Consolidated Financial Results
for the Fiscal Year Ended March 31, 2019 (IFRS)

May 9, 2019

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
Contact	: Yukio Tani Corporate Executive Officer, Director, Corporate Communications
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Scheduled date of annual general meeting of shareholders	: June 20, 2019
Scheduled date of securities report submission	: June 21, 2019
Scheduled date of dividend payment commencement	: June 21, 2019
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 2018 (April 1, 2018 to March 31, 2019)

(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	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2018	288,634	10.2	62,010	2.2	65,141	1.9	51,679	2.5	51,539	2.5
FY 2017	261,836	7.0	60,684	(16.0)	63,922	(14.2)	50,397	(10.1)	50,284	(9.9)

	Total comprehensive income for the year		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
	Million yen	%	Yen	Yen	%	%	%
FY 2018	50,821	(24.8)	100.25	100.24	9.5	10.3	21.5
FY 2017	67,607	(0.7)	97.00	96.99	9.6	10.4	23.2

(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, 2019	655,056	562,736	557,350	85.1	1,084.08
As of March 31, 2018	609,226	529,619	524,390	86.1	1,019.97

(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 2018	66,774	(49,763)	(22,279)	59,981
FY 2017	15,727	(34,189)	(62,549)	65,273

2. Dividends

	Annual dividends per share					Total dividends (annual)	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to owners of 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 2017	—	25.00	—	20.00	45.00	23,138	46.4	4.5
FY 2018	—	22.50	—	22.50	45.00	23,138	44.9	4.3
FY 2019 (Forecast)	—	22.50	—	22.50	45.00		43.7	

(Note) Breakdown of the second quarter end dividend for FY 2017:
Ordinary dividend ¥20, 300th anniversary commemorative dividend ¥5

3. Consolidated Financial Forecasts for FY 2019 (April 1, 2019 to March 31, 2020)

(% 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 2019	290,000	0.5	67,000	8.0	70,000	7.5	53,100	2.8	53,000	2.8	103.09

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, 2019 543,341,400 shares
As of March 31, 2018 543,341,400 shares
2) Number of treasury shares as of the end of the period:
As of March 31, 2019 29,220,860 shares
As of March 31, 2018 29,219,787 shares
3) Average number of shares outstanding during the period:
FY 2018 514,121,049 shares
FY 2017 518,390,834 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. Please refer to "(4) Outlook for FY 2019" on page 7 for information regarding the forecast of consolidated financial results.

Index of the Attachment

1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the Fiscal Year 2018

(Millions of yen)

	Fiscal year ended March 31, 2018	Fiscal year ended March 31, 2019	Change	Change (%)
Revenue	261,836	288,634	26,798	10.2%
Operating profit	60,684	62,010	1,325	2.2%
Profit before tax	63,922	65,141	1,219	1.9%
Profit for the year (attributable to owners of the Company)	50,284	51,539	1,255	2.5%

[Revenue]

Revenue totaled ¥288.6 billion, which was an increase of ¥26.8 billion (10.2%) from the previous fiscal year (year-on-year).

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction according to the drastic reform of NHI drug pricing system, its use was expanded for the treatment of renal cell carcinoma, and head and neck cancer approved in the fiscal year before last as well as gastric cancer etc. in the previous fiscal year, resulting in sales of ¥90.6 billion, an increase of ¥0.5 billion (0.5%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥26.9 billion (1.8% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥17.4 billion (23.3% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥14.5 billion (31.0% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥10.6 billion (6.6% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥8.9 billion (0.2% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥5.7 billion (66.8% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥4.9 billion (11.1% decrease year-on-year).
- Sales of long-term listed products were affected by the impact of NHI drug price reduction and generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥10.4 billion (27.9% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥7.3 billion (32.8% decrease year-on-year), respectively.
- Royalty and other revenue increased by ¥23.7 billion (42.4%) year-on-year to ¥79.7 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company and recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.

[Operating Profit]

Operating profit was ¥62.0 billion, an increase of ¥1.3 billion (2.2%) year-on-year.

- Cost of sales was ¥83.8 billion, an increase of ¥18.4 billion (28.2%) year-on-year mainly due to the impact of applying IFRS 15 noted below (¥9.6 billion increase compared with the previous accounting standards) and one-time expense in order to ensure stable supply of ingredients for Opdivo.
- Research and development costs increased by ¥1.2 billion (1.7%) year-on-year to ¥70.0 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥2.0 billion (2.9%) year-on-year to ¥70.0 billion mainly due to the rise in operating costs related to main new products such as Opdivo Intravenous Infusion and Forxiga Tablets.
- Other expenses include the payment of the settlement with Pfizer for the patent related litigation. In the previous fiscal year, a ¥2.9 billion gain on sales of property, plant and equipment was recorded in other income.

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

Profit attributable to owners of the Company increased by ¥1.3 billion (2.5%) year-on-year to ¥51.5 billion in association with the increase of the profit before tax.

Note: Our group has applied IFRS 15 "Revenue from Contracts with Customers" from the fiscal year ended March 31, 2019. For the consolidated statement of income for the fiscal year ended March 31, 2019, compared with the case calculated using the previous accounting standards, revenue increased by ¥8,889 million, cost of sales increased by ¥9,553 million, operating profit decreased by ¥664 million, and profit before tax decreased by ¥664 million.

(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 physiologically active substance 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 newly 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 during the fiscal year ended March 31, 2019 are as follows.

[Main Progress of Development Pipelines]
<Oncology>

“Opdivo” (including combination therapy with other drugs)

Melanoma

- In May 2018, approval for combination therapy with Yervoy was obtained in Japan for the treatment of unresectable melanoma.
- In August 2018, approval was obtained in Japan for the adjuvant treatment of melanoma.

Non-small cell lung cancer

- In January 2019, approval was obtained in Taiwan for the addition of treatment of non-small cell lung cancer previously treated with platinum-based chemotherapy.

Renal cell carcinoma

- In August 2018, approval for combination therapy with Yervoy was obtained in Japan for the treatment of unresectable or metastatic renal cell carcinoma.
- Approval for combination therapy with Yervoy was obtained in South Korea in October 2018 and Taiwan in November 2018 for the treatment of previously untreated intermediate and high risk advanced renal cell carcinoma.
- In August 2018, phase III of combination therapy with Cabozantinib (multi-kinase inhibitor) was initiated in Japan for the treatment of previously untreated advanced or metastatic renal cell carcinoma.

Malignant pleural mesothelioma

- In August 2018, approval was obtained in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy.

Colorectal cancer

- In March 2019, an approval application was filed in Japan for the treatment of MSI-H unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

Bladder cancer

- In January 2019, phase III of combination therapy with ONO-7701 (IDO1 inhibitor) was initiated in Japan for the treatment of bladder cancer.

Pancreatic cancer

- In July 2018, phase II of combination therapy with ONO-4687 / Cabiralizumab (Anti-CSF-1R antibody) was initiated in Japan for the treatment of pancreatic cancer.

Multiple myeloma

- In January 2019, phase II of treatment of multiple myeloma was discontinued in Japan for strategic reasons.

Solid tumor

- In August 2018, phase I of combination therapy with ONO-7475 (Axl/Mer inhibitor) was initiated in Japan for the treatment of advanced or metastatic solid tumor.
- In October 2018, phase I of combination therapy with ONO-7911 (PEGylated interleukin-2 formulation) was initiated in Japan for the treatment of solid tumor.
- In August 2018, phase I of combination therapy with Mogamulizumab (Anti-CCR4 antibody) for the treatment of solid tumor was discontinued in Japan due to the results not being able to confirm anticipated efficacy.

Other

- In August 2018, approval was obtained in Japan for a change in dosage and administration from a body weight conversion dose to a flat dose.
  Development and sales of Opdivo in regions other than Japan, South Korea, and Taiwan are handled by Bristol-Myers Squibb, which is a partner company.

Braftovi and Mektovi

- In April 2018, an approval application for combination therapy with ONO-7702 / Encorafenib (BRAF inhibitor) and ONO-7703 / Binimetinib (MEK inhibitor) was filed in Japan for the treatment of BRAF-mutant unresectable melanoma. Approval was obtained in January 2019, and they were released in February as Braftovi (BRAF inhibitor) and Mektovi (MEK inhibitor).

Demser

- In April 2018, an approval application for ONO-5371 / Metyrosine (tyrosine hydroxylase inhibitor) was filed in Japan for the improvement of status of catecholamine excess secretion and its accompanying symptoms in patients with pheochromocytoma. Approval was obtained in January 2019, and it was released as Demser (tyrosine hydroxylase inhibitor) in February 2019.

Kyprolis

- In March 2019, an approval application was filed in Japan for the addition of new dosage and administration of Kyprolis for the treatment of relapsed or refractory multiple myeloma.

ONO-7643 / Anamorelin

- In November 2018, an approval application for ONO-7643 / Anamorelin (ghrelin receptor agonist) was filed in Japan for the improvement of body weight loss and anorexia in patients with cancer cachexia.

ONO-4059 / Tirabrutinib

- In July 2018, phase II of ONO-4059 / Tirabrutinib (Btk inhibitor) was initiated in Japan for the treatment of primary macroglobulinemia and lymphoplasmacytic lymphoma.

ONO-7705

- In June 2018, phase I of ONO-7705 / Selinexor (XPO1 inhibitor) was initiated in Japan for the treatment of multiple myeloma and non-hodgkin lymphoma.

ONO-7579

- In August 2018, phase I/II of ONO-7579 (Trk inhibitor) for the treatment of solid tumor was discontinued in Europe and USA for strategic reasons.

<Areas other than Oncology>

Opalmon

- In June 2018, licensee Meiji Seika Pharma Co., Ltd. obtained approval for Opalmon for peripheral circulatory disorder in Thailand for the treatment of lumbar spinal canal and thromboangiitis obliterans.

Onoact

- In July 2018, an approval application for Onoact (short-acting β_1 blocker) was filed in Japan for the treatment of refractory and urgent fatal arrhythmia (ventricular fibrillation and hemodynamically unstable ventricular tachycardia), and approval was obtained in March 2019.

Rivastach Patch

- In September 2018, an approval application for the formulation containing a new ingredient of Rivastach Patch for Alzheimer's disease was filed in Japan, and approval was obtained in March 2019.

Forxiga

- In March 2019, approval was obtained for the addition of dosage and administration of Forxiga for the treatment of type-1 diabetes.

Orencia

- In March 2019, an approval application for Orencia IV and Orencia SC was filed in Japan for the addition of inhibition of the structural damage of the joints in rheumatoid arthritis.
- In January 2019, phase III of Orencia IV for the treatment of lupus nephritis was discontinued for strategic reasons.

Opdivo

- In January 2019, phase I and phase I/II of Opdivo for the treatment of sepsis was discontinued in USA and Japan respectively for strategic reasons.
- In January 2019, phase I of Opdivo for the treatment of hepatitis C was discontinued in Europe and USA for strategic reasons.

ONO-1162 / Ivabradine

- In December 2018, an approval application for ONO-1162 / Ivabradine (HCN channel inhibitor) was filed in Japan for the treatment of chronic heart failure with a sinus rhythm resting heart beat of 75 beats per minute or higher.

ONO-2370 / Opicapone

- In February 2019, an approval application for ONO-2370 / Opicapone (COMT inhibitor) was filed in Japan for improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) of parkinson's disease as an adjunctive therapy to levodopa preparations.

ONO-4059 / Tirabrutinib

- In November 2018, phase II of ONO-4059 / Tirabrutinib (Btk inhibitor) was initiated in Japan for the treatment of pemphigus.

ONO-5788

- In May 2018, phase I of ONO-5788 (growth hormone secretion inhibitor) was initiated in USA for the treatment of acromegaly.

ONO-7269

- In September 2018, phase I of ONO-7269 (FXIa inhibitor) was initiated in Japan for the treatment of cerebral infarction.

ONO-7684

- In January 2019, phase I of ONO-7684 (FXIa inhibitor) was initiated in Europe for the treatment of thrombosis.

ONO-8055

- In August 2018, phase I of ONO-8055 (PG receptor (EP2 / EP3) agonist) for the treatment of underactive bladder was discontinued in Japan for strategic reasons.

[Status of Drug Discovery / Research Alliance Activities]

- In May 2018, together with Keio University, Kochi University, the National Institutes of Biomedical Innovation, Health and Nutrition, Mitsubishi Tanabe Pharma Corporation, and Daiichi Sankyo Company, Limited, we established the Immune-mediated Inflammatory Diseases Consortium for Drug Development with the purpose of drug discovery research targeting immune-mediated inflammatory diseases.
- In September 2018, we entered into a collaboration agreement with Fate Therapeutics, Inc. in USA for the joint development and commercialization of off-the-shelf, iPSC-derived CAR-T cell product candidates for cancer.
- In March 2019, we entered into a research collaboration agreement with twoXAR, Inc. in USA to jointly discover and develop innovative drugs that meet unmet needs in the neurological disease area utilizing twoXAR's artificial intelligence (AI) technology.
- In March 2019, we entered into a strategic drug discovery alliance agreement in the UK with Cancer Research UK and LifeArc for cancer immunotherapy.
- In March 2019, we entered into a drug discovery alliance agreement with Vect-Horus S.A.S. in France for joint development of a new drug candidate compound in the field of neurodegenerative disease.

[Status of Licensing Activities]

- In January 2019, we entered into a license contract with Repare Therapeutics in Canada for exclusive development and commercialization in Japan, South Korea, Taiwan, Hong Kong, Macau (excluding mainland China) and ASEAN of the Pol-theta (Polθ) inhibitor being developed by Repare Therapeutics.

(2) Overview of Financial Position for the Fiscal Year 2018

(Millions of yen)

	As of March 31, 2018	As of March 31, 2019	Change
Total Assets	609,226	655,056	45,831
Equity attributable to owners of the Company	524,390	557,350	32,959
Ratio of equity attributable owners of the Company to total assets	86.1%	85.1%	
Equity attributable to owners of the Company per share	1,019.97 yen	1,084.08 yen	

Total assets increased to ¥655.1 billion by ¥45.8 billion from the end of the previous fiscal year.
Current assets decreased by ¥14.8 billion to ¥194.6 billion due to an decrease of marketable securities and cash and cash equivalents etc.
Non-current assets increased by ¥60.7 billion to ¥460.4 billion due to an increase of long-term time deposits and property, plant, and equipment etc.
Liabilities increased by ¥12.7 billion to ¥92.3 billion due to an increase of income taxes payable and provisions etc.
Equity attributable to owners of the Company increased by ¥33.0 billion to ¥557.4 billion due to an increase in retained earnings etc., despite a decrease in other components of equity.

(3) Overview of Cash Flows for the Fiscal Year 2018

(Millions of yen)

	Fiscal year ended March 31, 2018	Fiscal year ended March 31, 2019	Change
Cash and cash equivalents at the beginning of the fiscal year	146,323	65,273	
Cash flows from operating activities	15,727	66,774	51,047
Cash flows from investing activities	(34,189)	(49,763)	(15,574)
Cash flows from financing activities	(62,549)	(22,279)	40,270
Net increase (decrease) in cash and cash equivalents	(81,011)	(5,268)	
Effects of exchange rate changes on cash and cash equivalents	(40)	(24)	
Cash and cash equivalents at the end of the fiscal year	65,273	59,981	

Net increase/decrease in cash and cash equivalents was a decrease of ¥5.3 billion.
Net cash from operating activities was ¥66.8 billion, as a result of profit before tax of ¥65.1 billion etc.
Net cash used in investing activities was ¥49.8 billion, as a result of payments into time deposit of ¥55.8 billion and purchase of property, plant, and equipment of ¥22.3 billion etc., while proceeds from sales and redemption of investments amounted to ¥27.1 billion.
Net cash used in financing activities was ¥22.3 billion, as a result of dividends paid of ¥21.8 billion etc.

(4) Outlook for FY 2019

(Millions of yen)

	Actual (Fiscal year ended March 31, 2019)	Forecast (Fiscal year ending March 31, 2020)	Change	Change (%)
Revenue	288,634	290,000	1,366	0.5%
Operating profit	62,010	67,000	4,990	8.0%
Profit before tax	65,141	70,000	4,859	7.5%
Profit for the year (attributable to owners of the Company)	51,539	53,000	1,461	2.8%

[Revenue]
The business environment will continue to be harsh in the next fiscal year due to the negative impact of factors such as the special NHI drug price reduction associated with the hike in consumption tax and the spread of measures to promote generic drugs. Although the use of Opdivo Intravenous Infusion is expected to expand in the treatment of renal cell carcinoma, gastric cancer and head and neck cancer, sales are expected to decrease by ¥5.6 billion (6.2%) compared to the current fiscal year to ¥85 billion due to the impact of the NHI drug price reduction last November and a decrease in the number of new patients using the drug for lung cancer. Meanwhile, sales of main new products, Forxiga Tablets, Orencia SC, and Parsabiv Intravenous Injection for Dialysis are expected to increase. Furthermore, royalty and other revenue is expected to increase by ¥8.3 billion (10.4%) compared to the current fiscal year to ¥88.0 billion due to continued growth in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc. Therefore, revenue is expected to be ¥290.0 billion, an increase of ¥1.4 billion (0.5%) year-on-year.

[Profit]
Cost of sales is expected to be ¥77.0 billion, a decrease of ¥6.8 billion (8.1%) year-on-year, mainly because the one-time expense in order to ensure stable supply of ingredients for Opdivo that occurred in the fiscal year ended March 31, 2019 is not expected to arise in the following fiscal year.
Research and development costs are expected to be ¥72.0 billion, an increase of ¥2.0 billion (2.8%) 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 ¥72.0 billion, an increase of ¥2.0 billion (2.8%) year-on-year, mainly due to an increase of operating activity costs for new products and Opdivo.
Consequently, operating profit is forecasted to be ¥67.0 billion, an increase of ¥5.0 billion (8.0%) year-on-year, and profit attributable to owners of the Company is forecasted to be ¥53.0 billion, an increase of ¥1.5 billion (2.8%) year-on-year.

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

Distribution of profits to all our shareholders is one of our key management policies. We place great importance on the maintenance of stable dividends and profit sharing according to our financial results for the corresponding fiscal year. As for the dividend for the fiscal year ended March 31, 2019, 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, 2020 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, 2018	As of March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	65,273	59,981
Trade and other receivables	77,577	76,285
Marketable securities	9,670	687
Other financial assets	10,833	10,800
Inventories	31,290	32,821
Other current assets	14,821	14,042
Total current assets	209,464	194,617
Non-current assets:		
Property, plant, and equipment	94,321	108,870
Intangible assets	55,715	63,059
Investment securities	188,803	171,476
Investments in associates	116	113
Other financial assets	46,685	91,672
Deferred tax assets	10,192	21,079
Other non-current assets	3,929	4,171
Total non-current assets	399,761	460,439
Total assets	609,226	655,056

(Millions of yen)

	As of March 31, 2018	As of March 31, 2019
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,015	36,833
Borrowings	392	435
Other financial liabilities	3,756	515
Income taxes payable	8,742	15,980
Provisions	11,696	17,206
Other current liabilities	9,869	12,181
Total current liabilities	68,469	83,150
Non-current liabilities:		
Borrowings	320	1,765
Other financial liabilities	8	5
Retirement benefit liabilities	3,856	5,515
Provisions	30	—
Deferred tax liabilities	1,016	1,053
Long-term advances received	5,095	—
Other non-current liabilities	814	832
Total non-current liabilities	11,138	9,171
Total liabilities	79,607	92,321
Equity:		
Share capital	17,358	17,358
Capital reserves	17,175	17,202
Treasury shares	(38,148)	(38,151)
Other components of equity	68,021	61,852
Retained earnings	459,985	499,088
Equity attributable to owners of the Company	524,390	557,350
Non-controlling interests	5,228	5,386
Total equity	529,619	562,736
Total liabilities and equity	609,226	655,056

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

Consolidated Statement of Income

(Millions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Revenue	261,836	288,634
Cost of sales	(65,391)	(83,829)
Gross profit	196,445	204,805
Selling, general, and administrative expenses	(68,055)	(70,033)
Research and development costs	(68,821)	(70,008)
Other income	3,255	646
Other expenses	(2,139)	(3,400)
Operating profit	60,684	62,010
Finance income	3,277	3,282
Finance costs	(36)	(150)
Share of profit (loss) from investments in associates	(4)	(1)
Profit before tax	63,922	65,141
Income tax expense	(13,525)	(13,462)
Profit for the year	50,397	51,679
Profit for the year attributable to:		
Owners of the Company	50,284	51,539
Non-controlling interests	113	140
Profit for the year	50,397	51,679
Earnings per share:		
Basic earnings per share (Yen)	97.00	100.25
Diluted earnings per share (Yen)	96.99	100.24

Consolidated Statement of Comprehensive Income

(Millions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Profit for the year	50,397	51,679
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	17,797	(43)
Remeasurements of defined benefit plans	(478)	(890)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	2	(1)
Total of items that will not be reclassified to profit or loss	17,321	(935)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(112)	78
Total of items that may be reclassified subsequently to profit or loss	(112)	78
Total other comprehensive income (loss)	17,210	(857)
Total comprehensive income (loss) for the year	67,607	50,821
Comprehensive income (loss) for the year attributable to:		
Owners of the Company	67,477	50,658
Non-controlling interests	130	163
Total comprehensive income (loss) for the year	67,607	50,821

(3) Consolidated Statement of Changes in Equity

FY 2017 (from April 1, 2017 to March 31, 2018)

(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, 2017	17,358	17,144	(59,382)	51,752	492,237	519,110	5,101	524,211
Profit for the year					50,284	50,284	113	50,397
Other comprehensive income (loss)				17,193		17,193	17	17,210
Total comprehensive income (loss) for the year	–	–	–	17,193	50,284	67,477	130	67,607
Purchase of treasury shares			(38,773)			(38,773)		(38,773)
Retirement of treasury shares			60,007		(60,007)	–		–
Cash dividends					(23,453)	(23,453)	(3)	(23,457)
Share-based payments		30				30		30
Transfer from other components of equity to retained earnings				(924)	924	–		–
Total transactions with the owners	–	30	21,234	(924)	(82,536)	(62,196)	(3)	(62,199)
Balance as of March 31, 2018	17,358	17,175	(38,148)	68,021	459,985	524,390	5,228	529,619

FY 2018 (from 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

(4) Consolidated Statement of Cash Flows

(Millions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Cash flows from operating activities		
Profit before tax	63,922	65,141
Depreciation and amortization	9,213	10,621
Impairment losses	306	209
Interest and dividend income	(2,990)	(3,164)
Interest expense	14	27
(Increase) decrease in inventories	(5,971)	(1,567)
(Increase) decrease in trade and other receivables	(4,333)	1,251
Increase (decrease) in trade and other payables	300	998
Increase (decrease) in provisions	5,611	6,333
Increase (decrease) in retirement benefit liabilities	362	378
Increase (decrease) in long-term advances received	(181)	–
Other	(17,138)	1,854
Subtotal	49,114	82,081
Interest received	95	77
Dividends received	2,902	3,092
Interest paid	(14)	(27)
Income taxes paid	(36,370)	(18,449)
Net cash provided by (used in) operating activities	15,727	66,774
Cash flows from investing activities		
Purchases of property, plant, and equipment	(15,620)	(22,303)
Proceeds from sales of property, plant, and equipment	4,663	11
Purchases of intangible assets	(14,218)	(7,299)
Purchases of investments	(60)	(873)
Proceeds from sales and redemption of investments	21,315	27,123
Payments into time deposits	(30,800)	(55,800)
Proceeds from withdrawal of time deposits	800	10,800
Other	(269)	(1,423)
Net cash provided by (used in) investing activities	(34,189)	(49,763)
Cash flows from financing activities		
Dividends paid	(23,414)	(21,828)
Dividends paid to non-controlling interests	(3)	(5)
Repayments of long-term borrowings	(417)	(361)
Net increase (decrease) in short-term borrowings	58	(84)
Purchases of treasury shares	(38,773)	(1)
Net cash provided by (used in) financing activities	(62,549)	(22,279)
Net increase (decrease) in cash and cash equivalents	(81,011)	(5,268)
Cash and cash equivalents at the beginning of the year	146,323	65,273
Effects of exchange rate changes on cash and cash equivalents	(40)	(24)
Cash and cash equivalents at the end of the year	65,273	59,981

(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 "(5) Notes to Consolidated Financial Statements (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, 2019 are the same as the ones for the previous consolidated fiscal year, with the exception of changes in accounting policies on page 15.

(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 the following standards from the fiscal year ended March 31, 2019.

IFRS		Overview of establishment and amendments
IFRS 15	Revenue from Contracts with Customers	Issuance of a single and comprehensive model for accounting treatment for revenue from contracts with customers
IFRS 9 (amended in July 2014)	Financial Instruments	Impairment of financial assets and revision of hedge accounting
IFRIC 22	Foreign Currency Transactions and Advance Consideration	Clarification of the accounting for transactions that include the receipt or payment of advance consideration in a foreign currency

1) IFRS 15 “Revenue from Contracts with Customers”

Our group has applied IFRS 15 “Revenue from Contracts with Customers” (published in May 2014) and “Clarifications to IFRS 15” (published in April 2016) (hereinafter collectively referred to as “IFRS 15”) from the fiscal year ended March 31, 2019. Along with application of IFRS 15, excluding the interest and dividend income etc. based on IFRS 9 “Financial Instruments”, revenue is recognized by applying the following five steps.

Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

(i) Sale of merchandise

For the sale of merchandise, revenue is recognized at the point where it is delivered, since material risks and economic value associated with ownership of said merchandise is transferred to customers at the time of its delivery, and customers acquire control over it, and thereby our group’s performance obligations are considered to be satisfied.
The revenue arising from sale of merchandise is calculated by deducting the amount of rebates and discounts based on the number and amount of sales from the consideration in the sales contract, and the consideration to be refunded to customers and the amounts to be collected on behalf of third-parties is recognized as a refund liability. The most likely amount method based on contractual conditions and past results is used to estimate rebates etc. Revenue is recognized only to the extent that it is highly probable that there will not be a significant reversal of revenue previously recognized.
Consideration related to sale of merchandise is mainly received within one year from the delivery of merchandise to customers. This does not include significant financing components.

(ii) Royalty revenue etc.

Royalty revenue is consideration for license contracts etc. calculated on the basis of revenue etc. of the other party in the contract, and it is recognized as revenue taking the time of occurrence into consideration.
The license revenue is upfront payment and milestone revenue received under license contracts etc. related to development or rights to develop or sell products etc. executed between our group and third-parties. For license contracts etc., when performance obligations are satisfied at a specific point in time, performance obligations under the contract are considered to be satisfied at the time of granting development or selling rights etc. for upfront payment and milestone revenue, and at this point the upfront payment and milestone revenue is recognized as revenue. When performance obligations are satisfied over a certain period of time, the consideration is recognized as contract liabilities, and upfront payment and milestone revenue is recognized as revenue over a certain period of time such as the estimated development period according to the method of measuring the degree of progress regarding satisfaction of the performance obligations determined for each individual contract.
For milestone revenue, considering the probability that there will be a significant reversal of revenue previously recognized, it is recognized as revenue from the time that milestones specified in the contract are achieved.
The royalty revenue etc. are mainly received within one year from the vesting under the contract. This does not include significant financing components.

Based on the five-step approach above, as a result of reviewing the revenue recognition period for license revenue such as upfront payment received under license contracts in light of satisfying performance obligations, upfront payment received from license contracts, which was recognized over time as deferred income under previous standard, is recognized as one-time income at the time of granting development or selling rights etc.. Also, as result of a review in light of the definition of customers, certain items which were formerly deducted from revenue are treated as cost of sales from the fiscal year ended March 31, 2019.
For the application of these standards, our group adopted a method to recognize the cumulative effect recognized as a transitional measure on the date of initial application.
Also, certain accounts payable formerly included and presented within trade and other payables, as well as certain provisions , are included and presented within trade and other payables as refund liabilities from the fiscal year ended March 31, 2019.
Consequently, compared with the case calculated using the previous accounting standards, at the beginning of the fiscal year ended March 31, 2019, mainly trade and other payables increased by ¥618 million, retained earnings increased by ¥4,127 million, deferred tax assets decreased by ¥1,820 million, provisions decreased by ¥823 million, other current liabilities decreased by ¥646 million, and long-term advances received decreased by ¥5,095 million.
For the consolidated statement of income for the fiscal year ended March 31, 2019, compared with the case calculated using the previous accounting standards, revenue increased by ¥8,889 million, cost of sales increased by ¥9,553 million, operating profit decreased by ¥664 million, and profit before tax decreased by ¥664 million.
Also, for the consolidated statement of financial position as at the end of the fiscal year ended March 31, 2019, compared with the case calculated using the previous accounting standards, mainly trade and other payables increased by ¥996 million, retained earnings increased by ¥3,666 million, deferred tax assets decreased by ¥1,617 million, provisions decreased by ¥1,231 million, other current liabilities decreased by ¥17 million, and long-term advances received decreased by ¥5,030 million.

2) IFRS 9 “Financial Instruments”

Our group has applied IFRS 9 “Financial Instruments” (amended in July 2014) from the fiscal year ended March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

3) IFRIC 22 “Foreign Currency Transactions and Advance Consideration”

Our group has applied IFRIC 22 “Foreign Currency Transactions and Advance Consideration” from the fiscal year ended March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

(Changes in Method of Presentation)

Consolidated Statement of Cash Flows
“Proceeds from withdrawal of time deposits” included in “Other” in cash flows from investing activities for the fiscal year ended March 31, 2018 is separately listed from the fiscal year ended March 31, 2019 due to the increased quantitative materiality. In order to reflect this change in the presentation method, the Consolidated Financial Statements are classified for the fiscal year ended March 31, 2018.
As a result, ¥531 million for “Other,” which was shown in cash flows from investing activities in the Consolidated Statement of Cash Flows for the fiscal year ended March 31, 2018, is classified into ¥800 million in “Proceeds from withdrawal of time deposits” and (¥269) million in “Other.”

(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 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Revenue of goods and products	205,888	208,947
Royalty and other revenue	55,948	79,687
Total	261,836	288,634

Notes: 1. In "Royalty and other revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥39.8 billion for the fiscal year ended March 31, 2018 and ¥58.5 billion for the fiscal year ended March 31, 2019. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥6.7 billion for the fiscal year ended March 31, 2018 and ¥12.8 billion for the fiscal year ended March 31, 2019.

2. Our group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "Changes in Accounting Policies" on page 15. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

3) Revenue by geographic area

Details of revenue by geographic area are as follows:

(Millions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Japan	204,023	207,371
Americas	52,525	72,298
Asia	5,071	7,354
Europe	218	1,610
Total	261,836	288,634

Notes: 1. Revenue by geographic area is presented on the basis of the place of customers.

2. Our group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "Changes in Accounting Policies" on page 15. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

4) Major Customers

Details of revenue from major customers are as follows:

(Millions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Bristol-Myers Squibb Company and the group	43,662	63,442
Suzuken Co., Ltd. and the group	45,662	45,832
Medipal Holdings Corporation and the group	48,932	45,744
Alfresa Holdings Corporation and the group	31,987	32,213
Toho Holdings Co., Ltd. and the group	31,392	31,242

Notes: Our group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "Changes in Accounting Policies" on page 15. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

(Earnings per Share)

1) Basic Earnings per Share

(i) Basic earnings per share

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Basic earnings per share (Yen)	97.00	100.25

(ii) Basis of calculation of basic earnings per share

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Profit for the year attributable to owners of the Company (Millions of yen)	50,284	51,539
Weighted-average number of ordinary shares outstanding (Thousands of shares)	518,390	514,121

2) Diluted Earnings per Share

(i) Diluted earnings per share

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Diluted earnings per share (Yen)	96.99	100.24

(ii) Basis of calculation of diluted earnings per share

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 (From April 1, 2018 to March 31, 2019)
Profit for the year attributable to owners of the Company (Millions of yen)	50,284	51,539
Weighted-average number of ordinary shares outstanding (Thousands of shares)	518,390	514,121
Increase in common shares by share acquisition rights (Thousands of shares)	36	50
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	518,426	514,171

(Significant Subsequent Events)

Not Applicable

(Notes Regarding Assumption of a Going Concern)

Not Applicable

Fiscal Year 2018
(April 1, 2018 to March 31, 2019)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Fiscal Year 2018 (April 1, 2018 to March 31, 2019) Consolidated Financial Results (IFRS)】

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

Consolidated Financial Results for FY 2018 (April 1, 2018 to March 31, 2019) (IFRS)

Consolidated Financial Results

(Billions of yen)

	FY 2017 Actual (April 1, 2017 to March 31, 2018)	FY 2018 Actual (April 1, 2018 to March 31, 2019)	YoY
Revenue	261.8	288.6	10.2%
Operating profit	60.7	62.0	2.2%
Profit before tax	63.9	65.1	1.9%
Profit for the year (attributable to owners of the Company)	50.3	51.5	2.5%

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 2018 Actual (April 1, 2018 to March 31, 2019)					YoY		Forecasts
	Actual							
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec	Jan ~ Mar		Change	Change (%)	
Opdivo	22.8	22.6	25.9	19.2	90.6	0.5	0.5%	90.0
Glactive	7.1	6.6	7.4	5.7	26.9	(0.5)	(1.8%)	26.0
Orencia	4.3	4.3	4.8	4.0	17.4	3.3	23.3%	17.0
Forxiga	3.6	3.4	4.1	3.4	14.5	3.4	31.0%	14.5
Opalmon	2.9	2.6	2.8	2.1	10.4	(4.0)	(27.9%)	10.5
Emend / Proemend	2.7	2.6	2.9	2.4	10.6	0.7	6.6%	10.5
Recalbon	2.7	1.7	1.7	1.2	7.3	(3.6)	(32.8%)	7.5
Rivastach Patch	2.3	2.2	2.5	1.9	8.9	0.0	0.2%	9.0
Kyprolis	1.3	1.2	1.3	1.0	4.9	(0.6)	(11.1%)	6.5
Parsabiv	1.3	1.4	1.7	1.3	5.7	2.3	66.8%	5.5
Onon Capsules	1.1	0.8	1.1	1.3	4.4	(1.1)	(20.0%)	4.5
Onoact	1.1	1.0	1.5	0.9	4.6	(1.0)	(18.5%)	4.0
Staybla	1.0	0.9	1.0	0.8	3.7	(0.4)	(10.6%)	3.5
Onon Dry Syrup	0.7	0.5	0.8	0.7	2.7	(0.6)	(19.1%)	2.5

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

Details of Sales Revenue

(Billions of yen)

	FY 2017 (April 1, 2017 to March 31, 2018)	FY 2018 (April 1, 2018 to March 31, 2019)
Revenue of goods and products	205.9	208.9
Royalty and other revenue	55.9	79.7
Total	261.8	288.6

Notes: 1. In "Royalty and other revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥39.8 billion for the fiscal year ended March 31, 2018 and ¥58.5 billion for the fiscal year ended March 31, 2019. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥6.7 billion for the fiscal year ended March 31, 2018 and ¥12.8 billion for the fiscal year ended March 31, 2019.

2. Our group has applied IFRS 15 from the fiscal year ended March 31, 2019. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

Revenue by Geographic Area

(Billions of yen)

	FY 2017 (April 1, 2017 to March 31, 2018)	FY 2018 (April 1, 2018 to March 31, 2019)
Japan	204.0	207.4
Americas	52.5	72.3
Asia	5.1	7.4
Europe	0.2	1.6
Total	261.8	288.6

Notes: 1. Revenue by geographic area is presented on the basis of the place of customers.

2. Our group has applied IFRS 15 from the fiscal year ended March 31, 2019. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

Summary of Consolidated Financial Results for FY 2018 (April 1, 2018 to March 31, 2019) (IFRS)

1. Revenue ¥288.6 billion YoY an increase of 10.2% (FY 2017 ¥261.8 billion)

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction according to the drastic reform of NHI drug pricing system, its use was expanded for the treatment of renal cell carcinoma, and head and neck cancer approved in the fiscal year before last as well as gastric cancer etc. in the previous fiscal year, resulting in sales of ¥90.6 billion, an increase of ¥0.5 billion (0.5%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥26.9 billion (1.8% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥17.4 billion (23.3% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥14.5 billion (31.0% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥10.6 billion (6.6% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥8.9 billion (0.2% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥5.7 billion (66.8% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥4.9 billion (11.1% decrease year-on-year).
- Sales of long-term listed products were affected by the impact of NHI drug price reduction and generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥10.4 billion (27.9% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥7.3 billion (32.8% decrease year-on-year), respectively.
- Royalty and other revenue increased by ¥23.7 billion (42.4%) year-on-year to ¥79.7 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company and recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.

2. Operating profit ¥62.0 billion YoY an increase of 2.2% (FY 2017 ¥60.7 billion)

- Cost of sales was ¥83.8 billion, an increase of ¥18.4 billion (28.2%) year-on-year mainly due to the impact of applying IFRS 15 noted below (¥9.6 billion increase compared with the previous accounting standards) and one-time expense in order to ensure stable supply of ingredients for Opdivo.
- Research and development costs increased by ¥1.2 billion (1.7%) year-on-year to ¥70.0 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥2.0 billion (2.9%) year-on-year to ¥70.0 billion mainly due to the rise in operating costs related to main new products such as Opdivo Intravenous Infusion and Forxiga Tablets.
- Other expenses include the payment of the settlement with Pfizer for the patent related litigation. In the previous fiscal year, a ¥2.9 billion gain on sales of property, plant and equipment was recorded in other income.

3. Profit before tax ¥65.1 billion YoY an increase of 1.9% (FY 2017 ¥63.9 billion)

- Net financial income was ¥3.1 billion, a decrease of ¥0.1 billion (3.4%) year-on-year.

4. Profit for the year ¥51.5 billion YoY an increase of 2.5% (FY 2017 ¥50.3 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥1.3 billion (2.5%) year-on-year to ¥51.5 billion in association with the increase of the profit before tax.

Note: Our group has applied IFRS 15 "Revenue from Contracts with Customers" from the fiscal year ended March 31, 2019. For the consolidated statement of income for the fiscal year ended March 31, 2019, compared with the case calculated using the previous accounting standards, revenue increased by ¥8,889 million, cost of sales increased by ¥9,553 million, operating profit decreased by ¥664 million, and profit before tax decreased by ¥664 million.

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

Consolidated Financial Forecasts

(Billions of yen)

	FY 2017 Actual (April 1, 2017 to March 31, 2018)	FY 2018 Actual (April 1, 2018 to March 31, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)	YoY
Revenue	261.8	288.6	290.0	0.5%
Operating profit	60.7	62.0	67.0	8.0%
Profit before tax	63.9	65.1	70.0	7.5%
Profit for the year (attributable to owners of the Company)	50.3	51.5	53.0	2.8%

Sales Revenue of Major Products (Forecasts)

(Billions of yen)

Product	FY 2018 Actual (April 1, 2018 to March 31, 2019)			FY 2019 Forecasts (April 1, 2019 to March 31, 2020)		
	Actual	YoY		Forecasts	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo	90.6	0.5	0.5%	85.0	(5.6)	(6.2%)
Glactive	26.9	(0.5)	(1.8%)	26.5	(0.4)	(1.5%)
Orencia	17.4	3.3	23.3%	19.0	1.6	9.0%
Forxiga	14.5	3.4	31.0%	16.5	2.0	13.8%
Emend / Proemend	10.6	0.7	6.6%	11.5	0.9	8.4%
Rivastach Patch	8.9	0.0	0.2%	9.5	0.6	6.8%
Opalmon	10.4	(4.0)	(27.9%)	9.0	(1.4)	(13.1%)
Parsabiv	5.7	2.3	66.8%	7.0	1.3	22.4%
Kyprolis	4.9	(0.6)	(11.1%)	5.5	0.6	11.8%
Recalbon	7.3	(3.6)	(32.8%)	5.0	(2.3)	(31.9%)
Onoact	4.6	(1.0)	(18.5%)	4.5	(0.1)	(1.8%)
Onon Capsules	4.4	(1.1)	(20.0%)	3.5	(0.9)	(19.9%)
Staybla	3.7	(0.4)	(10.6%)	3.5	(0.2)	(5.3%)
Onon Dry Syrup	2.7	(0.6)	(19.1%)	2.0	(0.7)	(25.9%)

Details of Sales Revenue (Forecasts)

(Billions of yen)

	FY 2018 Actual (April 1, 2018 to March 31, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)
Revenue of goods and products	208.9	202.0
Royalty and other revenue	79.7	88.0
Total	288.6	290.0

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

1. Revenue ¥290.0 billion YoY an increase of ¥1.4 billion (0.5%) (FY 2018 ¥288.6 billion)

- The business environment will continue to be harsh in the next fiscal year due to the negative impact of factors such as the special NHI drug price reduction associated with the hike in consumption tax and the spread of measures to promote generic drugs. Although the use of Opdivo Intravenous Infusion is expected to expand in the treatment of renal cell carcinoma, gastric cancer and head and neck cancer, sales are expected to decrease by ¥5.6 billion (6.2%) compared to the current fiscal year to ¥85 billion due to the impact of the NHI drug price reduction last November and a decrease in the number of new patients using the drug for lung cancer. Meanwhile, sales of main new products, Forxiga Tablets, Orencia SC, and Parsabiv Intravenous Injection for Dialysis are expected to increase. Furthermore, royalty and other revenue is expected to increase by ¥8.3 billion (10.4%) compared to the current fiscal year to ¥88.0 billion due to continued growth in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc. Therefore, revenue is expected to be ¥290.0 billion, an increase of ¥1.4 billion (0.5%) year-on-year.

2. Operating profit ¥67.0 billion YoY an increase of ¥5.0 billion (8.0%) (FY 2018 ¥62.0 billion)

- Cost of sales is expected to be ¥77.0 billion, a decrease of ¥6.8 billion (8.1%) year-on-year, mainly because the one-time expense in order to ensure stable supply of ingredients for Opdivo that occurred in the fiscal year ended March 31, 2019 is not expected to arise in the following fiscal year.
- Research and development costs are expected to be ¥72.0 billion, an increase of ¥2.0 billion (2.8%) 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 ¥72.0 billion, an increase of ¥2.0 billion (2.8%) year-on-year, mainly due to an increase of operating activity costs for new products and Opdivo.
- Consequently, operating profit is forecasted to be ¥67.0 billion, an increase of ¥5.0 billion (8.0%) year-on-year.

3. Profit before tax ¥70.0 billion YoY an increase of ¥4.9 billion (7.5%) (FY 2018 ¥65.1 billion)

- Net financial income is expected to be ¥3.0 billion, a decrease of ¥0.1 billion (4.2%) year-on-year.

4. Profit for the year ¥53.0 billion YoY an increase of ¥1.5 billion (2.8%) (FY 2018 ¥51.5 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company is expected to be ¥53.0 billion, an increase of ¥1.5 billion (2.8%) year-on-year in association with the increase of the profit before tax.

Depreciation and Amortization, and Capital Expenditure

Depreciation and Amortization

(Billions of yen)

	FY 2017 (April 1, 2017 to March 31, 2018)	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)
Property, plant, and equipment	5.6	6.6	8.6
Intangible assets	3.6	4.0	5.4
Total	9.2	10.6	14.0
Ratio to sales revenue (%)	3.5%	3.7%	4.8%

Capital Expenditure

(Billions of yen)

	FY 2017 (April 1, 2017 to March 31, 2018)	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)
Property, plant, and equipment	18.6	21.4	11.7
Intangible assets	14.2	11.5	12.0
Total	32.8	32.9	23.7

Number of Employees (Consolidated)

	FY 2017 (as of March 31, 2018)	FY 2018 (as of March 31, 2019)
Number of employees	3,480	3,555

Status of Shares (as of March 31, 2019)

Number of Shares

	As of March 31, 2019
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	543,341,400

Number of Shareholders

	As of March 31, 2019
Number of shareholders	103,587

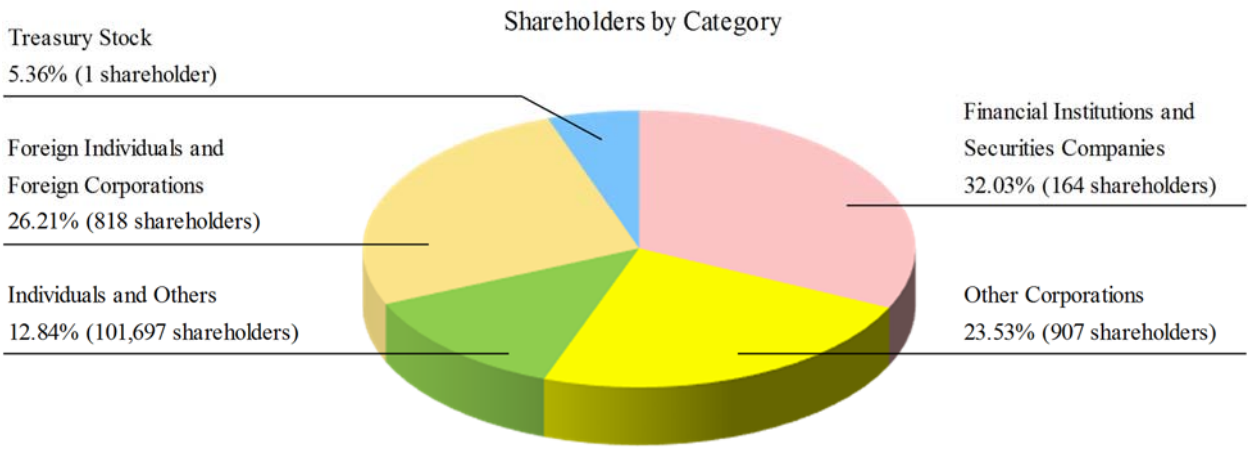
Principal Shareholders

(As of March 31, 2019)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	34,571	6.72%
Japan Trustee Services Bank, Ltd. (Trust account)	27,345	5.31%
STATE STREET BANK AND TRUST COMPANY 505001	21,718	4.22%
Meiji Yasuda Life Insurance Company	18,594	3.61%
Ono Scholarship Foundation	16,428	3.19%
KAKUMEISOU Co., LTD	16,161	3.14%
Japan Trustee Services Bank, Ltd. (Trust account5)	9,268	1.80%
MUFG Bank, Ltd.	8,640	1.68%
Aioi Nissay Dowa Insurance Co., Ltd.	8,606	1.67%
STATE STREET BANK WEST CLIENT - TREATY 505234	7,261	1.41%

Note:1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,157 thousand shares of treasury stock.
2. The shareholding percentage is calculated by deducting treasury stock (29,157 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%.

Main Status of Development Pipelines (Oncology)

As of April 26, 2019

1. Development Status in Japan

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	In-license (Helsinn Healthcare, S.A.)
Kyprolis for Intravenous Infusion *1	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)
Opdivo Intravenous Infusion *2	Additional indication	Colorectal cancer	Injection	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2019

*1: An approval application was filed for the addition of dosage and administration of Kyprolis for the treatment of relapsed or refractory multiple myeloma.

*2: An approval application was filed for additional indication of Opdivo for the treatment of MSI-H unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

Note: “In-house” compounds include a compound generated from collaborative research.

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	III	In-license (Array BioPharma Inc.)
Mektovi Tablet	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	In-license (Array BioPharma Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7701 ★ (BMS-986205)	New chemical entities	Melanoma / IDO1 inhibitor	Tablet	III	In-license (Co-development with Bristol-Myers Squibb)
	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	III	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary macroglobulinemia, Lymphoplasmacytic lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-4481 ★ (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7705 / Selinexor	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	I	In-house
ONO-7911 ★*3 (BMS-986321)	New chemical entities	Solid tumor / PEGylated interleukin-2	Injection	I	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

*3: Phase I of combination therapy with PEGylated interleukin-2 (ONO-7911) and Opdivo was initiated for the treatment of solid tumor.

Note: “In-house” compounds include a compound generated from collaborative research.

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

2. Development Status in South Korea and Taiwan

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
ONO-7702 / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	III	South Korea	In-license (Array BioPharma Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Array BioPharma Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	III	South Korea	In-license (Array BioPharma Inc.)
ONO-7701 ★ (BMS-986205)	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Pancreatic cancer	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Yervoy Injection ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Note: “In-house” compounds include a compound generated from collaborative research.

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

3. Development Status in Europe and the United States

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colorectal cancer	Injection	II / III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe	In-house (Out-license to Gilead Sciences, Inc.)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial cancer, Ovarian cancer)	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	I	USA	In-house

★: Combination with Opdivo.

Note: "In-house" compounds include a compound generated from collaborative research.

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

Main Status of Development Pipelines (Non-Oncology)

As of April 26, 2019

1. Development Status in Japan

<Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Onoact for Intravenous Infusion *4 50mg / 150mg (ONO-1101)	Additional indication	Ventricular arrhythmia / β_1 blocker (short acting)	Injection	In-house
Rivastach Patch *5	Change of formulation	Alzheimer's disease / Cholinesterase inhibitor	Patch	In-license (Novartis Pharma)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2019

*4: Approval was obtained for Onoact for Intravenous Infusion for the new treatment of refractory and urgent fatal arrhythmia (ventricular fibrillation and hemodynamically unstable ventricular tachycardia).

*5: Approval was obtained for Rivastach Patch for formulation with new ingredient.

Note: "In-house" compounds include a compound generated from collaborative research.

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / HCN channel inhibitor	Tablet	In-license (Les Laboratoires Servier)
ONO-2370 *6 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	In-license (Bial)
Orencia IV *7 Orencia SC *7	Additional indication	Structural damage of the joints in rheumatoid arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2019

*6: An approval application for a catechol-*O*-methyltransferase (COMT) inhibitor (ONO-2370 / Opicapone) was filed for improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) of parkinson's disease as an adjunctive therapy to levodopa preparations.

*7: An approval application for Orencia IV and Orencia SC was filed for the addition of inhibition of the structural damage of the joints in rheumatoid arthritis.

Note: "In-house" compounds include a compound generated from collaborative research.

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary Sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	III	In-license (Seikagaku Corporation)
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / β_1 blocker (short acting)	Injection	II / III	In-house
	Additional indication	Tachyarrhythmia upon sepsis / β_1 blocker (short acting)	Injection	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
ONO-4059 / Tirabrutinib	New chemical entities	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	I	In-house

Note: "In-house" compounds include a compound generated from collaborative research.

2. Development Status in Overseas

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe, USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-5788	New chemical entities	Acromegaly / Growth hormone secretion inhibitor	Capsule	I	USA	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	I	Europe	In-house

Note: "In-house" compounds include a compound generated from collaborative research.

Profile for Main Development

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis (ONO-7057) 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.

Orencia IV (ONO-4164) / BMS-188667 / Abatacept (injection)
Orencia (ONO-4164) 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). Also, in overseas, it is marketed for use in patients of rheumatoid arthritis and juvenile idiopathic arthritis.

Orencia SC (ONO-4164) / BMS-188667 / Abatacept (injection)
Orencia (ONO-4164) is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed.

ONO-1162 / Ivabradine (tablet)
ONO-1162 is an HCN channel blocker and is marketed in Europe for use in patients of stable angina and chronic heart failure, and in US for use in patients of chronic heart failure, respectively. In Japan, an approval application was filed for the treatment of chronic heart failure.

Onoact for Intravenous Infusion 50 mg/150 mg (ONO-1101) / Landiolol Hydrochloride (injection)
Development is being conducted for tachyarrhythmia upon sepsis, and tachyarrhythmia in low cardiac function in pediatric.

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-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-4059 / Tirabrutinib (tablet)
ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma, central nervous system lymphoma, primary macroglobulinemia, lymphoplasmacytic lymphoma, Sjögren syndrome and pemphigus.

ONO-4578 (tablet)
ONO-4578 is a prostaglandin receptor (EP4) antagonist being developed for the treatment of solid tumor.

ONO-7475 (tablet)
ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia and solid tumor.

Opdivo Intravenous Infusion (ONO-4538) / BMS-936558 / Nivolumab (injection)
Opdivo (ONO-4538), 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 (ONO-4480), a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment 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-4481 / Urelumab / BMS-663513 (injection)
ONO-4481, a human anti-human CD137 monoclonal antibody, is being developed for the treatment 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 / Relatlimab / BMS-986016 (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment 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-4686 / BMS-986207 (injection)
ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed for the treatment 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-4687 / Cabiralizumab / BMS-986227 (injection)
ONO-4687, a human anti-human CSF-1R monoclonal antibody, is being developed for the treatment 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-7701 / BMS-986205 (capsule)
ONO-7701, IDO1 inhibitor, is being developed for the treatment 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-4483 / Lirilumab / BMS-986015 (injection)
ONO-4483, a human anti-human KIR monoclonal antibody, is being developed for the treatment 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-7911 / BMS-986321 (injection)
ONO-7911, PEGylated interleukin-2 formulation, is being developed for the treatment 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.

Braftovi Capsule (ONO-7702) / Encorafenib (capsule)
Braftovi (ONO-7702), BRAF inhibitor, is marketed in Japan for the indication of melanoma. And it is being developed for the treatment of colorectal cancer.

Mektovi Tablet (ONO-7703) / Binimetinib (tablet)
Mektovi (ONO-7703), MEK inhibitor, is marketed in Japan for the indication of melanoma. And it is being developed for the treatment of colorectal cancer.

ONO-5704 / SI-613 (injection)
ONO-5704, hyaluronic acid-NSAID, is being developed for the treatment of osteoarthritis and enthesopathy.

ONO-7807 / BMS-986258 (injection)
ONO-7807, a human anti-human TIM-3 monoclonal antibody, is being developed for the treatment 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-7705 (tablet)
ONO-7705, XPO1 inhibitor, is being developed for the treatment of multiple myeloma and non-hodgkin lymphoma.

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

ONO-5788 (capsule)
ONO-5788, growth hormone secretion inhibitor, is being developed for the treatment of acromegaly.

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