

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

August 1, 2025

Company name Stock exchange listing Securities code URL Representative  Inquiries  Telephone Scheduled date of dividend payment commencement Supplementary materials for quarterly financial results Earnings announcement for quarterly financial results	: <b>ONO PHARMACEUTICAL CO., LTD.</b> : Tokyo Stock Exchange : 4528 : <a href="https://www.ono-pharma.com/en">https://www.ono-pharma.com/en</a> : Toichi Takino Representative Director, President and Chief Operating Officer : Ryuta Imura Senior Director of Corporate Communications : +81-(0)6-6263-5670 : — : Yes : Yes (for institutional investors and securities analysts)
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(Note: Amounts of less than one million yen are rounded.)

## 1. Consolidated Financial Results for the First Quarter of FY 2025 (From April 1, 2025 to June 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 Q1		127,536	8.4	21,995	(28.3)	22,650	(32.0)	17,631	(29.0)	17,673	(28.7)	6,797	(81.4)
FY 2024 Q1		117,675	(1.9)	30,690	(25.8)	33,310	(21.4)	24,835	(21.9)	24,794	(22.1)	36,595	(5.4)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2025 Q1	37.62	37.58
FY 2024 Q1	52.79	52.75

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 Q1	127,536	8.4	31,566	(10.1)	24,799	(13.7)	52.79
FY 2024 Q1	117,675	—	35,093	—	28,737	—	61.19

(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 June 30, 2025	1,023,589	778,342	772,638	75.5
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	—				
FY 2025 (Forecast)		40.00	—	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 June 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 June 30, 2025 28,919,831 shares

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

3) Average number of shares outstanding during the period:

Three months ended June 30, 2025 469,771,044 shares

Three months ended June 30, 2024 469,644,182 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 1st Quarter of FY 2025

#### ① Overview of Financial Results (Core basis)

(Millions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025	Change	Change (%)
Revenue	117,675	127,536	9,861	8.4%
Core operating profit	35,093	31,566	(3,527)	(10.1)%
Core profit for the period (attributable to owners of the Company)	28,737	24,799	(3,937)	(13.7)%

#### [Revenue]

Revenue totaled ¥127.5 billion, which was an increase of ¥9.9 billion (8.4%) from the corresponding period of the previous fiscal year (year on year).

##### <Sales of Domestic Products>

- Sales of Opdivo Intravenous Infusion for malignant tumors were decreased by ¥2.6 billion (8.2%) year on year to ¥29.4 billion, mainly due to the intensified competitive environment. Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were increased by ¥2.9 billion (13.1%) year on year to ¥25.1 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 ¥7.0 billion (1.8% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥3.6 billion (28.8% decrease year on year). Sales of Velexbro Tablets for malignant tumors were ¥3.0 billion (12.0% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥2.3 billion (17.2% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.2 billion (5.9% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥2.0 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., were ¥8.9 billion for the period from April 2025 to June 2025. Additionally, sales of ROMVIMZA™ (vimseltinib) for tenosynovial giant cell tumor (TGCT) treatment were ¥1.1 billion for the period from April 2025 to June 2025.

##### <Royalty and Others>

- Royalty and others increased by ¥1.4 billion (3.7%) year on year to ¥39.8 billion, mainly due to an increase in royalty revenue from Bristol-Myers Squibb Company.

#### [Core Operating Profit]

Core operating profit was ¥31.6 billion, a decrease of ¥3.5 billion (10.1%) year on year.

- Cost of sales decreased by ¥0.1 billion (0.2%) year on year to ¥28.1 billion.
- Research and development costs increased by ¥7.4 billion (25.6%) year on year to ¥36.3 billion mainly due to the inclusion of research and development expenses from Deciphera Pharmaceuticals, LLC, which were not recorded in the first quarter of the previous fiscal year.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥6.1 billion (24.4%) year on year to ¥31.1 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, which were not recorded in the first quarter of the previous fiscal year.

#### [Core profit for the period]

Core profit attributable to owners of the Company decreased by ¥3.9 billion (13.7%) year on year to ¥24.8 billion.

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

	Three months ended June 30, 2024	Three months ended June 30, 2025	Change	Change (%)
Revenue	117,675	127,536	9,861	8.4%
Operating profit	30,690	21,995	(8,695)	(28.3)%
Profit before tax	33,310	22,650	(10,660)	(32.0)%
Profit for the period (attributable to owners of the Company)	24,794	17,673	(7,121)	(28.7)%

**[Revenue]**

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

**[Operating Profit]**

- Cost of sales increased by ¥7.3 billion (24.7%) year on year to ¥37.0 billion, after adding the amortization of intangible assets acquired through acquisitions and in-licensing, as well as the expensing of inventory assets evaluated at fair value, to the core-basis cost of sales.
- Research and development costs is the same as on a core basis.
- Selling, general, and administrative expenses (except for research and development costs) were adjusted in the previous period to account for costs associated with the acquisition of Deciphera from the core-based expenses. As a result, selling, general, and administrative expenses increased by ¥3.2 billion (11.5%) year on year to ¥31.1 billion.

Therefore, Operating profit was ¥22.0 billion, a decrease of ¥8.7 billion (28.3%) year on year.

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

Profit attributable to owners of the Company decreased by ¥7.1 billion (28.7%) year on year to ¥17.7 billion.

#### (4) Overview of Financial Position for the 1st Quarter of FY 2025

(Millions of yen)

	As of March 31, 2025	As of June 30, 2025	Change
Total assets	1,064,046	<b>1,023,589</b>	(40,457)
Equity attributable to owners of the Company	782,451	<b>772,638</b>	(9,813)
Ratio of equity attributable to owners of the Company to total assets	73.5%	<b>75.5%</b>	
Equity attributable to owners of the Company per share	1,665.61 yen	<b>1,644.71 yen</b>	

Total assets decreased to ¥1,023.6 billion by ¥40.5 billion from the end of the previous fiscal year.

Current assets decreased by ¥68.4 billion to ¥386.7 billion, mainly due to a decrease in cash and cash equivalents.

Non-current assets increased by ¥28.0 billion to ¥636.9 billion, mainly due to an increase in intangible assets.

Liabilities decreased by ¥30.6 billion to ¥245.2 billion, mainly due to decreases in “trade and other payables” and borrowings.

Equity attributable to owners of the Company decreased by ¥9.8 billion to ¥772.6 billion, mainly due to cash dividends and a decrease in other components of equity, despite the recording of the profit for the period.

#### (5) Overview of Cash Flows for the 1st Quarter of FY 2025

(Millions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025	Change
Cash and cash equivalents at the beginning of the period	166,141	<b>204,567</b>	
Cash flows from operating activities	813	<b>3,373</b>	2,560
Cash flows from investing activities	(165,196)	<b>(43,043)</b>	122,153
Cash flows from financing activities	131,855	<b>(25,757)</b>	(157,612)
Net increase (decrease) in cash and cash equivalents	(32,527)	<b>(65,426)</b>	
Effects of exchange rate changes on cash and cash equivalents	635	<b>(150)</b>	
Cash and cash equivalents at the end of the period	134,248	<b>138,991</b>	

Net increase/decrease in cash and cash equivalents for the first quarter (three months) of the fiscal year 2025 was a decrease of ¥65.4 billion.

Net cash provided by operating activities was ¥3.4 billion, as a result of profit before tax of ¥22.6 billion and “depreciation and amortization” of ¥9.2 billion, etc., despite decreases in trade and other payables of ¥25.1 billion, etc.

Net cash used in investing activities was ¥43.0 billion, as a result of purchases of intangible assets of ¥45.8 billion etc.

Net cash used in financing activities was ¥25.8 billion, as a result of dividends paid of ¥17.4 billion and repayments of long-term borrowings of ¥7.5 billion, etc.

**(6) 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 June 30, 2025
Assets		
Current assets		
Cash and cash equivalents	204,567	138,991
Trade and other receivables	135,022	143,540
Marketable securities	4,479	165
Other financial assets	1,334	826
Inventories	74,864	70,765
Other current assets	34,838	32,392
Total current assets	455,104	386,679
Non-current assets		
Property, plant, and equipment	105,721	103,736
Goodwill	21,186	20,519
Intangible assets	330,041	360,084
Investment securities	88,558	89,706
Other financial assets	7,944	8,063
Deferred tax assets	51,020	50,201
Other non-current assets	4,473	4,602
Total non-current assets	608,942	636,910
Total assets	1,064,046	1,023,589



	(Millions of yen)	
	As of March 31, 2025	As of June 30, 2025
Liabilities and Equity		
Current liabilities		
Trade and other payables	89,329	63,147
Short-term borrowings	30,000	30,000
Lease liabilities	3,178	2,862
Other financial liabilities	1,482	3,146
Income taxes payable	4,058	8,408
Other current liabilities	20,249	21,893
Total current liabilities	148,296	129,456
Non-current liabilities		
Long-term borrowings	105,000	97,500
Lease liabilities	8,500	7,749
Other financial liabilities	0	0
Retirement benefit liabilities	2,640	2,714
Deferred tax liabilities	10,817	7,261
Other non-current liabilities	590	568
Total non-current liabilities	127,548	115,791
Total liabilities	275,844	245,248
Equity		
Share capital	17,358	17,358
Capital reserves	17,458	17,470
Treasury shares	(63,063)	(63,063)
Other components of equity	19,789	10,892
Retained earnings	790,908	789,980
Equity attributable to owners of the Company	782,451	772,638
Non-controlling interests	5,751	5,704
Total equity	788,203	778,342
Total liabilities and equity	1,064,046	1,023,589

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

**Condensed Interim Consolidated Statement of Income**

	(Millions of yen)	
	Three months ended June 30, 2024	Three months ended June 30, 2025
Revenue	117,675	127,536
Cost of sales	(29,671)	(37,013)
Gross profit	88,004	90,523
Selling, general, and administrative expenses	(27,886)	(31,086)
Research and development costs	(28,857)	(36,252)
Other income	37	113
Other expenses	(609)	(1,303)
Operating profit	30,690	21,995
Finance income	2,695	1,428
Finance costs	(75)	(773)
Share of profit (loss) from investments in associates	0	—
Profit before tax	33,310	22,650
Income tax expense	(8,474)	(5,019)
Profit for the period	24,835	17,631
Profit for the period attributable to:		
Owners of the Company	24,794	17,673
Non-controlling interests	42	(42)
Profit for the period	24,835	17,631
Earnings per share:		
Basic earnings per share (Yen)	52.79	37.62
Diluted earnings per share (Yen)	52.75	37.58

**Condensed Interim Consolidated Statement of Comprehensive Income**

	(Millions of yen)	
	Three months ended June 30, 2024	Three months ended June 30, 2025
Profit for the period	24,835	17,631
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	1,257	1,648
Remeasurements of defined benefit plans	(51)	11
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	1,206	1,660
Items that may be reclassified subsequently to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	—	(2)
Exchange differences on translation of foreign operations	12,316	(10,510)
Net fair value gain (loss) on cash flow hedges	(1,762)	(1,981)
Total of items that may be reclassified subsequently to profit or loss	10,554	(12,493)
Total other comprehensive income	11,760	(10,834)
Total comprehensive income for the period	36,595	6,797
Comprehensive income for the period attributable to:		
Owners of the Company	36,545	6,839
Non-controlling interests	50	(41)
Total comprehensive income for the period	36,595	6,797

### (3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 30, 2024

(Millions of yen)

	Equity attributable to owners of the Company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company			
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					24,794	24,794	42		24,835
Other comprehensive income				11,752		11,752	8		11,760
Total comprehensive income for the period	—	—	—	11,752	24,794	36,545	50		36,595
Purchase of treasury shares			(0)			(0)			(0)
Cash dividends					(18,786)	(18,786)	(11)		(18,797)
Share-based payments		11				11			11
Transfer from other components of equity to retained earnings				(1,493)	1,493	—			—
Total transactions with the owners	—	11	(0)	(1,493)	(17,293)	(18,776)	(11)		(18,787)
Balance as of June 30, 2024	17,358	17,469	(63,234)	63,454	775,684	810,731	5,682		816,413

Three months ended June 30, 2025

(Millions of yen)

	Equity attributable to owners of the Company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company			
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					17,673	17,673	(42)		17,631
Other comprehensive income				(10,834)		(10,834)	1		(10,834)
Total comprehensive income for the period	—	—	—	(10,834)	17,673	6,839	(41)		6,797
Cash dividends					(18,791)	(18,791)	(6)		(18,797)
Share-based payments		12				12			12
Transfer from other components of equity to retained earnings				(189)	189	—			—
Transfer to non-financial assets				2,127		2,127			2,127
Total transactions with the owners	—	12	—	1,937	(18,602)	(16,652)	(6)		(16,658)
Balance as of June 30, 2025	17,358	17,470	(63,063)	10,892	789,980	772,638	5,704		778,342

**(4) Condensed Interim Consolidated Statement of Cash Flows**

	(Millions of yen)	
	Three months ended June 30, 2024	Three months ended June 30, 2025
Cash flows from operating activities		
Profit before tax	33,310	22,650
Depreciation and amortization	4,379	9,238
Interest and dividend income	(1,545)	(1,427)
Interest expense	62	571
(Increase) decrease in inventories	100	3,592
(Increase) decrease in trade and other receivables	(6,956)	(8,061)
Increase (decrease) in trade and other payables	(7,748)	(25,079)
Increase (decrease) in retirement benefit liabilities	(116)	90
Increase (decrease) in accrued consumption tax	(451)	5
Other	477	5,173
Subtotal	21,513	6,752
Interest received	19	291
Dividends received	1,198	949
Interest paid	(62)	(571)
Income taxes paid	(21,854)	(4,048)
Net cash provided by (used in) operating activities	813	3,373
Cash flows from investing activities		
Purchases of property, plant, and equipment	(1,544)	(2,250)
Proceeds from sales of property, plant, and equipment	5	0
Purchases of intangible assets	(1,231)	(45,792)
Purchases of investments	(385)	(170)
Proceeds from sales and redemption of investments	3,561	5,383
Payments into time deposits	(394)	—
Proceeds from withdrawal of time deposits	200,394	386
Payments for the acquisition of subsidiaries	(364,816)	—
Other	(785)	(600)
Net cash provided by (used in) investing activities	(165,196)	(43,043)
Cash flows from financing activities		
Net Increase (decrease) in short-term loans	150,000	—
Dividends paid	(17,436)	(17,396)
Dividends paid to non-controlling interests	(11)	(6)
Repayments of long-term borrowings	—	(7,500)
Repayments of lease liabilities	(697)	(854)
Purchases of treasury shares	(0)	—
Net cash provided by (used in) financing activities	131,855	(25,757)
Net increase (decrease) in cash and cash equivalents	(32,527)	(65,426)
Cash and cash equivalents at the beginning of the period	166,141	204,567
Effects of exchange rate changes on cash and cash equivalents	635	(150)
Cash and cash equivalents at the end of the period	134,248	138,991

## (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 Events)

(Establishment of a Subsidiary)

On August 1, 2025, the Board of Directors resolved to establish Ono Global Reinsurance, Inc., as a wholly-owned subsidiary. The capital of this subsidiary will be equivalent to 10% or more of the Company's capital, classifying it as a specified subsidiary.

#### (1) Purpose

In order to improve our risk management systems, the Company will establish Ono Global Reinsurance, Inc., a subsidiary that underwrites non-life insurance of the Company and its group companies as reinsurance, for the purpose of establishing and operating stable insurance programs.

#### (2) Outline of Ono Global Reinsurance, Inc.:

Company Name	Ono Global Reinsurance, Inc.
Location	State of Hawaii, USA
Representative	Masaki Itoh, Managing Director
Establishment	December 2025 (planned)
Capital	¥10.0 billion (planned)
Business	Reinsurance underwriting for the Company and its group companies
Relationship	A wholly-owned subsidiary of the Company

## 4. Supplementary Information

### (1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

	Three months ended June 30, 2025 (April 1, 2025 to June 30, 2025)			FY 2025 Forecast (April 1, 2025 to March 31, 2026)		
Product name	Result	YoY		Forecast	YoY	
		Change	Change (%)		Change	Change (%)
<Domestic>						
Opdivo Intravenous Infusion	29.4	(2.6)	(8.2%)	125.0	4.7	3.9%
Forxiga Tablets	25.1	2.9	13.1%	80.0	(9.6)	(10.7%)
Orencia for Subcutaneous Injection	7.0	0.1	1.8%	28.0	1.4	5.2%
Glactiv Tablets	3.6	(1.4)	(28.8%)	12.0	(6.3)	(34.6%)
Velexbru Tablets	3.0	0.3	12.0%	11.0	0.5	4.4%
Ongentys Tablets	2.3	0.3	17.2%	9.0	1.4	17.8%
Parsabiv Intravenous Injection	2.2	0.1	5.9%	9.0	0.6	6.7%
Kyprolis for Intravenous Infusion	2.0	(0.3)	(12.1%)	9.0	0.4	4.6%
<Overseas>						
Opdivo	3.3	0.2	5.5%	13.5	0.4	2.9%
QINLOCK	8.9	—	—	34.0	8.5	33.4%
ROMVIMZA	1.1	—	—	5.0	—	—

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)

	Three months ended June 30, 2024	Three months ended June 30, 2025
Revenue of goods and products	79.3	87.8
Royalty and others	38.3	39.8
Total	117.7	127.5

Note: In "Royalty and others", royalty revenue of Opdivo from Bristol-Myers Squibb Company is included, which is ¥28.5 billion for the first quarter (three months) ended June 30, 2024, and ¥29.2 billion for the first quarter (three months) ended June 30, 2025. Royalty revenue of Keytruda® from Merck & Co., Inc. is also included, which is ¥6.3 billion for the first quarter (three months) ended June 30, 2024, and ¥6.5 billion for the first quarter (three months) ended June 30, 2025.

### (3) Revenue by Geographic Area

(Billions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025
Japan	77.0	75.3
USA	36.6	45.0
Asia	3.5	4.5
Europe	0.5	2.4
Others	—	0.4
Total	117.7	127.5

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

#### (4) Main Status of Development Pipelines

As of August 1, 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) Jun/2025 Approved (South Korea) Jul/2025 Approved (Taiwan) Jul/2025	In-house (Co-development with Bristol-Myers Squibb)
		MSI-H/dMMR colorectal cancer, First-line treatment (Combination with Yervoy)	Filed (Japan) Sep/2024	In-house (Co-development with Bristol-Myers Squibb)
		Hepatocellular carcinoma, Adjuvant therapy	P3	In-house (Co-development with Bristol-Myers Squibb)
		Non-small cell lung cancer, Neoadjuvant and adjuvant therapy (Combination with chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Bladder cancer, Neoadjuvant and adjuvant therapy (Combination with chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Gastric cancer, First-line treatment (Combination with Yervoy/chemotherapy)	P3	In-house (Co-development with Bristol-Myers Squibb)
		Rhabdoid tumor, Second-line treatment	P2	In-house (Co-development with Bristol-Myers Squibb)
		Richter transformation, Second-line treatment	P2	In-house (Co-development with Bristol-Myers Squibb)
ONO-7702 Encorafenib Braftovi (Oral medication)	BRAF inhibitor	Colorectal cancer, First-line treatment, BRAF-mutation (Combination with Cetuximab and chemotherapy (FOLFOX))	Filed (Japan) Dec/2024	In-license (Japan, South Korea) (Pfizer)
DCC-2618 QINLOCK (ripretinib) (Oral medication)	KIT inhibitor	Gastrointestinal stromal tumor, Second-line treatment for patients with KIT exon 11+17/18 mutations	P3	In-house
ONO-4578 (Oral medication)	Prostaglandin receptor (EP4) antagonist	Gastric cancer, First-line treatment (Standard treatment (Opdivo + Chemotherapy) combination)	P2	In-house
		Colorectal cancer, First-line treatment (Opdivo + standard treatment combination)	P2	In-house
		Non-small cell lung cancer, Second-line treatment (Opdivo + standard treatment combination)	P1	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	Hormone receptor-positive, HER2-negative breast cancer, First-line treatment (Standard Treatment Combination)	P1	In-house
ONO-4059 Tirabrutinib Hydrochloride Velexbru (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Primary central nervous system lymphoma, Second-line treatment and beyond	P2 (the U.S.)	In-house
		Primary central nervous system lymphoma, First-line treatment	P2 (the U.S.)	In-house
ONO-0530 Sapablursen (Subcutaneous injection)	TMPRSS6 gene expression inhibitor (Oligonucleotide)	Polycythemia vera	P2	In-license (Ionis Pharmaceuticals, Inc.)
ONO-4482 Relatlimab (Intravenous Injection)	Anti-LAG-3 antibody	Melanoma, Second-line treatment and beyond (Combination with Opdivo)	P1/2	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
ONO-7427 (Intravenous Injection)	Anti-CCR8 antibody	Solid tumor (Combination with Opdivo)	P1/2	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
DCC-3116 inelixisertib (Oral medication)	ULK inhibitor	Solid tumor (Combination with Sotorasib)	P1/2	In-house
		Advanced malignancies (Combination with ripretinib)	P1/2	In-house
DCC-3084 (Oral medication)	Pan-RAF inhibitor	Advanced malignancies	P1/2	In-house
DCC-3009 (Oral medication)	Pan-KIT inhibitor	Gastrointestinal stromal tumor	P1/2	In-house
ONO-7913 Magrolimab (Intravenous Injection)	Anti-CD47 antibody	Pancreatic cancer, First-line treatment (Combination with Opdivo)	P1	In-license (Japan, South Korea, Taiwan, ASEAN) (Gilead Sciences, Inc.)
		Colorectal cancer, First-line treatment (Combination with Opdivo)	P1	In-license (Japan, South Korea, Taiwan, ASEAN) (Gilead Sciences, Inc.)
ONO-4685 (Intravenous Injection)	PD-1 x CD3 bispecific antibody	T-cell lymphoma, Second-line treatment	P1	In-house
ONO-4538HSC (Subcutaneous injection)	A human anti-human PD-1 monoclonal antibody	Solid tumor	P1	In-license (Japan, South Korea, Taiwan) (Co-development with Bristol-Myers Squibb)
ONO-8250 (Intravenous Injection)	iPS cell-derived HER2-targeted CAR-T cell therapeutics	HER2-expressing solid tumors	P1	In-house (Co-development with Fate Therapeutics, Inc.)
ONO-7428 (Intravenous Injection)	Anti-ONCOKINE-1 antibody	Solid tumor	P1	In-license (NEX-I, Inc.)

(Areas Other than Oncology)

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Phase	In-house / In-license
DCC-3014 ROMVIMZA (vimseltinib) (Oral medication)	CSF-1R inhibitor	Tenosynovial giant cell tumor	Filed (Europe) Jul/2024	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 <sub>A</sub> ion channel	Primary generalized tonic-clonic seizures	P3	In-license (Japan) (SK Biopharmaceuticals)
		Partial-onset seizures	P3	In-license (Japan) (SK Biopharmaceuticals)
ONO-4059 Tirabrutinib hydrochloride Velexbru (Oral medication)	BTK (Bruton's tyrosine kinase) inhibitor	Steroid-resistant pemphigus	P3	In-house
Povetacicept (Subcutaneous injection)	BAFF/APRIL dual antagonist	Immunoglobulin A nephropathy (IgAN)	P3	In-license (Japan, South Korea) (Vertex Pharmaceuticals incorporated)
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 fiscal year ended March 31, 2025, is as follows:

**(Oncology)**

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Development status or reason for termination
ONO-4538 Nivolumab Opdivo (Intravenous Injection)	A human anti-human PD-1 monoclonal antibody	Hepatocellular carcinoma, First-line treatment (Combination with Yervoy)	In June 2025, the combination therapy of Opdivo and Yervoy was approved in Japan for the treatment of unresectable hepatocellular carcinoma.
ONO-7475 Tamnorzatinib (Oral medication)	Axl/Mer inhibitor	Pancreatic cancer, First-line treatment (Combination with Opdivo)	In July 2025, phase I of ONO-7475 (Axl/Mer inhibitor) was conducted in Japan, but the project was discontinued due to strategic reasons.
ONO-4538 Nivolumab Opdivo (Intravenous Injection)	A human anti-human PD-1 monoclonal antibody	Hepatocellular carcinoma, First-line treatment (Combination with Yervoy)	In July 2025, the combination therapy of Opdivo and Yervoy was approved in South Korea for the treatment of unresectable or metastatic hepatocellular carcinoma.
ONO-4538 Nivolumab Opdivo (Intravenous Injection)	A human anti-human PD-1 monoclonal antibody	Hepatocellular carcinoma, First-line treatment (Combination with Yervoy)	In July 2025, the combination therapy of Opdivo and Yervoy was approved in Taiwan for the treatment of unresectable or metastatic hepatocellular carcinoma.

**(Area other than oncology)**

Development code Generic name Product name (Dosage form)	Pharmacological Action	Target indication (Combination drug)	Development status or reason for termination
Povetacicept (Subcutaneous Injection)	BAFF/APRIL dual antagonist	Immunoglobulin A nephropathy (IgAN)	In June 2025, the Company entered into a licensing agreement with Vertex Pharmaceuticals Incorporated for "Povetacicept", which is undergoing Phase III trials, as a treatment for Immunoglobulin A nephropathy (IgAN). We acquired the exclusive rights for development and commercialization in Japan and South Korea.