

Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending March 31, 2024 (IFRS)

January 31, 2024

Company name	: ONO PHARMACEUTICAL CO., LTD.
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: https://www.ono-pharma.com/en
Representative	: Gyo Sagara President, Representative Director, and Chief Executive Officer
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Scheduled date of quarterly securities report submission	: February 6, 2024
Scheduled date of dividend payment commencement	: —
Supplementary materials for quarterly financial results	: Yes
Earnings announcement for 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 2023 (April 1, 2023 to December 31, 2023)

(1) Consolidated Operating Results (cumulative)

(% 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 2023 Q3	389,903	15.0	144,626	18.0	147,292	18.4	110,610	15.4	110,544	15.6	117,218	23.0
FY 2022 Q3	339,020	24.9	122,590	49.2	124,379	47.5	95,827	48.2	95,656	48.0	95,297	39.5

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2023 Q3	229.08	229.06
FY 2022 Q3	195.90	195.88

(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, 2023	891,725	790,680	784,657	88.0
As of March 31, 2023	882,437	747,812	741,869	84.1

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 2022	—	33.00	—	37.00	70.00
FY 2023	—	40.00	—		
FY 2023 (Forecast)				40.00	80.00

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

3. Consolidated Financial Forecast for FY 2023 (April 1, 2023 to March 31, 2024)

(% 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 2023	500,000	11.8	167,000	17.6	169,000	17.7	126,200	11.8	126,000	11.8	259.36

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

Notes

- (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None
- (2) Changes in accounting policies and changes in accounting estimates
 - 1) Changes in accounting policies required by IFRS: Yes
 - 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 shares)
 - 1) Number of shares issued and outstanding as of the end of the period (including treasury shares):

As of December 31, 2023	517,425,200 shares
As of March 31, 2023	517,425,200 shares
 - 2) Number of treasury shares as of the end of the period:

As of December 31, 2023	42,672,518 shares
As of March 31, 2023	29,091,218 shares
 - 3) Average number of shares outstanding during the period:

Nine months ended December 31, 2023	482,561,180 shares
Nine months ended December 31, 2022	488,291,864 shares

* This financial results report is not subject to quarterly review procedures by certified public accountants or an auditing firm.

* 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 4 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 FY 2023

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023	Change	Change (%)
Revenue	339,020	389,903	50,883	15.0%
Operating profit	122,590	144,626	22,036	18.0%
Profit before tax	124,379	147,292	22,913	18.4%
Profit for the period (attributable to owners of the Company)	95,656	110,544	14,888	15.6%

[Revenue]

Revenue totaled ¥389.9 billion, which was an increase of ¥50.9 billion (15.0%) from the corresponding period of the previous fiscal year (year on year).

- While the competitive environment intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to treatments for gastric cancer, esophageal cancer, and urothelial carcinoma, etc., resulting in sales of ¥114.9 billion, an increase of ¥5.8 billion (5.3%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure, and chronic kidney disease were ¥57.5 billion (37.3% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥20.0 billion (4.8% increase year on year). Sales of Glectiv Tablets for type-2 diabetes were ¥16.7 billion (5.3% decrease year on year). Sales of Velexbro Tablets for malignant tumors were ¥8.0 billion (22.0% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥7.1 billion (4.8% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥6.4 billion (2.0% decrease year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥4.9 billion (27.0% increase year on year).
- Royalty and others increased by ¥29.5 billion (26.0%) year on year to ¥143.0 billion mainly due to increases in royalty income from Bristol-Myers Squibb Company and Merck & Co., Inc., as well as the Company recorded the lump-sum income of ¥17.0 billion associated with the settlement of the litigation on patents with AstraZeneca UK Limited.

[Operating Profit]

Operating profit was ¥144.6 billion, an increase of ¥22.0 billion (18.0%) year on year.

- Cost of sales increased by ¥11.7 billion (13.9%) year on year to ¥95.5 billion mainly due to an increase in revenue of goods and products and the recording of impairment losses of ¥5.4 billion on sales licenses of Joyclu Intra-Articular Injection and Adlumiz Tablets.
- Research and development costs increased by ¥10.5 billion (15.9%) year on year to ¥76.5 billion mainly due to increases in research costs and development costs for clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.1 billion (10.8%) year on year to ¥73.3 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and expenses associated with IT and digital related information infrastructure enhancements.

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

Profit attributable to owners of the Company increased by ¥14.9 billion (15.6%) year on year to ¥110.5 billion in association with the increase of the profit before tax.

(2) Overview of Financial Position for the 3rd Quarter of FY 2023

(Millions of yen)

	As of March 31, 2023	As of December 31, 2023	Change
Total assets	882,437	891,725	9,288
Equity attributable to owners of the Company	741,869	784,657	42,789
Ratio of equity attributable to owners of the Company to total assets	84.1%	88.0%	
Equity attributable to owners of the Company per share	1,519.19 yen	1,652.80 yen	

Total assets increased to ¥891.7 billion by ¥9.3 billion from the end of the previous fiscal year.

Current assets increased by ¥9.2 billion to ¥354.3 billion mainly due to increases in “trade and other receivables” and “cash and cash equivalents”, despite there being a decrease in “other financial assets”.

Non-current assets increased by ¥0.1 billion to ¥537.5 billion mainly due to an increase in “investment securities”, despite there being a decrease in “intangible assets”.

Liabilities decreased by ¥33.6 billion to ¥101.0 billion mainly due to decreases in “income taxes payable” and “trade and other payables”.

Equity attributable to owners of the Company increased by ¥42.8 billion to ¥784.7 billion mainly due to the recording of the profit for the period, despite there being purchase of treasury shares and cash dividends.

(3) Overview of Cash Flows for the 3rd Quarter of FY 2023

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023	Change
Cash and cash equivalents at the beginning of the period	69,112	96,135	
Cash flows from operating activities	115,064	61,498	(53,565)
Cash flows from investing activities	(44,852)	19,373	64,224
Cash flows from financing activities	(30,872)	(75,358)	(44,486)
Net increase (decrease) in cash and cash equivalents	39,340	5,513	
Effects of exchange rate changes on cash and cash equivalents	141	599	
Cash and cash equivalents at the end of the period	108,593	102,247	

Net increase/decrease in cash and cash equivalents for the third quarter (nine months) of the fiscal year 2023 was an increase of ¥5.5 billion.

Net cash provided by operating activities was ¥61.5 billion, as a result of profit before tax of ¥147.3 billion, etc., while there were income taxes paid of ¥56.2 billion and an increase in trade and other receivables of ¥34.7 billion, etc.

Net cash provided by investing activities was ¥19.4 billion, as a result of proceeds from withdrawal of time deposits of ¥63.0 billion, while there were payments into time deposits of ¥33.0 billion and purchase of intangible assets of ¥7.0 billion, etc.

Net cash used in financing activities was ¥75.4 billion, as a result of purchase of treasury shares of ¥37.3 billion and dividends paid of ¥36.2 billion, etc.

(4) Future Outlook

There are no changes from the consolidated financial forecast for the year ending March 31, 2024, announced on November 1, 2023.

2. Basic Approach to the Selection of Accounting Standards

Our group has applied International Financial Reporting Standards (IFRSs) 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, 2023	As of December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	96,135	102,247
Trade and other receivables	114,396	150,497
Marketable securities	20	20
Other financial assets	68,134	33,289
Inventories	44,814	46,416
Other current assets	21,602	21,803
Total current assets	345,101	354,272
Non-current assets		
Property, plant, and equipment	108,420	104,778
Intangible assets	69,134	58,987
Investment securities	123,308	133,286
Investments in associates	115	118
Other financial assets	197,441	202,530
Deferred tax assets	35,604	34,863
Other non-current assets	3,314	2,891
Total non-current assets	537,336	537,453
Total assets	882,437	891,725

(Millions of yen)

	As of March 31, 2023	As of December 31, 2023
Liabilities and Equity		
Current liabilities		
Trade and other payables	66,794	53,112
Lease liabilities	2,490	2,266
Other financial liabilities	661	5,716
Income taxes payable	34,575	16,821
Other current liabilities	18,409	11,793
Total current liabilities	122,929	89,708
Non-current liabilities		
Lease liabilities	6,678	6,320
Other financial liabilities	0	0
Retirement benefit liabilities	3,350	3,465
Deferred tax liabilities	983	1,004
Other non-current liabilities	684	548
Total non-current liabilities	11,695	11,337
Total liabilities	134,625	101,045
Equity		
Share capital	17,358	17,358
Capital reserves	17,080	17,113
Treasury shares	(54,161)	(91,326)
Other components of equity	51,701	57,294
Retained earnings	709,890	784,218
Equity attributable to owners of the Company	741,869	784,657
Non-controlling interests	5,944	6,023
Total equity	747,812	790,680
Total liabilities and equity	882,437	891,725

**(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, 2022	Nine months ended December 31, 2023
Revenue	339,020	389,903
Cost of sales	(83,787)	(95,462)
Gross profit	255,233	294,441
Selling, general, and administrative expenses	(66,147)	(73,295)
Research and development costs	(65,974)	(76,493)
Other income	518	979
Other expenses	(1,041)	(1,007)
Operating profit	122,590	144,626
Finance income	2,409	3,120
Finance costs	(624)	(458)
Share of profit (loss) from investments in associates	4	4
Profit before tax	124,379	147,292
Income tax expense	(28,551)	(36,682)
Profit for the period	95,827	110,610
Profit for the period attributable to:		
Owners of the Company	95,656	110,544
Non-controlling interests	172	66
Profit for the period	95,827	110,610
Earnings per share:		
Basic earnings per share (Yen)	195.90	229.08
Diluted earnings per share (Yen)	195.88	229.06

Condensed Interim Consolidated Statement of Comprehensive Income

	(Millions of yen)	
	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Profit for the period	95,827	110,610
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	(743)	6,728
Remeasurements of defined benefit plans	(41)	(79)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	(4)
Total of items that will not be reclassified to profit or loss	(781)	6,645
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	377	1,000
Net fair value gain (loss) on cash flow hedges	(127)	(1,038)
Total of items that may be reclassified subsequently to profit or loss	250	(38)
Total other comprehensive income	(530)	6,608
Total comprehensive income for the period	95,297	117,218
Comprehensive income for the period attributable to:		
Owners of the Company	95,137	117,129
Non-controlling interests	160	88
Total comprehensive income for the period	95,297	117,218

(3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 2022

(Millions of yen)

	Equity attributable to owners of the Company							Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
Balance as of April 1, 2022	17,358	17,241	(74,683)	51,236	644,754	655,906	5,768	661,674
Profit for the period					95,656	95,656	172	95,827
Other comprehensive income				(519)		(519)	(12)	(530)
Total comprehensive income for the period	—	—	—	(519)	95,656	95,137	160	95,297
Purchase of treasury shares			(2)			(2)		(2)
Retirement of treasury shares		(20,356)	20,356			—		—
Disposition of treasury shares		(168)	168			—		—
Cash dividends					(29,786)	(29,786)	(6)	(29,792)
Share-based payments		130				130		130
Transfer from retained earnings to capital reserves		20,233			(20,233)	—		—
Transfer from other components of equity to retained earnings				(2,311)	2,311	—		—
Total transactions with the owners	—	(161)	20,522	(2,311)	(47,708)	(29,658)	(6)	(29,665)
Balance as of December 31, 2022	17,358	17,080	(54,161)	48,407	692,702	721,385	5,921	727,307

Nine months ended December 31, 2023

(Millions of yen)

	Equity attributable to owners of the Company							Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
Balance as of April 1, 2023	17,358	17,080	(54,161)	51,701	709,890	741,869	5,944	747,812
Profit for the period					110,544	110,544	66	110,610
Other comprehensive income				6,586		6,586	22	6,608
Total comprehensive income for the period	—	—	—	6,586	110,544	117,129	88	117,218
Purchase of treasury shares			(37,251)			(37,251)		(37,251)
Disposition of treasury shares		(1)	86			86		86
Cash dividends					(37,208)	(37,208)	(9)	(37,217)
Share-based payments		33				33		33
Transfer from other components of equity to retained earnings				(992)	992	—		—
Total transactions with the owners	—	33	(37,165)	(992)	(36,216)	(74,341)	(9)	(74,349)
Balance as of December 31, 2023	17,358	17,113	(91,326)	57,294	784,218	784,657	6,023	790,680

(4) Condensed Interim Consolidated Statement of Cash Flows

	(Millions of yen)	
	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Cash flows from operating activities		
Profit before tax	124,379	147,292
Depreciation and amortization	12,953	13,429
Impairment losses	1,154	5,447
Interest and dividend income	(2,327)	(3,117)
Interest expense	48	70
(Increase) decrease in inventories	(2,926)	(1,330)
(Increase) decrease in trade and other receivables	(23,818)	(34,696)
Increase (decrease) in trade and other payables	2,023	(7,718)
Increase (decrease) in retirement benefit liabilities	171	2
(Increase) decrease in retirement benefit assets	22	—
Increase (decrease) in accrued consumption tax	4,984	(3,614)
Other	2,738	(571)
Subtotal	119,402	115,195
Interest received	27	167
Dividends received	2,305	2,410
Interest paid	(48)	(70)
Income taxes paid	(6,622)	(56,203)
Net cash provided by (used in) operating activities	115,064	61,498
Cash flows from investing activities		
Purchase of property, plant, and equipment	(3,944)	(3,270)
Proceeds from sales of property, plant, and equipment	5	869
Purchase of intangible assets	(6,103)	(7,023)
Purchase of investments	(1,613)	(2,932)
Proceeds from sales and redemption of investments	7,367	2,820
Payments into time deposits	(52,975)	(33,009)
Proceeds from withdrawal of time deposits	12,811	63,009
Other	(400)	(1,092)
Net cash provided by (used in) investing activities	(44,852)	19,373
Cash flows from financing activities		
Dividends paid	(28,800)	(36,152)
Dividends paid to non-controlling interests	(6)	(9)
Repayments of lease liabilities	(2,065)	(1,946)
Purchase of treasury shares	(1)	(37,251)
Net cash provided by (used in) financing activities	(30,872)	(75,358)
Net increase (decrease) in cash and cash equivalents	39,340	5,513
Cash and cash equivalents at the beginning of the period	69,112	96,135
Effects of exchange rate changes on cash and cash equivalents	141	599
Cash and cash equivalents at the end of the period	108,593	102,247

(5) Notes to Condensed Interim Consolidated Financial Statements

(Note Regarding Assumption of Going Concern)

Not Applicable

(Changes in Accounting Policies)

Our Group has applied the following standard from the first quarter of the fiscal year ending March 31, 2024.

IFRS		Overview of establishment and amendments
IAS 12	Income Taxes	Clarification of accounting treatment for deferred taxes on lease and decommissioning obligations

Application of this standard does not have a material impact on our group's condensed interim consolidated financial statements.

(Segment Information)

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

(Significant Subsequent Events)

Not applicable

4. Supplementary Information

(1) Sales Revenue and Forecast of Major Products

(Billions of yen)

Product Name	Nine months ended December 31, 2023 (April 1, 2023 to December 31, 2023)						FY 2023 Forecast (April 1, 2023 to March 31, 2024)				
	Cumulative				YoY		Previous Forecast	Change from Previous Forecast	Revised Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	37.8	37.3	39.9	114.9	5.8	5.3%	155.0	(5.0)	150.0	7.7	5.4%
Forxiga Tablets	17.5	18.4	21.6	57.5	15.6	37.3%	70.0	5.0	75.0	18.5	32.7%
Orencia for Subcutaneous Injection	6.6	6.5	7.0	20.0	0.9	4.8%	25.5		25.5	0.7	3.0%
Glactiv Tablets	5.6	5.2	5.9	16.7	(0.9)	(5.3%)	21.0		21.0	(1.5)	(6.7%)
Velexbru Tablets	2.6	2.4	2.9	8.0	1.4	22.0%	9.5		9.5	1.0	11.3%
Kyprolis for Intravenous Infusion	2.2	2.4	2.5	7.1	0.3	4.8%	8.5		8.5	(0.2)	(2.3%)
Parsabiv Intravenous Injection	2.1	2.1	2.3	6.4	(0.1)	(2.0%)	8.0		8.0	(0.4)	(4.8%)
Ongentys Tablets	1.6	1.5	1.8	4.9	1.0	27.0%	6.5		6.5	1.5	30.5%
Onoact for Intravenous Infusion	1.0	1.0	1.3	3.4	(0.2)	(5.2%)	4.5		4.5	0.0	0.4%
Braftovi Capsules	0.9	0.9	0.9	2.7	0.2	6.2%	4.0		4.0	0.8	23.2%
Opalmon Tablets	1.0	0.9	1.0	2.9	(0.6)	(16.0%)	3.5		3.5	(0.9)	(19.9%)
Mektovi Tablets	0.7	0.7	0.7	2.0	0.0	2.1%	3.0		3.0	0.5	18.1%

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).

2. Regarding sales revenue forecast for the fiscal year ending March 31, 2024, only currently approved indications are covered.

(2) Details of Sales Revenue

(Billions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Revenue of goods and products	225.5	246.9
Royalty and others	113.5	143.0
Total	339.0	389.9

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥66.8 billion for the third quarter (nine months) ended December 31, 2022, and ¥73.9 billion for the third quarter (nine months) ended December 31, 2023. Royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥33.6 billion for the third quarter (nine months) ended December 31, 2022, and ¥38.9 billion for the third quarter (nine months) ended December 31, 2023.

(3) Revenue by Geographic Area

(Billions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Japan	220.6	240.2
Americas	106.4	118.6
Europe	3.4	20.6
Asia	8.6	10.4
Total	339.0	389.9

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

2. Due to the change in the place of a customer, we revised the classification of revenue by geographic area.

Therefore, revenue by geographic area is reclassified for the nine months ended December 31, 2022.

(4) Main Status of Development Pipelines (Oncology)

As of January 24, 2024

<Approved>

*) : “In-house” compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Malignant mesothelioma *1 (excluding malignant pleural mesothelioma)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

The change from the announcement of financial results for the second quarter of the fiscal year ending March 31, 2024, is as follows:

*1: An application of Opdivo was approved in Japan for the treatment of malignant mesothelioma (excluding malignant pleural methelioma).

<Filed>

*) : “In-house” compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Malignant epithelial tumors	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

<Clinical Trial Stage>

<Opdivo> *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
<Yervoy> *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

< ONO-4538 Subcutaneous Injection > *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-4538 HSC	New chemical entities	Solid tumor *2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
<I-O Related> *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-4578 *	New chemical entities	Gastric cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan S. Korea Taiwan	II	In-house
ONO-4482 * (BMS-986016) / Relatlimab	New chemical entities	Hepatocellular carcinoma / Anti-LAG-3 antibody	Injection	Japan S. Korea Taiwan	II	In-license (Co-development with Bristol-Myers Squibb)
	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 * / Tamnorratinib	New chemical entities	Pancreatic cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578 *	New chemical entities	Colorectal cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 * / Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 * / Atamparib	New chemical entities	Solid tumor / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)
ONO-7122 *	New chemical entities	Solid tumor / TGF-β inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 *	New chemical entities	Solid tumor / STING agonist	Injection	Japan	I	In-house
ONO-7226 *	New chemical entities	Solid tumor / Anti-ILT4 antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

The change from the announcement of financial results for the second quarter of the fiscal year ending March 31, 2024, is as follows:

*2: Phase I of subcutaneous injection “ONO-4538HSC (combination drug comprising nivolumab and vorhyaluronidase alfa)” for ONO-4538 was initiated in Japan for the treatment of solid tumor.

In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

<Others>						
*) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-7913 / Magrolimab	New chemical entities	Acute myeloid leukemia / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, Inc.)
ONO-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475 / Tammorzatinib	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578	New chemical entities	Hormone receptor-positive, HER2-negative breast cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma / PD-1 x CD3 bispecific antibody	Injection	Japan USA	I	In-house
ONO-7018	New chemical entities	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia / MALT1 inhibitor	Tablet	USA	I	In-license (Chordia Therapeutics Inc.)
ONO-8250 *3	New chemical entities	HER2-expressing solid tumors / iPS cell-derived HER2-targeted CAR-T cell therapeutics	Injection	USA	I	In-license (Fate Therapeutics, Inc.)

The changes from the announcement of financial results for the second quarter of the fiscal year ending March 31, 2024, are as follows:

*3: Phase I of ONO-8250 (iPS cell-derived HER2-targeted CAR-T cell therapeutics) was initiated in the U.S. for the treatment of HER2-expressing solid tumor.

* The Company had participated in multi-center trials of “ONO-7121”, a combination drug comprising Opdivo and relatlimab, its anti-LAG-3 antibody, for the treatment of colorectal cancer led by Bristol-Myers Squibb Company from Japan, South Korea and Taiwan. However, it was discontinued due to futility based on the analysis conducted by an independent data monitoring committee.

In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

(5) Main Status of Development Pipelines (Areas other than Oncology)

As of January 24, 2024

<Clinical Trial Stage>

*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-2017 / Cenobamate	New chemical entities	Primary generalized tonic-clonic seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
	New chemical entities	Partial-onset seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	III	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
	New chemical entities	Chemotherapy-induced peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-2808	New chemical entities	Multiple system atrophy / S1P5 receptor agonist	Tablet	USA	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house
ONO-1110	New chemical entities	Pain / Endocannabinoid regulation	Oral	Japan	I	In-house