

Consolidated Financial Results for the Fiscal Year Ended March 31, 2023 (IFRS)

May 10, 2023

Company name : **ONO PHARMACEUTICAL CO., LTD.**
 Stock exchange listing : Tokyo Stock Exchange
 Code number : 4528
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 Scheduled date of annual general meeting of shareholders : June 22, 2023
 Scheduled date of securities report submission : June 23, 2023
 Scheduled date of dividend payment commencement : June 23, 2023
 Supplementary materials for the financial results : Yes
 Earnings announcement for the financial results : Yes (for institutional investors and securities analysts)

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

1. Consolidated Financial Results for FY 2022 (April 1, 2022 to March 31, 2023)

(1) Consolidated Operating Results

(% change from the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Total comprehensive income for the year	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2022	447,187	23.8	141,963	37.6	143,532	36.7	112,913	39.9	112,723	40.0	115,791	45.5
FY 2021	361,361	16.8	103,195	4.9	105,025	4.1	80,684	6.9	80,519	6.8	79,606	(16.7)

	Basic earnings per share	Diluted earnings per share	Return on equity attributable to owners of the Company	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	Yen	Yen	%	%	%
FY 2022	230.85	230.79	16.1	17.7	31.7
FY 2021	162.19	162.16	12.5	14.1	28.6

(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	Equity attributable to owners of the Company per share
	Million yen	Million yen	Million yen	%	Yen
As of March 31, 2023	882,437	747,812	741,869	84.1	1,519.19
As of March 31, 2022	739,203	661,674	655,906	88.7	1,343.40

(3) Consolidated Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of the fiscal year
	Million yen	Million yen	Million yen	Million yen
FY 2022	159,610	(100,259)	(32,484)	96,135
FY 2021	61,829	6,038	(60,237)	69,112

2. Dividends

	Annual dividends per share					Total dividends (annual)	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to owners of the Company (consolidated)
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
FY 2021	—	28.00	—	28.00	56.00	27,651	34.5	4.3
FY 2022	—	33.00	—	37.00	70.00	34,188	30.3	4.9
FY 2023 (Forecast)	—	40.00	—	40.00	80.00		34.0	

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	475,000	6.2	153,000	7.8	154,000	7.3	115,200	2.0	115,000	2.0	235.49

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: 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 March 31, 2023 517,425,200 shares
 - As of March 31, 2022 528,341,400 shares
 - 2) Number of treasury shares as of the end of the period:
 - As of March 31, 2023 29,091,218 shares
 - As of March 31, 2022 40,096,713 shares
 - 3) Average number of shares outstanding during the period:
 - FY 2022 488,300,452 shares
 - FY 2021 496,459,665 shares

* This financial results report is not subject to audit 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. For cautionary notes concerning assumptions for financial forecasts and use of the financial forecasts, please refer to “(4) Future Outlook” on page 7.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the Fiscal Year 2022

① Overview of Financial Results

(Millions of yen)

	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Change	Change (%)
Revenue	361,361	447,187	85,826	23.8%
Operating profit	103,195	141,963	38,768	37.6%
Profit before tax	105,025	143,532	38,507	36.7%
Profit for the year (attributable to owners of the Company)	80,519	112,723	32,204	40.0%

[Revenue]

Revenue totaled ¥447.2 billion, which was an increase of ¥85.8 billion (23.8%) from the previous fiscal year (year on year).

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to treatments for gastric cancer, esophageal cancer, etc., resulting in sales of ¥142.3 billion, an increase of ¥29.9 billion (26.6%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥56.5 billion (54.3% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥24.8 billion (8.1% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥22.5 billion (8.3% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.7 billion (4.0% increase year on year). Sales of Velexbro Tablets for malignant tumors were ¥8.5 billion (36.2% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.4 billion (5.3% decrease year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥5.0 billion (72.9% increase year on year).
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥4.4 billion (7.6% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥2.5 billion (30.7% decrease year on year).
- Royalty and others increased by ¥36.7 billion (31.8%) year on year to ¥152.1 billion.

[Operating Profit]

Operating profit was ¥142.0 billion, an increase of ¥38.8 billion (37.6%) year on year.

- Cost of sales increased by ¥16.6 billion (17.7%) year on year to ¥110.1 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥19.5 billion (25.7%) year on year to ¥95.3 billion, mainly due to increases in research costs, costs for drug discovery collaboration, and development costs for clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥12.4 billion (16.1%) year on year to ¥89.5 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.
- Other expenses recorded in the fiscal year ended March 31, 2023 were ¥11.1 billion mainly due to a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc., and a contribution to Ono Pharma Oncology, Immunology, Neurology Research Foundation, which was established in January 2023. However, it was a decrease of ¥1.6 billion (12.9%) year on year mainly due to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody recorded in the fiscal year ended March 31, 2022.

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

Profit attributable to owners of the Company increased by ¥32.2 billion (40.0%) year on year to ¥112.7 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 ten new drug candidates which was made in-house in the clinical stage currently, 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 working on initiatives to improve the accuracy of efficacy and safety predictions by using accumulated clinical trial data. Moreover, to maximize the value of new drug candidate compounds, we collaborate with the Discovery & Research from the research stage and begin drawing up development strategies early on, with the aim of commencing early clinical trials for multiple diseases. By working to enhance our clinical development functions in Europe and the USA, we will build a framework that enables early clinical trials to be implemented flexibly in 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 fiscal year ended March 31, 2023 (including those at the end of the fiscal year and thereafter) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

“Opdivo / Nivolumab”

Non-small cell lung cancer

- In October 2022, an application was approved in South Korea for the neoadjuvant treatment of resectable non-small cell lung cancer in combination therapy with chemotherapy.
- In February 2023, an application was approved in Taiwan for the neoadjuvant treatment of resectable non-small cell lung cancer in combination therapy with chemotherapy.
- In March 2023, an application was approved in Japan for the neoadjuvant treatment of resectable non-small cell lung cancer in combination therapy with chemotherapy.

Renal cell carcinoma

- In May 2022, an application was approved in Taiwan for the treatment of previously untreated or advanced renal cell carcinoma in combination therapy with Cabometyx tablets / Cabozantinib malate, a kinase inhibitor of Takeda Pharmaceutical Company Limited.

Gastric cancer

- In December 2022, phase III of Opdivo for the adjuvant treatment of gastric cancer was conducted in Japan, South Korea, Taiwan and China, but the project was discontinued as the adjuvant treatment did not demonstrate a significant extension of the relapse-free survival (RFS), which is the primary endpoint, as assessed by the Independent Radiologic Review Committee (IRRC), versus the chemotherapy arm.

Esophageal cancer

- In May 2022, applications were approved in Japan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.
- In July 2022, applications were approved in Taiwan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of advanced or metastatic esophageal squamous cell carcinoma.
- In March 2023, applications were approved in South Korea for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma.

Urothelial carcinoma / Bladder cancer

- In April 2022, an application was approved in Taiwan for the adjuvant treatment in patients with muscle-invasive urothelial carcinoma at a high risk of recurrence after radical surgery.

Hepatocellular carcinoma

- In February 2023, an accelerated approval of Opdivo was granted in Taiwan for the treatment of hepatocellular carcinoma previously treated with sorafenib, but the approval was later withdrawn as no survival benefit was confirmed in phase III, a post-approval confirmatory study, for the treatment of unresectable hepatocellular carcinoma (HCC) previously untreated with systemic chemotherapy.
- In March 2023, an application was approved in Taiwan for combination therapy with Opdivo and Yervoy for the treatment of hepatocellular carcinoma previously treated with sorafenib.

Malignant mesothelioma (excluding malignant pleural mesothelioma)

- In February 2023, an application for approval of Opdivo was filed in Japan for the treatment of malignant mesothelioma (excluding malignant pleural mesothelioma).

Biliary tract cancer

- In April 2022, phase II of Opdivo for the treatment of biliary tract cancer was conducted in Japan, but the project was discontinued due to strategic reasons.

Pancreatic cancer

- In July 2022, phase II of Opdivo for the treatment of pancreatic cancer was conducted in Japan, but the project was discontinued.

Virus positive / negative solid carcinoma

- In July 2022, phase I / II of combination therapy with Opdivo and Yervoy for the treatment of virus positive / negative solid carcinoma was conducted in Japan, South Korea and Taiwan, but the project was discontinued due to strategic reasons.

“ONO-7018”

- In August 2022, phase I of ONO-7018 (MALT1 inhibitor) was initiated in the USA for the treatment of Non-Hodgkin lymphoma or chronic lymphocytic leukemia.

“ONO-7911”

- In April 2022, phase I of combination therapy with Opdivo and ONO-7911 (PEGylated IL-2) for the treatment of solid tumor was conducted in Japan, but the project was discontinued due to strategic reasons.

“ONO-7475”

- In September 2022, phase I / II of ONO-7475 (Axl / Mer inhibitor) for the treatment of acute leukemia was conducted in the USA, but the project was discontinued due to strategic reasons.

<Areas other than Oncology>

“Onoact for Intravenous Infusion / Landiolol Hydrochloride”

- In August 2022, an application for Onoact for Intravenous Infusion (a short-acting selective β_1 blocker) was approved in Japan for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

“Velexbu Tablets / Tirabrutinib Hydrochloride / ONO-4059”

- In April 2022, phase III of Velexbu Tablets (BTK inhibitor) was initiated in Japan for the treatment of pemphigus.
- In February 2023, phase I of Velexbu Tablets (BTK inhibitor) for the treatment of systemic sclerosis was conducted in Japan, but the project was discontinued due to the result not being able to confirm anticipated efficacy.

“ONO-2020”

- In July 2022, phase I of ONO-2020 (Epigenetic Regulation) was initiated in the USA for the treatment of neurodegenerative disease.

“ONO-2909”

- In October 2022, phase I of ONO-2909 (Prostaglandin receptor (DP1) antagonist) for the treatment of narcolepsy was conducted in Japan, but the project was discontinued due to the results not being able to confirm anticipated efficacy.

“ONO-7684”

- In January 2023, phase I of ONO-7684 (FX1a inhibitor) was initiated in Japan for healthy adult subjects.

“ONO-1110”

- In December 2022, phase I of ONO-1110 (Endocannabinoid regulation) was initiated in Japan for healthy adult subjects.

[Status of Drug Discovery / Research Alliance Activities]

- In April 2022, the Company entered into a drug discovery collaboration agreement with Domain Therapeutics S.A. in France and Université de Montréal in Canada to discover novel small molecules against a G-Protein Coupled Receptor (GPCR) selected as therapeutic target by the Company in a metabolic disease area, utilizing their unique GPCR drug discovery platform and expertise in medicinal chemistry and pharmacology for GPCR drug discovery.
- In June 2022, the Company entered into an agreement to expand the drug discovery collaboration agreement signed in September 2018 with Fate Therapeutics, Inc. in the USA for the discovery of iPSC-derived chimeric antigen receptor (CAR)-T cell therapies, to include the discovery of iPSC-derived chimeric antigen receptor (CAR)-NK cell therapies.
- In August 2022, the Company entered into an agreement to expand the research collaboration with Knowledge Palette, Inc. in Japan, aiming to build a data-driven new drug discovery platform using Knowledge Palette's large-scale transcriptome analysis technology.
- In November 2022, the Company entered into a drug discovery collaboration agreement with Memo Therapeutics AG in Switzerland to discover and develop antibody drugs in the immuno-oncology field.
- In November 2022, the Company exercised its option to ONO-8250/FT825, iPSC cell-derived chimeric antigen receptor (CAR)-T cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors, created under the collaboration agreement with Fate Therapeutics, Inc. in the USA, signed in September 2018.

- In November 2022, the Company entered into a worldwide drug discovery collaboration agreement with Captor Therapeutics S.A. in Poland to develop novel small molecule degrader drugs against a currently undrugged target of interest in neurodegenerative diseases.
- In December 2022, the Company entered into a multi target R&D collaboration agreement with PrecisionLife Limited in the U.K. to identify novel therapeutic targets and patient stratification biomarkers in central nervous system (CNS) disorders for development by the Company.
- In January 2023, the Company entered into an option and research collaboration agreement with Monash University in Australia to discover and develop antibodies targeting at G protein-coupled receptors (GPCRs), in order to create novel therapeutics for the treatment of autoimmune and inflammatory diseases.
- In January 2023, the Company entered into an agreement with KSQ Therapeutics in the USA to acquire multiple research-stage DNA damage response (DDR) programs identified using KSQ's proprietary, integrated discovery CRISPRomics platform technology.
- In February 2023, the Company entered into a collaboration and option agreement with Cue Biopharma, Inc. in the USA for CUE-401, a bispecific protein designed to induce and expand regulatory T cells (Tregs) for the treatment of autoimmune and inflammatory diseases.
- In March 2023, the Company entered into a drug discovery collaboration agreement with PeptiDream Inc. in Japan, to discover and develop novel macrocyclic constrained peptide drugs against multiple targets of the Company's interest.
- In March 2023, the Company entered into a drug discovery collaboration agreement with MOLCURE Inc. in Japan, to discover and develop innovative antibody drugs for multiple targets utilizing MOLCURE's AI-driven platform technology.
- In March 2023, the Company entered into a worldwide drug discovery collaboration agreement with Macomics Ltd. in the U.K. to develop new immuno-oncology antibody drugs against a novel macrophage target of interest in cancer.

[Status of Licensing Activities]

- In December 2022, the Company entered into an exclusive option and asset purchase agreement with Equillium Inc., in the USA regarding Equillium's rights to "itolizumab", an anti-CD6 monoclonal antibody, being developed by Equillium for patients with acute graft-versus-host disease. Upon exercise of the option, the Company will receive the Equillium's rights to itolizumab. These rights include all therapeutic indications and the rights to commercialize itolizumab in the USA, Canada, Australia and New Zealand.

(2) Overview of Financial Position for the Fiscal Year 2022

(Millions of yen)

	As of March 31, 2022	As of March 31, 2023	Change
Total assets	739,203	882,437	143,233
Equity attributable to owners of the Company	655,906	741,869	85,962
Ratio of equity attributable to owners of the Company to total assets	88.7%	84.1%	
Equity attributable to owners of the Company per share	1,343.40 yen	1,519.19 yen	

Total assets increased to ¥882.4 billion by ¥143.2 billion from the end of the previous fiscal year.

Current assets increased by ¥63.8 billion to ¥345.1 billion mainly due to increases in cash and cash equivalents and other financial assets.

Non-current assets increased by ¥79.4 billion to ¥537.3 billion mainly due to increases in other financial assets and deferred tax assets.

Liabilities increased by ¥57.1 billion to ¥134.6 billion mainly due to increases in income taxes payable and trade and other payables.

Equity attributable to owners of the Company increased by ¥86.0 billion to ¥741.9 billion mainly due to the recording of the profit for the year, despite there being cash dividends.

(3) Overview of Cash Flows for the Fiscal Year 2022

(Millions of yen)

	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Change
Cash and cash equivalents at the beginning of the fiscal year	61,045	69,112	
Cash flows from operating activities	61,829	159,610	97,781
Cash flows from investing activities	6,038	(100,259)	(106,297)
Cash flows from financing activities	(60,237)	(32,484)	27,753
Net increase (decrease) in cash and cash equivalents	7,631	26,868	
Effects of exchange rate changes on cash and cash equivalents	436	155	
Cash and cash equivalents at the end of the fiscal year	69,112	96,135	

Net increase/decrease in cash and cash equivalents was an increase of ¥26.9 billion.

Net cash provided by operating activities was ¥159.6 billion, as a result of profit before tax of ¥143.5 billion, and depreciation and amortization of ¥17.5 billion, etc.

Net cash used in investing activities was ¥100.3 billion, as a result of payments into time deposits of ¥138.2 billion, etc., while there were proceeds from withdrawal of time deposits of ¥48.0 billion, etc.

Net cash used in financing activities was ¥32.5 billion, as a result of dividends paid of ¥29.7 billion, etc.

(4) Future Outlook

(Millions of yen)

	Result (Fiscal year ended March 31, 2023)	Forecast (Fiscal year ending March 31, 2024)	Change	Change (%)
Revenue	447,187	475,000	27,813	6.2%
Operating profit	141,963	153,000	11,037	7.8%
Profit before tax	143,532	154,000	10,468	7.3%
Profit for the year (attributable to owners of the Company)	112,723	115,000	2,277	2.0%

Note: The annual exchange rate assumed in this forecast is 1 USD = 130 yen.

[Revenue]

Revenue of goods and products are expected to be ¥310.0 billion, an increase of ¥15.0 billion (5.1%) 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, despite the intensifying competitive environment. In other new main products, sales of Forxiga Tablets are expected to increase by ¥8.5 billion (15.0%) year on year to ¥65.0 billion, as well as anticipating higher sales of Velexbru Tablets and Ongentys Tablets. Furthermore, royalty and others are expected to increase by ¥12.9 billion (8.5%) year on year to ¥165.0 billion, anticipating that royalty revenue would grow continuously. Revenue is therefore expected to be ¥475.0 billion, an increase of ¥27.8 billion (6.2%) year on year.

[Profit]

Cost of sales is expected to be ¥113.0 billion, an increase of ¥2.9 billion (2.7%) year on year, due to an increase in revenue of goods and products.

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.

Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥96.0 billion, an increase of ¥6.5 billion (7.3%) year on year, 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 including the USA.

Other expenses are expected to decrease by ¥6.6 billion (59.3%) year on year to ¥4.5 billion, mainly due to the absence of a lump-sum payment associated with the settlement of 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 ¥153.0 billion, an increase of ¥11.0 billion (7.8%) year on year, and profit attributable to owners of the Company is expected to be ¥115.0 billion, an increase of ¥2.3 billion (2.0%) year on year.

(5) Basic policy for profit distribution and dividends for the fiscal year under review and the following fiscal year

Distribution of profits to all our shareholders is one of our key management policies. We place great importance on the maintenance of stable dividends and profit sharing according to our financial results for the corresponding fiscal year. As for the dividend for the fiscal year ended March 31, 2023, we expect to make a year-end dividend of 37 yen per share. With the payment of the second quarter dividend of 33 yen per share, the annual dividend is expected to be 70 yen per share. Also, the annual dividend for the following fiscal year ending March 31, 2024 is expected to be 80 yen per share. We actively utilize retained earnings for the future business development including research and development of new innovative drugs in Japan and abroad, alliance with bio-venture companies, and introduction of new drug candidate compounds for development risk reduction.

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. Consolidated Financial Statements and Major Notes

(1) Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2022	As of March 31, 2023
Assets		
Current assets		
Cash and cash equivalents	69,112	96,135
Trade and other receivables	99,788	114,396
Marketable securities	60	20
Other financial assets	47,797	68,134
Inventories	41,817	44,814
Other current assets	22,692	21,602
Total current assets	281,266	345,101
Non-current assets		
Property, plant, and equipment	112,131	108,420
Intangible assets	64,734	69,134
Investment securities	125,046	123,308
Investments in associates	108	115
Other financial assets	127,302	197,441
Deferred tax assets	25,074	35,604
Retirement benefit assets	377	—
Other non-current assets	3,165	3,314
Total non-current assets	457,937	537,336
Total assets	739,203	882,437

(Millions of yen)

	As of March 31, 2022	As of March 31, 2023
Liabilities and Equity		
Current liabilities		
Trade and other payables	49,689	66,794
Lease liabilities	2,301	2,490
Other financial liabilities	716	661
Income taxes payable	1,526	34,575
Other current liabilities	11,694	18,409
Total current liabilities	65,926	122,929
Non-current liabilities		
Lease liabilities	6,501	6,678
Other financial liabilities	0	0
Retirement benefit liabilities	3,322	3,350
Deferred tax liabilities	1,009	983
Other non-current liabilities	771	684
Total non-current liabilities	11,603	11,695
Total liabilities	77,529	134,625
Equity		
Share capital	17,358	17,358
Capital reserves	17,241	17,080
Treasury shares	(74,683)	(54,161)
Other components of equity	51,236	51,701
Retained earnings	644,754	709,890
Equity attributable to owners of the Company	655,906	741,869
Non-controlling interests	5,768	5,944
Total equity	661,674	747,812
Total liabilities and equity	739,203	882,437

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

Consolidated Statement of Income

	(Millions of yen)	
	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Revenue	361,361	447,187
Cost of sales	(93,511)	(110,062)
Gross profit	267,850	337,124
Selling, general, and administrative expenses	(77,057)	(89,486)
Research and development costs	(75,879)	(95,344)
Other income	980	734
Other expenses	(12,698)	(11,065)
Operating profit	103,195	141,963
Finance income	2,710	2,478
Finance costs	(874)	(913)
Share of profit (loss) from investments in associates	(6)	4
Profit before tax	105,025	143,532
Income tax expense	(24,340)	(30,619)
Profit for the year	80,684	112,913
Profit for the year attributable to		
Owners of the Company	80,519	112,723
Non-controlling interests	166	190
Profit for the year	80,684	112,913
Earnings per share		
Basic earnings per share (Yen)	162.19	230.85
Diluted earnings per share (Yen)	162.16	230.79

Consolidated Statement of Comprehensive Income

	(Millions of yen)	
	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Profit for the year	80,684	112,913
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	(2,094)	2,518
Remeasurements of defined benefit plans	199	(114)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	2	2
Total of items that will not be reclassified to profit or loss	(1,893)	2,406
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	814	472
Total of items that may be reclassified subsequently to profit or loss	814	472
Total other comprehensive income	(1,079)	2,878
Total comprehensive income for the year	79,606	115,791
Comprehensive income for the year attributable to:		
Owners of the Company	79,444	115,608
Non-controlling interests	161	182
Total comprehensive income for the year	79,606	115,791

(3) Consolidated Statement of Changes in Equity

FY 2021 (April 1, 2021 to March 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, 2021	17,358	17,231	(44,705)	62,299	581,950	634,133	5,610	639,743
Profit for the year					80,519	80,519	166	80,684
Other comprehensive income				(1,074)		(1,074)	(4)	(1,079)
Total comprehensive income for the year	—	—	—	(1,074)	80,519	79,444	161	79,606
Purchase of treasury shares			(30,009)			(30,009)		(30,009)
Disposition of treasury shares		(31)	31			0		0
Cash dividends					(27,703)	(27,703)	(4)	(27,707)
Share-based payments		41				41		41
Transfer from other components of equity to retained earnings				(9,988)	9,988	—		—
Total transactions with the owners	—	10	(29,978)	(9,988)	(17,714)	(57,671)	(4)	(57,675)
Balance as of March 31, 2022	17,358	17,241	(74,683)	51,236	644,754	655,906	5,768	661,674

FY 2022 (April 1, 2022 to March 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, 2022	17,358	17,241	(74,683)	51,236	644,754	655,906	5,768	661,674
Profit for the year					112,723	112,723	190	112,913
Other comprehensive income				2,886		2,886	(8)	2,878
Total comprehensive income for the year	—	—	—	2,886	112,723	115,608	182	115,791
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		142				142		142
Transfer from retained earnings to capital reserves		20,221			(20,221)	—		—
Transfer from other components of equity to retained earnings				(2,421)	2,421	—		—
Total transactions with the owners	—	(161)	20,522	(2,421)	(47,586)	(29,646)	(6)	(29,653)
Balance as of March 31, 2023	17,358	17,080	(54,161)	51,701	709,890	741,869	5,944	747,812

(4) Consolidated Statement of Cash Flows

	(Millions of yen)	
	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Cash flows from operating activities		
Profit before tax	105,025	143,532
Depreciation and amortization	17,721	17,451
Impairment losses	3,404	1,498
Interest and dividend income	(2,349)	(2,402)
Interest expense	70	74
(Increase) decrease in inventories	(2,464)	(2,945)
(Increase) decrease in trade and other receivables	(15,283)	(14,513)
Increase (decrease) in trade and other payables	8,177	13,090
Increase (decrease) in provisions	(20,721)	—
Increase (decrease) in retirement benefit liabilities	54	214
(Increase) decrease in retirement benefit assets	130	27
Increase (decrease) in accrued consumption tax	(1,000)	5,564
Other	1,069	2,347
Subtotal	93,835	163,935
Interest received	40	53
Dividends received	2,317	2,334
Interest paid	(70)	(74)
Income taxes paid	(34,293)	(6,637)
Net cash provided by (used in) operating activities	61,829	159,610
Cash flows from investing activities		
Purchases of property, plant, and equipment	(5,497)	(5,340)
Proceeds from sales of property, plant, and equipment	14	6
Purchases of intangible assets	(6,780)	(9,157)
Purchases of investments	(1,127)	(2,432)
Proceeds from sales and redemption of investments	22,782	7,864
Payments into time deposits	(57,486)	(138,159)
Proceeds from withdrawal of time deposits	55,800	47,996
Other	(1,667)	(1,037)
Net cash provided by (used in) investing activities	6,038	(100,259)
Cash flows from financing activities		
Dividends paid	(27,666)	(29,742)
Dividends paid to non-controlling interests	(4)	(6)
Repayments of lease liabilities	(2,560)	(2,733)
Purchases of treasury shares	(30,007)	(1)
Net cash provided by (used in) financing activities	(60,237)	(32,484)
Net increase (decrease) in cash and cash equivalents	7,631	26,868
Cash and cash equivalents at the beginning of the year	61,045	69,112
Effects of exchange rate changes on cash and cash equivalents	436	155
Cash and cash equivalents at the end of the year	69,112	96,135

(5) Notes to Consolidated Financial Statements

(Note Regarding Assumption of Going Concern)

Not Applicable

(Significant Accounting Policies)

The significant accounting policies that the Group has applied in the consolidated financial statements for the fiscal year ended March 31, 2023 are the same as the ones for the previous fiscal year except for the accounting policies concerning the share-based payments described below.

(Share-based Payments)

The Company has introduced incentive plans for the Members of its Board of Directors (excluding Outside Directors) and its Executive Officers in the form of the Tenure-Based Restricted Stock Remuneration System and the Performance-Based Restricted Stock Remuneration System. Following the introduction of these systems, all unexercised stock acquisition rights allotted to the Members of the Board of Directors of the Company as stock-based remuneration-type stock options in the past fiscal years have been waived, and in exchange for it, the same number of shares of the Company's ordinary shares as the ones that were the object of the stock acquisition rights waived by the eligible Directors have been granted as remuneration, etc. for such eligible Directors.

1) Tenure-Based Restricted Stock Remuneration System

Remuneration under the tenure-based restricted stock remuneration system is measured by reference to the fair value of the Company's ordinary share to be granted, and recognized as an expense over the vesting period of the remuneration with an equal amount recognized as an increase in equity.

2) Performance-Based Restricted Stock Remuneration System

The portion of the performance-based restricted stock remuneration system that is a cash-settled share-based payment transaction is recognized as an expense over the vesting period and the same amount is recognized as an increase in the liability. The portion of the system that constitutes an equity-settled share-based payment transaction is measured by reference to the fair value of the Company's ordinary share to be granted, and recognized as an expense over the vesting period with equal amount recognized as an increase in equity.

(Changes in Presentation)

(Consolidated Statement of Cash Flows)

"Increase (decrease) in accrued consumption tax" included in "Other" in cash flows from operating activities for the fiscal year ended March 31, 2022 is separately listed from the fiscal year ended March 31, 2023 due to the increased quantitative materiality. Prior year amounts have been reclassified to conform to the Company's current year presentation.

As a result, ¥70 million for "Other", which was shown in cash flows from operating activities in the consolidated statements of cash flows for the fiscal year ended March 31, 2022, is reclassified into (¥1,000) million in "increase (decrease) in accrued consumption tax" and ¥1,069 million in "Other".

(Segment Information)

1) Reportable Segments

Based on the Group's corporate philosophy, "Dedicated to the Fight against Disease and Pain," in order to fulfill medical needs that have not yet been met, the Group is dedicated to developing innovative new pharmaceutical drugs for patients and focuses its operating resources on a single segment of the pharmaceutical business (research and development, purchasing, manufacturing, and sales). Accordingly, segment information is omitted herein.

2) Details of Revenue

Details of revenue are as follows:

	(Millions of yen)	
	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Revenue of goods and products	245,956	295,045
Royalty and others	115,405	152,141
Total	361,361	447,187

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥69.9 billion for the fiscal year ended March 31, 2022 and ¥89.6 billion for the fiscal year ended March 31, 2023. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥30.8 billion for the fiscal year ended March 31, 2022 and ¥45.2 billion for the fiscal year ended March 31, 2023.

3) Revenue by Geographic Area

Details of revenue by geographic area are as follows:

(Millions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Japan	241,971	288,155
Americas	106,916	142,791
Asia	8,895	11,625
Europe	3,579	4,616
Total	361,361	447,187

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

4) Major Customers

Details of revenue from major customers are as follows:

(Millions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Bristol-Myers Squibb Company and the group	79,490	100,176
Medipal Holdings Corporation and the group	57,262	68,436
Suzuken Co., Ltd. and the group	49,438	58,693
Alfresa Holdings Corporation and the group	37,665	46,423
Toho Holdings Co., Ltd. and the group	36,119	45,376
Merck & Co., Inc. and the group	30,830	45,176

(Earnings per Share)

1) Basic Earnings per Share

(i) Basic earnings per share

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Basic earnings per share (Yen)	162.19	230.85

(ii) Basis of calculation of basic earnings per share

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Profit for the year attributable to owners of the Company (Millions of yen)	80,519	112,723
Weighted-average number of ordinary shares outstanding (Thousands of shares)	496,459	488,300

2) Diluted Earnings per Share

(i) Diluted earnings per share

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Diluted earnings per share (Yen)	162.16	230.79

(ii) Basis of calculation of diluted earnings per share

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Profit for the year attributable to owners of the Company (Millions of yen)	80,519	112,723
Adjustment to profit for the year attributable to owners of the Company (Millions of yen)	—	(15)
Profit for the year used in calculating diluted earnings per share (Millions of yen)	80,519	112,708
Weighted-average number of ordinary shares outstanding (Thousands of shares)	496,459	488,300
Increase in ordinary shares by share acquisition rights (Thousands of shares)	67	21
Increase in ordinary shares by restricted stock-based remuneration system (Thousands of shares)	—	30
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	496,527	488,353

(Significant Subsequent Events)

Not applicable.

Fiscal Year 2022
(April 1, 2022 to March 31, 2023)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

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

Consolidated Financial Results for FY 2022 (April 1, 2022 to March 31, 2023) (IFRS)

Consolidated Financial Results

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)	YoY
Revenue	361.4	447.2	23.8%
Operating profit	103.2	142.0	37.6%
Profit before tax	105.0	143.5	36.7%
Profit for the year (attributable to owners of the Company)	80.5	112.7	40.0%

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

Sales Revenue of Major Products

Product Name	FY 2022 (April 1, 2022 to March 31, 2023)					(Billions of yen)		
	Cumulative					YoY		Forecast
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar		Change	Change (%)	
Opdivo Intravenous Infusion	34.1	35.8	39.3	33.2	142.3	29.9	26.6%	145.0
Forxiga Tablets	13.1	13.3	15.5	14.7	56.5	19.9	54.3%	55.0
Orencia for Subcutaneous Injection	6.2	6.2	6.7	5.6	24.8	1.9	8.1%	24.5
Glactiv Tablets	6.0	5.7	5.9	4.9	22.5	(2.0)	(8.3%)	23.0
Kyprolis for Intravenous Infusion	2.2	2.2	2.4	1.9	8.7	0.3	4.0%	9.0
Parsabiv Intravenous Injection	2.1	2.1	2.3	1.9	8.4	(0.5)	(5.3%)	8.0
Velexbru Tablets	2.1	2.0	2.4	2.0	8.5	2.3	36.2%	8.5
Ongentys Tablets	1.2	1.2	1.4	1.2	5.0	2.1	72.9%	5.0
Onoact for Intravenous Infusion	1.1	1.0	1.4	0.9	4.5	(0.4)	(7.9%)	4.5
Opalmon Tablets	1.1	1.1	1.2	0.9	4.4	(0.4)	(7.6%)	4.5
Braftovi Capsules	0.9	0.8	0.9	0.7	3.2	0.5	18.2%	3.5
Mektovi Tablets	0.7	0.6	0.7	0.6	2.5	0.3	13.4%	2.5
Onon Capsules	0.7	0.5	0.6	0.7	2.5	(1.1)	(30.7%)	2.5

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

Details of Sales Revenue

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Revenue of goods and products	246.0	295.0
Royalty and others	115.4	152.1
Total	361.4	447.2

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥69.9 billion for the fiscal year ended March 31, 2022 and ¥89.6 billion for the fiscal year ended March 31, 2023. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥30.8 billion for the fiscal year ended March 31, 2022 and ¥45.2 billion for the fiscal year ended March 31, 2023.

Revenue by Geographic Area

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)
Japan	242.0	288.2
Americas	106.9	142.8
Asia	8.9	11.6
Europe	3.6	4.6
Total	361.4	447.2

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

Summary of Consolidated Financial Results for FY 2022 (April 1, 2022 to March 31, 2023) (IFRS)

1. Revenue ¥447.2 billion YoY an increase of 23.8% (FY 2021 ¥361.4 billion)

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to treatments for gastric cancer, esophageal cancer, etc., resulting in sales of ¥142.3 billion, an increase of ¥29.9 billion (26.6%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥56.5 billion (54.3% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥24.8 billion (8.1% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥22.5 billion (8.3% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.7 billion (4.0% increase year on year). Sales of Velebru Tablets for malignant tumors were ¥8.5 billion (36.2% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.4 billion (5.3% decrease year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥5.0 billion (72.9% increase year on year).
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥4.4 billion (7.6% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥2.5 billion (30.7% decrease year on year).
- Royalty and others increased by ¥36.7 billion (31.8%) year on year to ¥152.1 billion.

2. Operating profit ¥142.0 billion YoY an increase of 37.6% (FY 2021 ¥103.2 billion)

- Cost of sales increased by ¥16.6 billion (17.7%) year on year to ¥110.1 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥19.5 billion (25.7%) year on year to ¥95.3 billion, mainly due to increases in research costs, costs for drug discovery collaboration, and development costs for clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥12.4 billion (16.1%) year on year to ¥89.5 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.
- Other expenses recorded in the fiscal year ended March 31, 2023 were ¥11.1 billion mainly due to a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc., and a contribution to Ono Pharma Oncology, Immunology, Neurology Research Foundation, which was established in January 2023. However, it was a decrease of ¥1.6 billion (12.9%) year on year mainly due to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody recorded in the fiscal year ended March 31, 2022.

3. Profit before tax ¥143.5 billion YoY an increase of 36.7% (FY 2021 ¥105.0 billion)

- Net financial income, etc. was ¥1.6 billion, a decrease of ¥0.3 billion (14.2%) year on year.

4. Profit for the year ¥112.7 billion YoY an increase of 40.0% (FY 2021 ¥80.5 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥32.2 billion (40.0%) year on year to ¥112.7 billion in association with the increase of the profit before tax.

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

Consolidated Financial Forecast

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)	FY 2023 Forecast (April 1, 2023 to March 31, 2024)	YoY
Revenue	361.4	447.2	475.0	6.2%
Operating profit	103.2	142.0	153.0	7.8%
Profit before tax	105.0	143.5	154.0	7.3%
Profit for the year (attributable to owners of the Company)	80.5	112.7	115.0	2.0%

Sales Revenue of Major Products (Forecast)

(Billions of yen)

Product Name	FY 2022 (April 1, 2022 to March 31, 2023)			FY 2023 Forecast (April 1, 2023 to March 31, 2024)		
	Results	YoY		Forecast	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	142.3	29.9	26.6%	155.0	12.7	8.9%
Forxiga Tablets	56.5	19.9	54.3%	65.0	8.5	15.0%
Orencia for Subcutaneous Injection	24.8	1.9	8.1%	25.5	0.7	3.0%
Glactiv Tablets	22.5	(2.0)	(8.3%)	21.0	(1.5)	(6.7%)
Velexbru Tablets	8.5	2.3	36.2%	9.5	1.0	11.3%
Kyprolis for Intravenous Infusion	8.7	0.3	4.0%	8.5	(0.2)	(2.3%)
Parsabiv Intravenous Injection	8.4	(0.5)	(5.3%)	8.0	(0.4)	(4.8%)
Ongentys Tablets	5.0	2.1	72.9%	6.5	1.5	30.5%
Onoact for Intravenous Infusion	4.5	(0.4)	(7.9%)	4.5	0.0	0.4%
Braftovi Capsules	3.2	0.5	18.2%	4.0	0.8	23.2%
Opalmon Tablets	4.4	(0.4)	(7.6%)	3.5	(0.9)	(19.9%)
Mektovi Tablets	2.5	0.3	13.4%	3.0	0.5	18.1%

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	310.0
Royalty and others	152.1	165.0
Total	447.2	475.0

Summary of Consolidated Financial Forecast for FY 2023 (April 1, 2023 to March 31, 2024) (IFRS)

1. Revenue ¥475.0 billion YoY an increase of ¥27.8 billion (6.2%)

- Revenue of goods and products are expected to be ¥310.0 billion, an increase of ¥15.0 billion (5.1%) 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, despite the intensifying competitive environment. In other new main products, sales of Forxiga Tablets are expected to increase by ¥8.5 billion (15.0%) year on year to ¥65.0 billion, as well as anticipating higher sales of Velembro Tablets and Ongentys Tablets. Furthermore, royalty and others are expected to increase by ¥12.9 billion (8.5%) year on year to ¥165.0 billion, anticipating that royalty revenue would grow continuously. Revenue is therefore expected to be ¥475.0 billion, an increase of ¥27.8 billion (6.2%) year on year.

2. Operating profit ¥153.0 billion YoY an increase of ¥11.0 billion (7.8%)

- Cost of sales is expected to be ¥113.0 billion, an increase of ¥2.9 billion (2.7%) year on year, due to an increase in revenue of goods and products.
- 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.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥96.0 billion, an increase of ¥6.5 billion (7.3%) year on year, 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 including the USA.
- Other expenses are expected to decrease by ¥6.6 billion (59.3%) year on year to ¥4.5 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 ¥153.0 billion, an increase of ¥11.0 billion (7.8%) year on year.

3. Profit before tax ¥154.0 billion YoY an increase of ¥10.5 billion (7.3%)

- Net financial income, etc. is expected to be ¥1.0 billion, a decrease of ¥0.6 billion (36.3%) year on year.

4. Profit for the year ¥115.0 billion YoY an increase of ¥2.3 billion (2.0%) (attributable to owners of the Company)

- Profit attributable to owners of the Company is expected to be ¥115.0 billion, an increase of ¥2.3 billion (2.0%) year on year.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)	FY 2023 Forecast (April 1, 2023 to March 31, 2024)
Property, plant, and equipment	9.9	9.8	9.9
Intangible assets	7.8	7.7	8.3
Total	17.7	17.5	18.2
Ratio to sales revenue	4.9%	3.9%	3.9%

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

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	FY 2022 (April 1, 2022 to March 31, 2023)	FY 2023 Forecast (April 1, 2023 to March 31, 2024)
Property, plant, and equipment	9.3	7.7	7.5
Intangible assets	7.2	13.7	12.9
Total	16.5	21.4	20.4

Number of Employees (Consolidated)

	FY 2021 (as of March 31, 2022)	FY 2022 (as of March 31, 2023)
Number of employees	3,687	3,761

Status of Shares (as of March 31, 2023)

Number of Shares

	As of March 31, 2023
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	517,425,200

Number of Shareholders

	As of March 31, 2023
Number of shareholders	61,926

Principal Shareholders

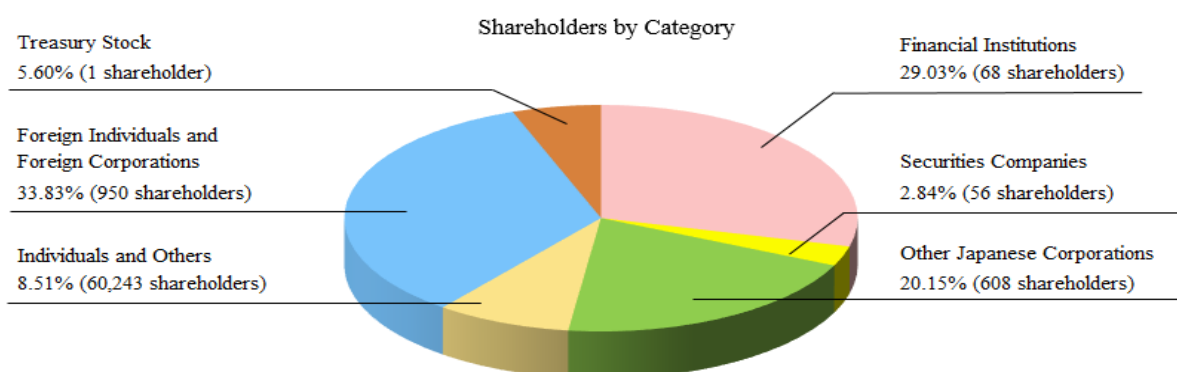
(As of March 31, 2023)

Name of shareholder	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	63,932	13.09
STATE STREET BANK AND TRUST COMPANY 505001	23,407	4.79
Custody Bank of Japan, Ltd. (Trust account)	22,876	4.68
Meiji Yasuda Life Insurance Company	18,594	3.80
Ono Scholarship Foundation	16,428	3.36
KAKUMEISOU Co., LTD.	16,153	3.30
STATE STREET BANK WEST CLIENT – TREATY 505234	8,924	1.82
MUFG Bank, Ltd.	8,640	1.76
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.59
SSBTC CLIENT OMNIBUS ACCOUNT	6,658	1.36

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,025 thousand shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (29,025 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 April 25, 2023

<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
Yervoy Injection * / Ipilimumab	Additional indication	Hepatocellular carcinoma *1	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *2	Injection	S. Korea	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023

*1: An application was approved in Taiwan for combination therapy with Opdivo and Yervoy for the treatment of hepatocellular carcinoma previously treated with sorafenib.

*2: Applications were approved in South Korea for combination therapy with Opdivo and Yervoy and combination therapy with Opdivo and chemotherapy for the treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma.

<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 *3 (excluding malignant pleural mesothelioma)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023

*3: An application for approval of Opdivo was filed in Japan for the treatment of malignant mesothelioma (excluding malignant pleural mesothelioma).

<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)
	Additional indication	Prostate 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)

<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-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 ★	New chemical entities	Solid tumor / 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
	New chemical entities	Solid tumor · Gastric 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

<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	TP53-mutant acute myeloid leukemia / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Myelodysplastic syndromes (MDS) / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
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	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.)

★: Combination with Opdivo.

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 April 25, 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
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Japan Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / SIP5 receptor agonist	Tablet	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

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023

*Phase I of Velexbru Tablets (BTK inhibitor) was conducted in Japan for the treatment of systemic sclerosis, but the project was discontinued due to the result not being able to confirm the anticipated efficacy.

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 (i.e., the interaction of PD-1 with its ligands PD-L1 and PD-L2), thereby enhancing the ability of the immune system to recognize cancer cells as foreign and eliminate them. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

Yervoy Injection (ONO-4480) / Ipilimumab (injection)

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

ONO-4482 / BMS-986016 / Relatlimab (injection)

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

ONO-4686 / BMS-986207 (injection)

ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed 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-4578 (tablet)

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

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 in Japan 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. Later, an application was 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 (tablet)

ONO-7475, an Axl/Mer inhibitor, is being developed in Japan for the treatment of EGFR-mutated non-small cell lung cancer and solid tumor.

ONO-7913 / Magrolimab (injection)

ONO-7913, an anti-CD47 antibody, is being developed in Japan for the treatment of pancreatic cancer, colorectal cancer, TP53-mutant acute myeloid leukemia, solid tumor and myelodysplastic syndromes. 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 addition, it is being developed in 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.

Onoact for Intravenous Infusion (ONO-1101) / Landiolol Hydrochloride (injection)

An application was approved for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

ONO-2017 / Cenobamate (tablet)

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

ONO-7684 (tablet)

ONO-7684, a FXIa inhibitor, is being developed in Japan and Europe for the treatment of thrombosis.

ONO-2808 (tablet)

ONO-2808, a S1P5 receptor agonist, is being developed in Japan and Europe for the treatment of neurodegenerative disease.

ONO-2910 (tablet)

ONO-2910, a Schwann cell differentiation promoter, is being developed in Japan for the treatment of diabetic polyneuropathy.

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.