

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

February 2, 2026

Company name	: ONO PHARMACEUTICAL CO., LTD.
Stock exchange listing	: Tokyo Stock Exchange
Securities Code	: 4528
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Scheduled date of dividend payment commencement	: —
Supplementary materials for the quarterly financial results	: Yes
Earnings announcement for the quarterly financial results	: Yes (for institutional investors and securities analysts)

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

1. Consolidated Financial Results for the Third Quarter of FY 2025 (April 1, 2025 to December 31, 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 Q3	397,036	6.0	88,292	24.8	89,377	24.1	68,870	21.8	68,949	21.8	92,420	53.1
FY 2024 Q3	374,562	(3.9)	70,754	(51.1)	72,037	(51.1)	56,533	(48.9)	56,592	(48.8)	60,357	(48.5)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2025 Q3	146.75	146.70
FY 2024 Q3	120.49	120.42

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 Q3	397,036	6.0	116,298	19.1	89,974	17.6	191.50
FY 2024 Q3	374,562	(3.9)	97,654	(36.8)	76,497	(38.1)	162.87

(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 December 31, 2025	1,084,397	845,357	839,670	77.4
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

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: Yes

Newly included : 1 company (Company name) Ono Global Reinsurance, Inc.

(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 December 31, 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 December 31, 2025 28,785,244 shares

As of March 31, 2025 28,919,831 shares

3) Average number of shares outstanding during the period:

Nine months ended December 31, 2025 469,839,305 shares

Nine months ended December 31, 2024 469,671,563 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 5 for information regarding the consolidated financial forecasts.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 3rd Quarter of Fiscal Year 2025

① Overview of Financial Results (Core basis)

(Millions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025	Change	Change (%)
Revenue	374,562	397,036	22,474	6.0%
Core operating profit	97,654	116,298	18,645	19.1%
Core profit for the period (attributable to owners of the Company)	76,497	89,974	13,477	17.6%

[Revenue]

Revenue totaled ¥397.0 billion, which was an increase of ¥22.5 billion (6.0%) 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 ¥6.8 billion (7.1%) year on year to ¥89.2 billion, mainly due to the intensified competitive environment. Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease increased by ¥3.9 billion (5.7%) year on year to ¥72.7 billion, mainly due to its expanded use, particularly in treatment for chronic kidney disease and chronic heart failure, despite the entry of generic products in December.
- With respect to other main products, sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥21.0 billion (1.0% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥10.4 billion (28.9% decrease year on year). Sales of Velexbu Tablets for malignant tumors were ¥9.2 billion (12.3% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥6.9 billion (16.6% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥6.9 billion (5.1% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥6.0 billion (12.9% 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 ¥11.3 billion (65.1%) year on year (the previous period included only six months of sales from July to December) to ¥28.6 billion. Additionally, sales of ROMVIMZA[®] (vimseltinib), also marketed by Deciphera, for tenosynovial giant cell tumor (TGCT) treatment were ¥5.4 billion.

<Royalty and Others>

- Royalty and others increased by ¥11.5 billion (9.7%) year on year to ¥129.2 billion, mainly due to an increase in royalty revenue from Bristol-Myers Squibb Company.

[Core Operating Profit]

Core operating profit was ¥116.3 billion, an increase of ¥18.6 billion (19.1%) year on year.

- Cost of sales was ¥83.2 billion, roughly unchanged from the corresponding period of the previous fiscal year.
- Research and development costs increased by ¥1.2 billion (1.1%) year on year to ¥104.6 billion mainly due to the inclusion of research and development expenses from Deciphera Pharmaceuticals, LLC (the previous period accounted for only six months of Deciphera's expenses (July to December), and the current period includes nine months (April to December)), despite a decrease in research costs.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥2.6 billion (2.9%) year on year to ¥92.8 billion mainly due to the inclusion of business operating costs from Deciphera Pharmaceuticals, LLC (the previous period accounted for only six months of Deciphera's expenses (July to December), and the current period includes nine months (April to December), despite the promotion of cost efficiency.

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

Core profit attributable to owners of the Company increased by ¥13.5 billion (17.6%) year on year to ¥90.0 billion in association with the increase of the profit before tax.

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

	Nine months ended December 31, 2024	Nine months ended December 31, 2025	Change	(Millions of yen) Change (%)
Revenue	374,562	397,036	22,474	6.0%
Operating profit	70,754	88,292	17,538	24.8%
Profit before tax	72,037	89,377	17,340	24.1%
Profit for the period (attributable to owners of the Company)	56,592	68,949	12,357	21.8%

[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, ¥9.1 billion in the previous fiscal year and ¥19.0 billion in the current fiscal year, etc. Additionally, the cost portion of inventory assets evaluated at fair value was adjusted, ¥10.5 billion in the previous fiscal year and ¥6.4 billion in the current fiscal year, etc.
- Research and Development Expenses: An impairment loss of ¥3.5 billion related to intangible assets was adjusted in the previous fiscal year, etc.
- Selling, General and Administrative Expenses (excluding R&D): Acquisition-related expenses of ¥3.0 billion for Deciphera were adjusted in the previous fiscal year, etc.
- Other Expenses: Loss on retirement benefit plan amendments of ¥1.7 billion was adjusted, arising from the transition of a portion of the defined benefit pension plan to defined contribution pension plan in the current fiscal year, etc.

Therefore, Operating profit increased by ¥17.5 billion (24.8%) year on year to ¥88.3 billion.

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

Profit attributable to owners of the Company increased by ¥12.4 billion (21.8%) year on year to ¥68.9 billion in association with the increase of the profit before tax.

(2) Overview of Financial Position for the 3rd Quarter of Fiscal Year 2025

(Millions of yen)

	As of March 31, 2025	As of December 31, 2025	Change
Total assets	1,064,046	1,084,397	20,351
Equity attributable to owners of the Company	782,451	839,670	57,219
Ratio of equity attributable to owners of the Company to total assets	73.5%	77.4%	
Equity attributable to owners of the Company per share	1,665.61 yen	1,786.94 yen	

Total assets increased to ¥1,084.4 billion by ¥20.4 billion from the end of the previous fiscal year.

Current assets decreased by ¥21.8 billion to ¥433.3 billion mainly due to decreases in “cash and cash equivalents” and inventories.

Non-current assets increased by ¥42.2 billion to ¥651.1 billion mainly due to increases in intangible assets.

Liabilities decreased by ¥36.8 billion to ¥239.0 billion mainly due to decreases in “trade and other payables” and loans, despite an increase in income tax payables.

Equity attributable to owners of the Company increased by ¥57.2 billion to ¥839.7 billion mainly due to the recording of the profit for the period and an increase in other components of equity, despite cash dividends.

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

(Millions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025	Change
Cash and cash equivalents at the beginning of the period	166,141	204,567	
Cash flows from operating activities	43,463	86,639	43,176
Cash flows from investing activities	(152,111)	(44,047)	108,065
Cash flows from financing activities	103,597	(59,829)	(163,425)
Net increase (decrease) in cash and cash equivalents	(5,052)	(17,237)	
Effects of exchange rate changes on cash and cash equivalents	(106)	1,055	
Cash and cash equivalents at the end of the period	160,982	188,385	

Net increase/decrease in cash and cash equivalents was a decrease of ¥17.2 billion.

Net cash provided by operating activities was ¥86.6 billion, as a result of profit before tax of ¥89.4 billion, etc.

Net cash used in investing activities was ¥44.0 billion, as a result of the acquisition of intangible assets of ¥47.0 billion, etc.

Net cash used in financing activities was ¥59.8 billion, as a result of dividends paid of ¥36.4 billion, and repayments of long-term loans of ¥22.5 billion, etc.

(4) Future Outlook

There are no changes from the consolidated financial forecast for the year ending March 31, 2026, announced on October 30, 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 December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	204,567	188,385
Trade and other receivables	135,022	149,485
Marketable securities	4,479	60
Other financial assets	1,334	827
Inventories	74,864	66,095
Other current assets	34,838	28,418
Total current assets	455,104	433,269
Non-current assets		
Property, plant, and equipment	105,721	101,702
Goodwill	21,186	22,183
Intangible assets	330,041	369,156
Investment securities	88,558	97,088
Other financial assets	7,944	8,326
Deferred tax assets	51,020	48,115
Other non-current assets	4,473	4,557
Total non-current assets	608,942	651,128
Total assets	1,064,046	1,084,397

(Millions of yen)

	As of March 31, 2025	As of December 31, 2025
Liabilities and Equity		
Current liabilities		
Trade and other payables	89,329	63,296
Short-term loans	30,000	31,642
Lease liabilities	3,178	2,714
Other financial liabilities	1,482	3,448
Income taxes payable	4,058	18,425
Other current liabilities	20,249	23,740
Total current liabilities	148,296	143,265
Non-current liabilities		
Long-term loans	105,000	82,500
Lease liabilities	8,500	7,574
Other financial liabilities	0	0
Retirement benefit liabilities	2,640	2,737
Deferred tax liabilities	10,817	2,380
Other non-current liabilities	590	584
Total non-current liabilities	127,548	95,775
Total liabilities	275,844	239,039
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	41,879
Retained earnings	790,908	825,743
Equity attributable to owners of the Company	782,451	839,670
Non-controlling interests	5,751	5,688
Total equity	788,203	845,357
Total liabilities and equity	1,064,046	1,084,397

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025
Revenue	374,562	397,036
Cost of sales	(102,713)	(108,657)
Gross profit	271,849	288,379
Selling, general, and administrative expenses	(93,739)	(92,900)
Research and development costs	(107,072)	(104,554)
Other income	776	710
Other expenses	(1,060)	(3,343)
Operating profit	70,754	88,292
Finance income	4,139	3,492
Finance costs	(2,859)	(2,407)
Share of profit (loss) from investments in associates	3	—
Profit before tax	72,037	89,377
Income tax expense	(15,504)	(20,507)
Profit for the period	56,533	68,870
Profit for the period attributable to		
Owners of the Company	56,592	68,949
Non-controlling interests	(59)	(79)
Profit for the period	56,533	68,870
Earnings per share		
Basic earnings per share (Yen)	120.49	146.75
Diluted earnings per share (Yen)	120.42	146.70

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025
Profit for the period	56,533	68,870
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	456	8,698
Remeasurements of defined benefit plans	(168)	1,008
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(1)	—
Total of items that will not be reclassified to profit or loss	286	9,706
Items that may be reclassified subsequently to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	64	(3)
Exchange differences on translation of foreign operations	3,837	15,812
Net fair value gain (loss) on cash flow hedge	(364)	(1,964)
Total of items that may be reclassified subsequently to profit or loss	3,537	13,845
Total other comprehensive income	3,824	23,551
Total comprehensive income for the period	60,357	92,420
Comprehensive income for the period attributable to:		
Owners of the Company	60,412	92,478
Non-controlling interests	(55)	(57)
Total comprehensive income for the period	60,357	92,420

(3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 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					56,592	56,592	(59)	56,533
Other comprehensive income				3,821		3,821	3	3,824
Total comprehensive income for the period	—	—	—	3,821	56,592	60,412	(55)	60,357
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(53)	138			85		85
Cash dividends					(37,574)	(37,574)	(11)	(37,585)
Share-based payments		35				35		35
Transfer from retained earnings to capital reserves		18			(18)	—		—
Transfer from other components of equity to retained earnings				(4,426)	4,426	—		—
Total transactions with the owners	—	—	137	(4,426)	(33,166)	(37,455)	(11)	(37,466)
Balance as of December 31, 2024	17,358	17,458	(63,096)	52,589	791,609	815,918	5,577	821,495

Nine months ended December 31, 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					68,949	68,949	(79)	68,870
Other comprehensive income				23,529		23,529	22	23,551
Total comprehensive income for the period	—	—	—	23,529	68,949	92,478	(57)	92,420
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(127)	294			167		167
Cash dividends					(37,587)	(37,587)	(6)	(37,594)
Share-based payments		35				35		35
Transfer from retained earnings to capital reserves		92			(92)	—		—
Transfer from other components of equity to retained earnings				(3,566)	3,566	—		—
Transfer to non-financial assets				2,127		2,127		2,127
Total transactions with the owners	—	—	294	(1,439)	(34,114)	(35,259)	(6)	(35,265)
Balance as of December 31, 2025	17,358	17,458	(62,769)	41,879	825,743	839,670	5,688	845,357

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025
Cash flows from operating activities		
Profit before tax	72,037	89,377
Depreciation and amortization	18,166	28,145
Impairment losses	3,510	—
Interest and dividend income	(4,043)	(3,058)
Interest expense	848	1,600
(Increase) decrease in inventories	11,534	10,081
(Increase) decrease in trade and other receivables	(9,313)	(13,662)
Increase (decrease) in trade and other payables	(6,455)	(25,238)
Increase (decrease) in retirement benefit liabilities	(229)	1,568
Increase (decrease) in accrued consumption tax	(2,149)	3,462
Other	1,002	9,466
Subtotal	84,910	101,741
Interest received	866	661
Dividends received	2,400	1,895
Interest paid	(848)	(1,600)
Income taxes paid	(43,865)	(16,059)
Net cash provided by (used in) operating activities	43,463	86,639
Cash flows from investing activities		
Purchases of property, plant, and equipment	(4,010)	(4,948)
Proceeds from sales of property, plant, and equipment	4	10
Purchases of intangible assets	(2,390)	(46,981)
Purchases of investments	(1,974)	(1,961)
Proceeds from sales and redemption of investments	19,639	10,435
Payments into time deposits	(991)	(626)
Proceeds from withdrawal of time deposits	203,281	1,024
Payments of the acquisition of subsidiaries	(364,816)	—
Other	(854)	(1,000)
Net cash provided by (used in) investing activities	(152,111)	(44,047)
Cash flows from financing activities		
Dividends paid	(36,524)	(36,431)
Dividends paid to non-controlling interests	(11)	(6)
Net increase/decrease in short-term loans	—	1,642
Repayment of long-term loans	(7,500)	(22,500)
Proceeds from long-term loans	150,000	—
Repayments of lease liabilities	(2,367)	(2,532)
Purchases of treasury shares	(1)	(1)
Net cash provided by (used in) financing activities	103,597	(59,829)
Net increase (decrease) in cash and cash equivalents	(5,052)	(17,237)
Cash and cash equivalents at the beginning of the period	166,141	204,567
Effects of exchange rate changes on cash and cash equivalents	(106)	1,055
Cash and cash equivalents at the end of the period	160,982	188,385

(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

4. Supplementary Information

(1) Sales Revenue and Forecast of Major Products

(Billions of yen)

	Nine months ended December 31, 2025 (April 1, 2025 to December 31, 2025)						FY 2025 Forecast (April 1, 2025 to March 31, 2026)		
Product Name	Cumulative				YoY		Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)		Change	Change (%)
<Domestic>									
Opdivo Intravenous Infusion	29.4	29.1	30.6	89.2	(6.8)	(7.1%)	120.0	(0.3)	(0.3%)
Forxiga Tablets	25.1	23.7	23.9	72.7	3.9	5.7%	80.0	(9.6)	(10.7%)
Orencia for Subcutaneous Injection	7.0	6.8	7.2	21.0	0.2	1.0%	28.0	1.4	5.2%
Glactiv Tablets	3.6	3.4	3.5	10.4	(4.2)	(28.9%)	12.0	(6.3)	(34.6%)
Velexbru Tablets	3.0	3.0	3.2	9.2	1.0	12.3%	11.0	0.5	4.4%
Ongentys Tablets	2.3	2.2	2.5	6.9	1.0	16.6%	9.0	1.4	17.8%
Parsabiv Intravenous Injection	2.2	2.3	2.5	6.9	0.3	5.1%	9.0	0.6	6.7%
Kyprolis for Intravenous Infusion	2.0	2.0	2.0	6.0	(0.9)	(12.9%)	9.0	0.4	4.6%
<Overseas>									
Opdivo	3.3	3.9	3.6	10.8	0.8	7.8%	13.5	0.4	2.9%
QINLOCK®	8.9	9.2	10.5	28.6	11.3	65.1%	36.0	10.5	41.2%
ROMVIMZA®	1.1	1.7	2.6	5.4	-	-	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.

(2) Details of Sales Revenue

(Billions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025
Revenue of goods and products	256.9	267.9
Royalty and others	117.7	129.2
Total	374.6	397.0

Note: In "Royalty and others", royalty revenue of Opdivo from Bristol-Myers Squibb Company is included, which is ¥86.3 billion for the third quarter (nine months) ended December 31, 2024, and ¥92.5 billion for the third quarter (nine months) ended December 31, 2025. Royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥19.4 billion for the third quarter (nine months) ended December 31, 2024, and ¥21.5 billion for the third quarter (nine months) ended December 31, 2025.

(3) Revenue by Geographic Area

(Billions of yen)

	Nine months ended December 31, 2024	Nine months ended December 31, 2025
Japan	232.3	226.3
USA	124.7	147.5
Asia	12.2	13.5
Europe	5.0	8.5
Others	0.4	1.2
Total	374.6	397.0

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

Main Status of Development Pipelines

As of February 2, 2026, 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 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 Approved (Taiwan) 26/01	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))	Approved (Japan) 25/11 Approved (South Korea) 26/01	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-4059 Tirabrutinib Hydrochloride Velembu (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Primary central nervous system lymphoma, Second-line treatment and beyond	P3 (USA)	In-house
		Primary central nervous system lymphoma, Second-line treatment and beyond	P2 (USA)	In-house
		Primary central nervous system lymphoma, First-line treatment	P2 (USA)	In-house
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-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 inleisertib (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 Besufetamig (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
		Chronic graft versus host disease (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 Velexbru (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 Besufetamig (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 Second 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-7702 Encorafenib Braftovi (Oral medication)	BRAF inhibitor	Colorectal cancer, First-line treatment, BRAF-mutation (Combination with Cetuximab and chemotherapy (FOLFOX))	In November 2025, an application of ONO-7702 in combination with Cetuximab and chemotherapy (FOLFOX) was approved in Japan for the treatment of BRAF-mutation unresectable, advanced or recurrent colorectal cancer.
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 January 2026, 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) or deficient mismatch repair (dMMR).
ONO-7702 Encorafenib Braftovi (Oral medication)	BRAF inhibitor	Colorectal cancer, First-line treatment, BRAF-mutation (Combination with Cetuximab and chemotherapy (FOLFOX))	In January 2026, an application of ONO-7702 in combination with Cetuximab and chemotherapy (FOLFOX) was approved in South Korea for the treatment of BRAF-mutation unresectable, advanced, or recurrent colorectal cancer.