

Fiscal Year 2024
(April 1, 2024 to March 31, 2025)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Fiscal Year 2024 (April 1, 2024 to March 31, 2025) Consolidated Financial Results (Core basis)】

Page 1	Consolidated Financial Results, Sales Revenue of Major Products Details of Sales Revenue, Revenue by Geographic Area
Page 2	Summary of Consolidated Financial Results for FY 2024 (April 1, 2024 to March 31, 2025) (Core Basis)
Page 3	Reconciliation from Full to Core basis for FY 2024 (April 1, 2024 to March 31, 2025)
Page 4	Consolidated Financial Forecast, Sales Revenue of Major Products (Forecast) Details of Sales Revenue (Forecast)
Page 5	Summary of Consolidated Financial Forecast for FY 2025 (April 1, 2025 to March 31, 2026) (Core Basis)
Page 6	Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets Number of Employees
Page 7	Status of Shares
Page 8~11	Main Status of Development Pipelines
Page 12~13	Profile for Main Development

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

Consolidated Financial Results for FY 2024 (April 1, 2024 to March 31, 2025) (Core basis)

Consolidated Financial Results

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)	YoY
Revenue	502.7	486.9	(3.1)%
Core operating profit	180.9	112.7	(37.7)%
Core profit before tax	142.5	90.4	(36.6)%

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

Sales Revenue of Major Products

Product Name	FY 2024 (April 1, 2024 to March 31, 2025)					(Billions of yen)		
	Cumulative					YoY		Forecast
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar		Change	Change (%)	
<Domestic>								
Opdivo Intravenous Infusion	32.1	30.6	33.3	24.3	120.3	(25.2)	(17.3)%	125.0
Forxiga Tablets	22.2	21.5	25.0	20.9	89.6	13.5	17.7%	89.0
Orencia for Subcutaneous Injection	6.9	6.6	7.3	5.8	26.6	0.8	3.0%	27.0
Glactiv Tablets	5.0	4.6	5.0	3.7	18.3	(2.8)	(13.4)%	18.5
Velexbru Tablets	2.7	2.5	3.0	2.3	10.5	0.3	3.1%	10.0
Kyprolis for Intravenous Infusion	2.3	2.2	2.4	1.7	8.6	(0.5)	(5.9)%	9.5
Parsabiv Intravenous Injection	2.1	2.1	2.4	1.8	8.4	0.2	2.5%	8.5
Ongentys Tablets	1.9	1.8	2.2	1.7	7.6	1.3	21.0%	7.5
<Overseas>								
Opdivo	3.1	3.4	3.5	3.1	13.1	1.1	9.3%	13.5
QINLOCK	—	8.1	9.2	8.1	25.5	—	—	25.0

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)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)
Revenue of goods and products	317.0	330.8
Royalty and others	185.7	156.1
Total	502.7	486.9

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥97.9 billion for the fiscal year ended March 31, 2024 and ¥113.0 billion for the fiscal year ended March 31, 2025, and royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥53.0 billion for the fiscal year ended March 31, 2024 and ¥26.4 billion for the fiscal year ended March 31, 2025.

Revenue by Geographic Area

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)
Japan	308.2	295.2
Americas	158.9	167.0
Asia	13.6	16.3
Europe	21.9	7.5
Others	—	0.7
Total	502.7	486.9

Note: 1. Revenue by geographic area is presented on the basis of the place of customers.

2. Due to the inclusion of revenue from Deciphera Pharmaceuticals, Inc., the Company has revised the classification of revenue by geographic area, starting from this consolidated accounting period.

Summary of Consolidated Financial Results for FY 2024 (April 1, 2024 to March 31, 2025) (Core Basis)

1. Revenue ¥486.9 billion YoY a decrease of 3.1% (FY 2023 ¥502.7 billion)

<Sales of Domestic Products>

- Sales of Opdivo Intravenous Infusion for malignant tumors were ¥120.3 billion, a decrease of ¥25.2 billion (17.3%) year on year, mainly due to the revision of the National Health Insurance (NHI) drug price. Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥89.6 billion, an increase of ¥13.5 billion (17.7% increase year on year), mainly due to its expanded use to the treatment for chronic kidney disease.
- With respect to other products, sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥26.6 billion (3.0% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥18.3 billion (13.4% decrease year on year). Sales of Velembro Tablets for malignant tumors were ¥10.5 billion (3.1% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.6 billion (5.9% decrease year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.4 billion (2.5% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥7.6 billion (21.0% increase year on year).

<Sales of Domestic Products>

- Sales of QINLOCK® (ripretinib) for gastrointestinal stromal tumor, marketed by Deciphera Pharmaceuticals, LLC, the operating company of Deciphera Pharmaceuticals, Inc., were ¥25.5 billion for the period from July 2024 to March 2025. Additionally, we began sales of ROMVIMZA® (vimseltinib) for tenosynovial giant cell tumor (TGCT) treatment in February 2025.

<Royalty and Others>

- Royalty and others decreased by ¥29.6 billion (15.9%) year on year to ¥156.1 billion mainly due to the absence of the lump-sum income of ¥17.0 billion recorded in the same period of the previous year associated with the settlement of the litigation on patents with AstraZeneca UK Limited, and a decrease in royalty revenue from Merck & Co., Inc., and others in line with a decrease in royalty rates.

2. Core operating profit ¥112.7 billion YoY a decrease of 37.7% (FY 2023 ¥180.9 billion)

- Core operating profit decreased by ¥68.3 billion (37.7%) year on year to ¥112.7 billion.
- Cost of sales decreased by ¥2.7 billion (2.5%) year on year to ¥106.9 billion.
- Research and development costs increased by ¥34.9 billion (32.1%) year on year to ¥143.3 billion, mainly due to increases in development costs for clinical trials, costs associated with the licensing agreement with LigaChem Biosciences, Inc., and the inclusion of research and development expenses from Deciphera Pharmaceuticals, LLC.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥21.9 billion (21.8%) year on year to ¥122.2 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets, and the recording of business operating costs from Deciphera Pharmaceuticals, LLC.

3. Profit for the year ¥90.4 billion YoY a decrease of 36.6% (FY 2023 ¥142.5 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company decreased by ¥52.2 billion (36.6%) year on year to ¥90.4 billion.

Reconciliation from Full to Core basis for FY 2024 (April 1, 2024 to March 31, 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	486.9				486.9
Cost of sales	(147.9)	14.6		26.5	(106.9)
Gross profit	338.9	14.6		26.5	380.0
SG&A expenses	(125.7)			3.5	(122.2)
R&D costs	(149.9)		6.0	0.5	(143.3)
Other income	1.1			(0.2)	1.0
Other expenses	(4.7)		2.0		(2.8)
Operating profit	59.7	14.6	8.0	30.3	112.7
Operating profit ratio	12.3%				23.1%
Finance income	4.8				4.8
Finance costs	(5.3)			1.8	(3.5)
Share of profit (loss) from investments in associates	0.1			(0.1)	0.0
Profit before tax	59.3	14.6	8.0	32.0	113.9
Income tax	(9.2)	(4.0)	(2.3)	(8.0)	(23.4)
Profit for the year	50.2	10.7	5.7	24.0	90.5
Non-controlling	(0.1)				(0.1)
Profit for the year (Attributable to owners of the company)	50.0	10.7	5.7	24.0	90.4

The "Other" category in the cost of sales includes the expensing of inventory assets evaluated at fair value related to the acquisition of Deciphera Pharmaceuticals, Inc., as well as a sales milestone of ¥13.6 billion for "Forxiga Tablets", which are sold under a co-promotion agreement with AstraZeneca, recorded as an expense.

For the "Other" category in the selling, general, and administrative expenses, it includes the costs associated with the acquisition of Deciphera Pharmaceuticals, Inc.

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

Consolidated Financial Forecast

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)	FY 2025 Forecast (April 1, 2025 to March 31, 2026)	YoY
Revenue	502.7	486.9	490.0	0.6%
Core operating profit	180.9	112.7	114.0	1.2%
Core profit for the year	142.5	90.4	91.0	0.7%

Sales Revenue of Major Products (Forecast)

(Billions of yen)

	FY 2024 (April 1, 2024 to March 31, 2025)			FY 2025 Forecast (April 1, 2025 to March 31, 2026)		
Product Name	Results	YoY		Forecast	YoY	
		Change	Change (%)		Change	Change (%)
<Domestic>						
Opdivo Intravenous Infusion	120.3	(25.2)	(17.3%)	125.0	4.7	3.9%
Forxiga Tablets	89.6	13.5	17.7%	80.0	(9.6)	(10.7%)
Orencia for Subcutaneous Injection	26.6	0.8	3.0%	28.0	1.4	5.2%
Glactiv Tablets	18.3	(2.8)	(13.4%)	12.0	(6.3)	(34.6%)
Velexbru Tablets	10.5	0.3	3.1%	11.0	0.5	4.4%
Kyprolis for Intravenous Infusion	8.6	(0.5)	(5.9%)	9.0	0.4	4.6%
Parsabiv Intravenous Injection	8.4	0.2	2.5%	9.0	0.6	6.7%
Ongentys Tablets	7.6	1.3	21.0%	9.0	1.4	17.8%
<Overseas>						
Opdivo	13.1	1.1	9.3%	13.5	0.4	2.9%
QINLOCK	25.5	—	—	34.0	8.5	33.4%
ROMVIMZA	N/A	—	—	5.0	—	—

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

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

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, an increase of ¥0.8 billion (0.2%) year on year. Among main products, while the competitive environment intensified, sales of Opdivo Intravenous Infusion are expected to be ¥125.0 billion, an increase of ¥4.7 billion (3.9%) year on year, mainly due to the expanded use particularly in treatment for non-small cell lung cancer and esophageal carcinoma. On the other hand, 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 gastrointestinal stromal tumors sold by Deciphera Pharmaceuticals, LLC, are expected to be ¥34.0 billion, an increase of ¥8.5 billion (33.4%) year on year, which is recorded for nine months in the current period and twelve months in the next. Sales of “ROMVIMZA”, a treatment for tenosynovial giant cell tumor (TGCT) which we began selling in February 2025, are expected to be ¥5.0 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, a decrease 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 will be recorded for nine months in the current period and twelve months in the next.
- 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 current period and twelve months in the next, the co-promotion costs will decrease due to the decline in sales of "Forxiga tablets," and we will also advance cost-efficiency measures.
- Therefore, 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 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)	FY 2025 Forecast (April 1, 2025 to March 31, 2026)
Property, plant, and equipment	10.1	10.6	10.8
Intangible assets	8.1	16.3	26.5
Total	18.1	26.9	37.3
Ratio to sales revenue	3.6%	5.5%	7.6%

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

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 (April 1, 2024 to March 31, 2025)	FY 2025 Forecast (April 1, 2025 to March 31, 2026)
Property, plant, and equipment	6.5	8.1	10.5
Intangible assets	11.3	2.6	45.2
Total	17.8	10.7	55.7

Number of Employees (Consolidated)

	FY 2023 (as of March 31, 2024)	FY 2024 (as of March 31, 2025)
Number of employees	3,853	4,287

Status of Shares (as of March 31, 2025)

Number of Shares

	As of March 31, 2025
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	498,692,800

Number of Shareholders

	As of March 31, 2025
Number of shareholders	105,681

Principal Shareholders

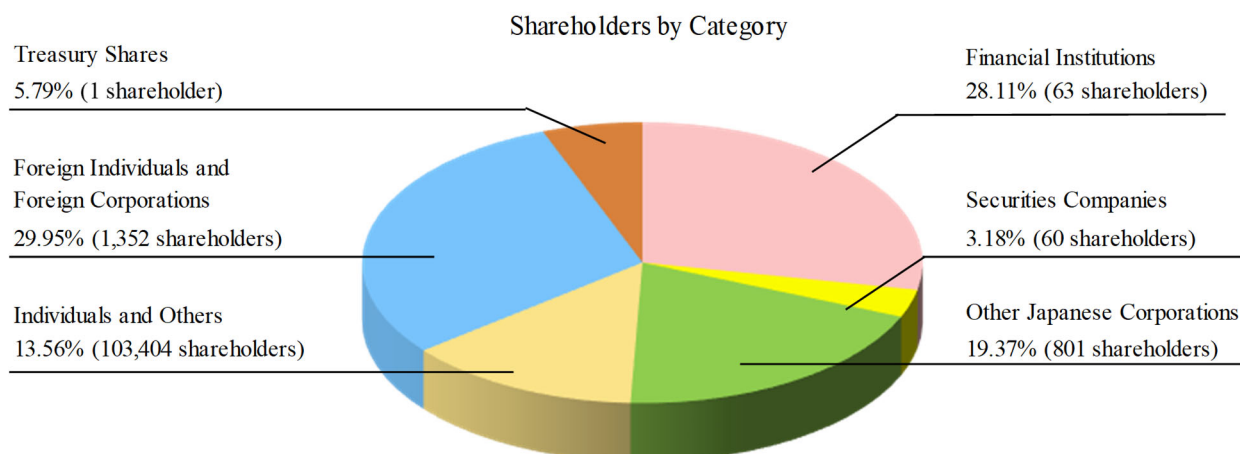
(As of March 31, 2025)

Name of shareholder	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	63,838	13.58
Meiji Yasuda Life Insurance Company	18,594	3.95
Ono Scholarship Foundation	16,428	3.49
KAKUMEISOU Co., LTD.	16,153	3.43
Custody Bank of Japan, Ltd. (Trust account)	16,018	3.40
STATE STREET BANK AND TRUST COMPANY 505001	10,069	2.14
STATE STREET BANK WEST CLIENT – TREATY 505234	9,240	1.96
MUFG Bank, Ltd.	8,640	1.83
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.65
STATE STREET BANK AND TRUST COMPANY 505103	6,185	1.31

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 28,919 thousand shares of treasury share.

2. The shareholding percentage is calculated by deducting treasury share (28,919 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 May 8, 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 Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
ONO-4538 Nivolumab Opdivo (Intravenous Injection)	A human anti-human PD-1 monoclonal antibody	Hepatocellular carcinoma, First-line treatment (Combination with Yervoy)	Filed (Japan) 24/08	In-house (Co-development with Bristol-Myers Squibb)
		MSI-H/dMMR colorectal cancer, First-line treatment (Combination with Yervoy)	Filed (Japan) 24/09	In-house (Co-development with Bristol-Myers Squibb)
		Hepatocellular carcinoma, Adjuvant therapy	P3	In-house (Co-development with Bristol-Myers Squibb)
		Non-small cell lung cancer, Neoadjuvant and adjuvant therapy (Combination with chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Bladder cancer, Neoadjuvant and adjuvant therapy (Combination with chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Gastric cancer, First-line treatment (Combination with Yervoy/chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Rhabdoid tumor, Second-line treatment	P2	In-house (Co-development with Bristol-Myers Squibb)
		Richter transformation, Second-line treatment	P2	In-house (Co-development with Bristol-Myers Squibb)
ONO-7702 Encorafenib Braftovi (Oral medication)	BRAF inhibitor	Colorectal cancer, First-line treatment, BRAF-mutation (Combination with Cetuximab and chemotherapy (FOLFOX))	Filed (Japan) 24/12	In-license (Japan, South Korea) (Pfizer)
DCC-2618 QINLOCK (ripretinib) (Oral medication)	KIT inhibitor	Gastrointestinal stromal tumor, Second-line treatment for patients with KIT exon 11+17/18 mutation	P3	In-house
ONO-4578 (Oral medication)	Prostaglandin receptor (EP4) antagonist	Gastric cancer, First-line treatment (Combination with Opdivo)	P2	In-house
		Colorectal cancer, First-line treatment (Combination with Opdivo)	P2	In-house
		Non-small cell lung cancer, Second-line treatment (Combination with Opdivo)	P1	In-house
		Hormone receptor-positive, HER2-negative breast cancer, First-line treatment	P1	In-house

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
ONO-4059 Tirabrutinib Hydrochloride Velexbru (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Primary central nervous system lymphoma, Second-line treatment and beyond	P2 (the U.S.)	In-house
		Primary central nervous system lymphoma, First-line treatment	P2 (the U.S.)	In-house
ONO-0530 Sapablursen (Subcutaneous injection)	TMPRSS6 gene expression inhibitor (Oligonucleotide)	Polycythemia vera	P2	In-license (Ionis Pharmaceuticals, Inc)
ONO-4482 Relatlimab (Intravenous Injection)	Anti-LAG-3 antibody	Melanoma, Second-line treatment and beyond (Combination with Opdivo)	P1/2	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
ONO-7427 (Intravenous Injection)	Anti-CCR8 antibody	Solid tumor (Combination with Opdivo)	P1/2	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
DCC-3116 (Oral medication)	ULK inhibitor	Solid tumor (Combination with Sotorasib)	P1/2	In-house
		Advanced malignancies (Combination with Ripretinib)	P1/2	In-house
DCC-3084 (Oral medication)	Pan-RAF inhibitor	Advanced malignancies	P1/2	In-house
DCC-3009 (Oral medication)	Pan-KIT inhibitor	Gastrointestinal stromal tumor	P1/2	In-house
ONO-7475 Tamnorzatinib (Oral medication)	Axl/Mer inhibitor	EGFR-mutated non-small cell lung cancer, First-line treatment (Combination with Osimertinib)	P1	In-house
ONO-7913 Magrolimab (Intravenous Injection)	Anti-CD47 antibody	Pancreatic cancer, First-line treatment (Combination with Opdivo)	P1	In-license (Japan, South Korea, Taiwan, ASEAN) (Gilead Sciences, Inc.)
		Colorectal cancer, First-line treatment (Combination with Opdivo)	P1	In-license (Japan, South Korea, Taiwan, ASEAN) (Gilead Sciences, Inc.)
ONO-4685 (Intravenous Injection)	PD-1 x CD3 bispecific antibody	T-cell lymphoma, Second-line treatment	P1	In-house
ONO-4538HSC (Subcutaneous injection)	A human anti-human PD-1 monoclonal antibody	Solid tumor	P1	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
ONO-8250 (Intravenous Injection)	iPS cell-derived HER2-targeted CAR-T cell therapeutics	HER2-expressing solid tumors	P1	In-house (Co-development with Fate Therapeutics, Inc.)
ONO-7428 (Intravenous Injection)	Anti-ONCOKINE-1 antibody	Solid tumor	P1	In-license (NEX-I, Inc.)

(Areas Other than Oncology)

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
DCC-3014 ROMVIMZA (Vimseltinib) (Oral medication)	CSF-1R inhibitor	Tenosynovial giant cell tumor	Filed (Europe) 24/07	In-house
		cGvHD	P2	In-house
ONO-2017 Cenobamate (Oral medication)	Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	Primary generalized tonic- clonic seizures	P3	In-license (Japan) (SK Biopharmaceuticals)
		Partial-onset seizures	P3	In-license (Japan) (SK Biopharmaceuticals)
ONO-4059 Tirabrutinib hydrochloride Velexbru (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Steroid-resistant pemphigus	P3	In-house
ONO-2808 (Oral medication)	S1P5 receptor agonist	Multiple system atrophy	P2	In-house
ONO-2020 (Oral medication)	Epigenetic regulation	Alzheimer's disease	P2	In-house
		Agitation associated with dementia due to Alzheimer's disease	P2	In-house
ONO-1110 (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 (Intravenous Injection)	PD-1×CD3 bispecific antibody	Autoimmune disease	P1	In-house
ONO-4915 (Intravenous Injection /Subcutaneous injection)	PD-1×CD19 bispecific antibody	Autoimmune disease	P1	In-house

The change from the announcement of financial results for the Third quarter of the fiscal year ended March 31, 2025, is as follows:

(Oncology)

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Development status or reason for termination
ONO-4578 (Oral medication)	Prostaglandin receptor (EP4) antagonist	Colorectal cancer, First-line treatment (Combination with Opdivo)	In February 2025, international phase II trials of ONO-4578 (Prostaglandin receptor (EP4) antagonist) in combination with Opdivo was initiated in the U.S. for the treatment of colorectal cancer.
ONO-7475 Tamnorzatinib (Oral medication)	Axl/Mer inhibitor	Pancreatic cancer, First-line treatment (Combination with Opdivo)	In March 2025, phase I of ONO-7475 (Axl/Mer inhibitor) in combination with Opdivo was conducted in Japan, but the project was discontinued due to not being able to confirm expected efficacy.
ONO-7914 (Intravenous injection)	STING agonist	Solid tumor (Combination with Opdivo)	In February 2025, phase I of ONO-7914 (STING agonist) in combination with Opdivo was conducted in Japan, but the project was discontinued due to strategic reasons.
ONO-0530 Sapablursen (Subcutaneous injection)	TMPRSS6 gene expression inhibitor (Oligonucleotide)	Polycythemia vera	In March 2025, the Company has entered into a licensing agreement with Ionis Pharmaceuticals, Inc., for “Sapablursen”, a drug under development for the treatment of polycythemia vera. This agreement grants us exclusive rights to develop and commercialize Sapablursen worldwide.
ONO-7018 (Oral medication)	MALT1 inhibitor	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	In April 2025, phase I of ONO-7018 (MALT1 inhibitor) for the treatment of non-Hodgkin lymphoma and chronic lymphocytic leukemia was conducted, but the project was discontinued due to strategic reasons.

(Areas Other than Oncology)

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Development status or reason for termination
DCC-3014 ROMVIMZA (Vimseltinib) (Oral medication)	CSF-1R inhibitor	Tenosynovial giant cell tumor	In February 2025, Deciphera Pharmaceutical, LLC received approval for the indication of tenosynovial giant cell tumor that may lead to worsening functional limitations or severe conditions if surgically resected.

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.

Mektovi Tablets (ONO-7703) / Binimetinib (oral)

Mektovi, a MEK inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved 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 Braftovi capsules after progression following cancer chemotherapy.

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-7475 / Tamnorzatinib (oral)

ONO-7475, an Axl/Mer inhibitor, is being developed in Japan for the treatment of EGFR-mutated non-small cell lung cancer and pancreatic cancer.

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 in Japan and Europe 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)

ONO-2017, an inhibition of voltage-gated sodium currents / positive allosteric modulator of GABA_A ion channel, is being developed in Japan for the treatment of primary generalized tonic-clonic seizures and partial-onset 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 treatment and fourth-line treatment + 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 patients with KIT exon 11+17/18 mutations.

ROMVIMZA (vimseltinib) (oral)

DCC-3014 is a CSF-1R inhibitor that has been approved in the United States 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. It is currently under new drug application (NDA) review in Europe. Additionally, it is being developed in the United States as a potential treatment for cGvHD.

DCC-3116 (oral)

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

DCC-3084 (oral)

DCC-3084, a pan-RAF inhibitor, is being developed in the USA for the potential treatment of solid tumor.

DCC-3009 (oral)

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