Consolidated Financial Results
for the Fiscal Year Ended March 31, 2020 (IFRS)

May 12, 2020

Company name : **ONO PHARMACEUTICAL CO., LTD.**
Stock exchange listing : Tokyo Stock Exchange
Code number : 4528
URL : https://www.ono.co.jp/
Representative : Gyo Sagara
President, Representative Director, and Chief Executive Officer
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Scheduled date of annual general meeting of shareholders : June 18, 2020
Scheduled date of securities report submission : June 30, 2020
Scheduled date of dividend payment commencement : June 19, 2020
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 2019 (April 1, 2019 to March 31, 2020)

(1) Consolidated Operating Results

(% change from the same period of 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 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
FY 2018	288,634	10.2	62,010	2.2	65,141	1.9	51,679	2.5	51,539	2.5	50,821	(24.8)

	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 2019	118.47	118.45	10.7	12.0	26.5
FY 2018	100.25	100.24	9.5	10.3	21.5

(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, 2020	673,444	568,022	562,484	83.5	1,126.95
As of March 31, 2019	655,056	562,736	557,350	85.1	1,084.08

(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 2019	74,157	(10,234)	(54,721)	69,005
FY 2018	66,774	(49,763)	(22,279)	59,981

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 2018	—	22.50	—	22.50	45.00	23,138	44.9	4.3
FY 2019	—	22.50	—	22.50	45.00	22,463	38.0	4.1
FY 2020 (Forecast)	—	22.50	—	22.50	45.00		37.2	

3. Consolidated Financial Forecasts for FY 2020 (April 1, 2020 to March 31, 2021)

(% change from the same period of 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 2020	303,000	3.6	80,000	3.2	82,000	2.9	61,100	2.0	61,000	2.2	121.04

(Note) At this time, it is difficult to accurately predict when the COVID-19 pandemic will be under control. Accordingly, the above financial forecasts reflect the effects of continuing to refrain from visiting medical institutions and other activities until the end of June 2020. If the restrictions on the activities continue in the second quarter and thereafter, although revenue is expected to decline slightly due to refraining from activities, restraints on consultations, etc., the impact on operating profit is estimated to be immaterial as expenditures will be controlled due to the decrease in business activities. Going forward, if any revisions to the financial forecasts are necessary, we will promptly announce them.

Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies due to other than (2) – 1) above: None
3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the period (including treasury shares):
As of March 31, 2020 528,341,400 shares
As of March 31, 2019 543,341,400 shares
2) Number of treasury shares as of the end of the period:
As of March 31, 2020 29,222,272 shares
As of March 31, 2019 29,220,860 shares
3) Average number of shares outstanding during the period:
FY 2019 503,975,206 shares
FY 2018 514,121,049 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 6.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the Fiscal Year 2019

(Millions of yen)

	Fiscal year ended March 31, 2019	**Fiscal year ended March 31, 2020**	Change	Change (%)
Revenue	288,634	**292,420**	3,786	1.3%
Operating profit	62,010	**77,491**	15,481	25.0%
Profit before tax	65,141	**79,696**	14,555	22.3%
Profit for the year (attributable to owners of the Company)	51,539	**59,704**	8,165	15.8%

[Revenue]

Revenue totaled ¥292.4 billion, which was an increase of ¥3.8 billion (1.3%) from the previous fiscal year (year-on-year).

- Despite the expanded use of Opdivo Intravenous Infusion for malignant tumors for the treatment of renal cell carcinoma etc., its sales were affected by the revision of the National Health Insurance (NHI) drug price reduction in November 2018 and intensifying competition with competitors' products, resulting in sales of ¥87.3 billion, a decrease of ¥3.3 billion (3.6%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥26.1 billion (3.1% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥19.8 billion (13.8% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥18.1 billion (24.7% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥10.7 billion (1.0% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥8.5 billion (4.2% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥7.1 billion (23.6% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥6.0 billion (21.9% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥8.3 billion (19.5% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥4.7 billion (35.4% decrease year-on-year), respectively.
- Royalty and others increased by ¥7.1 billion (8.9%) year-on-year to ¥86.8 billion, mainly due to the rise in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc.

[Operating Profit]

Operating profit was ¥77.5 billion, an increase of ¥15.5 billion (25.0%) year-on-year.

- Cost of sales decreased by ¥4.8 billion (5.7%) year-on-year to ¥79.1 billion. This was mainly due to the absence of the one-time cost burden during the period under review, which was incurred in the previous fiscal year, as it was necessary to receive a stable supply of ingredients for Opdivo.
- Research and development costs decreased by ¥3.5 billion (5.0%) year-on-year to ¥66.5 billion mainly due to decrease in clinical trial costs caused by the revision of clinical trial plans and the discontinuation of some clinical trials etc., as well as due to decrease in license fees associated with drug discovery.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥2.4 billion (3.4%) year-on year to ¥67.7 billion mainly due to delayed launches of new products expected in the fiscal year ended March 31, 2020, and the decrease in operating expenses caused by cancellation or postponement of academic lectures and refraining from visiting medical institutions by MRs due to the novel coronavirus (COVID-19).

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

Profit attributable to owners of the Company increased by ¥8.2 billion (15.8%) year-on-year to ¥59.7 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 Osteoarthritis, and so on. We are promoting development for the early launch of the product. 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, 2020 are as follows.

[Main Progress of Development Pipelines]

<Oncology>

"Opdivo / Nivolumab" (including combination therapy with other drugs)

Melanoma

- In May 2019, approval was obtained in Taiwan for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
- In July 2019, phase III of combination therapy with the IDO1 inhibitor (ONO-7701) for the treatment of melanoma was discontinued in Japan, Europe and USA because the Company reviewed the development plan of combination therapy of ONO-7701 and Opdivo based on the study results of combination therapy of a similar IDO1 inhibitor and anti-PD-1 antibody.

Non-small cell lung cancer

- In December 2019, an approval application for combination therapy with Yervoy was filed in Japan for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
- In February 2020, an approval application for combination therapy with platinum-based doublet chemotherapy was filed in Japan for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
- In March 2020, an approval application for combination therapy that adds platinum-based doublet chemotherapy to combination therapy with Yervoy was filed in Japan for the treatment of unresectable advanced or recurrent non-small cell lung cancer.

Hodgkin lymphoma

- In May 2019, approval was obtained in Taiwan for the treatment of adult patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or 3 or more lines of systemic therapy that includes autologous HSCT.

Colorectal cancer

- In May 2019, a single-agent Opdivo or in combination therapy with Yervoy was approved in Taiwan for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
- In February 2020, an application was approved in Japan for the treatment of microsatellite instability-high (MSI-H) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.
- In November 2019, an approval application for combination therapy with Yervoy was filed in Japan for the treatment of microsatellite instability-high (MSI-H) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.
- In July 2019, phase III of combination therapy with Yervoy was initiated in Japan for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) metastatic colorectal cancer.

Esophageal cancer

- In May 2019, an approval application was filed in Japan for the treatment of esophageal cancer and in February 2020, the application was approved for the treatment of unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy.
- In April 2020, an application was approved in South Korea 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.

Hepatocellular carcinoma

- In September 2019, phase III of combination therapy with Yervoy was initiated in Japan, South Korea and Taiwan for the treatment of hepatocellular carcinoma.

Biliary tract cancer

- In December 2019, phase II was initiated in Japan for the treatment of biliary tract cancer.

Solid tumor

- In June 2019, phase I/II of combination therapy with the liposomal formulation of Halaven was initiated in Japan with Eisai Co., Ltd. for the treatment of solid tumor.
- In July 2019, phase I of combination therapy with anti-CD137 antibody (ONO-4481) for the treatment of solid tumor was discontinued in Japan due to strategic reasons.

Dosage and administration

- In November 2019, an approval application was filed in Japan for the addition of monotherapy dosage and administration (480 mg per dose of intravenous infusion at four-week intervals).

"Kyprolis / Carfilzomib"
- In November 2019, an application was approved in Japan for the addition of dosage and administration of proteasome inhibitor Kyprolis for the treatment of relapsed or refractory multiple myeloma.

"Braftovi / Encorafenib" "Mektovi / Binimetinib"
- In March 2020, an approval application for Braftovi Capsule (BRAF inhibitor) and Mektovi Tablet (MEK inhibitor) was filed in Japan for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer in combination therapy with cetuximab (EGFR monoclonal antibody).

"Velexbru / ONO-4059 / Tirabrutinib"
- In August 2019, an approval application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was filed in Japan for the treatment of primary central nervous system lymphoma and in March 2020, the application was approved for the treatment of recurrent or refractory primary central nervous system lymphoma.
- In November 2019, an approval application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was filed in Japan for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic lymphoma.

"ONO-7912 (CPI-613) / Devimistat"
- In October 2019, phase III of cancer metabolism inhibitor (ONO-7912 (CPI-613) / Devimistat) was initiated in South Korea for the treatment of pancreatic cancer and acute myeloid leukemia.

"ONO-7913 / Magrolimab"
- In March 2020, phase I of monoclonal antibody against CD47 (ONO-7913) was initiated in Japan for the treatment of solid tumor.

"ONO-7705 / Selinexor"
- In February 2020, phase I of XPO1 inhibitor (ONO-7705 / Selinexor) introduced from Karyopharm for the treatment of multiple myeloma and non-hodgkin lymphoma was discontinued in Japan due to strategic reasons and the rights were returned to Karyopharm.

<Areas other than Oncology>

"Onoact / Landiolol Hydrochloride"
- In August 2019, an approval application for short-acting selective β_1 blocker (Onoact) was filed in Japan for the treatment of tachyarrhythmia upon sepsis (atrial fibrillation, atrial flutter and sinus tachycardia).

"Coralan / ONO-1162 / Ivabradine"
- In September 2019, approval for HCN channel blocker (Coralan Tablet / ONO-1162 / Ivabradine) was obtained in Japan for the treatment of chronic heart failure with a sinus rhythm and baseline resting heart rate of 75 beats per minute or higher (limited to patients receiving standard treatment of chronic heart failure, including β-blocker).

"Orencia / Abatacept"
- In February 2020, an application for selective T-cell co-stimulation modulators Orencia IV and Orencia SC was approved in Japan with Bristol-Myers Squibb K.K. for the addition of inhibition of the structural damage of the joints in the previously approved rheumatoid arthritis.
- In February 2020, phase III of the selective T-cell co-stimulation modulator Orencia SC for the treatment of untreated rheumatoid arthritis and primary Sjögren syndrome was discontinued in Japan due to the results not being able to confirm anticipated efficacy.

"ONO-5704 / SI-613"
- In January 2020, an approval application for the osteoarthritis treatment (ONO-5704 / SI-613) was filed in Japan with Seikagaku Corporation for the treatment of osteoarthritis (knee joint, hip joint, ankle joint).

"ONO-4685"
- In June 2019, phase I of PD-1 x CD3 bispecific antibody (ONO-4685) was initiated in Japan for the treatment of autoimmune disease.

"ONO-2808"
- In December 2019, phase I of S1P5 receptor agonist (ONO-2808) was initiated in Europe for the treatment of neurodegenerative diseases.

"ONO-5788"
- In November 2019, phase I of growth hormone secretion inhibitor (ONO-5788) for the treatment of acromegaly was discontinued in USA due to strategic reasons.

[Status of Drug Discovery / Research Alliance Activities]
- In March 2020, the Company entered into a new research and option agreement with Numab in Switzerland for discovery and development of multi-specific antibody drug for the treatment of various cancers.

[Status of Licensing Activities]
- In June 2019, the Company entered into a license agreement with Rafael Pharmaceuticals, Inc. in USA for exclusive development and commercialization in Japan, South Korea, Taiwan, and ASEAN of the cancer metabolism inhibitor CPI-613 (Devimistat) and other related compounds being developed by Rafael.
- In July 2019, the Company entered into a license agreement with Forty Seven, Inc. in USA for exclusive development and commercialization in Japan, South Korea, Taiwan, and ASEAN of the 5F9, a monoclonal antibody against CD47 being developed by Forty Seven.

[Status of Development Alliance Activities]
- In July 2019, Bayer, Bristol-Myers Squibb Company, and the Company entered into a clinical collaboration agreement to evaluate the combination therapy of Bayer's multi-kinase inhibitor, Stivarga (regorafenib) and Bristol-Myers Squibb's / ONO's anti-PD-1 immune checkpoint inhibitor, Opdivo (nivolumab) for the treatment of patients with micro-satellite stable metastatic colorectal cancer, the most common form of metastatic colorectal cancer.

(2) Overview of Financial Position for the Fiscal Year 2019

(Millions of yen)

	As of March 31, 2019	**As of March 31, 2020**	Change
Total Assets	655,056	**673,444**	18,388
Equity attributable to owners of the Company	557,350	**562,484**	5,135
Ratio of equity attributable owners of the Company to total assets	85.1%	**83.5%**	
Equity attributable to owners of the Company per share	1,084.08 yen	**1,126.95 yen**	

Total assets increased to ¥673.4 billion by ¥18.4 billion from the end of the previous fiscal year.
Current assets increased by ¥30.6 billion to ¥225.2 billion mainly due to an increase in other financial assets and cash and cash equivalents etc.
Non-current assets decreased by ¥12.2 billion to ¥448.2 billion mainly due to a decrease in investment securities etc., despite an increase in deferred tax assets and property, plant, and equipment resulting from right-of-use assets recorded as a result of the application of IFRS 16 etc.
Liabilities increased by ¥13.1 billion to ¥105.4 billion mainly due to an increase in lease liabilities as a result of the application of IFRS 16 and income taxes payable etc.
Equity attributable to owners of the Company increased by ¥5.1 billion to ¥562.5 billion mainly due to an increase in retained earnings etc., despite a decrease in other components of equity and purchase of treasury shares etc.

(3) Overview of Cash Flows for the Fiscal Year 2019

(Millions of yen)

	Fiscal year ended March 31, 2019	**Fiscal year ended March 31, 2020**	Change
Cash and cash equivalents at the beginning of the fiscal year	65,273	**59,981**	
Cash flows from operating activities	66,774	**74,157**	7,383
Cash flows from investing activities	(49,763)	**(10,234)**	39,529
Cash flows from financing activities	(22,279)	**(54,721)**	(32,442)
Net increase (decrease) in cash and cash equivalents	(5,268)	**9,202**	
Effects of exchange rate changes on cash and cash equivalents	(24)	**(179)**	
Cash and cash equivalents at the end of the fiscal year	59,981	**69,005**	

Net increase/decrease in cash and cash equivalents was an increase of ¥9.2 billion.
Net cash provided by operating activities was ¥74.2 billion, as a result of profit before tax of ¥79.7 billion etc.
Net cash used in investing activities was ¥10.2 billion, as a result of payments into time deposits (net amount) of ¥20.0 billion, purchases of intangible assets of ¥15.0 billion, and purchases of property, plant, and equipment of ¥7.5 billion etc., while there were proceeds from sales and redemption of investments of ¥31.4 billion etc.
Net cash used in financing activities was ¥54.7 billion, as a result of purchases of treasury shares of ¥29.6 billion and dividends paid of ¥22.8 billion etc.

(4) Future Outlook

(Millions of yen)

	Actual (Fiscal year ended March 31, 2020)	**Forecast (Fiscal year ending March 31, 2021)**	Change	Change (%)
Revenue	292,420	**303,000**	10,580	3.6%
Operating profit	77,491	**80,000**	2,509	3.2%
Profit before tax	79,696	**82,000**	2,304	2.9%
Profit for the year (attributable to owners of the Company)	59,704	**61,000**	1,296	2.2%

[Revenue]
For the next fiscal year, the severe business environment is expected to continue due to the impact of drug price revisions in April 2020 and the intensifying competition for market share with competing products. Although the use of Opdivo Intravenous Infusion is expected to decrease in the treatment of renal cell carcinoma, head and neck cancer, and gastric cancer due to entry of competing products, and in the second-line treatment of non-small cell lung cancer due to a decrease in the number of new patients using the drug, as we expect the expanded use in the treatment of esophageal cancer and entry into first-line treatment for non-small cell lung cancer, the sales are expected to increase by ¥2.7 billion (3.1%) compared to the current fiscal year to ¥90.0 billion. In other main new products, sales of Forxiga Tablets, Orencia SC, Parsabiv Intravenous Injection for Dialysis, Kyprolis for Intravenous Infusion etc. are expected to increase, and several new products are expected to be released. Furthermore, royalty and other revenue is expected to increase by ¥6.2 billion (7.1%) compared to the current fiscal year to ¥93.0 billion due to continued growth in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc. Therefore, revenue is expected to be ¥303.0 billion, an increase of ¥10.6 billion (3.6%) year-on-year.

[Profit]
Cost of sales is expected to be ¥81.5 billion, an increase of ¥2.4 billion (3.1%) year-on-year, mainly due to the start of production at the Yamaguchi Plant in March 2020.
Research and development costs are expected to be ¥69.0 billion, an increase of ¥2.5 billion (3.8%) year-on-year, providing for active investments to achieve sustainable growth, despite delays or suspensions of registrations of subjects for new or continuing clinical trials due to the impact of COVID-19. Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥70.0 billion, an increase of ¥2.3 billion (3.4%) year-on year, mainly due to temporary increase in operating expenses due to several new products to be launched and additional effects, despite the decrease in operating expenses caused by cancellation or postponement of academic lectures and refraining from visiting medical institutions by MRs due to COVID-19.
Consequently, operating profit is forecasted to be ¥80.0 billion, an increase of ¥2.5 billion (3.2%) year-on-year, and profit attributable to owners of the Company is forecasted to be ¥61.0 billion, an increase of ¥1.3 billion (2.2%) year-on-year.

Note: At this time, it is difficult to accurately predict when the COVID-19 pandemic will be under control. Accordingly, the above financial forecasts reflect the effects of continuing to refrain from visiting medical institutions and other activities until the end of June 2020. If the restrictions on the activities continue in the second quarter and thereafter, although revenue is expected to decline slightly due to refraining from activities, restraints on consultations, etc., the impact on operating profit is estimated to be immaterial as expenditures will be controlled due to the decrease in business activities. Going forward, if any revisions to the financial forecasts are necessary, we 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, 2020, we expect to make a year-end dividend of 22.5 yen per share. With the payment of the second quarter dividend of 22.5 yen per share, the annual dividend is expected to be 45 yen per share. Also, the annual dividend for the following fiscal year ending March 31, 2021 is expected to be 45 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, 2019	As of March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	59,981	69,005
Trade and other receivables	76,285	76,834
Marketable securities	687	614
Other financial assets	10,800	30,800
Inventories	32,821	32,906
Other current assets	14,042	15,063
Total current assets	194,617	225,222
Non-current assets:		
Property, plant, and equipment	108,870	114,628
Intangible assets	63,059	66,436
Investment securities	171,476	137,670
Investments in associates	113	108
Other financial assets	91,672	91,694
Deferred tax assets	21,079	34,817
Other non-current assets	4,171	2,871
Total non-current assets	460,439	448,222
Total assets	655,056	673,444

(Millions of yen)

	As of March 31, 2019	As of March 31, 2020
Liabilities and Equity		
Current liabilities:		
Trade and other payables	36,833	34,439
Borrowings	435	–
Lease liabilities	–	2,188
Other financial liabilities	515	450
Income taxes payable	15,980	20,346
Provisions	17,206	20,721
Other current liabilities	12,181	13,185
Total current liabilities	83,150	91,329
Non-current liabilities:		
Borrowings	1,765	–
Lease liabilities	–	6,173
Other financial liabilities	5	0
Retirement benefit liabilities	5,515	6,048
Deferred tax liabilities	1,053	1,059
Other non-current liabilities	832	813
Total non-current liabilities	9,171	14,093
Total liabilities	92,321	105,422
Equity:		
Share capital	17,358	17,358
Capital reserves	17,202	17,229
Treasury shares	(38,151)	(44,737)
Other components of equity	61,852	48,030
Retained earnings	499,088	524,605
Equity attributable to owners of the Company	557,350	562,484
Non-controlling interests	5,386	5,538
Total equity	562,736	568,022
Total liabilities and equity	655,056	673,444

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

Consolidated Statement of Income

(Millions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Revenue	288,634	292,420
Cost of sales	(83,829)	(79,063)
Gross profit	204,805	213,356
Selling, general, and administrative expenses	(70,033)	(67,679)
Research and development costs	(70,008)	(66,497)
Other income	646	822
Other expenses	(3,400)	(2,512)
Operating profit	62,010	77,491
Finance income	3,282	3,053
Finance costs	(150)	(845)
Share of profit (loss) from investments in associates	(1)	(4)
Profit before tax	65,141	79,696
Income tax expense	(13,462)	(19,808)
Profit for the period	51,679	59,888
Profit for the year attributable to:		
Owners of the Company	51,539	59,704
Non-controlling interests	140	184
Profit for the year	51,679	59,888
Earnings per share:		
Basic earnings per share (Yen)	100.25	118.47
Diluted earnings per share (Yen)	100.24	118.45

Consolidated Statement of Comprehensive Income

(Millions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Profit for the year	51,679	59,888
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	(43)	(1,909)
Remeasurements of defined benefit plans	(890)	(109)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(1)	(4)
Total of items that will not be reclassified to profit or loss	(935)	(2,022)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	78	(219)
Total of items that may be reclassified subsequently to profit or loss	78	(219)
Total other comprehensive income (loss)	(857)	(2,241)
Total comprehensive income (loss) for the year	50,821	57,647
Comprehensive income (loss) for the year attributable to:		
Owners of the Company	50,658	57,492
Non-controlling interests	163	155
Total comprehensive income (loss) for the year	50,821	57,647

(3) Consolidated Statement of Changes in Equity

FY 2018 (April 1, 2018 to March 31, 2019)

(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, 2018	17,358	17,175	(38,148)	68,021	459,985	524,390	5,228	529,619
Changes in Accounting Policies					4,127	4,127		4,127
Restated balance	17,358	17,175	(38,148)	68,021	464,112	528,517	5,228	533,746
Profit for the year					51,539	51,539	140	51,679
Other comprehensive income (loss)				(881)		(881)	24	(857)
Total comprehensive income (loss) for the year	–	–	–	(881)	51,539	50,658	163	50,821
Purchase of treasury shares			(3)			(3)		(3)
Cash dividends					(21,850)	(21,850)	(5)	(21,856)
Share-based payments		27				27		27
Transfer from other components of equity to retained earnings				(5,288)	5,288	–		–
Total transactions with the owners	–	27	(3)	(5,288)	(16,562)	(21,826)	(5)	(21,831)
Balance as of March 31, 2019	17,358	17,202	(38,151)	61,852	499,088	557,350	5,386	562,736

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

(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, 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

(4) Consolidated Statement of Cash Flows

(Millions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Cash flows from operating activities		
Profit before tax	65,141	79,696
Depreciation and amortization	10,621	14,214
Impairment losses	209	2,816
Interest and dividend income	(3,164)	(2,968)
Interest expense	27	76
(Increase) decrease in inventories	(1,567)	(173)
(Increase) decrease in trade and other receivables	1,251	(793)
Increase (decrease) in trade and other payables	998	1,992
Increase (decrease) in provisions	6,333	3,515
Increase (decrease) in retirement benefit liabilities	378	381
Other	1,854	865
Subtotal	82,081	99,621
Interest received	77	92
Dividends received	3,092	2,878
Interest paid	(27)	(76)
Income taxes paid	(18,449)	(28,357)
Net cash provided by (used in) operating activities	66,774	74,157
Cash flows from investing activities		
Purchases of property, plant, and equipment	(22,303)	(7,475)
Proceeds from sales of property, plant, and equipment	11	424
Purchases of intangible assets	(7,299)	(14,970)
Purchases of investments	(873)	–
Proceeds from sales and redemption of investments	27,123	31,439
Payments into time deposits	(55,800)	(45,800)
Proceeds from withdrawal of time deposits	10,800	25,800
Other	(1,423)	348
Net cash provided by (used in) investing activities	(49,763)	(10,234)
Cash flows from financing activities		
Dividends paid	(21,828)	(22,775)
Dividends paid to non-controlling interests	(5)	(3)
Repayments of long-term borrowings	(361)	–
Repayments of lease liabilities	–	(2,358)
Net increase (decrease) in short-term borrowings	(84)	–
Purchases of treasury shares	(1)	(29,584)
Net cash provided by (used in) financing activities	(22,279)	(54,721)
Net increase (decrease) in cash and cash equivalents	(5,268)	9,202
Cash and cash equivalents at the beginning of the year	65,273	59,981
Effects of exchange rate changes on cash and cash equivalents	(24)	(179)
Cash and cash equivalents at the end of the year	59,981	69,005

(5) Notes to Consolidated Financial Statements

(Reporting Entity)

Ono Pharmaceutical Co., Ltd. (the "Company") is a company incorporated in Japan. The addresses of its registered head office and principal business locations are disclosed on the Company's website (URL https://www.ono.co.jp/).

The consolidated financial statements of the Company comprise the Company and its subsidiaries (the "Group") and interests in the Group's associates. The Group manufactures and sells medical and general pharmaceutical products. The Group's business descriptions and principal activities are described in "(Segment Information)."

(Basis of Preparation)

1) Statements of Compliance with International Financial Reporting Standards

Since the requirements for a "Specified Company of the Designated International Financial Reporting Standards" prescribed in Article 1-2 of the Ordinance on Terminology, Forms and Preparation Methods of Consolidated Financial Statements (Ordinance of the Ministry of Finance No. 28 of 1976) are satisfied, and the consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards ("IFRS"), pursuant to the provision of Article 93 of the Ordinance.

2) Basis of Measurement

The Group's consolidated financial statements have been prepared on a historical cost basis, except for the financial instruments and others that are measured at fair value.

3) Functional Currency and Presentation Currency

The consolidated financial statements of the Group are presented in Japanese yen, which is the Company's functional currency, and figures have been rounded to the nearest million yen, except where otherwise indicated.

(Significant Accounting Policies)

The significant accounting policies that the Group has applied in the consolidated financial statements for the fiscal year ended March 31, 2020 are the same as the ones for the previous consolidated fiscal year, with the exception of changes in accounting policies on page 14.

(Significant Accounting Estimates and Associated Judgments)

The Group's consolidated financial statements include management estimates and assumptions for measurements of income and expenses, and assets and liabilities. These estimates and assumptions are based on management's best judgment along with historical experience and other various factors that are believed to be reasonable as of the closing date. However, there is a possibility that these estimates and assumptions may differ from actual results in the future due to their nature.

The estimates and underlying assumptions are continually reevaluated by management. The effects of revisions to the accounting estimates and assumptions are recognized in the period of the revision and future periods.

The estimates and assumptions that have a significant effect on the amounts recognized in the Group's consolidated financial statements are as follows:

• Impairment of property, plant, and equipment and intangible assets

With regard to property, plant, and equipment and intangible assets, if there is any indication that the recoverable amount of an asset is less than its carrying amount, the Group performs an impairment test.

Important factors that trigger the impairment test to be performed include significant changes adversely affecting the results of past or projected business performance, significant changes in the usage of acquired assets or changes in overall business strategy, and significant deterioration in industry trends or economic trends. The amount of impairment is determined based on the higher of the fair value less costs to sell or the value in use measured based on the valuation of risk-adjusted future cash flows discounted at an appropriate rate. Future cash flows are estimated based on business forecasts. There is a possibility that a future event may result in changes in assumptions used in such impairment tests and may affect future operating results of the Group.

• Recoverability of deferred tax assets

Deferred tax assets are recognized on temporary differences between the carrying amounts of assets and liabilities for accounting purposes and the corresponding tax bases using the effective tax rate applied to the temporary differences to the extent it is probable that future taxable profits will be available against which they can be utilized to recover the deferred tax assets.

• Basic rates for accounting of retirement benefits

The Group has a number of retirement benefit plans, including defined benefit plans.

The Group calculates the present value of defined benefit obligations and related service costs based on actuarial assumptions. The actuarial assumptions require estimates and judgments on variables, such as discount rates, net interest, etc.

The Group obtains advice from external pension actuaries with respect to the appropriateness of the actuarial assumptions including the variables.

The actuarial assumptions are determined based on the best estimates and judgments made by management; however, there is a possibility that these assumptions may be affected by changes in uncertain future economic conditions. In cases where the assumptions need to be revised, the revision may have a material impact on amounts recognized in the consolidated financial statements.

(Changes in Accounting Policies)

Our group has applied IFRS 16 “Leases” (issued in January 2016) (“IFRS 16”) from the fiscal year ended March 31, 2020.

On application of IFRS 16, right-of-use assets and lease liabilities were recognized on the date of initial application of IFRS 16 (April 1, 2019) for leases previously classified as operating leases under IAS 17 “Leases” (“IAS 17”).

In addition, operating lease payments that had been expensed as incurred under the previous accounting standard were recorded as depreciation charge for right-of-use assets and interest expense on lease liabilities in the consolidated statement of income for the fiscal year ended March 31, 2020, and reclassified from a reduction in cash flows from operating activities to a reduction in cash flows from financing activities in the consolidated statement of cash flows for the same period.

For lease transactions as a lessee, our group measures right-of-use assets at cost and lease liabilities at the present value of future lease payments at the commencement date of the lease transactions in accordance with IFRS 16.

A right-of-use asset is depreciated by using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term.

Lease payments are allocated to finance costs and repayments of lease liabilities based on the effective interest method. The finance costs are recognized in the consolidated statement of income.

However, our group has elected not to recognize right-of-use assets and lease liabilities for leases of intangible assets, leases for which the underlying asset is of low value (“low-value leases”), and short-term leases with a lease term of 12 months or less. Lease payments associated with low-value leases and short-term leases are recognized as expense on either a straight-line basis or another systematic basis over the lease term.

In accordance with the transition under IFRS 16, our group has retrospectively adopted IFRS 16 and recognized the cumulative effect of initially applying IFRS 16 as an adjustment to the opening balance of retained earnings for the fiscal year ended March 31, 2020. In transitioning to IFRS 16, our group has elected the practical expedient provided in paragraph C3 of IFRS 16 and carried forward the assessment of whether a contract contains a lease in accordance with IAS 17 and IFRIC 4 “Determining whether an Arrangement contains a Lease.”

Our group measures the lease liability at the present value of the lease payments that are not paid at the date of initial application by discounting them at the lessee’s incremental borrowing rate as of the date of initial application. The weighted average lessee’s incremental borrowing rate applied to lease liabilities recognized in the consolidated statement of financial position at the date of initial application is 0.9%. Our group initially measures the right-of-use assets at the initial measurement amount of the lease liability adjusted by the amount of any prepaid or accrued lease payments.

For leases that were classified as finance leases applying IAS 17, the right-of-use asset and the lease liability are measured at the carrying amount of the leased asset and lease liability at the end of the previous fiscal year.

As a result, as of the beginning of the fiscal year ended March 31, 2020, property, plant, and equipment and lease liabilities each increased by ¥6,245 million, compared with the amounts under the previous accounting standard. There is no impact for the opening balance of retained earnings at the date of initial application, because our group measures right-of-use assets at the date of initial application at the amount of lease liabilities measured after adjusting the amount of any prepaid and accrued lease payments.

The following is the reconciliation of operating lease contracts disclosed under IAS 17 as of March 31, 2019 and lease liabilities at the date of initial application recognized in the consolidated statement of financial position.

(Millions of yen)

	Amount
Operating lease contracts disclosed as of March 31, 2019	499
Operating lease contracts discounted at the incremental borrowing rate as of April 1, 2019	499
Finance lease contracts disclosed as of March 31, 2019	2,200
Cancelable operating lease contracts	5,757
Other	(11)
Lease liabilities as of April 1, 2019	8,445

When applying IFRS 16, our group used the following practical expedients provided in paragraph C10 of IFRS 16:

- A single discount rate is applied to a portfolio of leases with reasonably similar characteristics.

- Leases for which the lease term ends within 12 months of the date of initial application are accounted for in the same way as short-term leases.

- Initial direct costs are excluded from the measurement of the right-of-use asset at the date of initial application.

- Hindsight is used, such as in determining the lease term if the contract contains options to extend or terminate the lease.

(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 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Revenue of goods and products	208,947	205,614
Royalty and others	79,687	86,805
Total	288,634	292,420

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥58.5 billion for the fiscal year ended March 31, 2019 and ¥61.6 billion for the fiscal year ended March 31, 2020. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥12.8 billion for the fiscal year ended March 31, 2019 and ¥19.3 billion for the fiscal year ended March 31, 2020.

3) Revenue by Geographic Area

Details of revenue by geographic area are as follows:

(Millions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Japan	207,371	202,866
Americas	72,298	81,545
Asia	7,354	7,481
Europe	1,610	528
Total	288,634	292,420

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 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Bristol-Myers Squibb Company and the group	63,442	66,826
Medipal Holdings Corporation and the group	45,744	46,295
Suzuken Co., Ltd. and the group	45,832	45,828
Alfresa Holdings Corporation and the group	32,213	31,894
Toho Holdings Co., Ltd. and the group	31,242	30,637

(Earnings per Share)

1) Basic Earnings per Share

(i) Basic earnings per share

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Basic earnings per share (Yen)	100.25	118.47

(ii) Basis of calculation of basic earnings per share

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Profit for the year attributable to owners of the Company (Millions of yen)	51,539	59,704
Weighted-average number of ordinary shares outstanding (Thousands of shares)	514,121	503,975

2) Diluted Earnings per Share

(i) Diluted earnings per share

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Diluted earnings per share (Yen)	100.24	118.45

(ii) Basis of calculation of diluted earnings per share

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 (April 1, 2019 to March 31, 2020)
Profit for the year attributable to owners of the Company (Millions of yen)	51,539	59,704
Weighted-average number of ordinary shares outstanding (Thousands of shares)	514,121	503,975
Increase in common shares by share acquisition rights (Thousands of shares)	50	69
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	514,171	504,044

(Significant Subsequent Events)

Not Applicable

(Notes Regarding Assumption of a Going Concern)

Not Applicable

Fiscal Year 2019
(April 1, 2019 to March 31, 2020)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Fiscal Year 2019 (April 1, 2019 to March 31, 2020) Consolidated Financial Results (IFRS)】

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

Consolidated Financial Results for FY 2019 (April 1, 2019 to March 31, 2020) (IFRS)

Consolidated Financial Results

(Billions of yen)

	FY 2018 Actual (April 1, 2018 to March 31, 2019)	**FY 2019 Actual (April 1, 2019 to March 31, 2020)**	YoY
Revenue	288.6	**292.4**	1.3%
Operating profit	62.0	**77.5**	25.0%
Profit before tax	65.1	**79.7**	22.3%
Profit for the year (attributable to owners of the Company)	51.5	**59.7**	15.8%

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	**FY 2019 Actual (April 1, 2019 to March 31, 2020)**					YoY		Forecasts
	Cumulative							
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar		Change	Change (%)	
Opdivo	22.3	24.5	21.2	19.3	**87.3**	(3.3)	(3.6%)	85.0
Glactive	6.9	6.3	7.3	5.5	**26.1**	(0.8)	(3.1%)	26.5
Orencia	4.9	5.1	5.2	4.6	**19.8**	2.4	13.8%	19.0
Forxiga	4.4	4.3	5.1	4.3	**18.1**	3.6	24.7%	16.5
Emend / Proemend	2.9	3.0	3.0	1.8	**10.7**	0.1	1.0%	11.5
Rivastach Patch	2.3	2.1	2.4	1.8	**8.5**	(0.4)	(4.2%)	9.5
Opalmon	2.3	2.1	2.3	1.6	**8.3**	(2.0)	(19.5%)	9.0
Parsabiv	1.7	1.8	2.0	1.6	**7.1**	1.3	23.6%	7.0
Kyprolis	1.4	1.5	1.7	1.4	**6.0**	1.1	21.9%	5.5
Recalbon	1.4	1.2	1.3	0.9	**4.7**	(2.6)	(35.4%)	5.0
Onoact	1.3	1.1	1.6	0.8	**4.9**	0.3	6.2%	4.5
Onon Capsules	0.9	0.7	0.9	1.0	**3.5**	(0.9)	(21.0%)	3.5
Staybla	0.9	0.7	0.8	0.6	**3.1**	(0.6)	(17.1%)	3.5
Onon Dry Syrup	0.6	0.4	0.7	0.5	**2.2**	(0.5)	(19.1%)	2.0

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

Details of Sales Revenue

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	**FY 2019 (April 1, 2019 to March 31, 2020)**
Revenue of goods and products	208.9	**205.6**
Royalty and others	79.7	**86.8**
Total	288.6	**292.4**

Notes: In "Royalty and other revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥58.5 billion for the fiscal year ended March 31, 2019 and ¥61.6 billion for the fiscal year ended March 31, 2020. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥12.8 billion for the fiscal year ended March 31, 2019 and ¥19.3 billion for the fiscal year ended March 31, 2020.

Revenue by Geographic Area

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	**FY 2019 (April 1, 2019 to March 31, 2020)**
Japan	207.4	**202.9**
Americas	72.3	**81.5**
Asia	7.4	**7.5**
Europe	1.6	**0.5**
Total	288.6	**292.4**

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

Summary of Consolidated Financial Results for FY 2019 (April 1, 2019 to March 31, 2020) (IFRS)

1. Revenue ¥292.4 billion YoY an increase of 1.3% (FY 2018 ¥288.6 billion)

- Despite the expanded use of Opdivo Intravenous Infusion for malignant tumors for the treatment of renal cell carcinoma etc., its sales were affected by the revision of the National Health Insurance (NHI) drug price reduction in November 2018 and intensifying competition with competitors' products, resulting in sales of ¥87.3 billion, a decrease of ¥3.3 billion (3.6%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥26.1 billion (3.1% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥19.8 billion (13.8% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥18.1 billion (24.7% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥10.7 billion (1.0% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥8.5 billion (4.2% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥7.1 billion (23.6% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥6.0 billion (21.9% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥8.3 billion (19.5% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥4.7 billion (35.4% decrease year-on-year), respectively.
- Royalty and others increased by ¥7.1 billion (8.9%) year-on-year to ¥86.8 billion, mainly due to the rise in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc.

2. Operating profit ¥77.5 billion YoY an increase of 25.0% (FY 2018 ¥62.0 billion)

- Cost of sales decreased by ¥4.8 billion (5.7%) year-on-year to ¥79.1 billion. This was mainly due to the absence of the one-time cost burden during the period under review, which was incurred in the previous fiscal year, as it was necessary to receive a stable supply of ingredients for Opdivo.
- Research and development costs decreased by ¥3.5 billion (5.0%) year-on-year to ¥66.5 billion mainly due to decrease in clinical trial costs caused by the revision of clinical trial plans and the discontinuation of some clinical trials etc., as well as due to decrease in license fees associated with drug discovery.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥2.4 billion (3.4%) year-on year to ¥67.7 billion mainly due to delayed launches of new products expected in the fiscal year ended March 31, 2020, and the decrease in operating expenses caused by cancellation or postponement of academic lectures and refraining from visiting medical institutions by MRs due to the novel coronavirus (COVID-19).

3. Profit before tax ¥79.7 billion YoY an increase of 22.3% (FY 2018 ¥65.1 billion)

- Net financial income was ¥2.2 billion, a decrease of ¥0.9 billion (29.6%) year-on-year.

4. Profit for the year ¥59.7 billion YoY an increase of 15.8% (FY 2018 ¥51.5 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥8.2 billion (15.8%) year-on-year to ¥59.7 billion in association with the increase of the profit before tax.

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

Consolidated Financial Forecasts

(Billions of yen)

	FY 2018 Actual (April 1, 2018 to March 31, 2019)	FY 2019 Actual (April 1, 2019 to March 31, 2020)	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**	YoY
Revenue	288.6	292.4	**303.0**	3.6%
Operating profit	62.0	77.5	**80.0**	3.2%
Profit before tax	65.1	79.7	**82.0**	2.9%
Profit for the year (attributable to owners of the Company)	51.5	59.7	**61.0**	2.2%

Sales Revenue of Major Products (Forecasts)

(Billions of yen)

	FY 2019 Actual (April 1, 2019 to March 31, 2020)			**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**		
Product	Actual	YoY		**Forecasts**	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo	87.3	(3.3)	(3.6%)	**90.0**	2.7	3.1%
Glactive	26.1	(0.8)	(3.1%)	**25.0**	(1.1)	(4.1%)
Forxiga	18.1	3.6	24.7%	**22.5**	4.4	24.6%
Orencia	19.8	2.4	13.8%	**21.5**	1.7	8.4%
Rivastach Patch	8.5	(0.4)	(4.2%)	**8.5**	(0.0)	(0.3%)
Parsabiv	7.1	1.3	23.6%	**7.5**	0.4	6.1%
Kyprolis	6.0	1.1	21.9%	**6.5**	0.5	8.4%
Onoact	4.9	0.3	6.2%	**6.0**	1.1	23.4%
Opalmon	8.3	(2.0)	(19.5%)	**5.0**	(3.3)	(40.0%)
Proemend	2.6	0.1	3.0%	**3.5**	0.9	33.3%
Emend	8.1	0.0	0.4%	**3.5**	(4.6)	(56.7%)
Onon Capsules	3.5	(0.9)	(21.0%)	**3.0**	(0.5)	(13.1%)
Recalbon	4.7	(2.6)	(35.4%)	**2.0**	(2.7)	(57.8%)
New products to be launched	—			**5.0**	5.0	—

Details of Sales Revenue (Forecasts)

(Billions of yen)

	FY 2019 Actual (April 1, 2019 to March 31, 2020)	FY 2020 Forecasts (April 1, 2020 to March 31, 2021)
Revenue of goods and products	205.6	210.0
Royalty and other revenue	86.8	93.0
Total	292.4	303.0

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

1. Revenue ¥303.0 billion YoY an increase of ¥10.6 billion (3.6%) (FY 2019 ¥292.4 billion)

- For the next fiscal year, the severe business environment is expected to continue due to the impact of drug price revisions in April 2020 and the intensifying competition for market share with competing products. Although the use of Opdivo Intravenous Infusion is expected to decrease in the treatment of renal cell carcinoma, head and neck cancer, and gastric cancer due to entry of competing products, and in the second-line treatment of non-small cell lung cancer due to a decrease in the number of new patients using the drug, as we expect the expanded use in the treatment of esophageal cancer and entry into first-line treatment for non-small cell lung cancer, the sales are expected to increase by ¥2.7 billion (3.1%) compared to the current fiscal year to ¥90.0 billion. In other main new products, sales of Forxiga Tablets, Orencia SC, Parsabiv Intravenous Injection for Dialysis, Kyprolis for Intravenous Infusion etc. are expected to increase, and several new products are expected to be released. Furthermore, royalty and other revenue is expected to increase by ¥6.2 billion (7.1%) compared to the current fiscal year to ¥93.0 billion due to continued growth in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc. Therefore, revenue is expected to be ¥303.0 billion, an increase of ¥10.6 billion (3.6%) year-on-year.

2. Operating profit ¥80.0 billion YoY an increase of ¥2.5 billion (3.2%) (FY 2019 ¥77.5 billion)

- Cost of sales is expected to be ¥81.5 billion, an increase of ¥2.4 billion (3.1%) year-on-year, mainly due to the start of production at the Yamaguchi Plant in March 2020.
- Research and development costs are expected to be ¥69.0 billion, an increase of ¥2.5 billion (3.8%) year-on-year, providing for active investments to achieve sustainable growth, despite delays or suspensions of registrations of subjects for new or continuing clinical trials due to the impact of COVID-19.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥70.0 billion, an increase of ¥2.3 billion (3.4%) year-on year, mainly due to temporary increase in operating expenses due to several new products to be launched and additional effects, despite the decrease in operating expenses caused by cancellation or postponement of academic lectures and refraining from visiting medical institutions by MRs due to COVID-19.
- Consequently, operating profit is forecasted to be ¥80.0 billion, an increase of ¥2.5 billion (3.2%) year-on-year.

3. Profit before tax ¥82.0 billion YoY an increase of ¥2.3 billion (2.9%) (FY 2019 ¥79.7 billion)

- Net financial income is expected to be ¥2.0 billion, a decrease of ¥0.2 billion (9.3%) year-on-year.

4. Profit for the year ¥61.0 billion YoY an increase of ¥1.3 billion (2.2%) (FY 2019 ¥59.7 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company is expected to be ¥61.0 billion, an increase of ¥1.3 billion (2.2%) year-on-year.

Note: At this time, it is difficult to accurately predict when the COVID-19 pandemic will be under control. Accordingly, the above financial forecasts reflect the effects of continuing to refrain from visiting medical institutions and other activities until the end of June 2020. If the restrictions on the activities continue in the second quarter and thereafter, although revenue is expected to decline slightly due to refraining from activities, restraints on consultations, etc., the impact on operating profit is estimated to be immaterial as expenditures will be controlled due to the decrease in business activities. Going forward, if any revisions to the financial forecasts are necessary, we will promptly announce them.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	**FY 2019 (April 1, 2019 to March 31, 2020)**	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**
Property, plant, and equipment	6.6	**8.9**	**9.5**
Intangible assets	4.0	**5.3**	**7.2**
Total	10.6	**14.2**	**16.7**
Ratio to sales revenue (%)	3.7%	**4.9%**	**5.5%**

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

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	**FY 2019 (April 1, 2019 to March 31, 2020)**	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**
Property, plant, and equipment	21.4	9.5	6.5
Intangible assets	11.5	11.4	12.0
Total	32.9	21.0	18.5

Number of Employees (Consolidated)

	FY 2018 (as of March 31, 2019)	FY 2019 (as of March 31, 2020)
Number of employees	3,555	3,560

Status of Shares (as of March 31, 2020)

Number of Shares

	As of March 31, 2020
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, 2020
Number of shareholders	89,156

Principal Shareholders

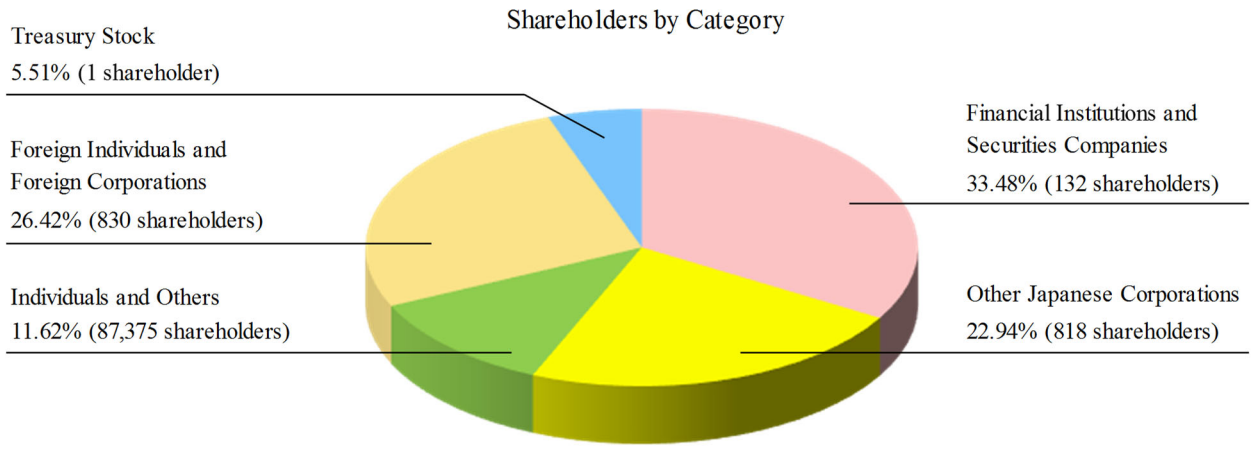
(As of March 31, 2020)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	39,254	7.86%
Japan Trustee Services Bank, Ltd. (Trust account)	25,169	5.04%
STATE STREET BANK AND TRUST COMPANY 505001	20,598	4.12%
Meiji Yasuda Life Insurance Company	18,594	3.72%
Ono Scholarship Foundation	16,428	3.29%
KAKUMEISOU Co., LTD	16,161	3.23%
Japan Trustee Services Bank, Ltd. (Trust account 5)	9,355	1.87%
Japan Trustee Services Bank, Ltd. (Trust account 7)	8,679	1.73%
MUFG Bank, Ltd.	8,640	1.73%
Aioi Nissay Dowa Insurance Co., Ltd.	8,606	1.72%

Note:1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,158 thousand shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (29,158 thousand shares).

Ownership and Distribution of Shares



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

I. Main Status of Development Pipelines (Oncology)

As of April 24, 2020

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Colorectal cancer *1 (MSI-H)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *2*3	Injection	Japan *2 S. Korea*3	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary central nervous system lymphoma *4 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2020

*1: An application for Opdivo was approved in Japan for the treatment of microsatellite instability-high (MSI-H) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

*2: An application for Opdivo was approved in Japan for the treatment of unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy.

*3: An application for Opdivo was approved in South Korea 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.

*4: An application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was approved in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma.

<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
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)
ONO-4059 / Tirabrutinib	Additional indication	Waldenstorm macroglobulinemia, Lymphoplasmacytic lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house
Yervoy Injection ★ / Ipilimumab	Additional indication	Colorectal cancer (MSI-H)	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule / Encorafenib	New chemical entities	Colorectal cancer *5 / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablet / Binimetinib	New chemical entities	Colorectal cancer *5 / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2020

*5: An approval application for Braftovi Capsule (BRAF inhibitor) and Mektovi Tablet (MEK inhibitor) was filed in Japan for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer in combination therapy with cetuximab (EGFR monoclonal antibody).

<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	Gastro-esophageal junction cancer and esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	Japan 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	Glioblastoma	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan	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	Esophageal cancer	Injection	Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	Japan	II	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	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	Non-small cell lung cancer	Injection	S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma	Injection	Japan	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-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	Japan S. Korea Taiwan	II	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-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
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 interleukin-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)

<Other>

***) :** "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-7702 / 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.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7703 / 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.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I	In-house
ONO-7913 *6 / 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 2020

*6: Phase I of anti-CD47 antibody (ONO-7913) was initiated for the treatment of solid tumor.

* Phase I of XPO1 inhibitor (ONO-7705 / Selinexor) for the treatment of multiple myeloma and non-hodgkin lymphoma was discontinued due to strategic reasons and the rights were returned to Karyopharm.

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 (Non-Oncology)

As of April 24, 2020

<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
Orencia IV Orencia SC / Abatacept	Additional indication	Prevention of the structural damage of the joints in rheumatoid arthritis *7 / T-cell activation inhibitor	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2020

*7: An application for selective T-cell co-stimulation modulators Orencia IV and Orencia SC was approved with Bristol-Myers Squibb K.K. for the addition of prevention of the structural damage of the joints in the previously approved rheumatoid arthritis.

<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
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	Japan	In-license (Bial)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication	Tachyarrhythmia upon sepsis / Short-acting selective β_1 blocker	Injection	Japan	In-house
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

<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)
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
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
ONO-4059 / Tirabrutinib	Additional indication	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	Japan	I	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	Europe	I	In-house

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2020

* Phase III of the selective T-cell co-stimulation modulator Orencia SC for the treatment of untreated rheumatoid arthritis and primary Sjögren syndrome was discontinued due to the results not being able to confirm anticipated efficacy.

Profile for Main Development

Opdivo Intravenous Infusion (ONO-4538 / BMS-936558) / Nivolumab (injection)
Opdivo, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer etc. PD-1 is 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-4687 / BMS-986227 / Cabiralizumab (injection)
ONO-4687, a human anti-human CSF-1R monoclonal antibody, is being developed for the treatment of pancreatic 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-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 solid tumor.

Braftovi Capsule (ONO-7702) / Encorafenib (capsule)
Braftovi, BRAF inhibitor, is marketed in Japan for the indication of melanoma, and an approval application was filed in Japan for the treatment of colorectal cancer.

Mektovi Tablet (ONO-7703) / Binimetinib (tablet)
Mektovi, MEK inhibitor, is marketed in Japan for the indication of melanoma, and an approval application was filed in Japan for the treatment of colorectal cancer.

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis is a proteasome inhibitor, being developed for change in dosage and administration after launched for multiple myeloma. 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.

ONO-7643 / Anamorelin (tablet)
ONO-7643 is a small-molecule ghrelin mimetic. An approval application was filed in Japan for the treatment of cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug for the systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

ONO-4059 / Tirabrutinib (tablet)
ONO-4059 is a Btk inhibitor. An application was approved in Japan for the treatment of primary central nervous system lymphoma. Also, an approval application was filed in Japan for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic lymphoma. In addition, it is being developed for the treatment of B cell lymphoma, Sjögren syndrome and pemphigus.

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 where it is indicated 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 and psoriatic 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 approval application was filed for the treatment of tachyarrhythmia upon sepsis.
Development is being conducted for tachyarrhythmia in low cardiac function in pediatric.

ONO-2370 / Opicapone (tablet)
ONO-2370 is a long acting COMT inhibitor. An approval application was filed in Japan for the treatment of parkinson’s disease. ONO-2370 is approved for the treatment of parkinson’s disease in overseas by Bial and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

ONO-5704 / SI-613 (injection)
ONO-5704 is a hyaluronic acid-NSAID. An approval application was filed for the treatment of osteoarthritis (knee joint, hip joint, ankle joint). Also, it is being developed for the treatment of enthesopathy.

ONO-7269 (injection)
ONO-7269, FXIa inhibitor, is being developed for the treatment of cerebral infarction.

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.