Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2020 (IFRS)

October 31, 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 / Head of Corporate Communications
Phone	: +81-(0)6-6263-5670
Scheduled date of quarterly securities report submission	: November 7, 2019
Scheduled date of dividend payment commencement	: December 2, 2019
Supplementary materials for quarterly financial results	: Yes
Earnings announcement for quarterly financial results	: Yes (for institutional investors and securities analysts)

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

1. Consolidated Financial Results for the Second Quarter of FY 2019 (April 1, 2019 to September 30, 2019)

(1) Consolidated Operating Results (cumulative)

(% change from the same period of the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the period		Profit attributable to owners of the Company		Total comprehensive income for the period	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2019 Q2	149,008	3.2	41,878	19.1	43,042	16.6	32,915	14.0	32,816	13.8	33,354	(28.4)
FY 2018 Q2	144,395	18.9	35,151	31.2	36,917	30.0	28,883	35.7	28,845	36.0	46,571	43.7

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2019 Q2	64.58	64.57
FY 2018 Q2	56.11	56.10

(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
	Million yen	Million yen	Million yen	%
As of September 30, 2019	642,125	554,948	549,477	85.6
As of March 31, 2019	655,056	562,736	557,350	85.1

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2018	—	22.50	—	22.50	45.00
FY 2019	—	22.50			
FY 2019 (Forecast)			—	22.50	45.00

(Note) Revisions to dividends forecast most recently announced: None

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

(Note) Revisions to financial forecast most recently announced: None

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 September 30, 2019	543,341,400	shares
As of March 31, 2019	543,341,400	shares

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

As of September 30, 2019	44,221,542	shares
As of March 31, 2019	29,220,860	shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2019	508,137,292	shares
Six months ended September 30, 2018	514,121,317	shares

* This financial results report is not subject to quarterly review 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 5 for information regarding the forecast of consolidated financial results.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of FY 2019

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019	Change	Change (%)
Revenue	144,395	149,008	4,613	3.2%
Operating profit	35,151	41,878	6,727	19.1%
Profit before tax	36,917	43,042	6,125	16.6%
Profit for the period (attributable to owners of the Company)	28,845	32,816	3,971	13.8%

[Revenue]

Revenue totaled ¥149.0 billion, which was an increase of ¥4.6 billion (3.2%) from the corresponding period of the previous fiscal year (year-on-year).

- Although sales of Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction of last November and intensifying competition with competitors' products, its use was expanded for the treatment of renal cell carcinoma, etc., and there was provisional demand due to the drug price revision associated with the consumption tax hike, resulting in sales of ¥46.8 billion, an increase of ¥1.4 billion (3.1%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.3 billion (3.3% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥10.0 billion (16.0% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥8.7 billion (24.4% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥5.9 billion (10.4% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥4.4 billion (3.7% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥3.5 billion (28.4% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥2.9 billion (13.5% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.5 billion (19.2% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥2.6 billion (41.1% decrease year-on-year), respectively.
- Royalty and others increased by ¥2.9 billion (7.3%) year-on-year to ¥42.2 billion, mainly due to the rise in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc.

[Operating Profit]

Operating profit was ¥41.9 billion, an increase of ¥6.7 billion (19.1%) year-on-year.

- Cost of sales was ¥41.7 billion, roughly even year-on-year.
- Research and development costs decreased by ¥2.1 billion (6.4%) year-on-year to ¥30.9 billion mainly due to a decrease in license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥0.5 billion (1.4%) year-on-year to ¥33.7 billion mainly due to a reduction in operating costs.

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

Profit attributable to owners of the Company increased by ¥4.0 billion (13.8%) year-on-year to ¥32.8 billion in association with the increase of the profit before tax.

(Research & Development Activities)

Upholding the corporate philosophy "Dedicated to Man's Fight against Disease and Pain," our group takes on the challenge against diseases that have not been overcome so far, and the disease area which has a low level of patient satisfaction with treatment and high medical needs. We are endeavoring to make creative and innovative drugs.

Currently, the development pipeline comprises new drug candidate compounds of anticancer drugs including antibody drugs in addition to Opdivo, candidates for treatment of Osteoarthritis, and so on. We are promoting development for the early launch of the product. Among these, the area of cancer treatment is positioned as an important strategic field because unmet medical needs are high.

In drug discovery research, based on the "Compound-Orient" drug discovery approach aiming to produce innovative new candidate compounds focusing on characteristic 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 second quarter (six months) ended September 30, 2019 (including those up to October 25, 2019) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

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

Melanoma

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

Hodgkin lymphoma

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

Colorectal cancer

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

Esophageal cancer

- In May 2019, an approval application was filed in Japan for the treatment of unresectable advanced or recurrent esophageal cancer.

Hepatocellular carcinoma

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

Solid tumor

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

"ONO-4059 / Tirabrutinib"

- In August 2019, an approval application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was filed in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma.

<Areas other than Oncology>

"Onoact / Landiolol Hydrochloride"

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

"Coralan / ONO-1162 / Ivabradine"

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

"ONO-4685"

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

[Status of Licensing Activities]

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

[Status of Development Alliance Activities]

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

(2) Overview of Financial Position for the 2nd Quarter of FY 2019

(Millions of yen)

	As of March 31, 2019	As of September 30, 2019	Change
Total Assets	655,056	642,125	(12,932)
Equity attributable to owners of the Company	557,350	549,477	(7,873)
Ratio of equity attributable owners of the Company to total assets	85.1%	85.6%	
Equity attributable to owners of the Company per share	1,084.08 yen	1,100.89 yen	

Total assets decreased to ¥642.1 billion by ¥12.9 billion from the end of the previous fiscal year.
Current assets increased by ¥15.3 billion to ¥209.9 billion mainly due to an increase in other financial assets etc., despite a decrease in cash and cash equivalents etc.
Non-current assets decreased by ¥28.2 billion to ¥432.2 billion mainly due to a decrease in other financial assets etc., despite an increase in property, plant, and equipment resulting from right-of-use assets recorded as a result of the application of IFRS 16.
Liabilities decreased by ¥5.1 billion to ¥87.2 billion due to decreases in trade and other payables and income taxes payable etc., despite increases in lease liabilities as a result of the application of IFRS 16 and provisions etc.
Equity attributable to owners of the Company decreased by ¥7.9 billion to ¥549.5 billion due to purchase of treasury shares etc., despite an increase in retained earnings etc.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2019

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019	Change
Cash and cash equivalents at the beginning of the period	65,273	59,981	
Cash flows from operating activities	35,591	34,875	(716)
Cash flows from investing activities	(11,952)	2,681	14,633
Cash flows from financing activities	(10,514)	(42,218)	(31,704)
Net increase (decrease) in cash and cash equivalents	13,125	(4,662)	
Effects of exchange rate changes on cash and cash equivalents	129	(247)	
Cash and cash equivalents at the end of the period	78,527	55,072	

Net increase/decrease in cash and cash equivalents was a decrease of ¥4.7 billion.
Net cash provided by operating activities was ¥34.9 billion, as a result of profit before tax of ¥43.0 billion and depreciation and amortization of ¥6.8 billion etc., while income taxes paid amounted to ¥15.6 billion etc.
Net cash provided by investing activities was ¥2.7 billion, as a result of proceeds from withdrawal of time deposits of ¥25.2 billion etc., while payments into time deposits of ¥10.2 billion, purchases of intangible assets of ¥9.0 billion, and purchases of property, plant, and equipment of ¥4.9 billion etc.
Net cash used in financing activities was ¥42.2 billion, as a result of purchases of treasury shares of ¥29.6 billion and dividends paid of ¥11.6 billion etc.

(4) Outlook for FY 2019

There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2020 announced on May 9, 2019.

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. Condensed Interim Consolidated Financial Statements and Major Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2019	As of September 30, 2019
Assets		
Current assets:		
Cash and cash equivalents	59,981	55,072
Trade and other receivables	76,285	78,939
Marketable securities	687	622
Other financial assets	10,800	30,800
Inventories	32,821	30,954
Other current assets	14,042	13,547
Total current assets	194,617	209,933
Non-current assets:		
Property, plant, and equipment	108,870	115,326
Intangible assets	63,059	65,169
Investment securities	171,476	170,493
Investments in associates	113	110
Other financial assets	91,672	56,639
Deferred tax assets	21,079	20,669
Other non-current assets	4,171	3,786
Total non-current assets	460,439	432,191
Total assets	655,056	642,125

(Millions of yen)

	As of March 31, 2019	As of September 30, 2019
Liabilities and Equity		
Current liabilities:		
Trade and other payables	36,833	28,123
Borrowings	435	–
Lease liabilities	–	2,171
Other financial liabilities	515	496
Income taxes payable	15,980	10,412
Provisions	17,206	20,720
Other current liabilities	12,181	11,189
Total current liabilities	83,150	73,111
Non-current liabilities:		
Borrowings	1,765	–
Lease liabilities	–	6,620
Other financial liabilities	5	4
Retirement benefit liabilities	5,515	5,589
Deferred tax liabilities	1,053	1,054
Other non-current liabilities	832	798
Total non-current liabilities	9,171	14,065
Total liabilities	92,321	87,176
Equity:		
Share capital	17,358	17,358
Capital reserves	17,202	17,215
Treasury shares	(38,151)	(67,735)
Other components of equity	61,852	61,841
Retained earnings	499,088	520,797
Equity attributable to owners of the Company	557,350	549,477
Non-controlling interests	5,386	5,471
Total equity	562,736	554,948
Total liabilities and equity	655,056	642,125

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Revenue	144,395	149,008
Cost of sales	(41,628)	(41,668)
Gross profit	102,767	107,340
Selling, general, and administrative expenses	(34,206)	(33,734)
Research and development costs	(33,048)	(30,935)
Other income	543	420
Other expenses	(906)	(1,213)
Operating profit	35,151	41,878
Finance income	1,805	1,586
Finance costs	(40)	(425)
Share of profit (loss) from investments in associates	1	3
Profit before tax	36,917	43,042
Income tax expense	(8,034)	(10,126)
Profit for the period	28,883	32,915
Profit for the period attributable to:		
Owners of the Company	28,845	32,816
Non-controlling interests	37	99
Profit for the period	28,883	32,915
Earnings per share:		
Basic earnings per share (Yen)	56.11	64.58
Diluted earnings per share (Yen)	56.10	64.57

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Profit for the period	28,883	32,915
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	17,076	580
Remeasurements of defined benefit plans	380	137
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	5	(5)
Total of items that will not be reclassified to profit or loss	17,461	712
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	227	(273)
Total of items that may be reclassified subsequently to profit or loss	227	(273)
Total other comprehensive income (loss)	17,688	439
Total comprehensive income (loss) for the period	46,571	33,354
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	46,523	33,266
Non-controlling interests	48	89
Total comprehensive income (loss) for the period	46,571	33,354

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 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, 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 period					28,845	28,845	37	28,883
Other comprehensive income (loss)				17,678		17,678	11	17,688
Total comprehensive income (loss) for the period	–	–	–	17,678	28,845	46,523	48	46,571
Purchase of treasury shares			(2)			(2)		(2)
Cash dividends					(10,282)	(10,282)	(5)	(10,288)
Share-based payments		13				13		13
Transfer from other components of equity to retained earnings				(380)	380	–		–
Total transactions with the owners	–	13	(2)	(380)	(9,902)	(10,271)	(5)	(10,276)
Balance as of September 30, 2018	17,358	17,188	(38,149)	85,318	483,055	564,769	5,271	570,040

Six months ended September 30, 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, 2019	17,358	17,202	(38,151)	61,852	499,088	557,350	5,386	562,736
Profit for the period					32,816	32,816	99	32,915
Other comprehensive income (loss)				450		450	(11)	439
Total comprehensive income (loss) for the period	–	–	–	450	32,816	33,266	89	33,354
Purchase of treasury shares			(29,584)			(29,584)		(29,584)
Cash dividends					(11,568)	(11,568)	(3)	(11,571)
Share-based payments		14				14		14
Transfer from other components of equity to retained earnings				(460)	460	–		–
Total transactions with the owners	–	14	(29,584)	(460)	(11,107)	(41,138)	(3)	(41,142)
Balance as of September 30, 2019	17,358	17,215	(67,735)	61,841	520,797	549,477	5,471	554,948

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Cash flows from operating activities		
Profit before tax	36,917	43,042
Depreciation and amortization	5,123	6,756
Impairment losses	24	85
Interest and dividend income	(1,687)	(1,579)
Interest expense	7	38
(Increase) decrease in inventories	(956)	1,746
(Increase) decrease in trade and other receivables	(1,145)	(2,909)
Increase (decrease) in trade and other payables	(1,387)	(1,996)
Increase (decrease) in provisions	3,040	3,514
Increase (decrease) in retirement benefit liabilities	235	277
Other	2,114	(57)
Subtotal	42,285	48,917
Interest received	41	49
Dividends received	1,650	1,531
Interest paid	(7)	(38)
Income taxes paid	(8,378)	(15,584)
Net cash provided by (used in) operating activities	35,591	34,875
Cash flows from investing activities		
Purchases of property, plant, and equipment	(14,347)	(4,919)
Purchases of intangible assets	(1,890)	(8,977)
Proceeds from sales and redemption of investments	4,060	1,837
Payments into time deposits	(10,200)	(10,200)
Proceeds from withdrawal of time deposits	10,200	25,200
Other	226	(260)
Net cash provided by (used in) investing activities	(11,952)	2,681
Cash flows from financing activities		
Dividends paid	(10,275)	(11,554)
Dividends paid to non-controlling interests	(5)	(3)
Repayments of long-term borrowings	(205)	–
Repayments of lease liabilities	–	(1,077)
Net increase (decrease) in short-term borrowings	(28)	–
Purchases of treasury shares	(1)	(29,583)
Net cash provided by (used in) financing activities	(10,514)	(42,218)
Net increase (decrease) in cash and cash equivalents	13,125	(4,662)
Cash and cash equivalents at the beginning of the period	65,273	59,981
Effects of exchange rate changes on cash and cash equivalents	129	(247)
Cash and cash equivalents at the end of the period	78,527	55,072

(5) Notes to Condensed Interim Consolidated Financial Statements

(Changes in Accounting Policies)

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

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

In addition, operating lease payments that had been expensed as incurred under the previous accounting standard were recorded as depreciation charge for right-of-use assets and interest expense on lease liabilities in the condensed interim consolidated statement of income for the second quarter (six months) ended September 30, 2019, and reclassified from a reduction in cash flows from operating activities to a reduction in cash flows from financing activities in the condensed interim consolidated statement of cash flows for the same period.

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

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

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

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

In accordance with the transition under IFRS 16, our group has retrospectively adopted IFRS 16 and recognized the cumulative effect of initially applying IFRS 16 as an adjustment to the opening balance of retained earnings for the second quarter (six months) ended September 30, 2019. In transitioning to IFRS 16, our group has elected the practical expedient provided in paragraph C3 of IFRS 16 and carried forward the assessment of whether a contract contains a lease in accordance with IAS 17 and IFRIC 4 “Determining whether an Arrangement contains a Lease.”

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

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

As a result, as of the beginning of the second quarter (six months) ended September 30, 2019, property, plant, and equipment and lease liabilities each increased by ¥6,245 million, compared with the amounts under the previous accounting standard. There is no impact for the opening balance of retained earnings at the date of initial application, because our group measures right-of-use assets at the date of initial application at the amount of lease liabilities measured after adjusting the amount of any prepaid and accrued lease payments.

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

(Millions of yen)

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

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

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

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

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

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

(Segment Information)

Segment information is omitted herein, because our group's business is a single segment of the pharmaceutical business.

(Significant Subsequent Events)

As of October 31, 2019, the Company completed the retirement of treasury shares based on the provisions of Article 178 of the Companies Act resolved in a written resolution in lieu of a resolution passed at a Board of Directors meeting on May 30, 2019.

(1) Class of shares retired	Common shares
(2) Number of shares retired	15,000,000 shares
(3) Date of retirement	October 31, 2019

(Notes Regarding Assumption of a Going Concern)

Not Applicable

2nd Quarter of Fiscal Year 2019 (Ending March 31, 2020)
(April 1, 2019 to September 30, 2019)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2019 (Ending March 31, 2020) (IFRS)】

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

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2019 (IFRS)

(Billions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY	Full year ended March 31, 2019
Revenue	144.4	149.0	3.2%	288.6
Operating profit	35.2	41.9	19.1%	62.0
Profit before tax	36.9	43.0	16.6%	65.1
Profit for the period (attributable to owners of the Company)	28.8	32.8	13.8%	51.5

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

1. Revenue ¥149.0 billion YoY an increase of 3.2% (FY 2018 2Q YTD ¥144.4 billion)

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction of last November and intensifying competition with competitors' products, its use was expanded for the treatment of renal cell carcinoma, etc., and there was provisional demand due to the drug price revision associated with the consumption tax hike, resulting in sales of ¥46.8 billion, an increase of ¥1.4 billion (3.1%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.3 billion (3.3% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥10.0 billion (16.0% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥8.7 billion (24.4% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥5.9 billion (10.4% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥4.4 billion (3.7% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥3.5 billion (28.4% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥2.9 billion (13.5% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.5 billion (19.2% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥2.6 billion (41.1% decrease year-on-year), respectively.
- Royalty and others increased by ¥2.9 billion (7.3%) year-on-year to ¥42.2 billion, mainly due to the rise in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc.

2. Operating profit ¥41.9 billion YoY an increase of 19.1% (FY 2018 2Q YTD ¥35.2 billion)

- Cost of sales was ¥41.7 billion, roughly even year-on-year.
- Research and development costs decreased by ¥2.1 billion (6.4%) year-on-year to ¥30.9 billion mainly due to a decrease in license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥0.5 billion (1.4%) year-on-year to ¥33.7 billion mainly due to a reduction in operating costs.

3. Profit before tax ¥43.0 billion YoY an increase of 16.6% (FY 2018 2Q YTD ¥36.9 billion)

- Net financial income was ¥1.2 billion, a decrease of ¥0.6 billion (34.1%) year-on-year.

4. Profit for the period ¥32.8 billion YoY an increase of 13.8% (FY 2018 2Q YTD ¥28.8 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥4.0 billion (13.8%) year-on-year to ¥32.8 billion in association with the increase of the profit before tax.

Sales Revenue Results and Forecasts of Major Products

(Billions of yen)

Product	Six months ended September 30, 2019 (April 1, 2019 to September 30, 2019)					FY 2019 Forecasts (April 1, 2019 to March 31, 2020)		
	Cumulative			YoY		Forecasts	YoY	
	Apr ~ Jun	Jul ~ Sep		Change	Change (%)		Change	Change (%)
Opdivo	22.3	24.5	46.8	1.4	3.1%	85.0	(5.6)	(6.2%)
Glactive	6.9	6.3	13.3	(0.5)	(3.3%)	26.5	(0.4)	(1.5%)
Orencia	4.9	5.1	10.0	1.4	16.0%	19.0	1.6	9.0%
Forxiga	4.4	4.3	8.7	1.7	24.4%	16.5	2.0	13.8%
Emend / Proemend	2.9	3.0	5.9	0.6	10.4%	11.5	0.9	8.4%
Rivastach Patch	2.3	2.1	4.4	(0.2)	(3.7%)	9.5	0.6	6.8%
Opalmon	2.3	2.1	4.5	(1.1)	(19.2%)	9.0	(1.4)	(13.1%)
Parsabiv	1.7	1.8	3.5	0.8	28.4%	7.0	1.3	22.4%
Kyprolis	1.4	1.5	2.9	0.3	13.5%	5.5	0.6	11.8%
Recalbon	1.4	1.2	2.6	(1.8)	(41.1%)	5.0	(2.3)	(31.9%)
Onoact	1.3	1.1	2.4	0.3	12.6%	4.5	(0.1)	(1.8%)
Onon Capsules	0.9	0.7	1.6	(0.4)	(18.3%)	3.5	(0.9)	(19.9%)
Staybla	0.9	0.7	1.6	(0.3)	(15.4%)	3.5	(0.2)	(5.3%)
Onon Dry Syrup	0.6	0.4	1.0	(0.2)	(14.2%)	2.0	(0.7)	(25.9%)

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecast for the FY 2019, only currently approved indications are covered.

Details of Sales Revenue

(Billions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Revenue of goods and products	105.0	106.8
Royalty and others	39.4	42.2
Total	144.4	149.0

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥28.1 billion for the second quarter (six months) ended September 30, 2018 and ¥30.7 billion for the second quarter (six months) ended September 30, 2019. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥5.6 billion for the second quarter (six months) ended September 30, 2018 and ¥8.5 billion for the second quarter (six months) ended September 30, 2019.

Revenue by Geographic Area

(Billions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Japan	105.3	105.3
Americas	34.3	39.4
Asia	3.5	4.1
Europe	1.3	0.2
Total	144.4	149.0

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

Consolidated Financial Forecasts for the Fiscal Year Ending March 31, 2020 (IFRS)

(Billions of yen)

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

Details of Revenue (Forecasts)

(Billions of yen)

	FY 2018 (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 others	79.7	88.0
Total	288.6	290.0

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

- The business environment continues to be harsh in this fiscal year due to the negative impact of factors such as 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 previous fiscal year to ¥85.0 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 others is expected to increase by ¥8.3 billion (10.4%) compared to the previous 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 current 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, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 2Q YTD (April 1, 2019 to September 30, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)
Property, plant, and equipment	6.6	4.3	9.1
Intangible assets	4.0	2.4	5.3
Total	10.6	6.8	14.4
Ratio to sales revenue (%)	3.7%	4.5%	5.0%

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

(Billions of yen)

	FY 2018 (April 1, 2018 to March 31, 2019)	FY 2019 2Q YTD (April 1, 2019 to September 30, 2019)	FY 2019 Forecasts (April 1, 2019 to March 31, 2020)
Property, plant, and equipment	21.4	4.7	10.9
Intangible assets	11.5	4.6	20.7
Total	32.9	9.2	31.7

Number of Employees (Consolidated)

	FY 2018 2Q (as of September 30, 2018)	FY 2018 (as of March 31, 2019)	FY 2019 2Q (as of September 30, 2019)
Number of employees	3,576	3,555	3,604

Status of Shares (as of September 30, 2019)

Number of Shares

	As of September 30, 2019
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	543,341,400

Number of Shareholders

	As of September 30, 2019
Number of shareholders	103,225

Principal Shareholders

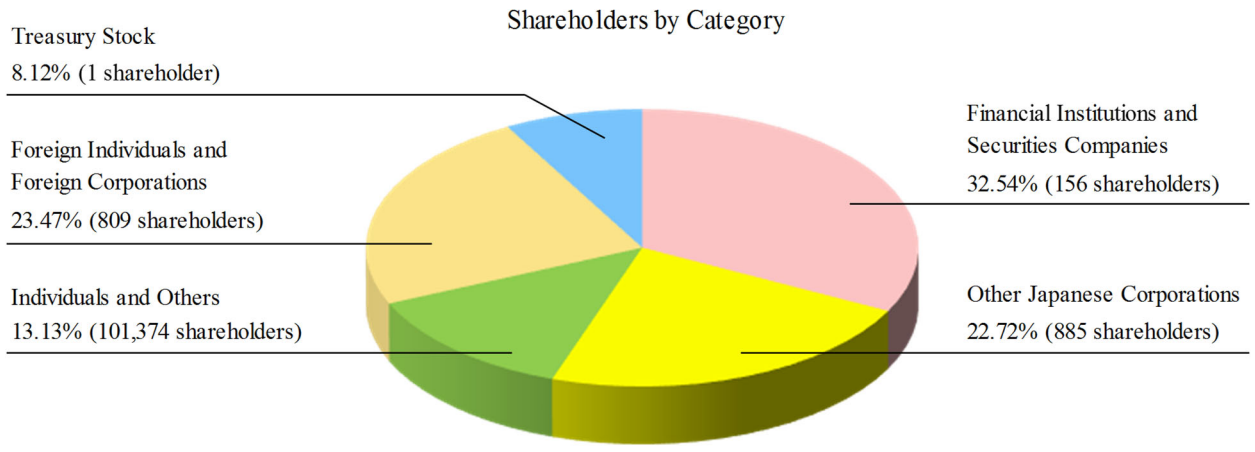
(As of September 30, 2019)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	36,135	7.23%
Japan Trustee Services Bank, Ltd. (Trust account)	25,254	5.05%
STATE STREET BANK AND TRUST COMPANY 505001	20,270	4.06%
Meiji Yasuda Life Insurance Company	18,594	3.72%
Ono Scholarship Foundation	16,428	3.29%
KAKUMEISOU Co., LTD	16,161	3.23%
Japan Trustee Services Bank, Ltd. (Trust account 5)	9,461	1.89%
MUFG Bank, Ltd.	8,640	1.73%
Aioi Nissay Dowa Insurance Co., Ltd.	8,606	1.72%
Japan Trustee Services Bank, Ltd. (Trust account 7)	7,408	1.48%

Note:1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 44,158 thousand shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (44,158 thousand shares).

Ownership and Distribution of Shares



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

I. Main Status of Development Pipelines (Oncology)

As of October 25, 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	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)
Opdivo Intravenous Infusion	Additional indication	Colorectal cancer (MSI-H)	Injection	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 *1 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	In-house

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2020

*1: An approval application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was filed for the treatment of recurrent or refractory primary central nervous system lymphoma

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	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)
	Additional indication	Colorectal cancer (MSI-H) *2	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma *3	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	III	In-license (Pfizer Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Mektovi Tablet	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	In-license (Pfizer Inc.)
ONO-7701 ★ (BMS-986205) / Linrodostat	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-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-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
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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7911 ★ (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated interleukin-2	Injection	I	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2020

*2: Phase III of combination therapy of Opdivo and Yervoy was initiated for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) metastatic colorectal cancer.

*3: Phase III of combination therapy of Opdivo and Yervoy was initiated for the treatment of hepatocellular carcinoma.

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)
	Additional indication	Hepatocellular carcinoma *4	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 (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Pfizer Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	III	South Korea	In-license (Pfizer Inc.)
ONO-7701 ★ (BMS-986205) / Linrodostat	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)

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

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2020
*4: Phase III of combination therapy of Opdivo and Yervoy was initiated for the treatment of hepatocellular carcinoma.

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.

II. Main Status of Development Pipelines (Non-Oncology)

As of October 25, 2019

1. Development Status in Japan

<Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Coralan / ONO-1162 / Ivabradine *5	New chemical entities	Chronic heart failure / HCN channel inhibitor	Tablet	In-license (Les Laboratoires Servier)

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2020

*5: Approval for HCN channel inhibitor (Coralan / ONO-1162 / Ivabradine) was obtained for the treatment of chronic heart failure with a sinus rhythm and baseline resting heart rate of 75 beats per minute or higher.

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-2370 / Opicapone	New chemical entities	Parkinson’s disease / Long acting COMT inhibitor	Tablet	In-license (Bial)
Orencia IV Orencia SC	Additional indication	Structural damage of the joints in rheumatoid arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)
Onoact for Intravenous Infusion *6 50mg / 150mg (ONO-1101)	Additional indication	Tachyarrhythmia upon sepsis / β_1 blocker (short acting)	Injection	In-house

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2020

*6: An approval application for Onoact for Intravenous Infusion was filed for the addition of treatment of tachyarrhythmia upon sepsis.

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
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
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	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 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 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).

Orencia SC (ONO-4164 / BMS-188667) / Abatacept (injection)
Orencia is marketed for use in patients of rheumatoid arthritis and psoriatic arthritis for whom other therapies have failed.
Also, development is being conducted for untreated rheumatoid arthritis, primary Sjögren syndrome and polymyositis / dermatomyositis.

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

ONO-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. An approval application was filed in Japan for the treatment of central nervous system lymphoma.
Also, development is being conducted for the treatment of primary macroglobulinemia, lymphoplasmacytic lymphoma, B cell 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, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

Yervoy Injection (ONO-4480) / Ipilimumab (injection)
Yervoy, a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4482 / BMS-986016 / Relatlimab (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of 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 / BMS-986227 / Cabiralizumab (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 / Linrodostat (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 / BMS-986015/ Lirilumab (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 / Bempegaldesleukin (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, 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, 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.

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