

Consolidated Financial Results for the Second Quarter of Fiscal Year Ending March 31, 2026 (IFRS)

October 30, 2025

Company name Stock exchange listing Securities Code URL Representative Inquiries Telephone Scheduled date of semi-annual securities report submission Scheduled date of dividend payment commencement Supplementary materials for the quarterly financial results Earnings announcement for the quarterly financial results	: ONO PHARMACEUTICAL CO., LTD. : Tokyo Stock Exchange : 4528 : https://www.ono-pharma.com/en : Toichi Takino Representative Director, President and Chief Operating Officer : Ryuta Imura Senior Director of Corporate Communications : +81-(0)6-6263-5670 : November 6, 2025 : December 1, 2025 : Yes : Yes (for institutional investors and securities analysts)
---	---

(Note: Amounts of less than one million yen are rounded.)

1. Consolidated Financial Results for the Second Quarter of FY 2025 (April 1, 2025 to September 30, 2025)

(1) Consolidated Operating Results (cumulative)

IFRS (Full) basis								(% change from the same period of the previous fiscal year)					
	Revenue		Operating profit		Profit before tax		Profit for the period		Profit attributable to owners of the Company		Total comprehensive income for the period		
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	
FY 2025 Q2	257,136	7.0	52,069	6.7	52,175	9.7	39,981	6.8	40,089	7.1	40,276	844.1	
FY 2024 Q2	240,339	(7.1)	48,788	(49.7)	47,544	(52.1)	37,440	(49.8)	37,435	(49.7)	4,266	(94.7)	

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2025 Q2	85.33	85.28
FY 2024 Q2	79.71	79.66

Core basis

	Revenue		Core operating profit		Core Profit for the period		Basic core earnings per share
	Million yen	%	Million yen	%	Million yen	%	yen
FY 2025 Q2	257,136	7.0	70,058	7.2	53,821	5.5	114.56
FY 2024 Q2	240,339	—	65,382	—	51,012	—	108.61

*In the consolidated accounting period for the third quarter of the fiscal year ended March 2025, the provisional accounting treatment related to the business combination has been finalized. As a result, the figures for the second quarter of the fiscal year ended March 2025 reflect the finalized adjustment of this provisional accounting treatment.

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets
	Million yen	Million yen	Million yen	%
As of September 30, 2025	1,058,514	811,998	806,350	76.2
As of March 31, 2025	1,064,046	788,203	782,451	73.5

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2024	—	40.00	—	40.00	80.00
FY 2025	—	40.00			
FY 2025 (Forecast)			—	40.00	80.00

(Note) Revisions to dividend forecast most recently announced: None

3. Consolidated Financial Forecast for FY 2025 (April 1, 2025 to March 31, 2026)

IFRS (Full) basis

(% change from the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2025	490,000	0.6	85,000	42.3	85,000	43.3	67,000	33.6	67,000	33.9	142.62

Core basis

(% change from the previous fiscal year)

	Revenue		Core operating profit		Core profit for the year		Basic core earnings per share
	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2025	490,000	0.6	114,000	1.2	91,000	0.7	193.71

(Note) Revisions to financial forecast most recently announced: None

Notes

(1) Significant changes in scope of consolidation during the period: None

(2) Changes in accounting policies and changes in accounting estimates

- 1) Changes in accounting policies required by IFRS: None
- 2) Changes in accounting policies due to other than (2) – 1) above: None
- 3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)

1) Number of shares issued and outstanding as of the end of the period (including treasury shares):

As of September 30, 2025 498,692,800 shares
As of March 31, 2025 498,692,800 shares

2) Number of treasury shares as of the end of the period:

As of September 30, 2025 28,785,143 shares
As of March 31, 2025 28,919,831 shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2025 469,817,518 shares
Six months ended September 30, 2024 469,661,929 shares

* Review of the attached consolidated quarterly financial statements by certified public accountants or an audit firm: None

* Note to ensure appropriate use of forecasts, and other comments in particular

Forecasts and other forward-looking statements included in this report are based on information currently available and certain assumptions that the Company deems reasonable. Actual performance and other results may differ significantly due to various factors. Please refer to “(4) Future Outlook” on page 7 for information regarding the consolidated financial forecasts.

Index of the Attachment

1. Overview of Operating Results and Other Information	2
(1) Overview of Operating Results for the 2nd Quarter of Fiscal Year 2025	2
(2) Overview of Financial Position for the 2nd Quarter of Fiscal Year 2025	6
(3) Overview of Cash Flows for the 2nd Quarter of Fiscal Year 2025	6
(4) Future Outlook	7
2. Basic Approach to the Selection of Accounting Standards.....	7
3. Consolidated Financial Statements and Major Notes	8
(1) Condensed Interim Consolidated Statement of Financial Position.....	8
(2) Condensed Interim Consolidated Statement of Income and Consolidated Statement of Comprehensive Income	10
(3) Condensed Interim Consolidated Statement of Changes in Equity	12
(4) Condensed Interim Consolidated Statement of Cash Flows.....	13
(5) Notes to Condensed Interim Consolidated Financial Statements	14
(Note Regarding Assumption of Going Concern)	14
(Segment Information).....	14
(Significant Subsequent Event)	14

1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of Fiscal Year 2025

① Overview of Financial Results (Core basis)

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025	Change	Change (%)
Revenue	240,339	257,136	16,797	7.0%
Core operating profit	65,382	70,058	4,675	7.2%
Core profit for the period (attributable to owners of the Company)	51,012	53,821	2,809	5.5%

[Revenue]

Revenue totaled ¥257.1 billion, which was an increase of ¥16.8 billion (7.0%) from the corresponding period of the previous fiscal year (year on year).

<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 Velexbro 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.

[Core Operating Profit]

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).

[Core profit for the period] (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.

② Overview of Financial Results (IFRS (Full) basis)

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025	Change	Change (%)
Revenue	240,339	257,136	16,797	7.0%
Operating profit	48,788	52,069	3,281	6.7%
Profit before tax	47,544	52,175	4,630	9.7%
Profit for the period (attributable to owners of the Company)	37,435	40,089	2,654	7.1%

[Revenue]

Revenue (IFRS (full) basis) is the same as on a core basis.

[Operating Profit]

The main adjustments are as follows.

- Cost of Sales: Amortization expenses, mainly related to intangible assets from the acquisition of Deciphera, were adjusted, ¥5.3 billion in the previous fiscal year and ¥12.5 billion in the current fiscal year. Additionally, the cost portion of inventory assets evaluated at fair value was adjusted, ¥4.8 billion in the previous fiscal year and ¥4.7 billion in the current fiscal year.
- Research and Development Expenses: An impairment loss of ¥3.5 billion related to intangible assets was adjusted in the previous fiscal year.
- Selling, General and Administrative Expenses (excluding R&D): Acquisition-related expenses of ¥3.0 billion for Deciphera were adjusted in the previous fiscal year.

Therefore, operating profit was ¥52.1 billion, an increase of ¥3.3 billion (6.7%) year on year.

[Profit for the period] (attributable to owners of the Company)

Profit attributable to owners of the Company increased by ¥2.7 billion (7.1%) year on year to ¥40.1 billion in association with the increase of the profit before tax.

Note : During the second quarter of fiscal year ended March 2025, provisional accounting treatment was applied to the business combination with Deciphera Pharmaceuticals, Inc. This accounting treatment was finalized by the end of fiscal year ended March 2025. Accordingly, for the purpose of comparison and analysis with the previous interim consolidated accounting period, revised figures reflecting the finalized accounting treatment have been used.

③ Research & Development Activities

Upholding the corporate philosophy “Dedicated to the Fight against Disease and Pain”, our group takes on the challenge against diseases that have not been overcome so far, and the disease area which has a low level of patient satisfaction with treatment and high medical needs. We are endeavoring to make creative and innovative drugs.

Currently, our development pipeline includes new drug candidates for anticancer treatments, including antibody drugs in addition to Opdivo, candidates for treatment of autoimmune disease and neurological disorder. Among these, the area of oncology is positioned as a key strategic field due to its high unmet medical needs, and we are working to further enhance the pipeline with the addition of Deciphera Pharmaceuticals’ pipeline.

In drug discovery research, we focus on the areas of oncology, immunology, neurology and specialties; all of which include diseases with high medical needs. We aim to delve into human disease biology within each of these domains to develop new drugs that can meet these medical needs. By actively promoting open innovation, which is one of our strengths, we identify unique drug discovery seeds and enhance our drug discovery capabilities by utilizing optimal modalities and advanced technologies such as digital technology.

In our priority therapeutic areas, we currently have 24 new drug candidates in clinical development, 15 of which were made in-house. We are also continuing to bolster our efforts in translational research, bridging the gap between basic and clinical research to accelerate drug discovery timelines and boost success rates. By organically leveraging informatics and research tools, such as human genome data and human iPS cells in the early stages of research, we are working to analyze the relationship between target molecules and diseases to identify physiological indicators (biomarkers) that can more accurately predict and evaluate the efficacy of new drug candidates in humans.

In order to improve the speed and success rates of clinical development, we strive to formulate the most effective development strategy in strong collaboration with the Discovery & Research from an earlier stage. Additionally, using many of the clinical trial data accumulated so far and samples gained through actual clinical trials, we are carrying out various types of analysis to increase the resolution of data in clinical trial results. To maximize the value of our drug candidates, we are formulating development and trial plans that enable the fastest possible approval in global markets, including Japan, the United States, and Europe. Additionally, we will leverage the development capabilities in the United States and Europe of Deciphera Pharmaceuticals, which joined our group last year, to ensure the steady execution of international joint trials.

We are also striving for the introduction of promising new drug candidates through licensing activities and are working to further strengthen research and development activities.

The main results of research and development activities during the second quarter (six months) ended September 30, 2025 (including those on and after September 30, 2025) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

“Opdivo / Nivolumab”

Hepatocellular carcinoma

- In June 2025, an application for approval of combination therapy with Opdivo and Yervoy was approved in Japan for the treatment of unresectable hepatocellular carcinoma.
- In July 2025, an application for approval of combination therapy with Opdivo and Yervoy was approved in South Korea and Taiwan for the treatment of unresectable or metastatic hepatocellular carcinoma.

MSI-H / dMMR Colorectal cancer

- In August 2025, an application for approval of the combination therapy of Opdivo and Yervoy was approved in Japan for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer.

Gastric cancer

- In October 2025, phase III trial was conducted in Japan, South Korea, and Taiwan for 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.

“Vexlexbru (ONO-4059)” / Tirabrutinib hydrochloride

- In August 2025, phase III of ONO-4059, Vexlexbru (BTK inhibitor), was initiated in the United States for the treatment of recurrent or refractory primary central nervous system lymphoma.

“DCC-2812”

- In August 2025, phase I of DCC-2812 (GCN2 activator) was initiated in the United States for the potential treatment of renal cell carcinoma, urothelial carcinoma, and castration-resistant prostate cancer.

“ONO-7018”

- In April 2025, phase I of ONO-7018 (MALT1 inhibitor) was conducted for the treatment of non-Hodgkin lymphoma and chronic lymphocytic leukemia, but the project was discontinued due to strategic reasons.

“ONO-7475 / tamnorzatinib”

- In July 2025, phase I of ONO-7475 (Axl/Mer inhibitor) for the treatment of EGFR-mutated non-small cell lung cancer was conducted in Japan, but the project was discontinued due to strategic reasons.

“DCC-3116 / inlexisertib”

- In September 2025, Phase I/II of DCC-3116 (ULK inhibitor) for the treatment of solid tumor (in combination with sotorasib) was conducted in the United States, but this cohort was discontinued due to strategic reasons.

“DCC-3084”

- In September 2025, Phase I/II of DCC-3084 (Pan-RAF inhibitor) for the treatment of advanced malignancies was conducted in the United States, but the project was discontinued due to strategic reasons.

<Areas Other than Oncology>

“ONO-8531 / povetacicept”

- In June 2025, the Company entered into a licensing agreement with Vertex Pharmaceuticals Incorporated for ONO-8531 (povetacicept), which is currently undergoing a Phase III clinical trial for the treatment of IgA nephropathy. Through this agreement, we obtained the rights for development and commercialization in Japan and South Korea.

“Gel-One (ONO-5532)”

- In August 2025, the Company entered into a joint development and commercialization agreement with Seikagaku Corporation on Gel-One (ONO-5532) for the treatment of osteoarthritis. In Japan, a Phase III clinical trial is being conducted for the treatment of knee osteoarthritis and hip osteoarthritis.

“ROMVIMZA (DCC-3014) / vimseltinib”

- 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 / cenobamate”

- In September 2025, an application of ONO-2017 (Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel) was filed in Japan for the treatment of partial-onset seizures (including secondary generalized seizures).

[Status of Licensing Activities]

- In June 2025, the Company entered into an exclusive collaboration and licensing agreement for the development and commercialization with Vertex Pharmaceuticals Incorporated in the United States for povetacicept, a therapeutic candidate targeting immunoglobulin A nephropathy (IgAN), primary membranous nephropathy (pMN) and other serious B cell-mediated diseases, in Japan and South Korea.
- In August 2025, the Company entered into an exclusive licensing agreement with Seikagaku Corporation for the co-development and commercialization of Gel-One, a treatment for osteoarthritis, in Japan.

(2) Overview of Financial Position for the 2nd Quarter of Fiscal Year 2025

(Millions of yen)

	As of March 31, 2025	As of September 30, 2025	Change
Total assets	1,064,046	1,058,514	(5,532)
Equity attributable to owners of the Company	782,451	806,350	23,898
Ratio of equity attributable to owners of the Company to total assets	73.5%	76.2%	
Equity attributable to owners of the Company per share	1,665.61 yen	1,716.05 yen	

Total assets decreased to ¥1,058.5 billion by ¥5.5 billion from the end of the previous fiscal year.

Current assets decreased by ¥34.7 billion to ¥420.5 billion mainly due to decreases in “cash and cash equivalents”, inventories and other current assets.

Non-current assets increased by ¥29.1 billion to ¥638.1 billion mainly due to increases in intangible assets.

Liabilities decreased by ¥29.3 billion to ¥246.5 billion mainly due to decreases in loans and “trade and other payables”, despite an increase in income tax payables.

Equity attributable to owners of the Company increased by ¥23.9 billion to ¥806.3 billion mainly due to the recording of the profit for the period, despite cash dividends.

(3) Overview of Cash Flows for the 2nd Quarter of Fiscal Year 2025

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025	Change
Cash and cash equivalents at the beginning of the period	166,141	204,567	
Cash flows from operating activities	34,723	54,564	19,841
Cash flows from investing activities	(160,930)	(41,817)	119,112
Cash flows from financing activities	129,687	(35,461)	(165,148)
Net increase (decrease) in cash and cash equivalents	3,480	(22,714)	
Effects of exchange rate changes on cash and cash equivalents	(2,530)	208	
Cash and cash equivalents at the end of the period	167,090	182,060	

Net increase/decrease in cash and cash equivalents was a decrease of ¥22.7 billion.

Net cash provided by operating activities was ¥54.6 billion, as a result of profit before tax of ¥52.2 billion and “depreciation and amortization” of ¥18.6 billion, despite a decrease in “trade and other payables” of ¥23.0 billion, etc.

Net cash used in investing activities was ¥41.8 billion, as a result of the acquisition of intangible assets of ¥46.1 billion, etc.

Net cash used in financing activities was ¥35.5 billion, as a result of dividends paid of ¥18.8 billion, and repayments of long-term loans of ¥15.0 billion, etc.

(4) Future Outlook

There are no changes from the consolidated financial forecast for the year ending March 31, 2026, announced on May 8, 2025.

2. Basic Approach to the Selection of Accounting Standards

Our group has applied International Financial Reporting Standards (IFRS) from the fiscal year ended March 31, 2014, for the purpose of improving comparability by disclosing financial information based on international standards and enhancing the convenience of various stakeholders such as shareholders, investors, and business partners.

3. Condensed Interim Consolidated Financial Statements and Major Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2025	As of September 30, 2025
Assets		
Current assets		
Cash and cash equivalents	204,567	182,060
Trade and other receivables	135,022	139,009
Marketable securities	4,479	40
Other financial assets	1,334	826
Inventories	74,864	69,155
Other current assets	34,838	29,363
Total current assets	455,104	420,454
Non-current assets		
Property, plant, and equipment	105,721	102,666
Goodwill	21,186	21,095
Intangible assets	330,041	361,886
Investment securities	88,558	89,044
Other financial assets	7,944	8,157
Deferred tax assets	51,020	50,590
Other non-current assets	4,473	4,622
Total non-current assets	608,942	638,060
Total assets	1,064,046	1,058,514

(Millions of yen)

	As of March 31, 2025	As of September 30, 2025
Liabilities and Equity		
Current liabilities		
Trade and other payables	89,329	65,317
Short-term loans	30,000	30,000
Lease liabilities	3,178	2,832
Other financial liabilities	1,482	1,091
Income taxes payable	4,058	19,565
Other current liabilities	20,249	21,743
Total current liabilities	148,296	140,547
Non-current liabilities		
Long-term loans	105,000	90,000
Lease liabilities	8,500	7,583
Other financial liabilities	0	0
Retirement benefit liabilities	2,640	2,694
Deferred tax liabilities	10,817	5,120
Other non-current liabilities	590	572
Total non-current liabilities	127,548	105,969
Total liabilities	275,844	246,516
Equity		
Share capital	17,358	17,358
Capital reserves	17,458	17,458
Treasury shares	(63,063)	(62,769)
Other components of equity	19,789	19,762
Retained earnings	790,908	814,540
Equity attributable to owners of the Company	782,451	806,350
Non-controlling interests	5,751	5,649
Total equity	788,203	811,998
Total liabilities and equity	1,064,046	1,058,514

**(2) Condensed Interim Consolidated Statement of Income
and Condensed Interim Consolidated Statement of Comprehensive Income**

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Revenue	240,339	257,136
Cost of sales	(63,969)	(71,976)
Gross profit	176,370	185,160
Selling, general, and administrative expenses	(58,424)	(61,171)
Research and development costs	(68,803)	(71,021)
Other income	572	557
Other expenses	(928)	(1,456)
Operating profit	48,788	52,069
Finance income	2,276	2,105
Finance costs	(3,522)	(1,999)
Share of profit (loss) from investments in associates	2	—
Profit before tax	47,544	52,175
Income tax expense	(10,104)	(12,193)
Profit for the period	37,440	39,981
Profit for the period attributable to		
Owners of the Company	37,435	40,089
Non-controlling interests	6	(107)
Profit for the period	37,440	39,981
Earnings per share		
Basic earnings per share (Yen)	79.71	85.33
Diluted earnings per share (Yen)	79.66	85.28

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Profit for the period	37,440	39,981
Other comprehensive income:		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	291	3,759
Remeasurements of defined benefit plans	(107)	(79)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	0	—
Total of items that will not be reclassified to profit or loss	184	3,680
Items that may be reclassified subsequently to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	70	(3)
Exchange differences on translation of foreign operations	(34,239)	(1,410)
Net fair value gain (loss) on cash flow hedge	811	(1,972)
Total of items that may be reclassified subsequently to profit or loss	(33,359)	(3,385)
Total other comprehensive income	(33,174)	295
Total comprehensive income for the period	4,266	40,276
Comprehensive income for the period attributable to:		
Owners of the Company	4,251	40,372
Non-controlling interests	15	(96)
Total comprehensive income for the period	4,266	40,276

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 2024

(Millions of yen)								
	Equity attributable to owners of the Company					Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings			
Balance as of April 1, 2024	17,358	17,458	(63,233)	53,194	768,183	792,961	5,644	798,604
Profit for the period					37,435	37,435	6	37,440
Other comprehensive income				(33,184)		(33,184)	9	(33,174)
Total comprehensive income for the period	—	—	—	(33,184)	37,435	4,251	15	4,266
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(53)	138			85		85
Cash dividends					(18,786)	(18,786)	(11)	(18,797)
Share-based payments		23				23		23
Transfer from retained earnings to capital reserves		30			(30)	—		—
Transfer from other components of equity to retained earnings				(1,968)	1,968	—		—
Total transactions with the owners	—	—	138	(1,968)	(16,848)	(18,679)	(11)	(18,690)
Balance as of September 30, 2024	17,358	17,458	(63,096)	18,043	788,769	778,533	5,647	784,181

Six months ended September 30, 2025

(Millions of yen)								
	Equity attributable to owners of the Company					Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings			
Balance as of April 1, 2025	17,358	17,458	(63,063)	19,789	790,908	782,451	5,751	788,203
Profit for the period					40,089	40,089	(107)	39,981
Other comprehensive income				284		284	11	295
Total comprehensive income for the period	—	—	—	284	40,089	40,372	(96)	40,276
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(127)	294			167		167
Cash dividends					(18,791)	(18,791)	(6)	(18,797)
Share-based payments		24				24		24
Transfer from retained earnings to capital reserves		104			(104)	—		—
Transfer from other components of equity to retained earnings				(2,437)	2,437	—		—
Transfer to non-financial assets				2,127		2,127		2,127
Total transactions with the owners	—	—	294	(311)	(16,457)	(16,474)	(6)	(16,480)
Balance as of September 30, 2025	17,358	17,458	(62,769)	19,762	814,540	806,350	5,649	811,998

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Cash flows from operating activities		
Profit before tax	47,544	52,175
Depreciation and amortization	11,274	18,551
Impairment losses	3,510	—
Interest and dividend income	(2,259)	(1,873)
Interest expense	293	1,106
(Increase) decrease in inventories	5,022	5,812
(Increase) decrease in trade and other receivables	4,539	(4,037)
Increase (decrease) in trade and other payables	(7,906)	(23,041)
Increase (decrease) in retirement benefit liabilities	(195)	(62)
Increase (decrease) in accrued consumption tax	(2,204)	2,483
Other	(3,988)	7,026
Subtotal	55,630	58,139
Interest received	279	494
Dividends received	1,264	1,000
Interest paid	(293)	(1,106)
Income taxes paid	(22,157)	(3,962)
Net cash provided by (used in) operating activities	34,723	54,564
Cash flows from investing activities		
Purchases of property, plant, and equipment	(2,806)	(3,910)
Proceeds from sales of property, plant, and equipment	6	7
Purchases of intangible assets	(1,975)	(46,120)
Purchases of investments	(906)	(1,233)
Proceeds from sales and redemption of investments	10,098	9,981
Payments into time deposits	(591)	(200)
Proceeds from withdrawal of time deposits	200,591	592
Payments of the acquisition of subsidiaries	(364,816)	—
Other	(532)	(934)
Net cash provided by (used in) investing activities	(160,930)	(41,817)
Cash flows from financing activities		
Dividends paid	(18,754)	(18,765)
Dividends paid to non-controlling interests	(11)	(6)
Repayment of long-term loans	—	(15,000)
Proceeds from long-term loans	150,000	—
Repayments of lease liabilities	(1,547)	(1,690)
Purchases of treasury shares	(1)	(1)
Net cash provided by (used in) financing activities	129,687	(35,461)
Net increase (decrease) in cash and cash equivalents	3,480	(22,714)
Cash and cash equivalents at the beginning of the period	166,141	204,567
Effects of exchange rate changes on cash and cash equivalents	(2,530)	208
Cash and cash equivalents at the end of the period	167,090	182,060

(5) Notes to Condensed Interim Consolidated Financial Statements

(Note Regarding Assumption of Going Concern)

Not Applicable

(Segment Information)

Segment information is omitted herein because our group's business is a single segment of the pharmaceutical business.

(Significant Subsequent Event)

Not Applicable

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)】

Page 1	Summary of Consolidated Financial Results for the 2nd Quarter of FY 2025 (Core basis)
Page 2	Sales Revenue Result and Forecast of Major Products Details of Sales Revenue, Revenue by Geographic Area
Page 3	Reconciliation from Full to Core basis for the 2nd Quarter of FY 2025 (April 1, 2025 to September 30, 2025)
Page 4	Consolidated Financial Forecast for FY 2025 (April 1 2025 to March 31, 2026) (Core basis)
Page 5	Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets Number of Employees
Page 6	Status of Shares
Page 7~11	Main Status of Development Pipelines
Page 12~13	Profile for Main Development

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 Velexbro 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)

	Six months ended September 30, 2025 (April 1, 2025 to September 30, 2025)					FY 2025 Forecast (April 1, 2025 to March 31, 2026)				
Product Name	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

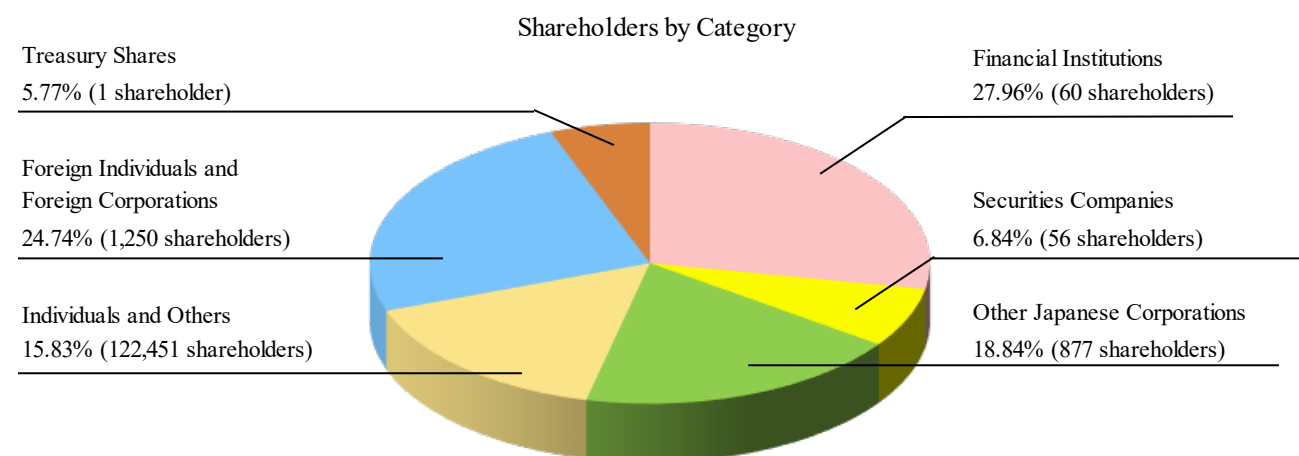
(As of September 30, 2025)

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 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)	Approved (Japan) 25/06 Approved (South Korea) 25/07 Approved (Taiwan) 25/07	In-house (Co-development with Bristol-Myers Squibb)
		MSI-H/dMMR colorectal cancer, First-line treatment (Combination with Yervoy)	Approved (Japan) 25/08	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)
		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 ripretinib QINLOCK (Oral medication)	KIT inhibitor	Gastrointestinal stromal tumor, Second-line treatment for patients with KIT exon 11+17/18 mutation	P3	In-house

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
ONO-4578 (Oral medication)	Prostaglandin receptor (EP4) antagonist	Gastric cancer, First-line treatment (Standard treatment (combination with Opdivo and chemotherapy))	P2	In-house
		Colorectal cancer, First-line treatment (combination with Opdivo and standard treatment)	P2	In-house
		Non-small cell lung cancer, Second-line treatment (combination with Opdivo and standard treatment)	P1	In-house
		Hormone receptor-positive, HER2-negative breast cancer, First-line treatment (with standard treatment)	P1	In-house
ONO-4059 Tirabrutinib Hydrochloride Velembu (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Primary central nervous system lymphoma, Second-line treatment and beyond	P3 (the U.S.)	In-house
		Primary central nervous system lymphoma, First-line treatment, second-line treatment and beyond	P2 (the U.S.)	In-house
ONO-0530 sapanisertib (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 inlecanatib (Oral medication)	ULK inhibitor	Advanced malignancies (Combination with ripretinib)	P1/2	In-house
DCC-3009 (Oral medication)	Pan-KIT inhibitor	Gastrointestinal stromal tumor	P1/2	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.)
DCC-2812 (Oral medication)	GCN2 activator	Renal cell carcinoma, urothelial carcinoma, castration-resistant prostate cancer	P1	In-house
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)

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
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 vimseltinib ROMVIMZA (Oral medication)	CSF-1R inhibitor	Tenosynovial giant cell tumor	Approved(USA) 25/02 Approved (Europe) 25/09	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	Partial-onset seizures	Filed (Japan) 25/09	In-license (Japan) (SK Biopharmaceuticals)
		Primary generalized tonic- clonic seizures	P3	In-license (Japan) (SK Biopharmaceuticals)
ONO-4059 Tirabrutinib hydrochloride Velembro (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Steroid-resistant pemphigus	P3	In-house
ONO-8531 povetacicept (Subcutaneous injection)	BAFF/APRIL dual antagonist	Immunoglobulin A nephropathy (IgAN)	P3	In-license (Japan, South Korea) (Vertex Pharmaceuticals Incorporated)
ONO-5532 Gel-One (Intra-articular injection)	Cross-linked hyaluronate	Knee osteoarthritis	P3	In-license (Japan) (Seikagaku Corporation)
		Hip osteoarthritis	P3	In-license (Japan) (Seikagaku Corporation)
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 First quarter of the fiscal year ending March 31, 2026, 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-4538 Nivolumab Opdivo (Intravenous injection)	A human anti-human PD-1 monoclonal antibody	MSI-H/dMMR colorectal cancer, First-line treatment (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 Tirabrutinib Hydrochloride Velexbru (Oral medication)	BTK(Bruton's tyrosine kinase) inhibitor	Primary central nervous system lymphoma, 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 (Intravenous injection)	GCN2 activator	Renal cell carcinoma, urothelial 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 inlexisertib (Oral medication)	ULK inhibitor	Solid tumor (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 (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 Nivolumab Opdivo (Intravenous Injection)	A human anti-human PD-1 monoclonal antibody	Gastric cancer (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 Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Development status or reason for termination
ONO-5532 Gel-One (Intra-articular injection)	Cross-linked hyaluronate	Knee osteoarthritis 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 vimseltinib ROMVIMZA (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 Cenobamate (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 (povetacept) (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.