

**Consolidated Financial Results
for the Fiscal Year Ended March 31, 2021 (IFRS)**

May 11, 2021

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 17, 2021
 Scheduled date of securities report submission : June 18, 2021
 Scheduled date of dividend payment commencement : June 18, 2021
 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 2020 (April 1, 2020 to March 31, 2021)

(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 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
FY 2019	292,420	1.3	77,491	25.0	79,696	22.3	59,888	15.9	59,704	15.8	57,647	13.4

	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 2020	151.11		151.09		12.6		14.2		31.8	
FY 2019	118.47		118.45		10.7		12.0		26.5	

(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, 2021	746,842	641,157	635,547	85.1	1,273.28
As of March 31, 2020	673,444	568,022	562,484	83.5	1,126.95

(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 2020	73,977	(57,586)	(24,754)	61,045
FY 2019	74,157	(10,234)	(54,721)	69,005

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 2019	—	22.50	—	22.50	45.00	22,463	38.0	4.1
FY 2020	—	22.50	—	27.50	50.00	24,960	33.1	4.2
FY 2021 (Forecast)	—	28.00	—	28.00	56.00		33.7	

3. Consolidated Financial Forecast for FY 2021 (April 1, 2021 to March 31, 2022)

(% 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 2021	350,000	13.2	105,000	6.8	107,000	6.1	83,100	10.1	83,000	10.0	166.29

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, 2021 528,341,400 shares

As of March 31, 2020 528,341,400 shares

2) Number of treasury shares as of the end of the period:

As of March 31, 2021 29,199,416 shares

As of March 31, 2020 29,222,272 shares

3) Average number of shares outstanding during the period:

FY 2020 499,137,173 shares

FY 2019 503,975,206 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 2020

(Millions of yen)

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021	Change	Change (%)
Revenue	292,420	309,284	16,865	5.8%
Operating profit	77,491	98,330	20,839	26.9%
Profit before tax	79,696	100,890	21,194	26.6%
Profit for the year (attributable to owners of the Company)	59,704	75,425	15,721	26.3%

[Revenue]

Revenue totaled ¥309.3 billion, which was an increase of ¥16.9 billion (5.8%) from the previous fiscal year (year-on-year).

- Although the environment became more challenging, use of Opdivo Intravenous Infusion for malignant tumors was expanded to the treatment of esophageal cancer, resulting in sales of ¥98.8 billion, an increase of ¥11.5 billion (13.2%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥25.5 billion (2.1% decrease year-on-year), sales of Forxiga Tablets for diabetes and chronic heart failure were ¥22.4 billion (23.7% increase year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥21.9 billion (10.4% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.1 billion (13.9% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥7.1 billion (18.8% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Rivastach Patches for Alzheimer's disease were ¥6.6 billion (22.5% decrease year-on-year), sales of Opalmon Tablets for peripheral circulatory disorder were ¥5.5 billion (34.5% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥2.9 billion (39.9% decrease year-on-year), respectively.
- Royalty and others increased by ¥7.9 billion (9.1%) year-on-year to ¥94.7 billion.

[Operating Profit]

Operating profit was ¥98.3 billion, an increase of ¥20.8 billion (26.9%) year-on-year.

- Cost of sales increased by ¥6.5 billion (8.2%) year-on-year to ¥85.6 billion mainly due to an increase in amortization of intangible assets, in addition to an increase in sales of goods and products.
- Research and development costs decreased by ¥4.1 billion (6.2%) year-on-year to ¥62.4 billion. Although development activities, including the registrations of subjects have resumed since June 2020, there has been a decrease in clinical trial costs caused by the impact of the novel coronavirus disease (COVID-19). That decrease outweighed increases in costs including joint research costs for joint research with universities and research institutions and milestone payments relating to drug discovery alliances with bio-venture companies.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥1.6 billion (2.3%) year-on-year to ¥69.2 billion, despite a decrease in operating expenses caused by refraining from visiting medical institutions by MRs due to the impact of COVID-19. Meanwhile, the increase is largely attributable to factors that included an increase in expenses associated with actively implementing online lectures, upgrading content on the Company's website, and utilizing the new sales platform, as well as increases in expenses pertaining to the launch of new products and additional indications, and an increase in co-promotion fees associated with expanding sales of Forxiga Tablets.
- Other income increased by ¥7.3 billion to ¥8.2 billion, mainly due to the upfront payment received under the license agreement with Roche in November 2020 for the patent relating to the anti-PD-L1 antibody.

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

Profit attributable to owners of the Company increased by ¥15.7 billion (26.3%) year-on-year to ¥75.4 billion in association with the increase of the profit before tax.

(Research & Development Activities)

Upholding the corporate philosophy “Dedicated to Man’s 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 unmet medical needs are high.

In drug discovery research, based on the “Compound-Orient” drug discovery approach aiming to produce innovative new candidate compounds focusing on characteristic bioactive lipids and unique target molecules, we are making an effort to produce innovative new drugs with medical impact by accumulating know-how on the respective disorders and ascertaining medical needs appropriately in the Oncology Research Center, Immunology Research Center, Neurology Research Center, and Specialty Research Center established in each priority area. In addition, we are aiming for the creation of new drugs that bring innovation to the medical field by implementing open innovation actively and globally, incorporating the world’s most advanced technologies and information, creating a network with the world’s top-class researchers, and using biologics such as antibodies, cells and viruses in addition to conventional small-molecule drugs. 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 (including those at the end of the fiscal year and thereafter) during the fiscal year ended March 31, 2021 are as follows.

[Main Progress of Development Pipelines]

<Oncology>

“Opdivo / Nivolumab” (including combination therapy with other drugs)

Gastric cancer

- In May 2020, an approval application was filed in Japan for the treatment of unresectable advanced or recurrent gastric cancer. (This application has been filed based on the clinical study data from ATTRACTION-4 study: ONO-4538-37.)
- In December 2020, an approval application was filed in Japan for the treatment of unresectable advanced or recurrent gastric cancer. (This application has been filed based on the clinical studies data from CheckMate-649 study: ONO-4538-44 and ATTRACTION-4 study: ONO-4538-37.)

Esophageal cancer

- In April 2020 in South Korea and June 2020 in Taiwan, applications were approved, respectively, for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer which is refractory or intolerant to prior fluoropyrimidine- and platinum-based chemotherapy.
- In February 2021, an approval application was filed in Japan for the adjuvant therapy of esophageal cancer.

Colorectal cancer

- In September 2020, an application was approved in Japan for combination therapy with Yervoy for the treatment of microsatellite instability-high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

Malignant pleural mesothelioma

- In October 2020, an approval application for combination therapy with Yervoy was filed in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.

Renal cell carcinoma

- In October 2020, an approval application for combination therapy with kinase inhibitor CABOMETYX Tablets / Cabozantinib s-malate, which is being developed by Takeda Pharmaceutical Company Limited, was filed in Japan for the treatment of unresectable or metastatic renal cell carcinoma.

Small cell lung cancer

- In October 2020, phase III of the single agent and combination therapy with Yervoy for the treatment of small cell lung cancer was discontinued due to strategic reasons.

Non-small cell lung cancer

- In November 2020, applications were approved in Japan for combination therapy with platinum-based chemotherapy, combination therapy with Yervoy, and combination therapy with Yervoy and platinum-based chemotherapy, respectively, for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
- In December 2020, an application was approved in South Korea for combination therapy with Yervoy (tumors express PD-L1 \geq 1%) for the treatment of advanced or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- In December 2020, an application was approved in South Korea for combination therapy with Yervoy and platinum-based chemotherapy for the treatment of advanced or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- In February 2021, an application was approved in Taiwan for combination therapy with Yervoy (tumors express PD-L1 \geq 1%) for the treatment of advanced or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- In February 2021, an application was approved in Taiwan for combination therapy with Yervoy and platinum-based chemotherapy for the treatment of advanced or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.

Biliary tract cancer

- In November 2020, phase II was initiated in Japan, South Korea, and Taiwan for the treatment of biliary tract cancer.

Urothelial cancer

- In March 2021, an approval application was filed in Japan for the adjuvant therapy of resected urothelial cancer.

Cancer of unknown primary

- In April 2021, an approval application was filed in Japan for the treatment of cancer of unknown primary.

Glioblastoma

- In January 2021, development for the treatment of glioblastoma was discontinued in Japan after it was deemed that it did not achieve the results anticipated.

Solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma)

- 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.

Dosage and administration

- In September 2020, an application was approved in Japan for additional dosage and administration to intravenously infuse at “480 mg every 4 weeks” in the monotherapy dosing regimen.
- In January 2021, an approval application was filed in Japan to expand the use for the treatment of pediatric patients with recurrent or refractory classical hodgkin lymphoma.

“Velexbru Tablets / Tirabrutinib Hydrochloride”

- In August 2020, an application was approved in Japan for Velexbru Tablets (Btk inhibitor) for the treatment of waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma.
- Velexbru Tablets was out-licensed to Gilead Sciences, Inc. (“Gilead,” based in USA) in 2014. However, Gilead returned the rights for oncology in all territories it held rights for. Gilead retains the rights except oncology.

“Braftovi Capsules / Encorafenib” “Mektovi Tablets / Binimetinib”

- In November 2020, an application was approved in Japan for Braftovi Capsules (BRAF inhibitor) and Mektovi Tablets (MEK inhibitor) for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer that has progressed after chemotherapy in triplet combination therapy with Braftovi Capsules, Mektovi Tablets, and cetuximab, an anti-human EGFR monoclonal antibody, and in doublet combination therapy with Braftovi Capsules and cetuximab.
- In November 2020, phase II of combination therapy of Braftovi Capsules and Mektovi Tablets was initiated in Japan for the treatment of BRAF-mutant thyroid cancer.

“Kyprolis / Carfilzomib”

- In November 2020, an additional twice-weekly regimen has been made available in Japan for Kyprolis (proteasome inhibitor) for a new DKd combination therapy with dexamethasone plus Darzalex Intravenous Infusion / daratumumab, a human anti-CD38 monoclonal antibody, for the approved indication of relapsed or refractory multiple myeloma.

“Adlumiz Tablets / Anamorelin Hydrochloride”

- In January 2021, an application was approved in Japan for Adlumiz Tablets / Anamorelin Hydrochloride (ghrelin receptor agonist) for the treatment of cancer cachexia in malignant tumors (non-small cell lung cancer, gastric cancer, pancreatic cancer or colorectal cancer).

“ONO-7912 (CPI-613) / Devimistat”

- In June 2020, phase I of cancer metabolism inhibitor (ONO-7912 (CPI-613) / Devimistat) was initiated in Japan for the treatment of pancreatic cancer.

“ONO-4687 (BMS-986227) / Cabiralizumab”

- In October 2020, phase II of ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R antibody) for the treatment of pancreatic cancer was discontinued.

“ONO-4578”

- In September 2020, phase I of prostaglandin receptor (EP4) antagonist (ONO-4578) was initiated in Japan for the treatment of colorectal cancer.
- In November 2020, phase I of ONO-4578 was initiated in Japan for the treatment of pancreatic cancer.
- In December 2020, phase I of ONO-4578 was initiated in Japan for the treatment of non-small cell lung cancer.

<Areas other than Oncology>

“Parsabiv Intravenous Injection Syringe / Etelcalcetide Hydrochloride”

- In June 2020, an application was approved in Japan for a new intravenous injection syringe for dialysis.

“Onoact / Landiolol Hydrochloride”

- In June 2020, an application was approved in Japan for the treatment of tachyarrhythmia associated with sepsis (atrial fibrillation, atrial flutter and sinus tachycardia).

“Ongentys Tablets / ONO-2370 / Opicapone”

- In June 2020, an application was approved in Japan for Ongentys Tablets / ONO-2370 / Opicapone (COMT inhibitor) for the improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in parkinson’s disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride.

“Forxiga Tablets / Dapagliflozin propylene glycolate hydrate”

- In November 2020, an application was approved in Japan for Forxiga Tablets / dapagliflozin propylene glycolate hydrate, a selective SGLT2 inhibitor for the treatment of patients with chronic heart failure who are receiving standard of care.

“Joyclu Intra-articular Injection / Diclofenac Etalhyaluronate Sodium”

- In March 2021, an application was approved in Japan for osteoarthritis treatment Joyclu Intra-articular Injection / diclofenac etalhyaluronate sodium for the treatment of osteoarthritis (knee joint and hip joint).

“Foipan Tablets / Camostat mesilate”

- In June 2020, phase I of protease enzyme inhibitor Foipan Tablets was initiated in Japan for the treatment of COVID-19.
- In November 2020, phase III of Foipan Tablets was initiated in Japan for the treatment of COVID-19.

“ONO-2910”

- In June 2020, phase I of Schwann cell differentiation promoter (ONO-2910) was initiated in Japan for healthy adult male subjects.
- In April 2021, phase II of ONO-2910 was initiated in Japan for patients with diabetic polyneuropathy.

“ONO-2909”

- In November 2020, phase I of prostaglandin receptor (DP1) antagonist (ONO-2909) was initiated in Japan for healthy adult subjects and for the treatment of narcolepsy.

“Velexbru Tablets / Tirabrutinib Hydrochloride”

- In December 2020, phase I of Velexbru Tablets (Btk inhibitor) was initiated in Japan for the treatment of systemic sclerosis.

“ONO-2808”

- In January 2021, phase I of S1P5 receptor agonist (ONO-2808) was initiated in Japan.

“ONO-7269”

- In January 2021, development of FXIa inhibitor (ONO-7269) for the treatment of cerebral infarction was discontinued in Japan due to strategic reasons.

[Status of Drug Discovery / Research Alliance Activities]

- In March 2021, the Company entered into a non-exclusive license agreement with PeptiDream Inc. on PeptiDream’s proprietary automated Peptide Discovery Platform System (PDPS) technology platform.
- In March 2021, the Company joined the University of California Drug Discovery Consortium with the aim of getting closer to the research themes of the seven participating University of California campuses in the United States at an early stage and efficiently promoting drug discovery research based on innovative ideas on drug discovery of the seven campuses.

[Status of Licensing Activities]

- In October 2020, the Company entered into a license agreement with SK Biopharmaceuticals Co., Ltd. in South Korea for exclusive development and commercialization in Japan of cenobamate, SK Biopharmaceuticals’ antiepileptic drug.
- In December 2020, the Company entered into a license agreement with Chordia Therapeutics Inc. for a global exclusive development and commercialization of CTX-177, a MALT1 inhibitor being developed by Chordia Therapeutics.
- In February 2021, the Company entered into a license agreement with Ribon Therapeutics, Inc. in the USA for exclusive development and commercialization in Japan, South Korea, Taiwan, and ASEAN of RBN-2397, a PARP7 inhibitor being developed by Ribon Therapeutics.

(2) Overview of Financial Position for the Fiscal Year 2020

(Millions of yen)

	As of March 31, 2020	As of March 31, 2021	Change
Total assets	673,444	746,842	73,398
Equity attributable to owners of the Company	562,484	635,547	73,062
Ratio of equity attributable to owners of the Company to total assets	83.5%	85.1%	
Equity attributable to owners of the Company per share	1,126.95 yen	1,273.28 yen	

Total assets increased to ¥746.8 billion by ¥73.4 billion from the end of the previous fiscal year.

Current assets increased by ¥22.4 billion to ¥247.6 billion mainly due to increases in other financial assets, trade and other receivables and inventories etc.

Non-current assets increased by ¥51.0 billion to ¥499.2 billion mainly due to increases in other financial assets and investment securities etc.

Liabilities increased by ¥0.3 billion to ¥105.7 billion mainly due to increases in trade and other payables etc., despite decreases in retirement benefit liabilities etc.

Equity attributable to owners of the Company increased by ¥73.1 billion to ¥635.5 billion mainly due to increases in retained earnings and other components of equity etc.

(3) Overview of Cash Flows for the Fiscal Year 2020

(Millions of yen)

	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021	Change
Cash and cash equivalents at the beginning of the fiscal year	59,981	69,005	
Cash flows from operating activities	74,157	73,977	(180)
Cash flows from investing activities	(10,234)	(57,586)	(47,351)
Cash flows from financing activities	(54,721)	(24,754)	29,967
Net increase (decrease) in cash and cash equivalents	9,202	(8,363)	
Effects of exchange rate changes on cash and cash equivalents	(179)	403	
Cash and cash equivalents at the end of the fiscal year	69,005	61,045	

Net increase/decrease in cash and cash equivalents was a decrease of ¥8.4 billion.

Net cash provided by operating activities was ¥74.0 billion, as a result of profit before tax of ¥100.9 billion etc., while income taxes paid amounted to ¥34.1 billion etc.

Net cash used in investing activities was ¥57.6 billion, as a result of payments into time deposits (net amount) of ¥50.1 billion and purchases of intangible assets of ¥13.3 billion etc.

Net cash used in financing activities was ¥24.8 billion, as a result of dividends paid of ¥22.4 billion etc.

(4) Future Outlook

(Millions of yen)

	Result (Fiscal year ended March 31, 2021)	Forecast (Fiscal year ending March 31, 2022)	Change	Change (%)
Revenue	309,284	350,000	40,716	13.2%
Operating profit	98,330	105,000	6,670	6.8%
Profit before tax	100,890	107,000	6,110	6.1%
Profit for the year (attributable to owners of the Company)	75,425	83,000	7,575	10.0%

[Revenue]

For the next fiscal year, the severe business environment is expected to continue due to the impact of drug price revisions in April 2021 and the intensifying competition for market share with competing products. Sales of Opdivo Intravenous Infusion are expected to be ¥120.0 billion, an increase of ¥21.2 billion year-on-year, due to its expanded use in first-line treatment for lung cancer and treatment of esophageal cancer, and also due to the likelihood of entry into first-line treatment for gastric cancer, despite the intensifying competitive environment. In other main new products, in addition to multiple new product launches and additional indications, we also anticipate increases in sales of products that include Forxiga Tablets approved for additional indications of chronic heart failure last year, Braftovi Capsules and Mektovi Tablets approved for additional indications of BRAF-mutant colorectal cancer, and also products such as Orencia for Subcutaneous Injection and Kyprolis for Intravenous Infusion. Furthermore, royalty and others are expected to grow continuously and to increase by ¥10.3 billion (10.8%) year-on-year to ¥105.0 billion. Therefore, revenue is forecasted to be ¥350.0 billion, an increase of ¥40.7 billion (13.2%) year-on-year.

[Profit]

Cost of sales is expected to be ¥96.0 billion, an increase of ¥10.4 billion (12.2%) year-on-year, due to an increase in sales of goods and products.

Research and development costs are expected to be ¥72.0 billion, an increase of ¥9.6 billion (15.4%) year-on-year, providing for active investments to achieve sustainable growth. Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥76.0 billion, an increase of ¥6.8 billion (9.8%) year-on-year, due to an increase in operating expenses involving several new products to be launched and additional indications for existing products, and also due to active investment in information infrastructure related to IT and digital technologies.

Consequently, operating profit is forecasted to be ¥105.0 billion, an increase of ¥6.7 billion (6.8%) year-on-year, and profit attributable to owners of the Company is forecasted to be ¥83.0 billion, an increase of ¥7.6 billion (10.0%) year-on-year.

Note: We assume that restrictions on certain activities will continue due to COVID-19, but we expect that the impact on operating profit will be immaterial. Going forward, if any revisions to the 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, 2021, we expect to make a year-end dividend of 27.5 yen per share. With the payment of the second quarter dividend of 22.5 yen per share, the annual dividend is expected to be 50 yen per share. Also, the annual dividend for the following fiscal year ending March 31, 2022 is expected to be 56 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, 2020	As of March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	69,005	61,045
Trade and other receivables	76,834	84,269
Marketable securities	614	2,978
Other financial assets	30,800	40,952
Inventories	32,906	39,151
Other current assets	15,063	19,246
Total current assets	225,222	247,642
Non-current assets:		
Property, plant, and equipment	114,628	113,866
Intangible assets	66,436	70,322
Investment securities	137,670	146,796
Investments in associates	108	112
Other financial assets	91,694	131,888
Deferred tax assets	34,817	33,619
Retirement benefit assets	—	7
Other non-current assets	2,871	2,590
Total non-current assets	448,222	499,200
Total assets	673,444	746,842

(Millions of yen)

	As of March 31, 2020	As of March 31, 2021
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,439	39,163
Lease liabilities	2,188	2,023
Other financial liabilities	450	616
Income taxes payable	20,346	19,047
Provisions	20,721	20,721
Other current liabilities	13,185	12,163
Total current liabilities	<u>91,329</u>	<u>93,733</u>
Non-current liabilities:		
Lease liabilities	6,173	7,030
Other financial liabilities	0	0
Retirement benefit liabilities	6,048	3,056
Deferred tax liabilities	1,059	1,052
Other non-current liabilities	813	813
Total non-current liabilities	<u>14,093</u>	<u>11,952</u>
Total liabilities	<u>105,422</u>	<u>105,685</u>
Equity:		
Share capital	17,358	17,358
Capital reserves	17,229	17,231
Treasury shares	(44,737)	(44,705)
Other components of equity	48,030	62,299
Retained earnings	524,605	583,363
Equity attributable to owners of the Company	<u>562,484</u>	<u>635,547</u>
Non-controlling interests	5,538	5,610
Total equity	<u>568,022</u>	<u>641,157</u>
Total liabilities and equity	<u>673,444</u>	<u>746,842</u>

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

Consolidated Statement of Income

	(Millions of yen)	
	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Revenue	292,420	309,284
Cost of sales	(79,063)	(85,573)
Gross profit	213,356	223,711
Selling, general, and administrative expenses	(67,679)	(69,230)
Research and development costs	(66,497)	(62,384)
Other income	822	8,165
Other expenses	(2,512)	(1,932)
Operating profit	77,491	98,330
Finance income	3,053	2,693
Finance costs	(845)	(137)
Share of profit (loss) from investments in associates	(4)	4
Profit before tax	79,696	100,890
Income tax expense	(19,808)	(25,392)
Profit for the year	59,888	75,497
Profit for the year attributable to:		
Owners of the Company	59,704	75,425
Non-controlling interests	184	72
Profit for the year	59,888	75,497
Earnings per share:		
Basic earnings per share (Yen)	118.47	151.11
Diluted earnings per share (Yen)	118.45	151.09

Consolidated Statement of Comprehensive Income

	(Millions of yen)	
	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Profit for the year	59,888	75,497
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	(1,909)	17,273
Remeasurements of defined benefit plans	(109)	2,370
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(4)	3
Total of items that will not be reclassified to profit or loss	(2,022)	19,646
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(219)	424
Total of items that may be reclassified subsequently to profit or loss	(219)	424
Total other comprehensive income (loss)	(2,241)	20,070
Total comprehensive income (loss) for the year	57,647	95,567
Comprehensive income (loss) for the year attributable to:		
Owners of the Company	57,492	95,488
Non-controlling interests	155	78
Total comprehensive income (loss) for the year	57,647	95,567

(3) Consolidated Statement of Changes in Equity

FY 2019 (April 1, 2019 to March 31, 2020)

(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, 2019	17,358	17,202	(38,151)	61,852	499,088	557,350	5,386	562,736
Profit for the year					59,704	59,704	184	59,888
Other comprehensive income (loss)				(2,212)		(2,212)	(29)	(2,241)
Total comprehensive income (loss) for the year	–	–	–	(2,212)	59,704	57,492	155	57,647
Purchase of treasury shares			(29,586)			(29,586)		(29,586)
Retirement of treasury shares			22,999		(22,999)	–		–
Cash dividends					(22,798)	(22,798)	(3)	(22,801)
Share-based payments		27				27		27
Transfer from other components of equity to retained earnings				(11,610)	11,610	–		–
Total transactions with the owners	–	27	(6,587)	(11,610)	(34,187)	(52,357)	(3)	(52,360)
Balance as of March 31, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022

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

(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, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
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	583,363	635,547	5,610	641,157

(4) Consolidated Statement of Cash Flows

	(Millions of yen)	
	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Cash flows from operating activities		
Profit before tax	79,696	100,890
Depreciation and amortization	14,214	15,820
Impairment losses	2,816	2,307
Interest and dividend income	(2,968)	(2,462)
Interest expense	76	73
(Increase) decrease in inventories	(173)	(6,107)
(Increase) decrease in trade and other receivables	(793)	(7,179)
Increase (decrease) in trade and other payables	1,992	6,361
Increase (decrease) in provisions	3,515	—
Increase (decrease) in retirement benefit liabilities	381	410
Other	865	(4,468)
Subtotal	99,621	105,645
Interest received	92	63
Dividends received	2,878	2,401
Interest paid	(76)	(73)
Income taxes paid	(28,357)	(34,060)
Net cash provided by (used in) operating activities	74,157	73,977
Cash flows from investing activities		
Purchases of property, plant, and equipment	(7,475)	(7,018)
Proceeds from sales of property, plant, and equipment	424	2
Purchases of intangible assets	(14,970)	(13,275)
Purchases of investments	—	(760)
Proceeds from sales and redemption of investments	31,439	14,033
Payments into time deposits	(45,800)	(80,939)
Proceeds from withdrawal of time deposits	25,800	30,800
Other	348	(429)
Net cash provided by (used in) investing activities	(10,234)	(57,586)
Cash flows from financing activities		
Dividends paid	(22,775)	(22,449)
Dividends paid to non-controlling interests	(3)	(6)
Repayments of lease liabilities	(2,358)	(2,296)
Purchases of treasury shares	(29,584)	(3)
Net cash provided by (used in) financing activities	(54,721)	(24,754)
Net increase (decrease) in cash and cash equivalents	9,202	(8,363)
Cash and cash equivalents at the beginning of the year	59,981	69,005
Effects of exchange rate changes on cash and cash equivalents	(179)	403
Cash and cash equivalents at the end of the year	69,005	61,045

(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, 2021 are the same as the ones for the previous consolidated fiscal year.

(Segment Information)

1) Reportable Segments

Based on the Group's corporate philosophy, "Dedicated to Man's 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 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Revenue of goods and products	205,614	214,544
Royalty and others	86,805	94,740
Total	292,420	309,284

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥61.6 billion for the fiscal year ended March 31, 2020 and ¥59.8 billion for the fiscal year ended March 31, 2021. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥19.3 billion for the fiscal year ended March 31, 2020 and ¥24.3 billion for the fiscal year ended March 31, 2021.

3) Revenue by Geographic Area

Details of revenue by geographic area are as follows:

	(Millions of yen)	
	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Japan	202,866	212,865
Americas	81,545	85,566
Asia	7,481	7,446
Europe	528	3,407
Total	292,420	309,284

Notes: 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 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Bristol-Myers Squibb Company and the group	66,826	65,470
Medipal Holdings Corporation and the group	46,295	47,577
Suzuken Co., Ltd. and the group	45,828	46,404
Alfresa Holdings Corporation and the group	31,894	34,422
Toho Holdings Co., Ltd. and the group	30,637	32,596

(Earnings per Share)

1) Basic Earnings per Share

(i) Basic earnings per share

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Basic earnings per share (Yen)	118.47	151.11

(ii) Basis of calculation of basic earnings per share

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Profit for the year attributable to owners of the Company (Millions of yen)	59,704	75,425
Weighted-average number of ordinary shares outstanding (Thousands of shares)	503,975	499,137

2) Diluted Earnings per Share

(i) Diluted earnings per share

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Diluted earnings per share (Yen)	118.45	151.09

(ii) Basis of calculation of diluted earnings per share

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Profit for the year attributable to owners of the Company (Millions of yen)	59,704	75,425
Weighted-average number of ordinary shares outstanding (Thousands of shares)	503,975	499,137
Increase in common shares by share acquisition rights (Thousands of shares)	69	66
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	504,044	499,203

(Significant Subsequent Events)

Not Applicable

Fiscal Year 2020
(April 1, 2020 to March 31, 2021)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

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

Consolidated Financial Results for FY 2020 (April 1, 2020 to March 31, 2021) (IFRS)

Consolidated Financial Results

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)	YoY
Revenue	292.4	309.3	5.8%
Operating profit	77.5	98.3	26.9%
Profit before tax	79.7	100.9	26.6%
Profit for the year (attributable to owners of the Company)	59.7	75.4	26.3%

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 2020 (April 1, 2020 to March 31, 2021)					(Billions of yen)		
	Cumulative					YoY		Forecasts
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar	Change	Change (%)		
Opdivo Intravenous Infusion	24.4	24.6	27.3	22.5	98.8	11.5	13.2%	98.0
Glactiv Tablets	6.5	6.4	6.9	5.6	25.5	(0.6)	(2.1%)	25.0
Forxiga Tablets	5.2	5.3	6.1	5.8	22.4	4.3	23.7%	22.5
Orencia for Subcutaneous Injection	5.4	5.4	5.9	5.1	21.9	2.1	10.4%	22.0
Parsabiv Intravenous Injection	1.9	2.0	2.4	1.8	8.1	1.0	13.9%	8.0
Rivastach Patches	2.0	2.0	1.9	0.6	6.6	(1.9)	(22.5%)	7.5
Kyprolis for Intravenous Infusion	1.7	1.8	1.9	1.7	7.1	1.1	18.8%	7.0
Onoact for Intravenous Infusion	1.0	1.1	1.4	1.1	4.7	(0.2)	(4.2%)	5.5
Opalmon Tablets	1.5	1.4	1.5	1.1	5.5	(2.9)	(34.5%)	5.0
Proemend for Intravenous Infusion	0.7	0.7	0.7	0.6	2.6	0.0	0.2%	2.5
Emend Capsules	0.8	0.7	0.6	0.4	2.5	(5.6)	(69.6%)	2.5
Onon Capsules	0.7	0.5	0.7	1.0	2.9	(0.5)	(15.6%)	2.5
Recalbon Tablets	0.8	0.7	0.8	0.6	2.9	(1.9)	(39.9%)	2.5
Newly launched products during FY 2020	0.1	0.5	0.9	1.0	2.4	—	—	3.0

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

2. Cumulative results for newly launched products during FY 2020 include ¥2.1 billion in sales of Velexbu Tablets launched in May 2020 and ¥0.3 billion in sales of Ongentys Tablets launched in August 2020.

Details of Sales Revenue

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Revenue of goods and products	205.6	214.5
Royalty and others	86.8	94.7
Total	292.4	309.3

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥61.6 billion for the fiscal year ended March 31, 2020 and ¥59.8 billion for the fiscal year ended March 31, 2021. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥19.3 billion for the fiscal year ended March 31, 2020 and ¥24.3 billion for the fiscal year ended March 31, 2021.

Revenue by Geographic Area

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)
Japan	202.9	212.9
Americas	81.5	85.6
Asia	7.5	7.4
Europe	0.5	3.4
Total	292.4	309.3

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

Summary of Consolidated Financial Results for FY 2020 (April 1, 2020 to March 31, 2021) (IFRS)

1. Revenue ¥309.3 billion YoY an increase of 5.8% (FY 2019 ¥292.4 billion)

- Although the environment became more challenging, use of Opdivo Intravenous Infusion for malignant tumors was expanded to include the treatment of esophageal cancer, resulting in sales of ¥98.8 billion, an increase of ¥11.5 billion (13.2%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥25.5 billion (2.1% decrease year-on-year), sales of Forxiga Tablets for diabetes and chronic heart failure were ¥22.4 billion (23.7% increase year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥21.9 billion (10.4% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.1 billion (13.9% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥7.1 billion (18.8% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Rivastach Patches for Alzheimer's disease were ¥6.6 billion (22.5% decrease year-on-year), sales of Opalmon Tablets for peripheral circulatory disorder were ¥5.5 billion (34.5% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥2.9 billion (39.9% decrease year-on-year), respectively.
- Royalty and others increased by ¥7.9 billion (9.1%) year-on-year to ¥94.7 billion.

2. Operating profit ¥98.3 billion YoY an increase of 26.9% (FY 2019 ¥77.5 billion)

- Cost of sales increased by ¥6.5 billion (8.2%) year-on-year to ¥85.6 billion mainly due to an increase in amortization of intangible assets, in addition to an increase in sales of goods and products.
- Research and development costs decreased by ¥4.1 billion (6.2%) year-on-year to ¥62.4 billion. Although development activities, including the registrations of subjects have resumed since June 2020, there has been a decrease in clinical trial costs caused by the impact of the novel coronavirus disease (COVID-19). That decrease outweighed increases in costs including joint research costs for joint research with universities and research institutions and milestone payments relating to drug discovery alliances with bio-venture companies.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥1.6 billion (2.3%) year-on-year to ¥69.2 billion, despite a decrease in operating expenses caused by refraining from visiting medical institutions by MRs due to the impact of COVID-19. Meanwhile, the increase is largely attributable to factors that included an increase in expenses associated with actively implementing online lectures, upgrading content on the Company's website, and utilizing the new sales platform, as well as increases in expenses pertaining to the launch of new products and additional indications, and an increase in co-promotion fees associated with expanding sales of Forxiga Tablets.
- Other income increased by ¥7.3 billion to ¥8.2 billion, mainly due to the upfront payment received under the license agreement with Roche in November 2020 for the patent relating to the anti-PD-L1 antibody.

3. Profit before tax ¥100.9 billion YoY an increase of 26.6% (FY 2019 ¥79.7 billion)

- Net financial income, etc. was ¥2.6 billion, an increase of ¥0.4 billion (16.1%) year-on-year.

4. Profit for the year ¥75.4 billion YoY an increase of 26.3% (FY 2019 ¥59.7 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥15.7 billion (26.3%) year-on-year to ¥75.4 billion in association with the increase of the profit before tax.

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

Consolidated Financial Forecasts

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 Forecasts (April 1, 2021 to March 31, 2022)	YoY
Revenue	292.4	309.3	350.0	13.2%
Operating profit	77.5	98.3	105.0	6.8%
Profit before tax	79.7	100.9	107.0	6.1%
Profit for the year (attributable to owners of the Company)	59.7	75.4	83.0	10.0%

Sales Revenue of Major Products (Forecasts)

(Billions of yen)

Product Name	FY 2020 (April 1, 2020 to March 31, 2021)			FY 2021 Forecasts (April 1, 2021 to March 31, 2022)		
	Results	YoY		Forecasts	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	98.8	11.5	13.2%	120.0	21.2	21.4%
Forxiga Tablets	22.4	4.3	23.7%	30.0	7.6	34.2%
Glactiv Tablets	25.5	(0.6)	(2.1%)	24.5	(1.0)	(3.9%)
Orencia for Subcutaneous Injection	21.9	2.1	10.4%	22.5	0.6	2.7%
Parsabiv Intravenous Injection	8.1	1.0	13.9%	8.0	(0.1)	(0.6%)
Kyprolis for Intravenous Infusion	7.1	1.1	18.8%	7.5	0.4	5.3%
Onoact for Intravenous Infusion	4.7	(0.2)	(4.2%)	4.0	(0.7)	(14.1%)
Opalmon Tablets	5.5	(2.9)	(34.5%)	4.0	(1.5)	(26.7%)
Velexbru Tablets	2.1	—	—	3.5	1.4	69.8%
Rivastach Patches	6.6	(1.9)	(22.5%)	3.0	(3.6)	(54.6%)
Braftovi Capsules	1.1	—	—	3.0	1.9	180.6%
Mektovi Tablets	1.0	—	—	2.5	1.5	150.9%
Onon Capsules	2.9	(0.5)	(15.6%)	2.5	(0.4)	(14.2%)
Ongentys Tablets	0.3	—	—	2.5	2.2	631.1%
New products to be launched	—	—	—	7.0	7.0	—

Details of Sales Revenue (Forecasts)

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 Forecasts (April 1, 2021 to March 31, 2022)
Revenue of goods and products	214.5	245.0
Royalty and others	94.7	105.0
Total	309.3	350.0

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

1. Revenue **¥350.0 billion** **YoY an increase of ¥40.7 billion (13.2%)**

- For the next fiscal year, the severe business environment is expected to continue due to the impact of drug price revisions in April 2021 and the intensifying competition for market share with competing products. Sales of Opdivo Intravenous Infusion are expected to be ¥120.0 billion, an increase of ¥21.2 billion year-on-year, due to its expanded use in first-line treatment for lung cancer and treatment of esophageal cancer, and also due to the likelihood of entry into first-line treatment for gastric cancer, despite the intensifying competitive environment. In other main new products, in addition to multiple new product launches and additional indications, we also anticipate increases in sales of products that include Forxiga Tablets approved for additional indications of chronic heart failure last year, Braftovi Capsules and Mektovi Tablets approved for additional indications of BRAF-mutant colorectal cancer, and also products such as Orencia for Subcutaneous Injection and Kyprolis for Intravenous Infusion. Furthermore, royalty and others are expected to grow continuously and to increase by ¥10.3 billion (10.8%) year-on-year to ¥105.0 billion. Therefore, revenue is forecasted to be ¥350.0 billion, an increase of ¥40.7 billion (13.2%) year-on-year.

2. Operating profit **¥105.0 billion** **YoY an increase of ¥6.7 billion (6.8%)**

- Cost of sales is expected to be ¥96.0 billion, an increase of ¥10.4 billion (12.2%) year-on-year, due to an increase in sales of goods and products.
- Research and development costs are expected to be ¥72.0 billion, an increase of ¥9.6 billion (15.4%) year-on-year, providing for active investments to achieve sustainable growth.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥76.0 billion, an increase of ¥6.8 billion (9.8%) year-on-year, due to an increase in operating expenses involving several new products to be launched and additional indications for existing products, and also due to active investment in information infrastructure related to IT and digital technologies.
- Consequently, operating profit is forecasted to be ¥105.0 billion, an increase of ¥6.7 billion (6.8%) year-on-year.

3. Profit before tax **¥107.0 billion** **YoY an increase of ¥6.1 billion (6.1%)**

- Net financial income, etc. is forecasted to be ¥2.0 billion, a decrease of ¥0.6 billion (21.8%) year-on-year.

4. Profit for the year **¥83.0 billion** **YoY an increase of ¥7.6 billion (10.0%)** **(attributable to owners of the Company)**

- Profit attributable to owners of the Company is forecasted to be ¥83.0 billion, an increase of ¥7.6 billion (10.0%) year-on-year.

Note: We assume that restrictions on certain activities will continue due to COVID-19, but we expect that the impact on operating profit will be immaterial. Going forward, if any revisions to the 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 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 Forecasts (April 1, 2021 to March 31, 2022)
Property, plant, and equipment	8.9	9.5	9.6
Intangible assets	5.3	6.3	7.9
Total	14.2	15.8	17.5
Ratio to sales revenue (%)	4.9%	5.1%	5.0%

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

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	FY 2020 (April 1, 2020 to March 31, 2021)	FY 2021 Forecasts (April 1, 2021 to March 31, 2022)
Property, plant, and equipment	9.5	9.1	12.9
Intangible assets	11.4	12.6	13.9
Total	21.0	21.7	26.8

Number of Employees (Consolidated)

	FY 2019 (as of March 31, 2020)	FY 2020 (as of March 31, 2021)
Number of employees	3,560	3,607

Status of Shares (as of March 31, 2021)

Number of Shares

	As of March 31, 2021
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, 2021
Number of shareholders	69,047

Principal Shareholders

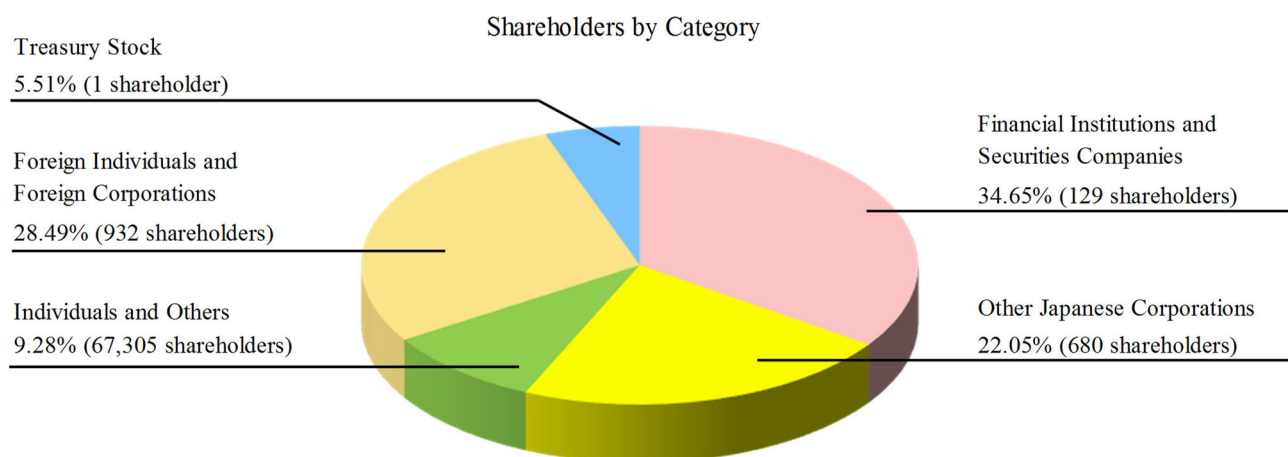
(As of March 31, 2021)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	44,141	8.84%
Custody Bank of Japan, Ltd. (Trust account)	26,871	5.38%
STATE STREET BANK AND TRUST COMPANY 505001	21,422	4.29%
Meiji Yasuda Life Insurance Company	18,594	3.72%
Ono Scholarship Foundation	16,428	3.29%
KAKUMEISOU Co., LTD	16,161	3.23%
Custody Bank of Japan, Ltd. (Trust account 7)	9,433	1.88%
MUFG Bank, Ltd.	8,640	1.73%
Aioi Nissay Dowa Insurance Co., Ltd.	8,193	1.64%
STATE STREET BANK WEST CLIENT – TREATY 505234	7,063	1.41%

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,135 thousand shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (29,135 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, 2021

<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	Non-small cell lung cancer *1	Injection	Taiwan	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 2021

*1: An application was approved in Taiwan for combination therapy of Opdivo and Yervoy for the treatment of unresectable advanced or recurrent non-small cell lung 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	Malignant pleural mesothelioma	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer *2	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *3	Injection	Japan	In-house (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 2021

*2: An approval application for Opdivo was filed in Japan for the adjuvant therapy of resected urothelial cancer.

*3: An approval application for Opdivo was filed in Japan for the adjuvant therapy of esophageal cancer.

<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	Esophageal cancer	Injection	S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan	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	Biliary tract 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	Head and neck cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	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-7701 * (BMS-986205) / Linrodostat	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
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-7807 * (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 * (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 *	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 * (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 *	New chemical entities	Colorectal cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor · Gastric cancer / PG receptor (EP4) antagonist	Tablet	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
Braftovi Capsules / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, 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-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)

★: Combination with Opdivo.

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2021

* Development of Opdivo for the treatment of solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma) was discontinued in Japan due to strategic reasons.

* Development of Opdivo for the treatment of central nervous system lymphoma / primary testicular lymphoma was discontinued in Japan due to strategic reasons.

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, 2021

< 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
Joyclu Intra-articular Injection / ONO-5704 / SI-613	New chemical entities	Osteoarthritis *4 / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2021

*4: An application for Joyclu Intra-articular Injection / ONO-5704 / SI-613 was approved in Japan for the treatment of osteoarthritis (knee joint and hip joint).

<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
Orencia SC / Abatacept	Additional indication	Polymyositis · Dermatomyositis / T-cell activation inhibitor	Injection	Japan	III	In-license (Co-development with Bristol-Myers Squibb)
Foipan Tablets / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) / Protease enzyme inhibitor	Tablet	Japan	III	In-house
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
Joyclu Intra-articular Injection / ONO-5704 / SI-613	Additional indication	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / Btk inhibitor	Tablet	Japan	II	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy *5 / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / 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 2021

*5: Phase II of Schwann cell differentiation promoter (ONO-2910) was initiated in Japan for patients with diabetic polyneuropathy.

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-7701 / BMS-986205 / Linrodostat (capsule)

ONO-7701, IDO1 inhibitor, is being developed for the treatment of bladder 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-4483 / BMS-986015/ Lirilumab (injection)

ONO-4483, a human anti-human KIR 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-7911 / BMS-986321 / Bempegaldesleukin (injection)

ONO-7911, PEGylated interleukin-2 formulation, 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-7807 / BMS-986258 (injection)

ONO-7807, a human anti-human TIM-3 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, 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 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. It has become a new treatment option for multiple myeloma, which is a cancer of plasma cells (one of blood cells) and prognosis is considered poor.

Adlumiz Tablets (ONO-7643) / Anamorelin Hydrochloride (tablet)

An application for Adlumiz, a small-molecule ghrelin receptor agonist, was approved and it has been marketed in Japan for the treatment of cancer cachexia in malignant tumors (non-small cell lung cancer, gastric cancer, pancreatic cancer or colorectal cancer).

Velexbru Tablets (ONO-4059) / Tirabrutinib (tablet)

Velexbru, a Btk inhibitor, has been marketed in Japan for the treatment of primary central nervous system lymphoma, and an additional indication was later approved for the treatment of waldenstrom macroglobulinemia and lymphoplasmacytic 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 and solid tumor.

ONO-7912 (CPI-613) / Devimistat (injection)

ONO-7912, a cancer metabolism inhibitor, is being developed for the treatment of pancreatic cancer and acute myeloid leukemia.

ONO-7913 / Magrolimab (injection)

ONO-7913, a monoclonal antibody against CD47, is being developed for the treatment of various kinds of cancer.

Orencia IV (ONO-4164 / BMS-188667) / Abatacept (injection)

Orencia IV is marketed in Japan for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, additionally approved for the treatment of active polyarticular juvenile idiopathic arthritis (JIA). Furthermore, an application was approved for the addition of prevention of the structural damage of the joints in rheumatoid arthritis.

Orencia SC (ONO-4164 / BMS-188667) / Abatacept (injection)

Orencia SC is marketed in Japan for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, an application was approved for the addition of prevention of the structural damage of the joints in rheumatoid arthritis.

Also, it is being developed for the treatment of polymyositis and dermatomyositis.

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.

Joyclu Intra-articular Injection (ONO-5704 / SI-613) / Diclofenac Etalhyaluronate Sodium (injection)

Joyclu is a hyaluronic acid-NSAID. An application was approved for the treatment of osteoarthritis (knee joint and hip joint). Also, it is being developed for the treatment of enthesopathy.

ONO-4685 (injection)

ONO-4685, PD-1 x CD3 bispecific antibody, is being developed for the treatment of autoimmune disease.

ONO-7684 (tablet)

ONO-7684, 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 diseases.

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.

Foipan Tablets (FOY-305) / Camostat mesilate (tablet)

Foipan Tablets, a protease enzyme inhibitor, is marketed in Japan for the treatment of chronic pancreatitis, etc. It is currently being developed for the treatment of COVID-19.