropathy. Is it possible, for example, to use UPCR data in Japan to file an application more quickly, or something like that?

**Okamoto :** I’ll start by addressing your question regarding povetacicept, but as a general rule, I refrain from commenting on matters directly related to our application strategy. I hope you’ll bear with me.

Regarding the review of tirabrutinib, yes, we are in the final stages of the review process, and I can confirm that the back-and-forth between the applicant and the FDA—or, as it’s commonly referred to, the interactions with the FDA—is proceeding smoothly.

**Imura :** Mr. Mamegano from BofA Securities, please.

**Mamegano :** I have two questions. First, regarding ONO-1110—the explanation this time was very clear, so thank you very much.

I wonder if safety could be a differentiating factor when it comes to THC as well. While the data we obtained this time seems to indicate efficacy compared to a placebo, when comparing it to THC, I can't help but feel that THC might actually be more effective.

The question is whether we can say that its efficacy is sufficiently competitive without comparing it to THC in the next step. In the next trial, what level of efficacy compared to a placebo would you consider sufficient to conclude that the treatment is effective, even without comparing it to THC?

**Okamoto :** This relates to what I mentioned earlier in my exchange with Mr. Seki: the target values we set correspond to the between-group differences compared to the so-called placebo. Currently, for peripheral neuropathic pain, interstitial cystitis, fibromyalgia—the specific "target values" vary for each condition. However, since we have set these values based on currently available drugs in the market, we believe that if the magnitude of efficacy is greater than or equivalent to those values, the drug will sufficiently address unmet medical needs.

As a general rule, placebo-controlled trials are recommended, and I do not believe it is necessary to demonstrate a difference in active-controlled trial.

**Mamegano :** Another question is about ONO-4578. Since Phase 3 trials are set to begin, I took a look at ClinicalTrials.gov, and I'd like to ask you a few questions about the handling of Claudin.

From what I can tell, I understand that it will be held at the All-Comers, regardless of whether Claudin appears, but is that actually okay? Also, regarding Claudin-positive cases, I believe zolbetuximab is one of the standard treatments, but the question is whether its use in combination with other therapies is permitted during the trial.

Also, since the evaluation is based on the OS, the question is whether crossover is permitted during the treatment phase. Please tell me what factors behind that.

**Okamoto :** First, regarding the study population, I'm very sorry, but since discussing the details of the protocol would involve revealing more than what has already been made public, there are certain aspects I cannot disclose. I hope you'll bear with me on this.

Strictly speaking, this applies only to PD-L1- and CPS-positive cases. As we mentioned at this year's R&D meeting, if a patient is positive for Claudin but negative for CPS, as a general rule, we would not even consider enrolling them in this clinical trial. Conversely, when a patient is positive for both Claudin and CPS, whether to enroll them in this clinical trial or which standard treatment to use—whether to use zolbetuximab—is ultimately up to the judgment of the principal investigators (PIs).

Regarding OS verification, as for crossover, both zolbetuximab and PD-1 antibody-based chemotherapy—in this case, OPDIVO-based chemotherapy—are used as first-line treatments worldwide. While there are differences depending on protein expression and other factors, both options are available. However, to the best of my knowledge, neither has been approved for use in a sequential regimen. Therefore, at least as far as we are concerned, we have not established any specific regulations regarding whether or not to permit crossover.

On the other hand, as you may be aware, there have recently been several successful cases involving new drugs for Claudin—developed by other companies—that target patients in the second-line setting or later.

However, since these are overall survival (OS) trials, the study design is such that we cannot make any specific statements regarding what treatments are used subsequently.

**Imura :** Mr. Hashiguchi from Daiwa Securities, please.

**Hashiguchi :** Is it correct to understand that, while the results for the overall population—without stratified analysis for ONO-1110—did not meet your company's criteria for efficacy, there was at least a numerical trend toward efficacy?

**Okamoto :** I'd prefer not to specify exactly where the issue lies in terms of the evaluation criteria, but if we consider with the NRS ratings. The primary endpoint, while the results may not have fallen within the range specified earlier, I am stating that there was no situation where the data were virtually indistinguishable from the placebo group, leaving no evidence of the drug's efficacy.

Although magnitude wasn't a factor in our decision-making, we could see that ONO-1110 had proven its effectiveness. I believe this is evident in the overall group.

**Hashiguchi :** Also, given that efficacy is not expected for pain caused by nociplastic pain, but is expected only for neuropathic pain and nociceptive pain, is this hypothesis mechanistically sound? Do you think the slight differences in the results among the three types of this time were just a coincidence, or is there an explanation for them?

**Okamoto :** While pain disorders are generally classified into three broad categories, the reason why this was not entirely evident in fibromyalgia—a representative example of pain-nociplastic pain —is not actually due to that classification. Rather, we believe it was because it was difficult to select a population suitable for evaluating drug efficacy in PoC trials for fibromyalgia.

So, to put it another way, that's where we can reliably identify the drug's efficacy. It's not that it's only effective in that specific context; rather, in this proof-of-concept trial, we weren't quite able to identify a population suitable for evaluating the drug's efficacy. On the other hand, regarding the two points mentioned above, since we were able to implement them, I believe we were ultimately able to confirm their effectiveness.

**Hashiguchi :** Does that mean you were able to draw the conclusion that this was the case in the fibromyalgia trial based on the results of the subgroup analysis of the two successful trials?

**Okamoto :** To give just one example, the trigger for postherpetic neuralgia is quite clear. It's exactly as the name suggests. While interstitial cystitis is a slightly different case, with fibromyalgia, the time it takes to reach a diagnosis is often very long, and there is considerable variation in disease-specific factors; for these reasons, I believe it was quite difficult to narrow down a suitable patient population before the start of the trial.

**Hashiguchi :** Just a quick check. I believe the method for modifying the primary endpoint for ONO-2808 has been changed—what was the rationale behind this change? Please tell me how I should think about the reproducibility of Phase 2.

**Okamoto :** As for our specific objectives—I'm afraid I can't go into detail—there are strategic reasons for this. I believe I mentioned this during the R&D Meeting as well, but could you please understand that we have already reached an agreement with the regulatory authorities on this approach prior to the start of the trials?

**Imura :** Ms. Yatsunami from Nissay Asset Management, please go ahead.

**Yatsunami :** We recognize that the new medium-term plan will begin next fiscal year. While several other companies have already announced their medium-term plans this fiscal year, as President Takino mentioned, given the steady progress we're making in strengthening our pipeline, I believe this is an excellent time to set out our long-term strategy and direction.

I believe you have already discussed the disclosure of the medium-term management plan with the capital markets through regular dialogues and other channels, and I believe I have also engaged in such discussions myself. Could you please share President Takino's personal thoughts on the next medium-term management plan and its disclosure?

**Takino** : As you now understand, sapablursen. Although I didn't mention sapablursen today, ONO-1110 will be added to sapablursen, ONO-4578, ONO-2808, and similar items this time. With our pipeline of candidates for around 2030 and beyond becoming significantly more robust, we are growing increasingly confident—and our expectations are rising—that each of these candidates will be able to effectively address unmet medical needs.

At this point, we are still considering how best to present the medium-term plan to everyone, but we will certainly highlight these future growth drivers. In particular, as we are aiming to enter a new phase of growth following OPDIVO, starting around 2030, we are currently considering whether this is the right time to make upfront investments toward that goal.

**Imura :** Mr. Wakao from JPMorgan Securities.

**Wakao :** First, regarding ONO-1110, in the subgroups that were analyzed and deemed valid, was a statistically significant difference observed compared to the placebo? Does that simply mean you set it up in advance and it met the criteria for effectiveness that were explained to you?

**Okamoto :** First of all, we did not perform any statistical analysis to determine whether there was a statistically significant difference in this study. We did not perform a significance test for the primary endpoint either, and while we will not perform a test, there is a confidence interval. As for the confidence interval—I'll refrain from disclosing the exact percentage today—we set a certain confidence interval and then determine whether the result falls within that range.

For example, with a 95% confidence interval, if the upper and lower bounds are drawn, a result that falls within that range is generally considered statistically significant at $\alpha = 0.05$—we did not perform a significance test in this case, so I'd like you to keep that in mind as a basic premise.

So, to put it simply, I hope you'll understand that when the results of the stratified analysis fall within this range, we interpret this to mean that they fall within a confidence interval that is sufficiently reliable.

**Wakao :** The second point concerns ONO-2020. I believe data on this will be available by the end of the year. Since CSF concentration is being measured in Phase 1, I assume you have confirmed this central nervous system penetration.

Furthermore, I understand that P1 has been established as a metric to confirm whether the anticipated pharmacological effects actually occur in humans, and I would like to know whether the study has progressed to P2 following an evaluation of that metric. If we're looking at something like the biomarkers

that have been established, is it safe to assume that changes in pharmacological effects were properly confirmed in Phase 1?

**Okamoto :** First, regarding Phase 1—and I may have mentioned this before—since this study was conducted on healthy adults, I think it might be a bit difficult to assess the so-called pharmacological effects.

As for the matter of biomarkers, we cannot comment here on any information that has not yet been disclosed or made public; however, one thing I can say is that regarding the results of Phase 2—which was a randomized placebo-controlled trial conducted as part of ONO-2020 study—we will definitely be able to share those results by the end of the year, so I ask for your patience in this regard. Excuse me for that.

**Wakao :** Based on the mechanism I had vaguely imagined, I was wondering if a biomarker could be identified, but I suppose you can't tell me about that just yet.

**Imura :** We've gone a little overtime. I'll take one from someone at the end. Mr. Ishii from the Iyaku Tsushinsha, please go ahead.

**Ishii :** As you explained in some detail today, the CNS pipeline area has grown considerably. I'd like to ask what scale you're aiming for in this area.

**Takino :** When you say "scale," I assume you mean something like sales volume. As for the number of patients and such, I think that information may have been included in the slide Mr. Okamoto showed toward the end. As for us, the indications for pain—and indeed, that pain itself—can potentially be developed in three different directions; moreover, as mentioned earlier regarding the ONO-2808 neurodegenerative diseases, this is already a "high-unmet need" situation, an area where no drugs currently exist.

Given this situation, if we can successfully bring the product to market through our global expansion efforts, I am hopeful that—considering the product's profile—it has great potential to become a relatively easy-to-use medication. In that sense, I believe it will become a product on a scale large enough to make a solid contribution to our next phase of growth and to build on the growth we've achieved so far with OPDIVO.

I do think it would be great if you had high expectations, and while several analysts asked questions about this earlier, regarding ONO-2020 results—though I don't intend to make any biased comments at this stage—I do hope you'll continue to have high expectations.

**Imura :** Since our time is up—even though there are still many of you with your hands raised—I'll have to wrap up the Q&A session here.

This concludes our presentation of the Q2 financial results meeting for the fiscal year ending March 2027. Thank you very much for taking time out of your very busy schedule to come here today.