Consolidated Financial Results
for the Fiscal Year Ended March 31, 2022 (IFRS)

May 11, 2022

Company name	: **ONO PHARMACEUTICAL CO., LTD.**
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: https://www.ono-pharma.com/
Representative	: Gyo Sagara President, Representative Director, and Chief Executive Officer
Contact	: Yukio Tani Corporate Executive Officer / Head of Corporate Communications
Phone	: +81-(0)6-6263-5670
Scheduled date of annual general meeting of shareholders	: June 23, 2022
Scheduled date of securities report submission	: June 24, 2022
Scheduled date of dividend payment commencement	: June 24, 2022
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 2021 (April 1, 2021 to March 31, 2022)

(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 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)
FY 2020	309,284	5.8	98,330	26.9	100,890	26.6	75,497	26.1	75,425	26.3	95,567	65.8

	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 2021	162.19	162.16	12.5	14.1	28.6
FY 2020	151.11	151.09	12.6	14.2	31.8

(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, 2022	739,203	661,674	655,906	88.7	1,343.40
As of March 31, 2021	745,428	639,743	634,133	85.1	1,270.45

(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 2021	61,829	6,038	(60,237)	69,112
FY 2020	73,977	(57,586)	(24,754)	61,045

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 2020	—	22.50	—	27.50	50.00	24,960	33.1	4.2
FY 2021	—	28.00	—	28.00	56.00	27,651	34.5	4.3
FY 2022 (Forecast)	—	33.00	—	33.00	66.00		29.3	

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

(% 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 2022	425,000	17.6	145,000	40.5	146,000	39.0	110,100	36.5	110,000	36.6	225.30

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: Yes
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, 2022 528,341,400 shares
As of March 31, 2021 528,341,400 shares
2) Number of treasury shares as of the end of the period:
As of March 31, 2022 40,096,713 shares
As of March 31, 2021 29,199,416 shares
3) Average number of shares outstanding during the period:
FY 2021 496,459,665 shares
FY 2020 499,137,173 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 8.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the Fiscal Year 2021

① Overview of Financial Results

(Millions of yen)

	Fiscal year ended March 31, 2021	**Fiscal year ended March 31, 2022**	Change	Change (%)
Revenue	309,284	**361,361**	52,076	16.8%
Operating profit	98,330	**103,195**	4,865	4.9%
Profit before tax	100,890	**105,025**	4,135	4.1%
Profit for the year (attributable to owners of the Company)	75,425	**80,519**	5,094	6.8%

[Revenue]

Revenue totaled ¥361.4 billion, which was an increase of ¥52.1 billion (16.8%) 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 first-line treatment for non-small cell lung cancer, esophageal cancer, and first-line treatment for gastric cancer, resulting in sales of ¥112.4 billion, an increase of ¥13.6 billion (13.8%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥36.7 billion (64.0% increase year on year), sales of Glactiv Tablets for type-2 diabetes were ¥24.5 billion (3.8% decrease year on year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥22.9 billion (4.5% increase year on year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.9 billion (10.2% increase year on year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.4 billion (17.5% increase year on year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies, etc. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.7 billion (13.4% decrease year on year), sales of Rivastach Patches for Alzheimer's disease were ¥2.9 billion (56.6% decrease year on year), respectively.
- Royalty and others increased by ¥20.7 billion (21.8%) year on year to ¥115.4 billion.

[Operating Profit]

Operating profit was ¥103.2 billion, an increase of ¥4.9 billion (4.9%) year on year.

- Cost of sales increased by ¥7.9 billion (9.3%) year on year to ¥93.5 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥13.5 billion (21.6%) year on year to ¥75.9 billion, due to increases in research expenses, expenses for collaborative development with alliance partners, and expenses for preparation of investigational products, as well as the recording of impairment losses in relation to intangible assets associated with compounds under development.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.8 billion (11.3%) year on year to ¥77.1 billion mainly due to expenses related to the launch of new products and additional indications, an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, and investments in information infrastructure related to IT and digital technologies.
- Other income decreased by ¥7.2 billion year on year to ¥1.0 billion, due to the absence of the upfront payment received under the license agreement with Roche in the previous fiscal year for the patent relating to the anti-PD-L1 antibody.
- Other expenses increased by ¥10.8 billion year on year to ¥12.7 billion. The increase is attributable to factors that include the Company having recorded a ¥7.3 billion difference because the total consisting of ¥5.0 billion associated with settlement of litigation on patents relating to the PD-1 antibody and donations of ¥23.0 billion paid to Kyoto University exceeded the provision for royalties on patents of ¥20.7 billion that had already been recorded; along with the Company also having recorded expenses associated with the collaboration agreement relating to Opdivo with Bristol-Myers Squibb Company.

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

Profit attributable to owners of the Company increased by ¥5.1 billion (6.8%) year on year to ¥80.5 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 treatment is positioned as an important strategic field because medical needs are high.

In drug discovery research, having designated oncology, immunology, neurology, and specialty domains with high medical needs as our priority areas of research, we extensively investigate biology of human disease in the respective domains, and make efforts to enhance our drug discovery capabilities aiming to discover and develop new drugs that meet medical needs. To that end, by actively promoting our strategy of "Open Innovation," which is our strength, we are finding original drug seeds and are pursuing the discovery and development of innovative new drugs with a significant medical impact by exploiting the latest technologies in and outside the company, in fields such as informatics, human disease modeling, and synthesis of new drug candidate compounds.

A total of eight new drug candidate compounds in our priority therapeutic areas have proceeded to 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 analyze the relationship between target molecules and diseases and make efforts to find physiological indicators (biomarkers) to 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 will 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, 2022 (including those at the end of the fiscal year and thereafter) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

"Opdivo / Nivolumab"

Gastric cancer

- In June 2021, an application was approved in South Korea for combination therapy with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma.
- In October 2021, an application was approved in Taiwan for combination therapy with fluoropyrimidine- and platinum- containing chemotherapy for the treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma without human epidermal growth factor receptor 2 (HER2) overexpression.
- In November 2021, an application for combination therapy with chemotherapy was approved in Japan for the treatment of unresectable advanced or recurrent gastric cancer.

Esophageal cancer

- In September 2021, approval applications were filed in Japan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.
- In November 2021, an application was approved in Japan for the adjuvant treatment of esophageal cancer or gastroesophageal junction cancer.
- In December 2021, an application was approved in Taiwan for the adjuvant treatment of patients with completely resected esophageal cancer or gastroesophageal junction cancer with residual pathologic disease who have received neoadjuvant concurrent chemoradiotherapy.
- In February 2022, an application was approved in South Korea for the adjuvant treatment in patients with esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy and complete resection.

Malignant pleural mesothelioma

- In May 2021, an application for combination therapy with Yervoy was approved in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.
- In June 2021, an application for combination therapy with Yervoy was approved in South Korea for the treatment of unresectable malignant pleural mesothelioma.
- In September 2021, an application for combination therapy with Yervoy was approved in Taiwan for the treatment of unresectable malignant pleural mesothelioma.

Renal cell carcinoma

- In August 2021, an application for combination therapy with Cabometyx tablets / Cabozantinib s-malate, a tyrosine kinase inhibitor being developed by Takeda Pharmaceutical Company Limited was approved in Japan for the treatment of unresectable or metastatic renal cell carcinoma.
- In February 2022, an application for combination therapy with Cabometyx tablets / Cabozantinib s-malate was approved in South Korea for the first-line treatment of advanced renal cell carcinoma.

Urothelial carcinoma / Bladder cancer
- In February 2022, an application was approved in South Korea for the adjuvant treatment in patients with muscle-invasive bladder carcinoma (MIBC) at a high risk of recurrence after undergoing radical resection.
- In March 2022, an application was approved in Japan for the adjuvant treatment of urothelial carcinoma.
- 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.

Colorectal cancer
- In February 2022, combination therapy with Yervoy was approved in South Korea for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Non-small cell lung cancer
- In June 2021, the package insert was revised in Japan for combination therapy with Bevacizumab (anti-VEGF humanized monoclonal antibody) and chemotherapy for the treatment of unresectable, advanced or recurrent non-small cell lung cancer.
- In January 2022, combination therapy with Bevacizumab and chemotherapy was approved in Taiwan for the first-line treatment of advanced or recurrent no-squamous non-small cell lung cancer with no epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- In February 2022, combination therapy with Bevacizumab and chemotherapy was approved in South Korea for the first-line treatment of advanced or recurrent no-squamous non-small cell lung cancer with no EGFR mutation or ALK genomic tumor aberrations.
- In April 2022, an approval application was filed in Japan for the neoadjuvant treatment of non-small cell lung cancer in combination therapy with chemotherapy.

Cancer of unknown primary
- In December 2021, an application was approved in Japan for expanded use for the treatment of cancer of unknown primary.

Hodgkin lymphoma
- In September 2021, an application was approved in Japan for the dosage and administration for the treatment of pediatric patients with recurrent or refractory classical hodgkin lymphoma.

Solid tumor
- In April 2021, development for the treatment of solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma) was discontinued in Japan due to strategic reasons.

Central nervous system lymphoma / Primary testicular lymphoma
- In April 2021, development for the treatment of central nervous system lymphoma / primary testicular lymphoma was discontinued in Japan due to strategic reasons.

Head and neck cancer
- In July 2021, development involving combination therapy with Yervoy for the treatment of head and neck cancer was underway in Japan, South Korea and Taiwan, but the primary endpoints were not met.

Biliary tract cancer
- In April 2022, phase II for the treatment of biliary tract cancer was conducted in Japan, but the project was removed from the development pipeline as the application was abandoned due to strategic reasons.

“Velexbru Tablets / Tirabrutinib Hydrochloride / ONO-4059”
- In November 2021, an application for Velexbru Tablets (BTK inhibitor) was approved in South Korea for the treatment of recurrent or refractory primary central nervous system lymphoma.
- In February 2022, an application for Velexbru Tablets (BTK inhibitor) was approved in Taiwan for the treatment of recurrent or refractory primary central nervous system lymphoma.
- In July 2021, phase II of ONO-4059 (BTK inhibitor) was initiated in the USA for the treatment of primary central nervous system lymphoma.

“Braftovi Capsules / Encorafenib” “Mektovi Tablets / Binimetinib”
- In August 2021, an application was approved in South Korea for Braftovi Capsules / Encorafenib (BRAF inhibitor) for use in combination therapy with Cetuximab (an anti-human EGFR monoclonal antibody) for the treatment of adult patients with advanced or recurrent $BRAF^{V600E}$-mutant colorectal cancer after prior therapy.
- In August 2021, phase III of Braftovi Capsules (BRAF inhibitor) and Mektovi Tablets (MEK inhibitor) for the treatment of melanoma was discontinued in South Korea due to strategic reasons.
- In August 2021, phase III of Mektovi Tablets (MEK inhibitor) for the treatment of colorectal cancer was discontinued in South Korea due to strategic reasons.

“ONO-7475”
- In April 2021, phase I of ONO-7475 (Axl/Mer inhibitor) was initiated in Japan for the treatment of EGFR-mutated non-small cell lung cancer.

“ONO-7913 / Magrolimab”
- In October 2021, phase III of ONO-7913 (anti-CD47 antibody) was initiated in Japan for the treatment of TP53-mutant acute myeloid leukemia.
- In January 2022, phase III of ONO-7913 (anti-CD47 antibody) was initiated in South Korea and Taiwan for the treatment of acute myeloid leukemia
- In April 2021, phase I of combination therapy of Opdivo and ONO-7913 (anti-CD47 antibody) was initiated in Japan for the treatment of pancreatic cancer and colorectal cancer.
- In April 2021, phase I of ONO-7913 (anti-CD47 antibody) was initiated in Japan for the treatment of myelodysplastic syndromes (MDS).

“ONO-7119”
- In August 2021, phase I of combination therapy of Opdivo and ONO-7119 (PARP7 inhibitor) was initiated in Japan for the treatment of solid tumor.

“ONO-4578”
- In July 2021, phase I of ONO-4578 (Prostaglandin receptor (EP4) antagonist) was initiated in Japan for the treatment of hormone receptor-positive, HER2-negative breast cancer.

"ONO-4483"
- In July 2021, development of combination therapy for Opdivo and ONO-4483 (anti-KIR antibody) for the treatment of solid tumor was discontinued in Japan due to strategic reasons.

"ONO-4685"
- In October 2021, phase I of ONO-4685 (PD-1 x CD3 bispecific antibody) was initiated in the USA for the treatment of T-cell lymphoma.

"ONO-7122"
- In October 2021, phase I of combination therapy for Opdivo and ONO-7122 (TGF-β inhibitor) was initiated in Japan for the treatment of solid tumor.

"ONO-7914"
- In November 2021, phase I of combination therapy for Opdivo and ONO-7914 (STING agonist) was initiated in Japan for the treatment of solid tumor.

"ONO-7701/Linrodostat"
- In February 2022, phase III of combination therapy for Opdivo and ONO-7701 (IDO1 inhibitor) for the treatment of bladder cancer was discontinued in Japan, South Korea and Taiwan due to strategic reasons.

"ONO-7807"
- In March 2022, phase I/II of combination therapy for Opdivo and ONO-7807 (anti-TIM-3 antibody) for the treatment of solid tumor was discontinued in Japan due to strategic reasons.

"ONO-7912"
- Phase III of ONO-7912 (cancer metabolism inhibitor) for the treatment of pancreatic cancer and phase III for the treatment of acute myeloid leukemia conducted by Rafael Pharmaceuticals, Inc. were not able to confirm anticipated efficacy. Based on these results, phase I for the treatment of pancreatic cancer in Japan was discontinued in February 2022.

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

<Areas other than Oncology>

"Forxiga Tablets / Dapagliflozin propylene glycolate hydrate"
- In August 2021, an application was approved in Japan for Forxiga Tablets (selective SGLT2 inhibitor) for the treatment of chronic kidney disease (excluding patients with end-stage renal disease or undergoing dialysis).

"Onoact for Intravenous Infusion / Landiolol Hydrochloride"
- In October 2021, an approval application for Onoact for Intravenous Infusion (a short-acting selective β_1 blocker) was filed in Japan for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

"Velexbru Tablets / Tirabrutinib Hydrochloride / ONO-4059"
- In April 2022, phase III of Velexbru Tablets (BTK inhibitor) was initiated in Japan for the treatment of pemphigus.
- ONO-4059 (BTK inhibitor) was out-licensed to Gilead Sciences, Inc. in 2014. However, Gilead returned the rights to develop and commercialize ONO-4059 in areas other than oncology during the fiscal year ended March 31, 2022, in addition to the rights to develop and commercialize ONO-4059 in oncology area, which it had already returned.

"Foipan Tablets / Camostat mesilate"
- In June 2021, phase III of Foipan Tablets (a protease enzyme inhibitor) for the treatment of the novel coronavirus disease (COVID-19) was discontinued due to the results not being able to confirm anticipated efficacy.

"Orencia SC / Abatacept"
- In January 2022, phase III of Orencia SC (T-cell activation inhibitor) for the treatment of polymyositis and dermatomyositis was discontinued due to the results not being able to confirm anticipated efficacy.

"Joyclu Intra-articular Injection / Diclofenac Etalhyaluronate Sodium"
- In March 2022, phase II of Joyclu Intra-articular Injection (Hyaluronic acid-NSAID) for the treatment of enthesopathy was conducted in Japan, but the project was removed from the development pipeline because it was not possible to achieve the primary endpoint.

"ONO-2017"
- In December 2021, Phase III of ONO-2017 (inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel) was initiated in Japan for the treatment of primary generalized tonic-clonic seizures.
- Phase III of ONO-2017 (inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel) is being conducted in Japan for the treatment of partial-onset seizures.

"ONO-2910"
- In April 2021, phase II of ONO-2910 (Schwann cell differentiation promoter) was initiated in Japan for the treatment of diabetic polyneuropathy.

"ONO-4685"
- In September 2021, phase I of ONO-4685 (PD-1 x CD3 bispecific antibody) was initiated in Europe for the treatment of autoimmune disease.

[Status of Drug Discovery / Research Alliance Activities]

- In August 2021, the Company entered into a research collaboration agreement with Healx Limited in the UK to jointly discover and develop innovative drugs that meet unmet medical needs utilizing Healx's artificial intelligence (AI) technology.
- In August 2021, the Company entered into a drug discovery collaboration agreement with MiraBiologics, Inc. to discover and create the next generation of biopharmaceuticals utilizing MiraBiologics' proprietary LassoGraft Technology®, a new technology that combines cyclic peptide searching method and protein engineering.
- In December 2021, the Company entered into an agreement with Vanderbilt University in the USA to extend drug discovery collaboration. Under the agreement concluded initially in November 2015, the Company and Vanderbilt University have been engaged in jointly identifying compounds to validate if an under-explored family of ion channels or transporters has a potential for a therapeutic target, and based on the validation, is working to discover clinical candidates for the treatment of CNS disorders.
- In January 2022, the Company entered into a drug discovery collaboration agreement with Neurimmune AG in Switzerland. The collaboration is focused on creating antibody drugs against new therapeutic targets in the field of neurodegenerative diseases utilizing Neurimmune's proprietary Reverse Translational Medicine™ technology platform, a unique antibody drug creation approach.
- In March 2022, the Company entered into a drug discovery collaboration agreement with Iktos in France. Iktos will apply Iktos's unique artificial intelligence (AI) drug discovery technology platform and know-how, helping to bring new insights and directions into the drug discovery process based on a comprehensive data-driven chemical structure generation technology complementing the Company's drug discovery program to expedite the identification of novel small molecule compounds against therapeutic targets selected by the Company.
- In March 2022, the Company exercised its option to enter into a development and license agreement with Numab Therapeutics AG in Switzerland for a multispecific antibody candidate in the immuno-oncology area that was generated through a research collaboration between the two companies initiated in 2017.
- 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 new 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.

(2) Overview of Financial Position for the Fiscal Year 2021

(Millions of yen)

	As of March 31, 2021	**As of March 31, 2022**	Change
Total assets	745,428	**739,203**	(6,225)
Equity attributable to owners of the Company	634,133	**655,906**	21,773
Ratio of equity attributable to owners of the Company to total assets	85.1%	**88.7%**	
Equity attributable to owners of the Company per share	1,270.45 yen	**1,343.40 yen**	

Total assets decreased to ¥739.2 billion by ¥6.2 billion from the end of the previous fiscal year.
Current assets increased by ¥33.6 billion to ¥281.3 billion mainly due to increases in trade and other receivables and cash and cash equivalents.
Non-current assets decreased by ¥39.8 billion to ¥457.9 billion mainly due to decreases in investment securities and deferred tax assets.
Liabilities decreased by ¥28.2 billion to ¥77.5 billion mainly due to decreases in provisions and income taxes payable.
Equity attributable to owners of the Company increased by ¥21.8 billion to ¥655.9 billion mainly due to an increase in retained earnings, despite the purchase of treasury shares.

(3) Overview of Cash Flows for the Fiscal Year 2021

(Millions of yen)

	Fiscal year ended March 31, 2021	**Fiscal year ended March 31, 2022**	Change
Cash and cash equivalents at the beginning of the fiscal year	69,005	**61,045**	
Cash flows from operating activities	73,977	**61,829**	(12,147)
Cash flows from investing activities	(57,586)	**6,038**	63,624
Cash flows from financing activities	(24,754)	**(60,237)**	(35,483)
Net increase (decrease) in cash and cash equivalents	(8,363)	**7,631**	
Effects of exchange rate changes on cash and cash equivalents	403	**436**	
Cash and cash equivalents at the end of the fiscal year	61,045	**69,112**	

Net increase/decrease in cash and cash equivalents was an increase of ¥7.6 billion.
Net cash provided by operating activities was ¥61.8 billion, as a result of profit before tax of ¥105.0 billion, etc., while income taxes paid of ¥34.3 billion and a decrease in provisions of ¥20.7 billion, etc.
Net cash provided by investing activities was ¥6.0 billion, as a result of proceeds from sales and redemption of investments of ¥22.8 billion, etc., while purchase of intangible assets paid of ¥6.8 billion and purchase of property, plant, and equipment paid of ¥5.5 billion.
Net cash used in financing activities was ¥60.2 billion, as a result of purchases of treasury shares of ¥30.0 billion and dividends paid of ¥27.7 billion, etc.

(4) Future Outlook

(Millions of yen)

	Result (Fiscal year ended March 31, 2022)	**Forecast (Fiscal year ending March 31, 2023)**	Change	Change (%)
Revenue	361,361	**425,000**	63,639	17.6%
Operating profit	103,195	**145,000**	41,805	40.5%
Profit before tax	105,025	**146,000**	40,975	39.0%
Profit for the year (attributable to owners of the Company)	80,519	**110,000**	29,481	36.6%

[Revenue]
Revenue of goods and products are expected to be ¥290.0 billion, an increase of ¥44.0 billion (17.9%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be ¥155.0 billion, an increase of ¥42.6 billion year on year, due to its expanded use in first-line treatment for non-small cell lung cancer and gastric cancer, urothelial carcinoma and cancer of unknown primary, despite the intensifying competitive environment. In other new main products, the Company expects sales of Forxiga Tablets, which were approved for additional indications of chronic kidney disease last year, to increase by ¥10.3 billion year on year to ¥47.0 billion, as well as anticipating higher sales of Kyprolis for Intravenous Infusion, Velexbru Tablets, and Ongentys Tablets. Furthermore, royalty and others are expected to continue to grow and to increase by ¥19.6 billion (17.0%) year on year to ¥135.0 billion. Revenue is therefore forecast to be ¥425.0 billion, an increase of ¥63.6 billion (17.6%) year on year.

[Profit]
Cost of sales is expected to be ¥104.0 billion, an increase of ¥10.5 billion (11.2%) year on year, due to an increase in revenue of goods and products.
Research and development costs are expected to be ¥87.0 billion, an increase of ¥11.1 billion (14.7%) 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; global development study; and collaborative development.
Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥88.0 billion, an increase of ¥10.9 billion (14.2%) year on year, due to an increase 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 ¥11.2 billion year on year to ¥1.5 billion, due in part to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody, and other costs recorded in the fiscal year ended March 31, 2022.
Therefore, operating profit is expected to be ¥145.0 billion, an increase of ¥41.8 billion (40.5%) year on year, and profit attributable to owners of the Company is expected to be ¥110.0 billion, an increase of ¥29.5 billion (36.6%) year on year.

Note: We assume that restrictions on certain activities will continue due to COVID-19, but that the impact on financial results will be immaterial. Going forward, if any revisions to financial forecasts are necessary, the Company will promptly announce them.

(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, 2022, we expect to make a year-end dividend of 28 yen per share. With the payment of the second quarter dividend of 28 yen per share, the annual dividend is expected to be 56 yen per share. Also, the annual dividend for the following fiscal year ending March 31, 2023 is expected to be 66 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, 2021	As of March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	61,045	69,112
Trade and other receivables	84,269	99,788
Marketable securities	2,978	60
Other financial assets	40,952	47,797
Inventories	39,151	41,817
Other current assets	19,246	22,692
Total current assets	247,642	281,266
Non-current assets:		
Property, plant, and equipment	113,866	112,131
Intangible assets	68,285	64,734
Investment securities	146,796	125,046
Investments in associates	112	108
Other financial assets	131,888	127,302
Deferred tax assets	34,242	25,074
Retirement benefit assets	7	377
Other non-current assets	2,590	3,165
Total non-current assets	497,787	457,937
Total assets	745,428	739,203

(Millions of yen)

	As of March 31, 2021	As of March 31, 2022
Liabilities and Equity		
Current liabilities:		
Trade and other payables	39,163	49,689
Lease liabilities	2,023	2,301
Other financial liabilities	616	716
Income taxes payable	19,047	1,526
Provisions	20,721	—
Other current liabilities	12,163	11,694
Total current liabilities	93,733	65,926
Non-current liabilities:		
Lease liabilities	7,030	6,501
Other financial liabilities	0	0
Retirement benefit liabilities	3,056	3,322
Deferred tax liabilities	1,052	1,009
Other non-current liabilities	813	771
Total non-current liabilities	11,952	11,603
Total liabilities	105,685	77,529
Equity:		
Share capital	17,358	17,358
Capital reserves	17,231	17,241
Treasury shares	(44,705)	(74,683)
Other components of equity	62,299	51,236
Retained earnings	581,950	644,754
Equity attributable to owners of the Company	634,133	655,906
Non-controlling interests	5,610	5,768
Total equity	639,743	661,674
Total liabilities and equity	745,428	739,203

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

Consolidated Statement of Income

(Millions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Revenue	309,284	361,361
Cost of sales	(85,573)	(93,511)
Gross profit	223,711	267,850
Selling, general, and administrative expenses	(69,230)	(77,057)
Research and development costs	(62,384)	(75,879)
Other income	8,165	980
Other expenses	(1,932)	(12,698)
Operating profit	98,330	103,195
Finance income	2,693	2,710
Finance costs	(137)	(874)
Share of profit (loss) from investments in associates	4	(6)
Profit before tax	100,890	105,025
Income tax expense	(25,392)	(24,340)
Profit for the year	75,497	80,684
Profit for the year attributable to:		
Owners of the Company	75,425	80,519
Non-controlling interests	72	166
Profit for the year	75,497	80,684
Earnings per share:		
Basic earnings per share (Yen)	151.11	162.19
Diluted earnings per share (Yen)	151.09	162.16

Consolidated Statement of Comprehensive Income

(Millions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Profit for the year	75,497	80,684
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	17,273	(2,094)
Remeasurements of defined benefit plans	2,370	199
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	2
Total of items that will not be reclassified to profit or loss	19,646	(1,893)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	424	814
Total of items that may be reclassified subsequently to profit or loss	424	814
Total other comprehensive income (loss)	20,070	(1,079)
Total comprehensive income (loss) for the year	95,567	79,606
Comprehensive income (loss) for the year attributable to:		
Owners of the Company	95,488	79,444
Non-controlling interests	78	161
Total comprehensive income (loss) for the year	95,567	79,606

(3) Consolidated Statement of Changes in Equity

FY 2020 (April 1, 2020 to March 31, 2021)

(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, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
Changes in Accounting Policies					(1,414)	(1,414)		(1,414)
Restated balance	17,358	17,229	(44,737)	48,030	523,191	561,071	5,538	566,609
Profit for the year					75,425	75,425	72	75,497
Other comprehensive income (loss)				20,064		20,064	6	20,070
Total comprehensive income (loss) for the year	–	–	–	20,064	75,425	95,488	78	95,567
Purchase of treasury shares			(5)			(5)		(5)
Disposition of treasury shares		(38)	38			0		0
Cash dividends					(22,461)	(22,461)	(6)	(22,467)
Share-based payments		40				40		40
Transfer from other components of equity to retained earnings				(5,795)	5,795	–		–
Total transactions with the owners	–	2	32	(5,795)	(16,666)	(22,426)	(6)	(22,432)
Balance as of March 31, 2021	17,358	17,231	(44,705)	62,299	581,950	634,133	5,610	639,743

FY 2021 (April 1, 2021 to March 31, 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, 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 (loss)				(1,074)		(1,074)	(4)	(1,079)
Total comprehensive income (loss) 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

(4) Consolidated Statement of Cash Flows

(Millions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Cash flows from operating activities		
Profit before tax	100,890	105,025
Depreciation and amortization	15,820	17,721
Impairment losses	2,307	3,404
Interest and dividend income	(2,462)	(2,349)
Interest expense	73	70
(Increase) decrease in inventories	(6,107)	(2,464)
(Increase) decrease in trade and other receivables	(7,179)	(15,283)
Increase (decrease) in trade and other payables	6,361	8,177
Increase (decrease) in provisions	—	(20,721)
Increase (decrease) in retirement benefit liabilities	410	54
(Increase) decrease in retirement benefit assets	—	130
Other	(4,468)	70
Subtotal	105,645	93,835
Interest received	63	40
Dividends received	2,401	2,317
Interest paid	(73)	(70)
Income taxes paid	(34,060)	(34,293)
Net cash provided by (used in) operating activities	73,977	61,829
Cash flows from investing activities		
Purchases of property, plant, and equipment	(7,018)	(5,497)
Proceeds from sales of property, plant, and equipment	2	14
Purchases of intangible assets	(13,275)	(6,780)
Purchases of investments	(760)	(1,127)
Proceeds from sales and redemption of investments	14,033	22,782
Payments into time deposits	(80,939)	(57,486)
Proceeds from withdrawal of time deposits	30,800	55,800
Other	(429)	(1,667)
Net cash provided by (used in) investing activities	(57,586)	6,038
Cash flows from financing activities		
Dividends paid	(22,449)	(27,666)
Dividends paid to non-controlling interests	(6)	(4)
Repayments of lease liabilities	(2,296)	(2,560)
Purchases of treasury shares	(3)	(30,007)
Net cash provided by (used in) financing activities	(24,754)	(60,237)
Net increase (decrease) in cash and cash equivalents	(8,363)	7,631
Cash and cash equivalents at the beginning of the year	69,005	61,045
Effects of exchange rate changes on cash and cash equivalents	403	436
Cash and cash equivalents at the end of the year	61,045	69,112

(5) Notes to Consolidated Financial Statements

(Note Regarding Assumption of a 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, 2022 are the same as the ones for the previous fiscal year except for the change listed below.

(Changes in Accounting Policies)

The Group had previously recognized intangible assets for configuration or customization costs in cloud computing agreements by applying IAS 38 "Intangible Assets." However, effective from the fiscal year ended March 31, 2022, the Group has changed the method to recognize the costs of configuration or customization services as an expense when they are received, in accordance with the IFRS Interpretations Committee's agenda decision issued in April 2021.

This change in accounting policy has been applied retrospectively, and the consolidated financial statements for the previous fiscal year are presented after such retrospective application.

Because the cumulative effect was reflected in net assets as of the beginning of the previous fiscal year, deferred tax assets increased by ¥623 million, while retained earnings and intangible assets decreased by ¥1,414 million and ¥2,037 million, respectively, as of the beginning of the previous fiscal year. The effect of this change on the consolidated statement of income for the fiscal years ended March 31, 2021 and 2022 is immaterial.

(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 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Revenue of goods and products	214,544	245,956
Royalty and others	94,740	115,405
Total	309,284	361,361

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥59.8 billion for the fiscal year ended March 31, 2021 and ¥69.9 billion for the fiscal year ended March 31, 2022. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥24.3 billion for the fiscal year ended March 31, 2021 and ¥30.8 billion for the fiscal year ended March 31, 2022.

3) Revenue by Geographic Area

Details of revenue by geographic area are as follows:

(Millions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Japan	212,865	241,971
Americas	85,566	105,890
Asia	7,446	8,895
Europe	3,407	4,605
Total	309,284	361,361

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 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Bristol-Myers Squibb Company and the group	65,470	79,490
Medipal Holdings Corporation and the group	47,577	57,262
Suzuken Co., Ltd. and the group	46,404	49,438
Alfresa Holdings Corporation and the group	34,422	37,665
Toho Holdings Co., Ltd. and the group	32,596	36,119

(Earnings per Share)

1) Basic Earnings per Share

(i) Basic earnings per share

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Basic earnings per share (Yen)	151.11	162.19

(ii) Basis of calculation of basic earnings per share

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Profit for the year attributable to owners of the Company (Millions of yen)	75,425	80,519
Weighted-average number of ordinary shares outstanding (Thousands of shares)	499,137	496,459

2) Diluted Earnings per Share

(i) Diluted earnings per share

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Diluted earnings per share (Yen)	151.09	162.16

(ii) Basis of calculation of diluted earnings per share

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)
Profit for the year attributable to owners of the Company (Millions of yen)	75,425	80,519
Weighted-average number of ordinary shares outstanding (Thousands of shares)	499,137	496,459
Increase in common shares by share acquisition rights (Thousands of shares)	66	67
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	499,203	496,527

(Significant Subsequent Events)

On April 28, 2022, based on a resolution passed by the Board of Directors on April 6, 2022, the Company retired treasury shares pursuant to the provisions of Article 178 of the Companies Act.

(1) Class of shares retired	Ordinary shares
(2) Number of shares retired	10,916,200 shares
(3) Date of retirement	April 28, 2022

Fiscal Year 2021
(April 1, 2021 to March 31, 2022)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Fiscal Year 2021 (April 1, 2021 to March 31, 2022) Consolidated Financial Results (IFRS)】

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

Consolidated Financial Results for FY 2021 (April 1, 2021 to March 31, 2022) (IFRS)

Consolidated Financial Results

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 (April 1, 2021 to March 31, 2022)**	YoY
Revenue	309.3	**361.4**	16.8%
Operating profit	98.3	**103.2**	4.9%
Profit before tax	100.9	**105.0**	4.1%
Profit for the year (attributable to owners of the Company)	75.4	**80.5**	6.8%

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

Sales Revenue of Major Products

(Billions of yen)

Product Name	**FY 2021 (April 1, 2021 to March 31, 2022)**					YoY		Forecasts
	Cumulative							
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar		Change	Change (%)	
Opdivo Intravenous Infusion	29.0	27.1	28.9	27.4	**112.4**	13.6	13.8%	110.0
Forxiga Tablets	7.5	8.2	10.9	10.1	**36.7**	14.3	64.0%	36.5
Glactiv Tablets	6.5	6.3	6.6	5.2	**24.5**	(1.0)	(3.8%)	24.5
Orencia for Subcutaneous Injection	5.7	5.5	6.3	5.3	**22.9**	1.0	4.5%	22.5
Parsabiv Intravenous Injection	2.2	2.3	2.4	1.9	**8.9**	0.8	10.2%	9.0
Kyprolis for Intravenous Infusion	2.0	2.2	2.3	1.9	**8.4**	1.2	17.5%	8.5
Velexbru Tablets	1.4	1.4	1.8	1.5	**6.3**	4.2	204.1%	6.0
Onoact for Intravenous Infusion	1.2	1.1	1.6	1.0	**4.9**	0.2	4.5%	5.0
Opalmon Tablets	1.2	1.2	1.3	1.0	**4.7**	(0.7)	(13.4%)	5.0
Rivastach Patches	0.8	0.7	0.8	0.5	**2.9**	(3.7)	(56.6%)	3.0
Braftovi Capsules	0.7	0.7	0.7	0.7	**2.7**	1.7	156.9%	3.0
Mektovi Tablets	0.5	0.6	0.6	0.5	**2.2**	1.2	124.7%	2.5
Onon Capsules	1.1	0.7	0.9	0.9	**3.6**	0.6	22.0%	4.0
Ongentys Tablets	0.2	0.7	1.1	0.9	**2.9**	2.5	742.4%	3.0
Newly launched products during FY 2021	0.3	0.2	0.3	0.2	**1.0**	1.0	-	1.0

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Cumulative results for newly launched products during FY 2021 include sales of Adlumiz Tablets launched in April 2021 and Joyclu Intra-articular Injection launched in May 2021.

Details of Sales Revenue

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 (April 1, 2021 to March 31, 2022)**
Revenue of goods and products	214.5	**246.0**
Royalty and others	94.7	**115.4**
Total	309.3	**361.4**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is 59.8 billion for the fiscal year ended March 31, 2021 and ¥69.9 billion for the fiscal year ended March 31, 2022. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥24.3 billion for the fiscal year ended March 31, 2021 and ¥30.8 billion for the fiscal year ended March 31, 2022.

Revenue by Geographic Area

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 (April 1, 2021 to March 31, 2022)**
Japan	212.9	**242.0**
Americas	85.6	**105.9**
Asia	7.4	**8.9**
Europe	3.4	**4.6**
Total	309.3	**361.4**

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

Summary of Consolidated Financial Results for FY 2021 (April 1, 2021 to March 31, 2022) (IFRS)

1. Revenue ¥361.4 billion YoY an increase of 16.8% (FY 2020 ¥309.3 billion)

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to first-line treatment for non-small cell lung cancer, esophageal cancer, and first-line treatment for gastric cancer, resulting in sales of ¥112.4 billion, an increase of ¥13.6 billion (13.8%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥36.7 billion (64.0% increase year on year), sales of Glactiv Tablets for type-2 diabetes were ¥24.5 billion (3.8% decrease year on year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥22.9 billion (4.5% increase year on year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.9 billion (10.2% increase year on year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.4 billion (17.5% increase year on year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies, etc. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.7 billion (13.4% decrease year on year), sales of Rivastach Patches for Alzheimer's disease were ¥2.9 billion (56.6% decrease year on year), respectively.
- Royalty and others increased by ¥20.7 billion (21.8%) year on year to ¥115.4 billion.

2. Operating profit ¥103.2 billion YoY an increase of 4.9% (FY 2020 ¥98.3 billion)

- Cost of sales increased by ¥7.9 billion (9.3%) year on year to ¥93.5 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥13.5 billion (21.6%) year on year to ¥75.9 billion, due to increases in research expenses, expenses for collaborative development with alliance partners, and expenses for preparation of investigational products, as well as the recording of impairment losses in relation to intangible assets associated with compounds under development.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.8 billion (11.3%) year on year to ¥77.1 billion mainly due to expenses related to the launch of new products and additional indications, an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, and investments in information infrastructure related to IT and digital technologies.
- Other income decreased by ¥7.2 billion year on year to ¥1.0 billion, due to the absence of the upfront payment received under the license agreement with Roche in the previous fiscal year for the patent relating to the anti-PD-L1 antibody.
- Other expenses increased by ¥10.8 billion year on year to ¥12.7 billion. The increase is attributable to factors that include the Company having recorded a ¥7.3 billion difference because the total consisting of ¥5.0 billion associated with settlement of litigation on patents relating to the PD-1 antibody and donations of ¥23.0 billion paid to Kyoto University exceeded the provision for royalties on patents of ¥20.7 billion that had already been recorded; along with the Company also having recorded expenses associated with the collaboration agreement relating to Opdivo with Bristol-Myers Squibb Company.

3. Profit before tax ¥105.0 billion YoY an increase of 4.1% (FY 2020 ¥100.9 billion)

- Net financial income, etc. was ¥1.8 billion, a decrease of ¥0.7 billion (28.5%) year on year.

4. Profit for the year ¥80.5 billion YoY an increase of 6.8% (FY 2020 ¥75.4 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥5.1 billion (6.8%) year on year to ¥80.5 billion in association with the increase of the profit before tax.

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

Consolidated Financial Forecasts

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 Forecasts (April 1, 2022 to March 31, 2023)**	YoY
Revenue	309.3	361.4	**425.0**	17.6%
Operating profit	98.3	103.2	**145.0**	40.5%
Profit before tax	100.9	105.0	**146.0**	39.0%
Profit for the year (attributable to owners of the Company)	75.4	80.5	**110.0**	36.6%

Sales Revenue of Major Products (Forecasts)

(Billions of yen)

Product Name	FY 2021 (April 1, 2021 to March 31, 2022)			**FY 2022 Forecasts (April 1, 2022 to March 31, 2023)**		
	Results	YoY		**Forecasts**	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	112.4	13.6	13.8%	155.0	42.6	37.8%
Forxiga Tablets	36.7	14.3	64.0%	47.0	10.3	28.2%
Orencia for Subcutaneous Injection	22.9	1.0	4.5%	23.0	0.1	0.5%
Glactiv Tablets	24.5	(1.0)	(3.8%)	23.0	(1.5)	(6.3%)
Kyprolis for Intravenous Infusion	8.4	1.2	17.5%	9.0	0.6	7.6%
Parsabiv Intravenous Injection	8.9	0.8	10.2%	8.0	(0.9)	(9.9%)
Velexbru Tablets	6.3	4.2	204.1%	7.0	0.7	11.7%
Ongentys Tablets	2.9	2.5	742.4%	5.0	2.1	73.6%
Onoact for Intravenous Infusion	4.9	0.2	4.5%	4.5	(0.4)	(7.6%)
Opalmon Tablets	4.7	(0.7)	(13.4%)	3.5	(1.2)	(26.0%)
Braftovi Capsules	2.7	1.7	156.9%	3.5	0.8	27.4%
Mektovi Tablets	2.2	1.2	124.7%	2.5	0.3	11.7%
Onon Capsules	3.6	0.6	22.0%	2.5	(1.1)	(29.7%)

Details of Sales Revenue (Forecasts)

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 Forecasts (April 1, 2022 to March 31, 2023)**
Revenue of goods and products	246.0	**290.0**
Royalty and others	115.4	**135.0**
Total	361.4	**425.0**

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

1. Revenue ¥425.0 billion YoY an increase of ¥63.6 billion (17.6%)

- Revenue of goods and products are expected to be ¥290.0 billion, an increase of ¥44.0 billion (17.9%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be ¥155.0 billion, an increase of ¥42.6 billion year on year, due to its expanded use in first-line treatment for non-small cell lung cancer and gastric cancer, urothelial carcinoma and cancer of unknown primary, despite the intensifying competitive environment. In other new main products, the Company expects sales of Forxiga Tablets, which were approved for additional indications of chronic kidney disease last year, to increase by ¥10.3 billion year on year to ¥47.0 billion, as well as anticipating higher sales of Kyprolis for Intravenous Infusion, Velexbru Tablets, and Ongentys Tablets. Furthermore, royalty and others are expected to continue to grow and to increase by ¥19.6 billion (17.0%) year on year to ¥135.0 billion. Revenue is therefore forecast to be ¥425.0 billion, an increase of ¥63.6 billion (17.6%) year on year.

2. Operating profit ¥145.0 billion YoY an increase of ¥41.8 billion (40.5%)

- Cost of sales is expected to be ¥104.0 billion, an increase of ¥10.5 billion (11.2%) year on year, due to an increase in revenue of goods and products.
- Research and development costs are expected to be ¥87.0 billion, an increase of ¥11.1 billion (14.7%) 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; global development study; and collaborative development.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥88.0 billion, an increase of ¥10.9 billion (14.2%) year on year, due to an increase 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 ¥11.2 billion year on year to ¥1.5 billion, due in part to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody, and other costs recorded in the fiscal year ended March 31, 2022.
- Therefore, operating profit is expected to be ¥145.0 billion, an increase of ¥41.8 billion (40.5%) year on year.

3. Profit before tax ¥146.0 billion YoY an increase of ¥41.0 billion (39.0%)

- Net financial income, etc. is forecast to be ¥1.0 billion, a decrease of ¥0.8 billion (45.3%) year on year.

4. Profit for the year ¥110.0 billion YoY an increase of ¥29.5 billion (36.6%) (attributable to owners of the Company)

- Profit attributable to owners of the Company is forecast to be ¥110.0 billion, an increase of ¥29.5 billion (36.6%) year on year.

Note: We assume that restrictions on certain activities will continue due to COVID-19, but that the impact on financial results will be immaterial. Going forward, if any revisions to financial forecasts are necessary, the Company will promptly announce them.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 (April 1, 2021 to March 31, 2022)**	**FY 2022 Forecasts (April 1, 2022 to March 31, 2023)**
Property, plant, and equipment	9.5	**9.9**	**9.4**
Intangible assets	6.3	**7.8**	**8.2**
Total	15.8	**17.7**	**17.5**
Ratio to sales revenue (%)	5.1%	**4.9%**	**4.1%**

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

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 (April 1, 2021 to March 31, 2022)**	**FY 2022 Forecasts (April 1, 2022 to March 31, 2023)**
Property, plant, and equipment	9.1	**9.3**	**7.4**
Intangible assets	11.9	**7.2**	**13.1**
Total	21.0	**16.5**	**20.5**

Note: Effective from the fiscal year ended March 31, 2022, we have changed the method to recognize the costs of configuration or customization services as an expense when they are received. In association with this change in accounting policy, the amount of capital investment in intangible assets for the fiscal year ended March 31, 2021 was retrospectively adjusted.

Number of Employees (Consolidated)

	FY 2020 (as of March 31, 2021)	FY 2021 (as of March 31, 2022)
Number of employees	3,607	**3,687**

Status of Shares (as of March 31, 2022)

Number of Shares

	As of March 31, 2022
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	528,341,400

Number of Shareholders

	As of March 31, 2022
Number of shareholders	64,637

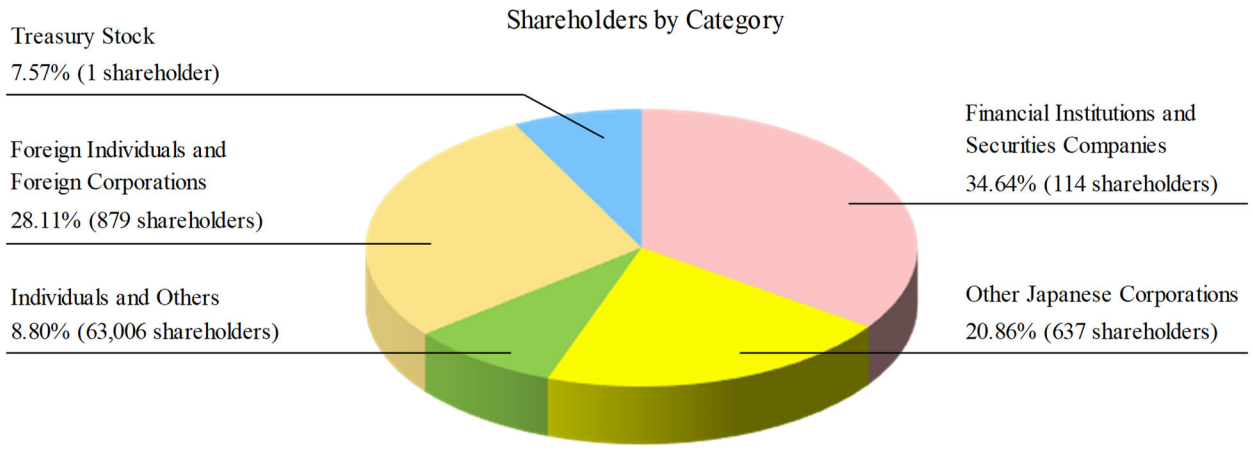
Principal Shareholders

(As of March 31, 2022)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	76,107	15.58
Custody Bank of Japan, Ltd. (Trust account)	26,807	5.48
STATE STREET BANK AND TRUST COMPANY 505001	21,645	4.43
Meiji Yasuda Life Insurance Company	18,594	3.80
Ono Scholarship Foundation	16,428	3.36
KAKUMEISOU Co., LTD	16,161	3.30
MUFG Bank, Ltd.	8,640	1.76
Aioi Nissay Dowa Insurance Co., Ltd.	7,979	1.63
STATE STREET BANK WEST CLIENT – TREATY 505234	7,806	1.59
SSBTC CLIENT OMNIBUS ACCOUNT	7,086	1.45

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 40,031 thousand shares of treasury stock.
2. The shareholding percentage is calculated by deducting treasury stock (40,031 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 26, 2022

<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
Velexbru Tablets / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma *1 / BTK inhibitor	Tablet	Taiwan	In-house
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial carcinoma *2	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Colorectal cancer *3	Injection	S. Korea	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 2022

*1: An application for Velexbru Tablets (BTK inhibitor) was approved in Taiwan for the treatment of recurrent or refractory primary central nervous system lymphoma.

*2: An application for Opdivo was approved in Japan for the adjuvant treatment of urothelial carcinoma.

*3: An application for the combination therapy of Opdivo and Yervoy was approved in South Korea for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer.

<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
Yervoy Injection ★ / Ipilimumab	Additional indication	Esophageal cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

<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)
	Additional indication	Pancreatic cancer	Injection	Japan S. Korea Taiwan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	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	Esophageal cancer	Injection	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 Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	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	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
	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

★: Combination with Opdivo.

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2022

* With regard to Opdivo, phase II for the treatment of biliary tract cancer was conducted in Japan, but the project was removed from the pipeline as the application was abandoned due to strategic reasons.
* Phase III of combination therapy for Opdivo and ONO-7701 (IDO1 inhibitor) for the treatment of bladder cancer was discontinued in Japan, South Korea and Taiwan due to strategic reasons.
* Phase I/II of combination therapy for Opdivo and ONO-7807 (anti-TIM-3 antibody) for the treatment of solid tumor was discontinued in Japan due to strategic reasons.
* Phase I of combination therapy for Opdivo and ONO-7911 (PEGylated IL-2) for the treatment of solid tumor was discontinued in Japan due to strategic reasons.
* Phase III of ONO-7912 (cancer metabolism inhibitor) for the treatment of pancreatic cancer and phase III for the treatment of acute myeloid leukemia conducted by Rafael Pharmaceuticals, Inc. were not able to confirm anticipated efficacy. Based on these results, phase I for the treatment of pancreatic cancer in Japan was discontinued.

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 26, 2022

< 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
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	In-house

<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 *4 / 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	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / S1P5 receptor agonist	Tablet	Japan Europe	I	In-house
ONO-2909	New chemical entities	Narcolepsy / Prostaglandin receptor(DP1) antagonist	Tablet	Japan	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2022

*4: Phase III of Velexbru Tablets (BTK inhibitor) was initiated in Japan for the treatment of pemphigus.

* Phase II of Joyclu Intra-articular Injection (hyaluronic acid-NSAID) for the treatment of enthesopathy was conducted in Japan, but the project was removed from the development pipeline as it was not possible to achieve the primary endpoint.

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 one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.
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 is a Prostaglandin receptor (EP4) antagonist 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. In addition, it is being developed 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 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 (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 primary central nervous system lymphoma. In addition, it is being developed for the treatment of pemphigus and systemic sclerosis.

ONO-7475 (tablet)
ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia, EGFR-mutated non-small cell lung cancer and solid tumor.

ONO-7912 (CPI-613) / Devimistat (injection)
ONO-7912 is a cancer metabolism inhibitor being developed including the exploration of indications.

ONO-7913 / Magrolimab (injection)
ONO-7913, an anti-CD47 antibody, is being developed for the treatment of various kinds of cancer.

ONO-7119
ONO-7119 is a PARP7 inhibitor being developed for the treatment of solid tumor.

ONO-7122
ONO-7122 is a TGF-β inhibitor being developed for the treatment of solid tumor.

ONO-7914
ONO-7914 is a STING agonist being developed for the treatment of solid tumor.

Onoact for Intravenous Infusion (ONO-1101) / Landiolol Hydrochloride (injection)
An application was approved for the treatment of tachyarrhythmia upon sepsis.
Development is being conducted for tachyarrhythmia in low cardiac function in pediatric.

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

ONO-4685 (injection)
ONO-4685, a PD-1 x CD3 bispecific antibody, is being developed for the treatment of autoimmune disease and T-cell lymphoma.

ONO-7684 (tablet)
ONO-7684, a FXIa inhibitor, is being developed for the treatment of thrombosis.

ONO-2808 (tablet)
ONO-2808, a S1P5 receptor agonist, is being developed for the treatment of neurodegenerative disease.

ONO-2910 (tablet)
ONO-2910, a Schwann cell differentiation promoter, is being developed for the treatment of diabetic polyneuropathy.

ONO-2909 (tablet)
ONO-2909, a Prostaglandin receptor (DP1) antagonist, is being developed for the treatment of narcolepsy.