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

November 1, 2023

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 : November 7, 2023
Scheduled date of dividend payment commencement : December 1, 2023
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 Second Quarter of FY 2023 (April 1, 2023 to September 30, 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 Q2	258,713	19.4	97,036	20.9	99,296	22.6	74,520	19.3	74,491	19.5	80,632	29.5
FY 2022 Q2	216,701	24.5	80,270	38.0	81,019	36.8	62,442	34.8	62,339	34.7	62,263	19.2

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2023 Q2	153.33	153.32
FY 2022 Q2	127.67	127.66

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets
	Million yen	Million yen	Million yen	%
As of September 30, 2023	895,918	783,288	777,290	86.8
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: Yes

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 September 30, 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 September 30, 2023	38,934,293	shares
As of March 31, 2023	29,091,218	shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2023	485,813,059	shares
Six months ended September 30, 2022	488,277,710	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 forecast, and other comments in particular
Forecast 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 6 for information regarding the consolidated financial forecast.

Index of the Attachment

1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of FY 2023

① Overview of Financial Results

(Millions of yen)

	Six months ended September 30, 2022	**Six months ended September 30, 2023**	Change	Change (%)
Revenue	216,701	**258,713**	42,012	19.4%
Operating profit	80,270	**97,036**	16,766	20.9%
Profit before tax	81,019	**99,296**	18,277	22.6%
Profit for the period (attributable to owners of the Company)	62,339	**74,491**	12,153	19.5%

[Revenue]

Revenue totaled ¥258.7 billion, which was an increase of ¥42.0 billion (19.4%) 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 ¥75.0 billion, an increase of ¥5.1 billion (7.3%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure, and chronic kidney disease were ¥35.9 billion (36.1% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.0 billion (4.5% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥10.8 billion (7.5% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥5.0 billion (22.0% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.6 billion (3.9% increase year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.1 billion (2.9% decrease year on year). Sales of Ongentys Tablets for parkinson's disease were ¥3.1 billion (27.9% increase year on year).
- Royalty and others increased by ¥27.0 billion (37.6%) year on year to ¥98.8 billion 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 ¥97.0 billion, an increase of ¥16.8 billion (20.9%) year on year.

- Cost of sales increased by ¥11.1 billion (20.6%) year on year to ¥64.8 billion mainly due to increases 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 ¥9.7 billion (24.6%) year on year to ¥49.4 billion mainly due to increases in research costs, costs for drug discovery collaborations, development costs for clinical trials, and joint development costs for in-licensed products, etc.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥4.7 billion (10.8%) year on year to ¥47.6 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 ¥12.2 billion (19.5%) year on year to ¥74.5 billion in association with the increase of the profit before tax.

② Research & Development Activities

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

Currently, the development pipeline comprises new drug candidate compounds of anticancer drugs including antibody drugs in addition to Opdivo, candidates for treatment of autoimmune disease and neurological disorder, and so on, and development is proceeding. Among these, the area of cancer is positioned as an important strategic field because medical needs are high.

In drug discovery research, we focus on the areas of oncology, immunology, neurology and specialties; all of which include diseases with high medical needs. In each of these areas, we are working to strengthen our drug discovery capabilities by delving into the biology of human disease with the aim of discovering new drugs that can satisfy medical needs. To that end, by actively promoting "open innovation", which is one of our strengths, we aim to discover original drug discovery seeds and create breakthrough new drugs with medical impact by utilizing a variety of cutting-edge internal and external technologies, such as informatics, human disease modeling, and the discovery of new drug candidate compounds.

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

In order to boost development speed and success rates, we are carrying out various types of analysis, etc., by using accumulated clinical trial data and samples gained through actual clinical trials. Moreover, to maximize the value of new drug candidate compounds, we collaborate with the Discovery & Research from the research stage to begin drawing up development strategies early on and conduct clinical trials for multiple diseases. By working to enhance our clinical development functions in Europe and the USA, we are building a framework that enables clinical trials to be implemented around the world (Japan, the USA, and Europe).

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

The main results of research and development activities during the second quarter (six months) ended September 30, 2023 (including those on and after September 30, 2023) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

"Opdivo / Nivolumab"

Malignant epithelial tumors

- In June 2023, an application for approval of Opdivo was filed in Japan for the treatment of malignant epithelial tumors.

Prostate cancer

- In August 2023, phase III of Opdivo for the treatment of prostate cancer was conducted in Japan, South Korea, and Taiwan, but the project was discontinued due to the results not being able to confirm efficacy.

"Braftovi Capsules / Encorafenib" and "Mektovi Tablets / Binimetinib"

- In May 2023, applications for approval of Braftovi Capsules and Mektovi Tablets were filed in Japan for the treatment of radically unresectable BRAF-mutant thyroid cancer, in doublet combination therapy with Braftovi and Mektovi.

"ONO-4686"

- In October 2023, although the Company participated in phase I/II trials from Japan for the treatment of solid tumors under the leadership of Bristol-Myers Squibb Company in combination therapy with Opdivo and ONO-4686 (Anti-TIGIT antibody), the project was discontinued due to strategic reasons.

"ONO-4578"

- Phase II of combination therapy with Opdivo and ONO-4578 (Prostaglandin receptor antagonist) for the treatment of gastric cancer was initiated in Japan in August 2023, and in South Korea and Taiwan in October 2023.

"ONO-4685"

- In September 2023, Phase I of ONO-4685 (PD-1 x CD3 bispecific antibody) was initiated in Japan for the treatment of T-cell lymphoma.

"ONO-7226"

- In May 2023, Phase I of combination therapy with Opdivo and ONO-7226 (Anti-ILT4 antibody) was initiated in Japan for the treatment of solid tumor.

"ONO-7475"

- In August 2023, Phase I of combination therapy with Opdivo and ONO-7475 (Axl/Mer inhibitor) was initiated in Japan for the treatment of pancreatic cancer.

"ONO-7913"

- In September 2023, phase I of ONO-7913 (Anti-CD47 antibody) was conducted in Japan for the treatment of myelodysplastic syndrome, but the project was discontinued because overseas phase III trials (ENHANCE trials) for the same group of patients, which were carried out under the leadership of Gilead Sciences, Inc., were discontinued due to being ineffectual.

- In October 2023, the Company participated in collaborative international phase III trials of ONO-7913 (Anti-CD47 antibody) from Japan for the treatment of TP53-mutant acute myeloid leukemia under the leadership of Gilead Sciences, Inc., but the project was discontinued due to not being able to confirm efficacy.

"ONO-7121"

- Phase III of ONO-7121 (A combination drug comprising Opdivo and anti-LAG-3 antibodies) is being conducted in Japan, South Korea, and Taiwan for the treatment of colorectal cancer.

"ONO-4482"

- Phase II of combination therapy with Opdivo and ONO-4482 (Anti-LAG-3 antibody) is being conducted in Japan, South Korea, and Taiwan for the treatment of hepatocellular carcinoma.

<Areas other than Oncology>

"ONO-2910"

-In June 2023, phase II of ONO-2910 (a Schwann cell differentiation promoter) was initiated in Japan for the treatment of chemotherapy-induced peripheral neuropathy.

"ONO-2808"

-In July 2023, phase II of ONO-2808 (S1P5 receptor agonist) was initiated in the USA for the treatment of multiple system atrophy.

"ONO-7684"

-In August 2023, phase I of ONO-7684 (FXIa inhibitor) for the treatment of thrombosis was conducted in Japan and Europe, but the project was discontinued due to strategic reasons.

[Status of Drug Discovery / Research Alliance Activities]

- In August 2023, the Company entered into a drug discovery collaboration agreement with Twist Bioscience Corporation in the USA to discover and develop innovative antibodies for autoimmune diseases by utilizing the Twist Biopharma Solutions Library of Libraries.
- In September 2023, the Company entered into a drug discovery collaboration agreement with Adimab, LLC in the USA to discover bispecific antibody product candidates in the oncology field by utilizing the Adimab's therapeutic antibody discovery and engineering technologies.
- In October 2023, the Company entered into a research collaboration agreement with Turbine in UK to identify and validate novel therapeutic targets in the field of oncology by utilizing the Turbine's AI-driven cell simulation platform.

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

(Millions of yen)

	As of March 31, 2023	**As of September 30, 2023**	Change
Total assets	882,437	**895,918**	13,481
Equity attributable to owners of the Company	741,869	**777,290**	35,422
Ratio of equity attributable to owners of the Company to total assets	84.1%	**86.8%**	
Equity attributable to owners of the Company per share	1,519.19 yen	**1,624.50 yen**	

Total assets increased to ¥895.9 billion by ¥13.5 billion from the end of the previous fiscal year.
Current assets increased by ¥10.2 billion to ¥355.3 billion mainly due to increases in "trade and other receivables" and "cash and cash equivalents", despite a decrease in other financial assets.
Non-current assets increased by ¥3.3 billion to ¥540.6 billion mainly due to an increase in investment securities, despite a decrease in intangible assets.
Liabilities decreased by ¥22.0 billion to ¥112.6 billion mainly due to decreases in trade and other payables and income taxes payable.
Equity attributable to owners of the Company increased by ¥35.4 billion to ¥777.3 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 2nd Quarter of FY 2023

(Millions of yen)

	Six months ended September 30, 2022	**Six months ended September 30, 2023**	Change
Cash and cash equivalents at the beginning of the period	69,112	**96,135**	
Cash flows from operating activities	80,977	**36,721**	(44,256)
Cash flows from investing activities	(37,925)	**20,713**	58,638
Cash flows from financing activities	(15,065)	**(46,647)**	(31,582)
Net increase (decrease) in cash and cash equivalents	27,987	**10,787**	
Effects of exchange rate changes on cash and cash equivalents	653	**782**	
Cash and cash equivalents at the end of the period	97,752	**107,704**	

Net increase/decrease in cash and cash equivalents for the second quarter (six months) of the fiscal year ending March 31, 2024, was an increase of ¥10.8 billion.
Net cash provided by operating activities was ¥36.7 billion, as a result of profit before tax of ¥99.3 billion, etc., while there were income taxes paid of ¥34.8 billion and an increase in trade and other receivables of ¥26.0 billion, etc.
Net cash provided by investing activities was ¥20.7 billion, as a result of proceeds from withdrawal of time deposits of ¥60.5 billion, etc., while there were payments into time deposits of ¥30.5 billion and purchase of intangible assets of ¥6.4 billion, etc.
Net cash used in financing activities was ¥46.6 billion, as a result of purchase of treasury shares of ¥27.2 billion and dividends paid of ¥18.0 billion, etc.

(4) Future Outlook

The forecast of consolidated financial results for the fiscal year ending March 31, 2024, as announced on May 10, 2023, has been revised as follows:

Revisions to the forecast of consolidated financial results for the fiscal year ending March 31, 2024
(April 1, 2023 to March 31, 2024)

(Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit for the year	Profit attributable to owners of the Company	Basic earnings per share
Previous forecast (A)	475,000	153,000	154,000	115,200	115,000	235.49 yen
Revised forecast (B)	500,000	167,000	169,000	126,200	126,000	259.36 yen
Change (B-A)	25,000	14,000	15,000	11,000	11,000	
Change (%)	5.3%	9.2%	9.7%	9.5%	9.6%	
(Reference) Consolidated results of FY 2022	447,187	141,963	143,532	112,913	112,723	230.85 yen

Note: The previous forecast was based on an assumed foreign exchange rate of 1 USD=130 yen, which has been revised to 1 USD =140 yen in the revised forecast for the second half.

Revenue is forecasted to be ¥500.0 billion, an upward revision of ¥25.0 billion from the previously announced forecast, mainly due to expected sales of Forxiga Tablets of ¥70.0 billion, an upward revision of ¥5.0 billion from the previously announced forecast, and the recording of the lump-sum income of ¥17.0 billion associated with the settlement of the litigation on patents with AstraZeneca UK Limited.

Cost of sales is forecasted to be ¥122.0 billion, an upward revision of ¥9.0 billion from the previously announced forecast, mainly due to an increase associated with the revision to the revenue forecast of goods and products, as well as the recording of impairment losses of ¥5.4 billion on sales licenses of Joyclu Intra-Articular Injection and Adlumiz Tablets.

A forecast of research and development costs is not revised from the previously announced forecast.

Selling, general, and administrative expenses (except for research and development costs) are forecasted to be ¥98.0 billion, an upward revision of ¥2.0 billion from the previously announced forecast, mainly due to an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, as well as expenses associated with IT and digital-related information infrastructure enhancements.

As a result, operating profit is forecasted to be ¥167.0 billion (up ¥14.0 billion from the previously announced forecast). Profit before tax is forecasted to be ¥169.0 billion (up ¥15.0 billion). Profit for the year is forecasted to be ¥126.2 billion (up ¥11.0 billion). Profit attributable to owners of the Company is forecasted to be ¥126.0 billion (up ¥11.0 billion).

Note: The financial forecasts and statements contained in this announcement are prepared based on information that is available as of the date the announcement is made. Actual results may differ from those set forth in the announcements due to various uncertain factors.

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 September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	96,135	107,704
Trade and other receivables	114,396	141,668
Marketable securities	20	20
Other financial assets	68,134	33,409
Inventories	44,814	48,588
Other current assets	21,602	23,881
Total current assets	345,101	355,271
Non-current assets		
Property, plant, and equipment	108,420	105,917
Intangible assets	69,134	60,399
Investment securities	123,308	133,851
Investments in associates	115	124
Other financial assets	197,441	202,536
Deferred tax assets	35,604	35,006
Other non-current assets	3,314	2,815
Total non-current assets	537,336	540,647
Total assets	882,437	895,918

(Millions of yen)

	As of March 31, 2023	As of September 30, 2023
Liabilities and Equity		
Current liabilities		
Trade and other payables	66,794	52,973
Lease liabilities	2,490	2,338
Other financial liabilities	661	6,107
Income taxes payable	34,575	25,675
Other current liabilities	18,409	13,929
Total current liabilities	122,929	101,023
Non-current liabilities		
Lease liabilities	6,678	6,636
Other financial liabilities	0	0
Retirement benefit liabilities	3,350	3,419
Deferred tax liabilities	983	1,016
Other non-current liabilities	684	536
Total non-current liabilities	11,695	11,607
Total liabilities	134,625	112,630
Equity		
Share capital	17,358	17,358
Capital reserves	17,080	17,102
Treasury shares	(54,161)	(81,262)
Other components of equity	51,701	56,757
Retained earnings	709,890	767,335
Equity attributable to owners of the Company	741,869	777,290
Non-controlling interests	5,944	5,998
Total equity	747,812	783,288
Total liabilities and equity	882,437	895,918

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Revenue	216,701	258,713
Cost of sales	(53,712)	(64,765)
Gross profit	162,990	193,948
Selling, general, and administrative expenses	(42,945)	(47,604)
Research and development costs	(39,628)	(49,360)
Other income	457	894
Other expenses	(602)	(842)
Operating profit	80,270	97,036
Finance income	1,224	2,321
Finance costs	(478)	(64)
Share of profit (loss) from investments in associates	3	4
Profit before tax	81,019	99,296
Income tax expense	(18,577)	(24,776)
Profit for the period	62,442	74,520
Profit for the period attributable to:		
Owners of the Company	62,339	74,491
Non-controlling interests	103	29
Profit for the period	62,442	74,520
Earnings per share:		
Basic earnings per share (Yen)	127.67	153.33
Diluted earnings per share (Yen)	127.66	153.32

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Profit for the period	62,442	74,520
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	(1,394)	7,630
Remeasurements of defined benefit plans	(26)	(50)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	1	4
Total of items that will not be reclassified to profit or loss	(1,418)	7,584
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	1,206	1,709
Net fair value gain (loss) on cash flow hedge	32	(3,182)
Total of items that may be reclassified subsequently to profit or loss	1,239	(1,472)
Total other comprehensive income	(180)	6,112
Total comprehensive income for the period	62,263	80,632
Comprehensive income for the period attributable to:		
Owners of the Company	62,166	80,569
Non-controlling interests	96	63
Total comprehensive income for the period	62,263	80,632

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 2022

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
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					62,339	62,339	103	62,442
Other comprehensive income				(173)		(173)	(7)	(180)
Total comprehensive income for the period	—	—	—	(173)	62,339	62,166	96	62,263
Purchase of treasury shares			(2)			(2)		(2)
Retirement of treasury shares		(20,356)	20,356			—		—
Disposition of treasury shares		(168)	168			—		—
Cash dividends					(13,671)	(13,671)	(6)	(13,677)
Share-based payments		118				118		118
Transfer from retained earnings to capital reserves		20,245			(20,245)	—		—
Transfer from other components of equity to retained earnings				(2,223)	2,223	—		—
Total transactions with the owners	—	(161)	20,522	(2,223)	(31,693)	(13,555)	(6)	(13,562)
Balance as of September 30, 2022	17,358	17,080	(54,161)	48,841	675,400	704,518	5,858	710,375

Six months ended September 30, 2023

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
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					74,491	74,491	29	74,520
Other comprehensive income				6,078		6,078	34	6,112
Total comprehensive income for the period	—	—	—	6,078	74,491	80,569	63	80,632
Purchase of treasury shares			(27,187)			(27,187)		(27,187)
Disposition of treasury shares		(1)	86			86		86
Cash dividends					(18,068)	(18,068)	(9)	(18,077)
Share-based payments		23				23		23
Transfer from other components of equity to retained earnings				(1,022)	1,022	—		—
Total transactions with the owners	—	22	(27,101)	(1,022)	(17,047)	(45,148)	(9)	(45,156)
Balance as of September 30, 2023	17,358	17,102	(81,262)	56,757	767,335	777,290	5,998	783,288

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from operating activities		
Profit before tax	81,019	99,296
Depreciation and amortization	8,629	9,086
Impairment losses	—	5,440
Interest and dividend income	(1,218)	(1,607)
Interest expense	32	46
(Increase) decrease in inventories	(2,024)	(3,476)
(Increase) decrease in trade and other receivables	(11,671)	(25,992)
Increase (decrease) in trade and other payables	45	(7,538)
Increase (decrease) in retirement benefit liabilities	81	(2)
(Increase) decrease in retirement benefit assets	18	—
Increase (decrease) in accrued consumption tax	2,151	(4,451)
Other	1,816	(595)
Subtotal	78,878	70,206
Interest received	22	66
Dividends received	1,206	1,271
Interest paid	(32)	(46)
Income taxes refund (paid)	904	(34,776)
Net cash provided by (used in) operating activities	80,977	36,721
Cash flows from investing activities		
Purchase of property, plant, and equipment	(3,267)	(2,510)
Proceeds from sales of property, plant, and equipment	0	842
Purchase of intangible assets	(2,138)	(6,381)
Purchase of investments	(1,143)	(1,918)
Proceeds from sales and redemption of investments	7,062	2,820
Payments into time deposits	(50,100)	(30,455)
Proceeds from withdrawal of time deposits	12,110	60,455
Other	(450)	(2,140)
Net cash provided by (used in) investing activities	(37,925)	20,713
Cash flows from financing activities		
Dividends paid	(13,650)	(18,049)
Dividends paid to non-controlling interests	(6)	(9)
Repayments of lease liabilities	(1,407)	(1,402)
Purchase of treasury shares	(1)	(27,187)
Net cash provided by (used in) financing activities	(15,065)	(46,647)
Net increase (decrease) in cash and cash equivalents	27,987	10,787
Cash and cash equivalents at the beginning of the period	69,112	96,135
Effects of exchange rate changes on cash and cash equivalents	653	782
Cash and cash equivalents at the end of the period	97,752	107,704

(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.

2nd Quarter of Fiscal Year 2023 (Ending March 31, 2024)
(April 1, 2023 to September 30, 2023)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2023 (Ending March 31, 2024 (IFRS)】

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

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2023 (IFRS)

(Billions of yen)

	Six months ended September 30, 2022	**Six months ended September 30, 2023**	YoY	Full year ended March 31, 2023
Revenue	216.7	**258.7**	19.4%	447.2
Operating profit	80.3	**97.0**	20.9%	142.0
Profit before tax	81.0	**99.3**	22.6%	143.5
Profit for the year (attributable to owners of the Company)	62.3	**74.5**	19.5%	112.7

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

1. Revenue ¥258.7 billion YoY an increase of 19.4% (FY 2022 2Q YTD ¥216.7 billion)

- While the competitive environment intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to treatments for gastric cancer, esophageal cancer, and urothelial cancer etc., resulting in sales of ¥75.0 billion, an increase of ¥5.1 billion (7.3%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure, and chronic kidney disease were ¥35.9 billion (36.1% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.0 billion (4.5% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥10.8 billion (7.5% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥5.0 billion (22.0% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.6 billion (3.9% increase year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.1 billion (2.9% decrease year on year). Sales of Ongentys Tablets for parkinson's disease were ¥3.1 billion (27.9% increase year on year).
- Royalty and others increased by ¥27.0 billion (37.6%) year on year to ¥98.8 billion 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.

2. Operating profit ¥97.0 billion YoY an increase of 20.9% (FY 2022 2Q YTD ¥80.3 billion)

- Operating profit increased by ¥16.8 billion (20.9%) year on year to ¥97.0 billion.
- Cost of sales increased by ¥11.1 billion (20.6%) year on year to ¥64.8 billion, mainly due to increases 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 ¥9.7 billion (24.6%) year on year to ¥49.4 billion, mainly due to increases in research costs, costs for drug discovery collaboration, development costs for clinical trials, and joint development costs for in-licensed products, etc.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥4.7 billion (10.8%) year on year to ¥47.6 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.

3. Profit before tax ¥99.3 billion YoY an increase of 22.6% (FY 2022 2Q YTD ¥81.0 billion)

- Net financial income, etc., was ¥2.3 billion, an increase of ¥1.5 billion (201.8%) year on year.

4. Profit for the period ¥74.5 billion YoY an increase of 19.5% (FY 2022 2Q YTD ¥62.3 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥12.2 billion (19.5%) year on year to ¥74.5 billion in association with the increase of the profit before tax.

Sales Revenue Result and Forecast of Major Products

(Billions of Yen)

Product Name	Six months ended September 30, 2023 (April 1, 2023 to September 30, 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		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	37.8	37.3	**75.0**	5.1	7.3%	155.0		**155.0**	12.7	8.9%
Forxiga Tablets	17.5	18.4	**35.9**	9.5	36.1%	65.0	5.0	**70.0**	13.5	23.8%
Orencia for Subcutaneous Injection	6.6	6.5	**13.0**	0.6	4.5%	25.5		**25.5**	0.7	3.0%
Glactiv Tablets	5.6	5.2	**10.8**	(0.9)	(7.5%)	21.0		**21.0**	(1.5)	(6.7%)
Velexbru Tablets	2.6	2.4	**5.0**	0.9	22.0%	9.5		**9.5**	1.0	11.3%
Kyprolis for Intravenous Infusion	2.2	2.4	**4.6**	0.2	3.9%	8.5		**8.5**	(0.2)	(2.3%)
Parsabiv Intravenous Injection	2.1	2.1	**4.1**	(0.1)	(2.9%)	8.0		**8.0**	(0.4)	(4.8%)
Ongentys Tablets	1.6	1.5	**3.1**	0.7	27.9%	6.5		**6.5**	1.5	30.5%
Onoact for Intravenous Infusion	1.0	1.0	**2.1**	(0.1)	(3.5%)	4.5		**4.5**	0.0	0.4%
Braftovi Capsules	0.9	0.9	**1.7**	0.1	5.5%	4.0		**4.0**	0.8	23.2%
Opalmon Tablets	1.0	0.9	**1.9**	(0.4)	(16.0%)	3.5		**3.5**	(0.9)	(19.9%)
Mektovi Tablets	0.7	0.7	**1.3**	0.1	4.1%	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.

Details of Sales Revenue

(Billions of yen)

	Six months ended September 30, 2022	**Six months ended September 30, 2023**
Revenue of goods and products	144.9	**159.9**
Royalty and others	71.8	**98.8**
Total	216.7	**258.7**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥42.1 billion for the second quarter (six months) ended September 30, 2022 and ¥47.4 billion for the second quarter (six months) ended September 30, 2023. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥21.4 billion for the second quarter (six months) ended September 30, 2022 and ¥25.6 billion for the second quarter (six months) ended September 30, 2023.

Revenue by Geographic Area

(Billions of yen)

	Six months ended September 30, 2022	**Six months ended September 30, 2023**
Japan	141.9	**155.4**
Americas	67.2	**77.0**
Europe	2.2	**19.4**
Asia	5.5	**7.0**
Total	216.7	**258.7**

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, the Company revised the classification of revenue by geographic area. Therefore, revenue by geographic area is reclassified for the six months ended September 30, 2022.

Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2024 (IFRS)

Consolidated Financial Forecast

(Billions of yen)

	FY 2022 (April 1, 2022 to March 31, 2023)	**FY 2023 Forecast (April 1, 2023 to March 31, 2024)**	YoY
Revenue	447.2	**500.0**	11.8%
Operating profit	142.0	**167.0**	17.6%
Profit before tax	143.5	**169.0**	17.7%
Profit for the year (attributable to owners of the Company)	112.7	**126.0**	11.8%

Details of Sales Revenue (Forecast)

(Billions of yen)

	FY 2022 (April 1, 2022 to March 31, 2023)	**FY 2023 Forecast (April 1, 2023 to March 31, 2024)**
Revenue of goods and products	295.0	**315.0**
Royalty and others	152.1	**185.0**
Total	447.2	**500.0**

1. Revenue ¥500.0 billion YoY an increase of ¥52.8 billion (11.8%)

- Revenue of goods and products are expected to be ¥315.0 billion, an increase of ¥20.0 billion (6.8%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be ¥155.0 billion, an increase of ¥12.7 billion (8.9%) year on year, due to its expanded use in treatments for gastric cancer, esophageal cancer, and urothelial carcinoma, etc., despite the intensifying competitive environment. In other new main products, sales of Forxiga Tablets are expected to increase by ¥13.5 billion (23.8%) year on year to ¥70.0 billion. Furthermore, royalty and others are expected to increase by ¥32.9 billion (21.6%) year on year to ¥185.0 billion mainly due to that royalty revenue would grow continuously and the Company recorded the lump-sum income of ¥17.0 billion associated with the settlement of the litigation on patents with AstraZeneca UK Limited. Revenue is therefore expected to be ¥500.0 billion, an increase of ¥52.8 billion (11.8%) year on year.

2. Operating profit ¥167.0 billion YoY an increase of ¥25.0 billion (17.6%)

- Cost of sales is expected to be ¥122.0 billion, an increase of ¥11.9 billion (10.8%) year on year mainly due to an increase in revenue of goods and products, as well as the Company recorded impairment losses of ¥5.4 billion on sales licenses of Joyclu Intra-Articular Injection and Adlumiz Tablets.
- Research and development costs are expected to be ¥109.0 billion, an increase of ¥13.7 billion (14.3%) year on year, due to aggressive investment for the realization of sustained growth through further expansion of collaborative research with advanced companies and academia with cutting-edge technology and research themes, and global development study, etc.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥98.0 billion, an increase of ¥8.5 billion (9.5%) year on year, mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets, active investments in information infrastructure related to IT and digital technologies, and active investments to strengthen global businesses in the USA, etc.
- Other expenses are expected to decrease by ¥6.1 billion (54.8%) year on year to ¥5.0 billion, mainly due to the absence of a lump-sum payment associated with the settlement of the litigation on patents with Dana-Farber Cancer Institute, Inc., recorded in the fiscal year ended March 31, 2023.

  Therefore, operating profit is expected to be ¥167.0 billion, an increase of ¥25.0 billion (17.6%) year on year.

3. Profit before tax ¥169.0 billion YoY an increase of ¥25.5 billion (17.7%)

- Net financial income, etc., is expected to be ¥2.0 billion, an increase of ¥0.4 billion (27.5%) year on year.

4. Profit for the year ¥126.0 billion YoY an increase of ¥13.3 billion (11.8%) (attributable to owners of the Company)

- Profit attributable to owners of the Company is expected to be ¥126.0 billion, an increase of ¥13.3 billion (11.8%) year on year.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2022 (April 1, 2022 to March 31, 2023)	**FY 2023 2Q YTD (April 1, 2023 to September 30, 2023)**	**FY 2023 Forecast (April 1, 2023 to March 31, 2024)**
Property, plant, and equipment	9.8	**5.0**	**10.0**
Intangible assets	7.7	**4.1**	**7.8**
Total	17.5	**9.1**	**17.8**
Ratio to sales revenue	3.9%	**3.5%**	**3.6%**

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

(Billions of yen)

	FY 2022 (April 1, 2022 to March 31, 2023)	**FY 2023 2Q YTD (April 1, 2023 to September 30, 2023)**	**FY 2023 Forecast (April 1, 2023 to March 31, 2024)**
Property, plant, and equipment	7.7	**2.3**	**7.0**
Intangible assets	13.7	**0.9**	**11.7**
Total	21.4	**3.1**	**18.7**

Number of Employees (Consolidated)

	FY 2022 2Q (as of September 30, 2022)	FY 2022 (as of March 31, 2023)	**FY 2023 2Q (as of September 30, 2023)**
Number of employees	3,765	3,761	**3,843**

Status of Shares (as of September 30, 2023)

Number of Shares

	As of September 30, 2023
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	517,425,200

Number of Shareholders

	As of September 30, 2023
Number of shareholders	66,080

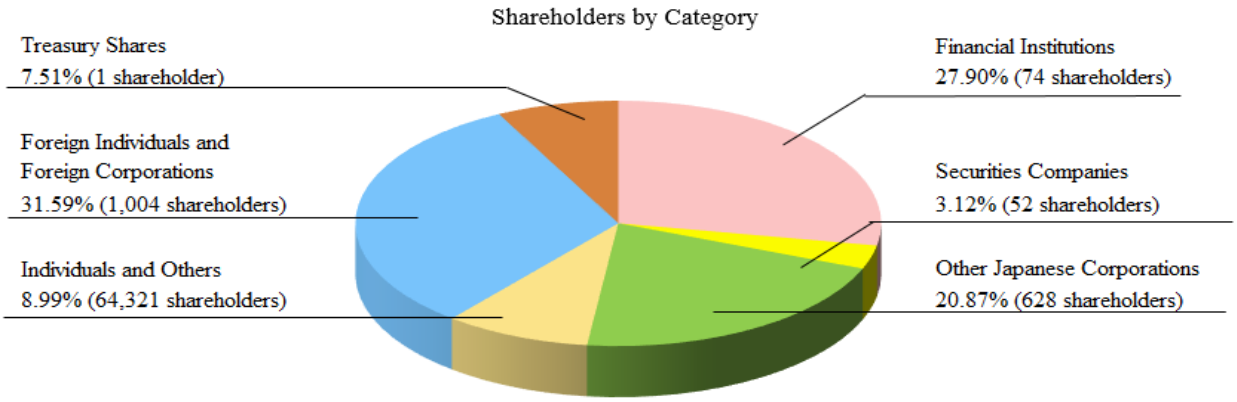
Principal Shareholders

(As of September 30, 2023)

Name of shareholder	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	62,398	13.03
Custody Bank of Japan, Ltd. (Trust account)	21,214	4.43
Meiji Yasuda Life Insurance Company	18,594	3.88
Ono Scholarship Foundation	16,428	3.43
KAKUMEISOU Co., LTD.	16,153	3.37
STATE STREET BANK WEST CLIENT – TREATY 505234	9,947	2.07
MUFG Bank, Ltd.	8,640	1.80
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.62
NORTHERN TRUST CO. (AVFC) RE NON TREATY CLIENTS ACCOUNT	7,507	1.56
JP MORGAN CHASE BANK 385781	5,705	1.19

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 38,869 thousand shares of treasury shares.
2. The shareholding percentage is calculated by deducting treasury shares (38,869 thousand shares).

Ownership and Distribution of Shares



Note: The ratio by shareholders listed above is rounded down to two decimal places. Therefore, their total does not amount to 100%.

I. Main Status of Development Pipelines (Oncology)

As of October 27, 2023

<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 mesothelioma (excluding malignant pleural mesothelioma)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	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)

<Opdivo Combination Drugs> ***) :** "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-7121*1 (Combination Drugs with Relatlimab)	New chemical entities	Colorectal cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

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

*1: Phase III of ONO-7121 (A combination drug comprising Opdivo and anti-LAG-3 antibody) is being conducted in Japan, South Korea, and Taiwan for the treatment of colorectal cancer.

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

<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*2 / Prostaglandin receptor (EP4) antagonist	Tablet	Japan S. Korea Taiwan	II	In-house
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Hepatocellular carcinoma*3 / 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 ★ / Tamnorzatinib	New chemical entities	Pancreatic cancer*4 / 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 changes from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2024, are as follows:

*2: Phase II of the combination therapy with Opdivo and ONO-4578 (Prostaglandin receptor (EP4) antagonist) was initiated in Japan, South Korea, and Taiwan for the treatment of gastric cancer.

*3: Phase II of the combination therapy with ONO-4482 (anti-LAG-3 antibody) and Opdivo is being conducted in Japan, South Korea, and Taiwan for the treatment of hepatocellular carcinoma.

*4: Phase I of ONO-7475 (Axl/Mer inhibitor) was initiated in Japan for the treatment of pancreatic cancer.

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 / Tamnorzatinib	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*5 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.)

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

*5: Phase I of ONO-4685 (PD-1 x CD3 bispecific antibody) was initiated in Japan for the treatment of T-cell lymphoma.

* Phase III of Opdivo for the treatment of prostate cancer was conducted in Japan, South Korea, and Taiwan, but the project was discontinued due to the result not being able to confirm efficacy.
* Although the Company participated in phase I/II trials from Japan for the treatment of solid tumors under the leadership of Bristol-Myers Squibb Company in combination therapy with Opdivo and ONO-4686 (Anti-TIGIT antibody), the project was discontinued due to strategic reasons.
* The Company participated in collaborative international phase III trials of ONO-7913 (Anti-CD47 antibody) from Japan for the treatment of TP53-mutant acute myeloid leukemia under the leadership of Gilead, but the project was discontinued due to not being able to confirm efficacy.
* Phase I of ONO-7913 (Anti-CD47 antibody) was conducted in Japan for the treatment of myelodysplastic syndromes, but the project was discontinued because overseas phase III trials (ENHANCE trials) for the same group of patients, which were carried out under the leadership of Gilead, were discontinued due to being ineffectual.

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

II. Main Status of Development Pipelines (Areas other than Oncology)

As of October 27, 2023

<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

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

* Phase I of ONO-7684 (FXIa inhibitor) for the treatment of thrombosis was conducted in Japan and Europe, but the project was discontinued due to strategic reasons.

Profile for Main Development

Opdivo Intravenous Infusion (ONO-4538 / BMS-936558) / Nivolumab (injection)
Opdivo, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer, etc. PD-1 is a receptor expressed on the surface of activated lymphocytes, and plays a role in a regulatory pathway that suppresses the activated lymphocytes in the body (negative signal). Available evidence suggests that cancer cells exploit this pathway to escape from immune responses. Opdivo is thought to provide benefit by blocking PD-1-mediated negative regulation of lymphocytes, thereby enhancing the ability of the immune system to recognize cancer cells as foreign and eliminate them.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

Yervoy Injection (ONO-4480) / Ipilimumab (injection)
Yervoy, a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of various kinds of cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4482 / BMS-986016 / Relatlimab (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of melanoma and hepatocellular carcinoma.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4578 (tablet)
ONO-4578, a Prostaglandin receptor (EP4) antagonist, is being developed for the treatment of gastric cancer, colorectal cancer, pancreatic cancer, non-small cell lung cancer, and hormone receptor-positive HER2-negative breast cancer.

Braftovi Capsules (ONO-7702) / Encorafenib (capsule)
Braftovi, a BRAF inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved in Japan and South Korea for the treatment of BRAF-mutant colorectal cancer. Also, it is being developed for the treatment of untreated BRAF-mutant colorectal cancer. In addition, it is being developed in Japan for the treatment of BRAF-mutant thyroid cancer.

Mektovi Tablets (ONO-7703) / Binimetinib (tablet)
Mektovi, a MEK inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved for the treatment of BRAF-mutant colorectal cancer. In addition, it is being developed in Japan for the treatment of BRAF-mutant thyroid cancer.

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis, a proteasome inhibitor, has been marketed for the treatment of multiple myeloma, and an additional twice-weekly regimen was later made available for a new DKd combination therapy with Dexamethasone plus Darzalex (generic name: Daratumumab) Intravenous Infusion, a human anti-CD38 monoclonal antibody.

Velexbru Tablets (ONO-4059) / Tirabrutinib Hydrochloride (tablet)
Velexbru, a BTK inhibitor, has been marketed in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma, and additional indications were later approved for the treatment of waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma. Applications were approved in South Korea and Taiwan for the treatment of recurrent or refractory B-cell primary central nervous system lymphoma. In addition, it is being developed in the USA for the treatment of primary central nervous system lymphoma, and in Japan for the treatment of pemphigus.

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

ONO-7913 / Magrolimab (injection)
ONO-7913, an anti-CD47 antibody, is being developed in Japan for the treatment of pancreatic cancer and colorectal cancer. In addition, it is being developed in South Korea and Taiwan for the treatment of acute myeloid leukemia.

ONO-7119 / Atamparib (tablet)
ONO-7119, a PARP7 inhibitor, is being developed in Japan for the treatment of solid tumor.

ONO-7122 (injection)
ONO-7122, a TGF-β inhibitor, is being developed in Japan for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7914 (injection)
ONO-7914, STING agonist, is being developed in Japan for the treatment of solid tumor.

ONO-4685 (injection)
ONO-4685, PD-1 x CD3 bispecific antibody, is being developed in Japan and Europe for the treatment of autoimmune disease. In the oncology area, it is being developed in Japan and the USA for the treatment of T-cell lymphoma.

ONO-7018 (tablet)
ONO-7018, MALT1 inhibitor, is being developed in the USA for the treatment of Non-Hodgkin lymphoma and chronic lymphocytic leukemia.

ONO-7226 (injection)
ONO-7226, anti-ILT4 antibody, is being developed in Japan for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7121 (injection)
ONO-7121, combination drugs with Opdivo and ONO-4482 (anti LAG-3 antibody / Relatlimab), is being developed in Japan, South Korea, and Taiwan for the treatment of colorectal cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-2017 / Cenobamate (tablet)
ONO-2017, an inhibition of voltage-gated sodium currents / positive allosteric modulator of $GABA_A$ ion channel, is being developed in Japan for the treatment of primary generalized tonic-clonic seizures and partial-onset seizures.

ONO-2808 (tablet)
ONO-2808, a S1P5 receptor agonist, is being developed in the USA for the treatment of multiple system atrophy.

ONO-2910 (tablet)
ONO-2910, a Schwann cell differentiation promoter, is being developed in Japan for the treatment of diabetic polyneuropathy and chemotherapy-induced peripheral neuropathy.

ONO-2020 (tablet)
ONO-2020, an epigenetic regulation, is being developed in the USA for the treatment of neurodegenerative disease.

ONO-1110 (oral)
ONO-1110, an endocannabinoid regulation, is being developed in Japan for the treatment of pain.