2nd Quarter of Fiscal Year 2025 (Ending March 31, 2026)
(April 1, 2025 to September 30, 2025)

# Supplementary Materials
# (Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

**Contents**

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2025 (Ending March 31, 2026) (Core basis)】



Note: “(Billions of yen)” are rounded.

## Summary of Consolidated Financial Results for the 2nd Quarter of FY 2025 (Core basis)

(Billions of yen)

| | Six months ended September 30, 2024 | **Six months ended September 30, 2025** | YoY | Full year ended March 31, 2025 |
|---|---|---|---|---|
| Revenue | 240.3 | **257.1** | 7.0% | 486.9 |
| Core operating profit | 65.4 | **70.1** | 7.2% | 112.7 |
| Core profit for the period (attributable to owners of the Company) | 51.0 | **53.8** | 5.5% | 90.4 |

Note: The business of the Company and its affiliates consists of a single segment, the pharmaceutical business.

### 1. Revenue ¥257.1 billion YoY an increase of 7.0% (FY 2024 2Q YTD ¥240.3 billion)

<Sales of Domestic Products>

- Sales of Opdivo Intravenous Infusion for malignant tumors decreased by ¥4.1 billion (6.5%) year on year to ¥58.5 billion, mainly due to the intensified competitive environment. Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease increased by ¥5.1 billion (11.6%) year on year to ¥48.8 billion, mainly due to its expanded use, particularly in treatment for chronic kidney disease and chronic heart failure.
- With respect to other main products, sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.8 billion (2.1% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥6.9 billion (28.2% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥6.0 billion (15.8% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥4.5 billion (18.6% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.5 billion (7.4% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.0 billion (12.1% decrease year on year).

<Sales of Overseas Products>

- Sales of QINLOCK® (ripretinib) for gastrointestinal stromal tumor, marketed by Deciphera Pharmaceuticals, LLC, the operating company of Deciphera Pharmaceuticals, Inc., increased by ¥10.0 billion (123.3%) year on year (the previous period included only three months of sales from July to September) to ¥18.1 billion. Additionally, sales of ROMVIMZA™ (vimseltinib), also marketed by Deciphera, for tenosynovial giant cell tumor (TGCT) treatment were ¥2.8 billion.

<Royalty and Others>

- Royalty and others increased by ¥5.1 billion (6.7%) year on year to ¥82.2 billion, mainly due to an increase in royalty revenue from Bristol-Myers Squibb Company.

### 2. Core operating profit ¥ 70.1 billion YoY an increase of 7.2 % (FY 2024 2Q YTD ¥ 65.4 billion)

- Core operating profit was ¥70.1 billion, an increase of ¥4.7 billion (7.2%) year on year.
- Cost of sales increased by ¥0.9 billion (1.7%) year on year to ¥54.8 billion mainly due to an increase of cost of goods sold.
- Research and development costs increased by ¥5.7 billion (8.8%) year on year to ¥71.0 billion mainly due to the costs associated with the licensing agreement with LigaChem Biosciences, Inc., as well as the inclusion of research and development expenses from Deciphera Pharmaceuticals, LLC. The previous period accounted for only three months of Deciphera's expenses (July to September), whereas the current period includes six months (April to September).
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥5.6 billion (10.2%) year on year to ¥61.1 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and the inclusion of business operating costs from Deciphera Pharmaceuticals, LLC. The previous period accounted for only three months of Deciphera's expenses (July to September), whereas the current period includes six months (April to September).

### 3. Core profit for the period ¥ 53.8 billion YoY an increase of 5.5 % (FY 2024 2Q YTD ¥ 51.0 billion) (attributable to owners of the Company)

- Core profit attributable to owners of the Company increased by ¥2.8 billion (5.5%) year on year to ¥53.8 billion.

**Sales Revenue Result and Forecast of Major Products**

(Billions of Yen)

| Product Name | Six months ended September 30, 2025 (April 1, 2025 to September 30, 2025) | | | | | FY 2025 Forecast (April 1, 2025 to March 31, 2026) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Cumulative | | | YoY | | Previous Forecast | Change from Previous Forecast | **Revised Forecast** | YoY | |
| | Apr ~ Jun | Jul ~ Sep | | Change | Change (%) | | | | Change | Change (%) |
| **<Domestic>** | | | | | | | | | | |
| Opdivo Intravenous Infusion | 29.4 | 29.1 | **58.5** | (4.1) | (6.5%) | 125.0 | (5.0) | **120.0** | (0.3) | (0.3%) |
| Forxiga Tablets | 25.1 | 23.7 | **48.8** | 5.1 | 11.6% | 80.0 | | **80.0** | (9.6) | (10.7%) |
| Orencia for Subcutaneous Injection | 7.0 | 6.8 | **13.8** | 0.3 | 2.1% | 28.0 | | **28.0** | 1.4 | 5.2% |
| Glactiv Tablets | 3.6 | 3.4 | **6.9** | (2.7) | (28.2%) | 12.0 | | **12.0** | (6.3) | (34.6%) |
| Velexbru Tablets | 3.0 | 3.0 | **6.0** | 0.8 | 15.8% | 11.0 | | **11.0** | 0.5 | 4.4% |
| Ongentys Tablets | 2.3 | 2.2 | **4.5** | 0.7 | 18.6% | 9.0 | | **9.0** | 1.4 | 17.8% |
| Parsabiv Intravenous Injection | 2.2 | 2.3 | **4.5** | 0.3 | 7.4% | 9.0 | | **9.0** | 0.6 | 6.7% |
| Kyprolis for Intravenous Infusion | 2.0 | 2.0 | **4.0** | (0.5) | (12.1%) | 9.0 | | **9.0** | 0.4 | 4.6% |
| **<Overseas>** | | | | | | | | | | |
| Opdivo | 3.3 | 3.9 | **7.2** | 0.7 | 11.5% | 13.5 | | **13.5** | 0.4 | 2.9% |
| QINLOCK® | 8.9 | 9.2 | **18.1** | 10.0 | 123.3% | 34.0 | 2.0 | **36.0** | 10.5 | 41.2% |
| ROMVIMZA™ | 1.1 | 1.7 | **2.8** | – | – | 5.0 | 3.0 | **8.0** | – | – |

Notes: 1. Sales revenue of domestic products is shown in a gross sales basis (shipment price).
2. Sales revenue of overseas products is shown in a net sales basis.

**Details of Sales Revenue**

(Billions of yen)

| | Six months ended September 30, 2024 | **Six months ended September 30, 2025** |
|---|---|---|
| Revenue of goods and products | 163.3 | **175.0** |
| Royalty and others | 77.0 | **82.2** |
| Total | 240.3 | **257.1** |

Note: In "Royalty and others", royalty revenue from Opdivo by Bristol-Myers Squibb Company is included, amounting to ¥56.4 billion for the second quarter (six months) ended September 30, 2024, and ¥59.4 billion for the second quarter (six months) ended September 30, 2025. In addition, royalty revenue from Keytruda® by Merck & Co., Inc. is included, amounting to ¥12.8 billion for the second quarter (six months) ended September 30, 2024, and ¥13.8 billion for the second quarter (six months) ended September 30, 2025.

**Revenue by Geographic Area**

(Billions of yen)

| | Six months ended September 30, 2024 | **Six months ended September 30, 2025** |
|---|---|---|
| Japan | 150.7 | **148.8** |
| USA | 79.2 | **93.5** |
| Asia | 7.5 | **8.9** |
| Europe | 2.8 | **5.1** |
| Others | 0.2 | **0.8** |
| Total | 240.3 | **257.1** |

Notes: Revenue by geographic area is presented on the basis of the place of customers.

**Reconciliation from Full to Core basis for the 2nd Quarter of FY 2025 (April 1, 2025 to September 30, 2025)**

<Definition of core basis>
Core financial results are calculated by deducting items that are not inherently related to the company's business performance or are one-time occurrences from the IFRS-based financial results. Adjustment items include amortization expenses arising from intangible assets acquired through acquisitions or in-licensing, impairment losses, compensation or settlement costs from litigation, and losses due to disasters.

(Billions of yen)

| | IFRS (Full) basis | Amortization | Impairment loss | Others | Core basis |
|---|---|---|---|---|---|
| **Sales revenue** | **257.1** | | | | **257.1** |
| Cost of sales | **(72.0)** | 12.5 | | 4.7 | **(54.8)** |
| **Gross profit** | **185.2** | 12.5 | | 4.7 | **202.4** |
| SG&A expenses | **(61.2)** | | | 0.1 | **(61.1)** |
| R&D costs | **(71.0)** | | | | **(71.0)** |
| Other income | **0.6** | | | | **0.6** |
| Other expenses | **(1.5)** | | | 0.7 | **(0.8)** |
| **Operating profit** | **52.1** | 12.5 | | 5.5 | **70.1** |
| **Operating profit ratio** | **20.2%** | | | | **27.2%** |
| Finance income | **2.1** | | | (0.2) | **1.9** |
| Finance costs | **(2.0)** | | | 0.7 | **(1.3)** |
| **Profit before tax** | **52.2** | 12.5 | | 6.0 | **70.7** |
| Income tax | **(12.2)** | (3.3) | | (1.5) | **(17.0)** |
| **Profit for the period** | **40.0** | 9.2 | | 4.5 | **53.7** |
| Non-controlling | **(0.1)** | | | | **(0.1)** |
| **Profit for the period (Attributable to owners of the company)** | **40.1** | 9.2 | | 4.5 | **53.8** |

The "Other" category in the cost of sales represents the adjustment for the expense of inventory assets evaluated at fair value related to the acquisition of Deciphera Pharmaceuticals, Inc. The “Other” category in the other expenses represents the adjustment for costs associated with the termination of office lease. The “Other” category in the finance costs represents the adjustment for gains or losses from the valuation of investment securities.

## Consolidated Financial Forecast for FY 2025 (April 1, 2025, to March 31, 2026) (Core Basis)

### Consolidated Financial Forecast

(Billions of yen)

| | FY 2024 (April 1, 2024 to March 31, 2025) | **FY 2025 (April 1, 2025 to March 31, 2026)** | YoY |
|---|---|---|---|
| Revenue | 486.9 | **490.0** | 0.6% |
| Core operating profit | 112.7 | **114.0** | 1.2% |
| Core profit for the year (attributable to owners of the Company) | 90.4 | **91.0** | 0.7% |

### Details of Sales Revenue (Forecast)

(Billions of yen)

| | FY 2024 (April 1, 2024 to March 31, 2025) | **FY 2025 Forecast (April 1, 2025 to March 31, 2026)** |
|---|---|---|
| Revenue of goods and products | 330.8 | **330.0** |
| Royalty and others | 156.1 | **160.0** |
| Total | 486.9 | **490.0** |

**1. Revenue ¥490.0 billion YoY an increase of ¥3.1 billion (0.6%)**

- Revenue of goods and products are expected to be ¥330.0 billion, a decrease of ¥0.8 billion (0.2%) year on year. Among main products, sales of Opdivo Intravenous Infusion are expected to be ¥120.0 billion, a decrease of ¥0.3 billion (0.3%) year on year, mainly due to the competitive environment intensified. Also, sales of Forxiga Tablets are expected to be ¥80.0 billion, a decrease of ¥9.6 billion (10.7%) year on year, mainly due to the anticipated impact of generic products following the expiration of some patents covering type 2 diabetes after December 2025.
  Furthermore, sales of “QINLOCK”, a treatment for GIST, sold by Deciphera Pharmaceuticals, LLC, are expected to be ¥36.0 billion, an increase of ¥10.5 billion (41.2%) year on year. Sales of “ROMVIMZA”, a treatment for TGCT which we began selling in February 2025, are expected to be ¥8.0 billion.
  Royalty and others are expected to increase by ¥3.9 billion (2.5%) year on year to ¥160.0 billion.
  Revenue is therefore expected to be ¥490.0 billion, an increase of ¥3.1 billion (0.6%) year on year.

**2. Core Operating profit ¥114.0 billion YoY an increase of ¥1.3 billion (1.2%)**

- Cost of sales is expected to be ¥103.5 billion, a decrease of ¥3.4 billion (3.1%) year on year, mainly due to the decline in sales of Forxiga Tablets and long-listed products.
- Research and development costs are expected to be ¥150.0 billion, an increase of ¥6.7 billion (4.7%) year on year, mainly due to the development costs associated with "Sapablursen", which was in-licensed from Ionis Pharmaceuticals, Inc., in the United States, as well as the research and development expenses of Deciphera Pharmaceuticals, LLC, which were recorded for nine months in the previous period and will be recorded for twelve months in the current period.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥120.0 billion, a decrease of ¥2.2 billion (1.8%) year on year. This is because, while the costs related to the business operations of Deciphera Pharmaceuticals, LLC, will increase, being recorded for nine months in the previous period and twelve months in the current period, we will advance cost-efficiency measures.
- Therefore, core operating profit is expected to be ¥114.0 billion, an increase of ¥1.3 billion (1.2%) year on year.

**3. Core profit for the year ¥91.0 billion YoY an increase of ¥0.6 billion (0.7%) (attributable to owners of the Company)**

- Core profit attributable to owners of the Company is expected to be ¥91.0 billion, an increase of ¥0.6 billion (0.7%) year on year.

## Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

### Depreciation and Amortization

(Billions of yen)

| | FY 2024 (April 1, 2024 to March 31, 2025) | **FY 2025 2Q YTD (April 1, 2025 to September 30, 2025)** | **FY 2025 Forecast (April 1, 2025 to March 31, 2026)** |
|---|---|---|---|
| Property, plant, and equipment | 10.6 | **5.3** | **10.7** |
| Intangible assets | 16.3 | **13.3** | **26.4** |
| **Total** | 26.9 | **18.6** | **37.1** |
| **Ratio to sales revenue** | 5.5% | **7.2%** | **7.6%** |

### Capital Expenditure (Based on Constructions) and Investments on Intangible Assets

(Billions of yen)

| | FY 2024 (April 1, 2024 to March 31, 2025) | **FY 2025 2Q YTD (April 1, 2025 to September 30, 2025)** | **FY 2025 Forecast (April 1, 2025 to March 31, 2026)** |
|---|---|---|---|
| Property, plant, and equipment | 8.1 | **3.8** | **9.1** |
| Intangible assets | 2.6 | **46.5** | **47.3** |
| **Total** | 10.7 | **50.3** | **56.5** |

## Number of Employees (Consolidated)

| | FY 2024 2Q (as of September 30, 2024) | FY 2024 (as of March 31, 2025) | **FY 2025 2Q (as of September 30, 2025)** |
|---|---|---|---|
| Number of employees | 4,258 | 4,287 | **4,276** |

## Status of Shares (as of September 30, 2025)

### Number of Shares

| | As of September 30, 2025 |
|---|---|
| Total number of authorized shares | 1,500,000,000 |
| Number of shares issued and outstanding | 498,692,800 |

### Number of Shareholders

| | As of September 30, 2025 |
|---|---|
| Number of shareholders | 124,695 |

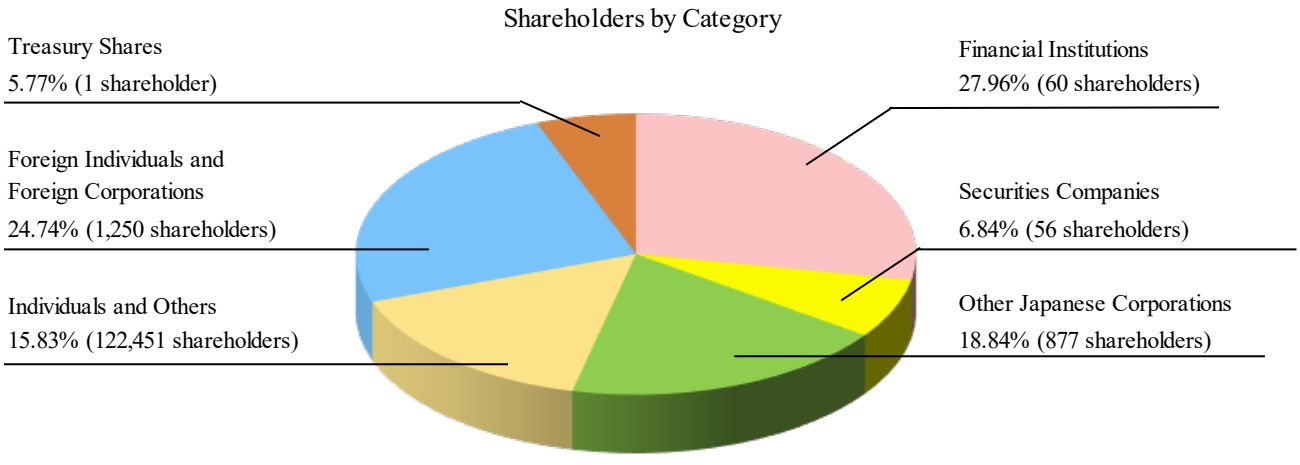
### Principal Shareholders

(As of September 30, 2025)

| Name of shareholder | Number of shares held (Thousands of shares) | Shareholding percentage |
|---|---|---|
| The Master Trust Bank of Japan, Ltd. (Trust account) | 61,845 | 13.16 |
| Custody Bank of Japan, Ltd. (Trust account) | 19,541 | 4.15 |
| Meiji Yasuda Life Insurance Company | 18,594 | 3.95 |
| Ono Scholarship Foundation | 16,428 | 3.49 |
| KAKUMEISOU Co., LTD. | 16,153 | 3.43 |
| JP Morgan Securities Japan Co., Ltd | 12,306 | 2.61 |
| STATE STREET BANK AND TRUST COMPANY 505001 | 11,794 | 2.51 |
| MUFG Bank, Ltd. | 8,640 | 1.83 |
| Aioi Nissay Dowa Insurance Co., Ltd. | 7,779 | 1.65 |
| STATE STREET BANK AND TRUST COMPANY 505103 | 6,266 | 1.33 |

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 28,785 thousand shares of treasury share.
2. The shareholding percentage is calculated by deducting treasury share (28,785 thousand shares).

### Ownership and Distribution of Shares




Note: The ratio by shareholders listed above is rounded down to two decimal places. Therefore, their total does not amount to 100%.

**Main Status of Development Pipelines**

As of October 30, 2025, we have listed our pipeline, which includes projects that we are developing clinically either independently (including through our wholly-owned subsidiaries) or in collaboration with partners, as well as those for which we hold contractual rights for potential future clinical development and/or commercialization. Please note that this does not encompass all development activities.

- For regions where we have obtained marketing approval for any indication, the product name is also listed.
- The development stage is indicated for the main countries/regions where we hold rights.
- The start date for clinical trials is based on the date of acceptance of the clinical trial notification, unless otherwise specified.
- Regarding in-house/in-license products, those in which the Ono Group was involved in the drug discovery process during joint research are considered in-house, while those for which we hold commercialization rights are considered in-license. For limited rights, the specific countries/regions are listed separately.

## (Oncology)

| Development code<br>Generic name<br>Product name<br>(Dosage form) | Pharmacological Action | Target indication<br>(Combination drug) | Phase | In-house / In-license |
|---|---|---|---|---|
| ONO-4538<br>Nivolumab<br>Opdivo<br>(Intravenous injection) | A human anti-human PD-1 monoclonal antibody | Hepatocellular carcinoma,<br>First-line treatment<br>(Combination with Yervoy) | Approved<br>(Japan)<br>25/06<br>Approved<br>(South Korea)<br>25/07<br>Approved<br>(Taiwan)<br>25/07 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | MSI-H/dMMR colorectal cancer,<br>First-line treatment<br>(Combination with Yervoy) | Approved<br>(Japan) 25/08 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | Hepatocellular carcinoma,<br>Adjuvant therapy | P3 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | Non-small cell lung cancer,<br>Neoadjuvant and adjuvant therapy<br>(Combination with chemotherapy) | P3 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | Bladder cancer,<br>Neoadjuvant and adjuvant therapy<br>(Combination with chemotherapy) | P3 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | Rhabdoid tumor,<br>Second-line treatment | P2 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| | | Richter transformation,<br>Second-line treatment | P2 | In-house<br>(Co-development with Bristol-Myers Squibb) |
| ONO-7702<br>Encorafenib<br>Braftovi<br>(Oral medication) | BRAF inhibitor | Colorectal cancer, First-line treatment, BRAF-mutation<br>(Combination with Cetuximab and chemotherapy (FOLFOX)) | Filed<br>(Japan) 24/12 | In-license<br>(Japan, South Korea)<br>(Pfizer) |
| DCC-2618<br>ripretinib<br>QINLOCK<br>(Oral medication) | KIT inhibitor | Gastrointestinal stromal tumor,<br>Second-line treatment for patients with KIT exon 11+17/18 mutation | P3 | In-house |

| Development code<br>Generic name<br>Product name<br>(Dosage form) | Pharmacological Action | Target indication<br>(Combination drug) | Phase | In-house / In-license |
|---|---|---|---|---|
| ONO-4578<br>(Oral medication) | Prostaglandin receptor (EP4) antagonist | Gastric cancer,<br>First-line treatment<br>(Standard treatment (combination with Opdivo and chemotherapy)) | P2 | In-house |
| | | Colorectal cancer,<br>First-line treatment<br>(combination with Opdivo and standard treatment) | P2 | In-house |
| | | Non-small cell lung cancer,<br>Second-line treatment<br>(combination with Opdivo and standard treatment) | P1 | In-house |
| | | Hormone receptor-positive, HER2-negative breast cancer,<br>First-line treatment<br>(with standard treatment) | P1 | In-house |
| ONO-4059<br>Tirabrutinib Hydrochloride<br>Velexbru<br>(Oral medication) | BTK (Bruton's tyrosine kinase) inhibitor | Primary central nervous system lymphoma,<br>Second-line treatment and beyond | P3 (the U.S.) | In-house |
| | | Primary central nervous system lymphoma,<br>First-line treatment, second-line treatment and beyond | P2 (the U.S.) | In-house |
| ONO-0530<br>sapablursen<br>(Subcutaneous injection) | TMPRSS6 gene expression inhibitor (Oligonucleotide) | Polycythemia vera | P2 | In-license<br>(Ionis Pharmaceuticals, Inc) |
| ONO-4482<br>relatlimab<br>(Intravenous injection) | Anti-LAG-3 antibody | Melanoma,<br>Second-line treatment and beyond<br>(Combination with Opdivo) | P1/2 | In-license (Japan, South Korea, Taiwan)<br>(Co-development with Bristol-Myers Squibb) |
| ONO-7427<br>(Intravenous injection) | Anti-CCR8 antibody | Solid tumor<br>(Combination with Opdivo) | P1/2 | In-license (Japan, South Korea, Taiwan)<br>(Co-development with Bristol-Myers Squibb) |
| DCC-3116<br>inlexisertib<br>(Oral medication) | ULK inhibitor | Advanced malignancies<br>(Combination with ripretinib) | P1/2 | In-house |
| DCC-3009<br>(Oral medication) | Pan-KIT inhibitor | Gastrointestinal stromal tumor | P1/2 | In-house |
| ONO-7913<br>magrolimab<br>(Intravenous injection) | Anti-CD47 antibody | Pancreatic cancer,<br>First-line treatment<br>(Combination with Opdivo) | P1 | In-license (Japan, South Korea, Taiwan, ASEAN)<br>(Gilead Sciences, Inc.) |
| | | Colorectal cancer,<br>First-line treatment<br>(Combination with Opdivo) | P1 | In-license (Japan, South Korea, Taiwan, ASEAN)<br>(Gilead Sciences, Inc.) |
| DCC-2812<br>(Oral medication) | GCN2 activator | Renal cell carcinoma, urothelial carcinoma, castration-resistant prostate cancer | P1 | In-house |
| ONO-4685<br>(Intravenous injection) | PD-1 x CD3 bispecific antibody | T-cell lymphoma,<br>Second-line treatment | P1 | In-house |
| ONO-4538HSC<br>(Subcutaneous injection) | A human anti-human PD-1monoclonal antibody | Solid tumor | P1 | In-license (Japan, South Korea, Taiwan)<br>(Co-development with Bristol-Myers Squibb) |

| Development code<br>Generic name<br>Product name<br>(Dosage form) | Pharmacological Action | Target indication<br>(Combination drug) | Phase | In-house / In-license |
|---|---|---|---|---|
| ONO-8250<br>(Intravenous injection) | iPS cell-derived HER2-targeted CAR-T cell therapeutics | HER2-expressing solid tumors | P1 | In-house<br>(Co-development with Fate Therapeutics, Inc.) |
| ONO-7428<br>(Intravenous injection) | Anti-ONCOKINE-1 antibody | Solid tumor | P1 | In-license<br>(NEX-I, Inc.) |

**(Areas Other than Oncology)**

| Development code<br>Generic name<br>Product name<br>（Dosage form） | Pharmacological Action | Target indication<br>(Combination drug) | Phase | In-house / In-license |
|---|---|---|---|---|
| DCC-3014<br>vimseltinib<br>ROMVIMZA<br>(Oral medication) | CSF-1R inhibitor | Tenosynovial giant cell tumor | Approved(USA)<br>25/02<br>Approved (Europe)<br>25/09 | In-house |
| | | cGvHD | P2 | In-house |
| ONO-2017<br>Cenobamate<br>(Oral medication) | Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel | Partial-onset seizures | Filed (Japan)<br>25/09 | In-license (Japan)<br>(SK Biopharmaceuticals) |
| | | Primary generalized tonic-clonic seizures | P3 | In-license (Japan)<br>(SK Biopharmaceuticals) |
| ONO-4059<br>Tirabrutinib hydrochloride<br>Velexbru<br>（Oral medication） | BTK (Bruton's tyrosine kinase) inhibitor | Steroid-resistant pemphigus | P3 | In-house |
| ONO-8531<br>povetacicept<br>(Subcutaneous injection) | BAFF/APRIL dual antagonist | Immunoglobulin A nephropathy (IgAN) | P3 | In-license<br>(Japan, South Korea)<br>(Vertex Pharmaceuticals Incorporated) |
| ONO-5532<br>Gel-One<br>(Intra-articular injection) | Cross-linked hyaluronate | Knee osteoarthritis | P3 | In-license (Japan)<br>(Seikagaku Corporation) |
| | | Hip osteoarthritis | P3 | In-license (Japan)<br>(Seikagaku Corporation) |
| ONO-2808<br>(Oral medication) | S1P5 receptor agonist | Multiple system atrophy | P2 | In-house |
| ONO-2020<br>(Oral medication) | Epigenetic regulation | Alzheimer's disease | P2 | In-house |
| | | Agitation associated with dementia due to Alzheimer's disease | P2 | In-house |
| ONO-1110<br>(Oral medication) | Endocannabinoid regulation | Postherpetic neuralgia | P2 | In-house |
| | | Major depressive disorder | P2 | In-house |
| | | Fibromyalgia | P2 | In-house |
| | | Social anxiety disorder | P2 | In-house |
| | | Hunner type interstitial cystitis | P2 | In-house |
| ONO-4685<br>(Intravenous injection) | PD-1×CD3 bispecific antibody | Autoimmune disease | P1 | In-house |
| ONO-4915<br>(Intravenous injection /Subcutaneous injection) | PD-1×CD19 bispecific antibody | Autoimmune disease | P1 | In-house |

The change from the announcement of financial results for the First quarter of the fiscal year ending March 31, 2026, is as follows:

## (Oncology)

| Development code<br>Generic name<br>Product name<br>（Dosage form） | Pharmacological Action | Target indication<br>(Combination drug) | Development status or reason for termination |
|---|---|---|---|
| ONO-4538<br>Nivolumab<br>Opdivo<br>(Intravenous injection) | A human anti-human PD-1 monoclonal antibody | MSI-H/dMMR colorectal cancer, First-line treatment<br>(Combination with Yervoy) | In August 2025, an application of ONO-4538 in combination with Yervoy was approved in Japan for the treatment of unresectable advanced or recurrent colorectal cancer with high microsatellite instability (MSI-High). |
| ONO-4059<br>Tirabrutinib Hydrochloride<br>Velexbru<br>(Oral medication) | BTK(Bruton's tyrosine kinase) inhibitor | Primary central nervous system lymphoma,<br>Second-line treatment and beyond | In August 2025, phase III of ONO-4059 (BTK inhibitor) was initiated in the U.S., for the treatment of recurrent or refractory primary central nervous system lymphoma. |
| DCC-2812<br>(Intravenous injection) | GCN2 activator | Renal cell carcinoma, urotherial carcinoma, castration-resistant prostate cancer | In August 2025, phase I of DCC-2812 (GCN2 activation) was initiated in the U.S., for the treatment of renal cell carcinoma, urothelial carcinoma, and castration-resistant prostate cancer |
| DCC-3116<br>inlexisertib<br>(Oral medication) | ULK inhibitor | Solid tumor<br>(Combination with Sotorasib) | In September 2025, phase I/II of DCC-3116 (ULK inhibitor) for the treatment of solid tumor in combination with sotorasib was conducted, but this cohort was discontinued due to strategic reasons. |
| DCC-3084<br>(Oral medication) | Pan-RAF inhibitor | Advanced malignancies | In September 2025, phase I/II of DCC-3084 (Pan-RAF inhibitor) for the treatment of advanced malignancies was conducted, but the project was discontinued due to strategic reasons. |
| ONO-4538<br>Nivolumab<br>Opdivo<br>(Intravenous Injection) | A human anti-human PD-1 monoclonal antibody | Gastric cancer<br>(Combination with Yervoy/ chemotherapy) | In October 2025, a Phase III trial was conducted in Japan, South Korea, and Taiwan for the first-line treatment of gastric cancer using a combination of Opdivo, Yervoy, and chemotherapy. However, as the primary endpoint of overall survival did not show a statistically significant improvement compared to the chemotherapy group, the development has been discontinued. |

## (Areas Other than Oncology)

| Development code<br>Generic name<br>Product name<br>（Dosage form） | Pharmacological Action | Target indication<br>(Combination drug) | Development status or reason for termination |
|---|---|---|---|
| ONO-5532<br>Gel-One<br>(Intra-articular injection) | Cross-linked hyaluronate | Knee osteoarthritis<br>Hip osteoarthritis | In August 2025, the Company entered into a joint development and commercialization agreement on ONO-5532 (Gel-One) for the treatment of osteoarthritis. In Japan, phase III clinical trial is being conducted for the treatment of knee osteoarthritis and hip osteoarthritis. |
| DCC-3014<br>vimseltinib<br>ROMVIMZA<br>(Oral medication) | CSF-1R inhibitor | Tenosynovial giant cell tumor | In September 2025, an application of DCC-3014, ROMVIMZA (CSF-1R inhibitor), was approved in Europe for the treatment of tenosynovial giant cell tumor associated with clinically significant functional impairment, where surgical treatment is not expected to be effective or may result in intolerable morbidity or disability. |
| ONO-2017<br>Cenobamate<br>(Oral medication) | Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel | Partial-onset seizures | In September 2025, an application of ONO-2017 (Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel) was filed in Japan for the treatment of partial-onset seizures (including secondary generalized seizures). |

**Profile for Main Development**

Opdivo Intravenous Infusion (ONO-4538 / BMS-936558) / Nivolumab (injection)
Opdivo, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of various kinds of cancers, etc. PD-1 is a receptor expressed on the surface of activated lymphocytes and plays a role in a regulatory pathway that suppresses the activated lymphocytes in the body (negative signal). Research indicates that cancer cells exploit this pathway to escape from immune responses. Opdivo is thought to provide benefit by blocking PD-1-mediated negative regulation of lymphocytes, thereby enhancing the ability of the immune system to recognize cancer cells as foreign and eliminate them.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

Yervoy Injection (ONO-4480) / Ipilimumab (injection)
Yervoy, a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of various kinds of cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4482 / BMS-986016 / relatlimab (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of melanoma.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4578 (oral)
ONO-4578, a Prostaglandin receptor (EP4) antagonist, is being developed for the treatment of gastric cancer, colorectal cancer, non-small cell lung cancer, and Hormone receptor-positive, HER2-negative breast cancer.

Braftovi Capsules (ONO-7702) / Encorafenib (oral)
Braftovi, a BRAF inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved in Japan and South Korea for the treatment of BRAF-mutant colorectal cancer. Additionally, we have obtained approval in Japan for the treatment of unresectable BRAF-mutant thyroid cancer and unresectable anaplastic BRAF-mutant thyroid cancer, in combination with Mektovi tablets after progression following cancer chemotherapy. Furthermore, we are advancing the development for untreated BRAF-mutant colorectal cancer.

Velexbru Tablets (ONO-4059) / Tirabrutinib Hydrochloride (oral)
Velexbru, a BTK inhibitor, has been marketed in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma, and additional indications were later approved for the treatment of waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma. Additionally, applications were approved in South Korea and Taiwan for the treatment of recurrent or refractory B-cell primary central nervous system lymphoma. Furthermore, it is being developed in the USA for the treatment of primary central nervous system lymphoma, and in Japan for the treatment of pemphigus.

ONO-7913 / Magrolimab (injection)
ONO-7913, an anti-CD47 antibody, is being developed in Japan for the treatment of pancreatic cancer and colorectal cancer.

ONO-4685 (injection)
ONO-4685, a PD-1 x CD3 bispecific antibody, is being developed for the treatment of autoimmune disease. In the oncology area, it is being developed in Japan and the USA for the treatment of T-cell lymphoma.

ONO-4538HSC (subcutaneous injection)
ONO-4538HSC, a combination drug comprising nivolumab and volhyaluronidase alfa, is being developed in Japan for the treatment of solid tumor.

ONO-8250 (injection)
ONO-8250, an iPS cell-derived HER2-targeted CAR-T cell therapeutics, is being developed in the USA for the treatment of HER2-expressing solid tumor.

ONO-7427 (injection)
ONO-7427, an anti-CCR8 antibody, is being developed in Japan for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7428 (injection)
ONO-7428, an anti-ONCOKINE-1 antibody, is being developed in Japan for the treatment of solid tumor.

ONO-0530 / sapablursen (subcutaneous injection)
ONO-0530, an antisense oligonucleotide targeting TMPRSS6, is being developed for the treatment of polycythemia vera.

ONO-2017 / Cenobamate (oral)
An application of ONO-2017, an inhibition of voltage-gated sodium currents / positive allosteric modulator of $GABA_A$ ion channel, for the treatment of partial-onset seizures was filed in Japan. In addition, it is being developed in Japan for the treatment of primary generalized tonic-clonic seizures.

ONO-2808 (oral)
ONO-2808, a S1P5 receptor agonist, is being developed in Japan and the USA for the treatment of multiple system atrophy.

ONO-2020 (oral)

ONO-2020, an epigenetic regulation, is being developed for the treatment of Alzheimer's disease in Japan and the USA, and for the treatment of agitation associated with dementia due to Alzheimer's disease in Japan.

ONO-1110 (oral)

ONO-1110, an endocannabinoid regulation, is being developed in Japan for the treatment of postherpetic neuralgia, major depressive disorder, fibromyalgia, social anxiety disorder, and hunner type interstitial cystitis.

ONO-4915 (injection / subcutaneous injection)

ONO-4915, a PD-1×CD19 bispecific antibody, is being developed in Japan for the treatment of autoimmune disease.

QINLOCK (ripretinib) (oral)

QINLOCK is a KIT inhibitor that has been approved by the US FDA for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received treatment with three or more kinase inhibitors, including imatinib. It is based on the favorable results in fourth-line and fourth-line +GIST patients in the Phase 3 INVICTUS trial and has been approved in regions such as North America, Europe, and Australia. In addition, it is being developed as a potential second-line treatment for GIST patients with KIT exon 11+17/18 mutations in the Phase 3 INSIGHT study.

ROMVIMZA (vimseltinib) (oral)

ROMVIMZA (DCC-3014) is a CSF-1R inhibitor that has been approved in the United States and Europe as a treatment for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. Additionally, it is being developed in the United States as a potential treatment for cGvHD.

DCC-3116 (inlexisertib) (oral)

DCC-3116, a ULK inhibitor, is being developed in combination with ripretinib for the potential treatment of solid tumor in the United States.

DCC-3009 (oral)

DCC-3009, a pan-KIT inhibitor, is being developed in the United States for the potential treatment of gastrointestinal stromal tumor.

ONO-8531 (povetacicept) (subcutaneous injection)

ONO-8531, BAFF/APRIL dual antagonist, is being developed for the treatment of multiple serious B-cell mediated diseases, including IgA nephropathy and primary membranous nephropathy.

ONO-5532 (Gel-One) (intra-articular injection)

ONO-5532 is an intra-articular injection containing cross-linked hyaluronic acid as its active ingredient. It has been marketed overseas since 2012 under the names "Gel-One®" in the United States and "HyLink®" in Taiwan and Italy. In Japan, it is being developed for the treatment of knee osteoarthritis and hip osteoarthritis.

DCC-2812 (oral)

DCC-2812, a GCN2 activation, is being developed for the treatment of renal cell carcinoma, urothelial carcinoma, and castration-resistant prostate cancer.