Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2021 (IFRS)

October 29, 2020

Company name	: **ONO PHARMACEUTICAL CO., LTD.**
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: https://www.ono.co.jp/
Representative	: Gyo Sagara President, Representative Director, and Chief Executive Officer
Contact	: Yukio Tani Corporate Executive Officer / Head of Corporate Communications
Phone	: +81-(0)6-6263-5670
Scheduled date of quarterly securities report submission	: November 6, 2020
Scheduled date of dividend payment commencement	: December 1, 2020
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 2020 (April 1, 2020 to September 30, 2020)

(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 2020 Q2	150,474	1.0	52,401	25.1	53,674	24.7	39,888	21.2	39,849	21.4	53,797	61.3
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)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2020 Q2	79.84	79.83
FY 2019 Q2	64.58	64.57

(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, 2020	706,795	610,598	605,023	85.6
As of March 31, 2020	673,444	568,022	562,484	83.5

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 2019	—	22.50	—	22.50	45.00
FY 2020	—	22.50			
FY 2020 (Forecast)			—	22.50	45.00

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

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

(% change from the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2020	305,000	4.3	87,000	12.3	88,500	11.0	65,200	8.9	65,000	8.9	130.23

(Note) Revisions to financial forecasts most recently announced: Yes

Notes

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

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

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the period (including treasury shares):

As of September 30, 2020	528,341,400	shares
As of March 31, 2020	528,341,400	shares

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

As of September 30, 2020	29,198,575	shares
As of March 31, 2020	29,222,272	shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2020	499,132,780	shares
Six months ended September 30, 2019	508,137,292	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) Future outlook” on page 6 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 2020

(Millions of yen)

	Six months ended September 30, 2019	**Six months ended September 30, 2020**	Change	Change (%)
Revenue	149,008	**150,474**	1,466	1.0%
Operating profit	41,878	**52,401**	10,523	25.1%
Profit before tax	43,042	**53,674**	10,632	24.7%
Profit for the period (attributable to owners of the Company)	32,816	**39,849**	7,033	21.4%

[Revenue]

Revenue totaled ¥150.5 billion, which was an increase of ¥1.5 billion (1.0%) from the corresponding period of the previous fiscal year (year-on-year).

- While competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors expanded for the treatment of esophageal cancer while its use for the treatment of renal cell carcinoma and gastric cancer remained firm, resulting in sales of ¥49.1 billion, an increase of ¥2.3 billion (4.8%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.0 billion (2.3% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥10.9 billion (8.9% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥10.5 billion (20.5% increase year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥4.1 billion (7.0% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥3.9 billion (11.9% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥3.5 billion (19.8% 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 ¥2.9 billion (35.4% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥1.5 billion (41.3% decrease year-on-year), and sales of Emend Capsules for chemotherapy-induced nausea and vomiting were ¥1.5 billion (67.8% decrease year-on-year), respectively.
- Royalty and others increased by ¥1.7 billion (4.1%) year-on-year to ¥44.0 billion.

[Operating Profit]

Operating profit was ¥52.4 billion, an increase of ¥10.5 billion (25.1%) year-on-year.

- Cost of sales increased by ¥0.1 billion (0.2%) year-on-year to ¥41.8 billion.
- Research and development costs decreased by ¥5.2 billion (16.8%) year-on-year to ¥25.7 billion due to the decrease in clinical trial costs caused by the delay of registrations of subjects for new clinical trials and the suspension of registrations of subjects for continuing clinical trials as a result of the impact of the novel coronavirus disease (COVID-19), despite having resumed development activities including the registrations of subjects since June.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥3.9 billion (11.6%) year-on-year to ¥29.8 billion mainly due to the decrease in operating expenses caused by the revision of academic lectures and refraining from visiting medical institutions by MRs due to the impact of COVID-19.

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

Profit attributable to owners of the Company increased by ¥7.0 billion (21.4%) year-on-year to ¥39.8 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 bioactive lipids and unique target molecules, we are making an effort to produce innovative new drugs with medical impact by accumulating know-how on the respective disorders and ascertaining medical needs appropriately in the Oncology Research Center, Immunology Research Center, Neurology Research Center, and Specialty Research Center established in each priority area. In addition, we are aiming for the creation of new drugs that bring innovation to the medical field by implementing open innovation actively and globally, incorporating the world's most advanced technologies and information, creating a network with the world's top-class researchers, and using biologics such as antibodies, cells and viruses in addition to conventional small-molecule drugs. We are also striving for the introduction of promising new drug candidate compounds through licensing activities and are working to further strengthen research and development activities.

The main results of research and development activities during the second quarter (six months) ended September 30, 2020 (including those on and after September 30, 2020) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

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

Gastric cancer

- In May 2020, an approval application was filed in Japan for the treatment of unresectable advanced or recurrent gastric cancer.

Esophageal cancer

- In April 2020, an application was approved in South Korea for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer which is refractory or intolerant to prior fluoropyrimidine- and platinum-based chemotherapy.
- In June 2020, an application was approved in Taiwan for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer progressing after fluoropyrimidine- and platinum-based chemotherapy.

Colorectal cancer

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

Malignant pleural mesothelioma

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

Renal cell carcinoma

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

Small cell lung cancer

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

Dosage and administration

- In September 2020, an application was approved in Japan for additional dosage and administration to intravenously infuse at "480 mg (over 30 minutes) every 4 weeks" in the monotherapy dosing regimen.

"Velexbru Tablets / Tirabrutinib Hydrochloride"

- In August 2020, an application was approved in Japan for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic lymphoma.

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

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

"ONO-4687 (BMS-986227) / Cabiralizumab"

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

<Areas other than Oncology>

"Parsabiv Intravenous Injection Syringe / Etelcalcetide Hydrochloride"

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

"Onoact / Landiolol Hydrochloride"

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

"Ongentys Tablets / ONO-2370 / Opicapone"

- In June 2020, an application was approved in Japan for the improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in parkinson's disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride.

"Foipan Tablets / Camostat mesilate"

- In June 2020, phase I was initiated in Japan on protease enzyme inhibitor Foipan Tablets as a treatment of COVID-19.

"ONO-2910"

- In June 2020, phase I of Schwann cell differentiation promoter (ONO-2910) was initiated in Japan for healthy adult male subjects.

[Status of Licensing Activities]

- In October 2020, the Company entered into a license agreement with SK Biopharmaceuticals Co., Ltd. in South Korea for exclusive development and commercialization in Japan of cenobamate, SK Biopharmaceuticals' antiepileptic drug.

(2) Overview of Financial Position for the 2nd Quarter of FY 2020

(Millions of yen)

	As of March 31, 2020	**As of September 30, 2020**	Change
Total Assets	673,444	**706,795**	33,351
Equity attributable to owners of the Company	562,484	**605,023**	42,539
Ratio of equity attributable to owners of the Company to total assets	83.5%	**85.6%**	
Equity attributable to owners of the Company per share	1,126.95 yen	**1,212.12 yen**	

Total assets increased to ¥706.8 billion by ¥33.4 billion from the end of the previous fiscal year.
Current assets increased by ¥1.5 billion to ¥226.8 billion mainly due to increases in cash and cash equivalents and inventories etc., despite a decrease in other financial assets.
Non-current assets increased by ¥31.8 billion to ¥480.0 billion mainly due to increases in investment securities and other financial assets etc., despite decreases in intangible assets and deferred tax assets etc.
Liabilities decreased by ¥9.2 billion to ¥96.2 billion mainly due to decreases in income taxes payable and trade and other payables etc.
Equity attributable to owners of the Company increased by ¥42.5 billion to ¥605.0 billion mainly due to increases in retained earnings and other components of equity etc.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2020

(Millions of yen)

	Six months ended September 30, 2019	**Six months ended September 30, 2020**	Change
Cash and cash equivalents at the beginning of the period	59,981	**69,005**	
Cash flows from operating activities	34,875	**31,314**	(3,561)
Cash flows from investing activities	2,681	**(4,033)**	(6,715)
Cash flows from financing activities	(42,218)	**(12,488)**	29,730
Net increase (decrease) in cash and cash equivalents	(4,662)	**14,793**	
Effects of exchange rate changes on cash and cash equivalents	(247)	**3**	
Cash and cash equivalents at the end of the period	55,072	**83,800**	

Net increase/decrease in cash and cash equivalents was an increase of ¥14.8 billion.
Net cash provided by operating activities was ¥31.3 billion, as a result of profit before tax of ¥53.7 billion etc., while income taxes paid amounted to ¥19.8 billion etc.
Net cash used in investing activities was ¥4.0 billion, as a result of purchases of property, plant, and equipment of ¥3.3 billion and purchases of intangible assets of ¥3.0 billion etc.
Net cash used in financing activities was ¥12.5 billion, as a result of dividends paid of ¥11.2 billion etc.

(4) Future outlook

The forecasts of consolidated financial results for the fiscal year ending March 31, 2021, as announced on May 12, 2020, has been revised as follows:

Revisions to the forecasts of consolidated financial results for the fiscal year ending March 31, 2021
(April 1, 2020 to March 31, 2021)

(Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit for the year	Profit attributable to owners of the Company	Basic earnings per share
Previous forecast (A)	303,000	80,000	82,000	61,100	61,000	121.04 yen
Revised forecast (B)	305,000	87,000	88,500	65,200	65,000	130.23 yen
Amount of change (B-A)	2,000	7,000	6,500	4,100	4,000	
Change (%)	0.7	8.8	7.9	6.7	6.6	
(Reference) Consolidated results of FY 2019	292,420	77,491	79,696	59,888	59,704	118.47 yen

Revenue is forecasted to be ¥305.0 billion, an upward revision of ¥2.0 billion from the previously announced forecast. Although revenue from royalty and others is expected to be below the previously announced forecast, revenue of goods and products, including Opdivo, has exceeded the previously announced forecast.
Cost of sales is forecasted to be ¥84.0 billion, an increase of ¥2.5 billion from the previously announced forecast.
Research and development costs are forecasted to be ¥65.0 billion, a decrease of ¥4.0 billion from the previously announced forecast due to the continued impact of COVID-19 despite having resumed development activities including the registrations of subjects.
Selling, general, and administrative expenses (except for research and development costs) are forecasted to be ¥67.0 billion, a decrease of ¥3.0 billion from the previously announced forecast due to the continued impact of COVID-19 despite the scheduled launch of new products and approval of several additional indications in the second half of the fiscal year and the strengthening of information provision activities.
As a result, operating profit is forecasted to be ¥87.0 billion (up ¥7.0 billion from the previously announced forecast), profit before tax is forecasted to be ¥88.5 billion (up ¥6.5 billion), profit for the year is forecasted to be ¥65.2 billion (up ¥4.1 billion) and profit attributable to owners of the Company is forecasted to be ¥65.0 billion (up ¥4.0 billion) for the fiscal year ending March 31, 2021.

Note: The financial forecasts and statements contained in this announcement are made based on information that is available as of the date the announcement is made. Actual results may differ from those set forth in the announcements due to various uncertain factors.

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, 2020	As of September 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	69,005	83,800
Trade and other receivables	76,834	80,638
Marketable securities	614	2,350
Other financial assets	30,800	5,936
Inventories	32,906	37,135
Other current assets	15,063	16,913
Total current assets	225,222	226,772
Non-current assets:		
Property, plant, and equipment	114,628	113,813
Intangible assets	66,436	65,285
Investment securities	137,670	152,553
Investments in associates	108	112
Other financial assets	91,694	116,778
Deferred tax assets	34,817	28,991
Other non-current assets	2,871	2,491
Total non-current assets	448,222	480,023
Total assets	673,444	706,795

(Millions of yen)

	As of March 31, 2020	As of September 30, 2020
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,439	31,707
Lease liabilities	2,188	2,044
Other financial liabilities	450	444
Income taxes payable	20,346	14,545
Provisions	20,721	20,721
Other current liabilities	13,185	12,096
Total current liabilities	91,329	81,557
Non-current liabilities:		
Lease liabilities	6,173	7,259
Other financial liabilities	0	0
Retirement benefit liabilities	6,048	5,518
Deferred tax liabilities	1,059	1,055
Other non-current liabilities	813	808
Total non-current liabilities	14,093	14,640
Total liabilities	105,422	96,197
Equity:		
Share capital	17,358	17,358
Capital reserves	17,229	17,209
Treasury shares	(44,737)	(44,702)
Other components of equity	48,030	60,654
Retained earnings	524,605	554,504
Equity attributable to owners of the Company	562,484	605,023
Non-controlling interests	5,538	5,575
Total equity	568,022	610,598
Total liabilities and equity	673,444	706,795

(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, 2019	Six months ended September 30, 2020
Revenue	149,008	150,474
Cost of sales	(41,668)	(41,760)
Gross profit	107,340	108,714
Selling, general, and administrative expenses	(33,734)	(29,817)
Research and development costs	(30,935)	(25,733)
Other income	420	365
Other expenses	(1,213)	(1,127)
Operating profit	41,878	52,401
Finance income	1,586	1,403
Finance costs	(425)	(137)
Share of profit (loss) from investments in associates	3	6
Profit before tax	43,042	53,674
Income tax expense	(10,126)	(13,786)
Profit for the period	32,915	39,888
Profit for the period attributable to:		
Owners of the Company	32,816	39,849
Non-controlling interests	99	38
Profit for the period	32,915	39,888
Earnings per share:		
Basic earnings per share (Yen)	64.58	79.84
Diluted earnings per share (Yen)	64.57	79.83

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2019	Six months ended September 30, 2020
Profit for the period	32,915	39,888
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	580	13,417
Remeasurements of defined benefit plans	137	515
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(5)	(0)
Total of items that will not be reclassified to profit or loss	712	13,932
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(273)	(23)
Total of items that may be reclassified subsequently to profit or loss	(273)	(23)
Total other comprehensive income (loss)	439	13,909
Total comprehensive income (loss) for the period	33,354	53,797
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	33,266	53,754
Non-controlling interests	89	43
Total comprehensive income (loss) for the period	33,354	53,797

(3) Condensed Interim Consolidated Statement of Changes in Equity

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

Six months ended September 30, 2020

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
Profit for the period					39,849	39,849	38	39,888
Other comprehensive income (loss)				13,904		13,904	5	13,909
Total comprehensive income (loss) for the period	–	–	–	13,904	39,849	53,754	43	53,797
Purchase of treasury shares			(2)			(2)		(2)
Disposition of treasury shares		(38)	38			0		0
Cash dividends					(11,230)	(11,230)	(6)	(11,236)
Share-based payments		18				18		18
Transfer from other components of equity to retained earnings				(1,280)	1,280	–		–
Total transactions with the owners	–	(20)	35	(1,280)	(9,950)	(11,215)	(6)	(11,221)
Balance as of September 30, 2020	17,358	17,209	(44,702)	60,654	554,504	605,023	5,575	610,598

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2019	Six months ended September 30, 2020
Cash flows from operating activities		
Profit before tax	43,042	53,674
Depreciation and amortization	6,756	7,764
Impairment losses	85	–
Interest and dividend income	(1,579)	(1,317)
Interest expense	38	36
(Increase) decrease in inventories	1,746	(4,215)
(Increase) decrease in trade and other receivables	(2,909)	(3,747)
Increase (decrease) in trade and other payables	(1,996)	(76)
Increase (decrease) in provisions	3,514	–
Increase (decrease) in retirement benefit liabilities	277	211
Other	(57)	(2,478)
Subtotal	48,917	49,852
Interest received	49	34
Dividends received	1,531	1,285
Interest paid	(38)	(36)
Income taxes paid	(15,584)	(19,822)
Net cash provided by (used in) operating activities	34,875	31,314
Cash flows from investing activities		
Purchases of property, plant, and equipment	(4,919)	(3,307)
Purchases of intangible assets	(8,977)	(2,998)
Purchases of investments	–	(450)
Proceeds from sales and redemption of investments	1,837	2,915
Payments into time deposits	(10,200)	(30,335)
Proceeds from withdrawal of time deposits	25,200	30,200
Other	(260)	(59)
Net cash provided by (used in) investing activities	2,681	(4,033)
Cash flows from financing activities		
Dividends paid	(11,554)	(11,221)
Dividends paid to non-controlling interests	(3)	(6)
Repayments of lease liabilities	(1,077)	(1,260)
Purchases of treasury shares	(29,583)	(2)
Net cash provided by (used in) financing activities	(42,218)	(12,488)
Net increase (decrease) in cash and cash equivalents	(4,662)	14,793
Cash and cash equivalents at the beginning of the period	59,981	69,005
Effects of exchange rate changes on cash and cash equivalents	(247)	3
Cash and cash equivalents at the end of the period	55,072	83,800

(5) Notes to Condensed Interim Consolidated Financial Statements

(Segment Information)

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

(Significant Subsequent Events)

Not Applicable

(Notes Regarding Assumption of a Going Concern)

Not Applicable

2nd Quarter of Fiscal Year 2020 (Ending March 31, 2021)
(April 1, 2020 to September 30, 2020)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2020 (Ending March 31, 2021) (IFRS)】

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

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2020 (IFRS)

(Billions of yen)

	Six months ended September 30, 2019	**Six months ended September 30, 2020**	YoY	Full year ended March 31, 2020
Revenue	149.0	**150.5**	1.0%	292.4
Operating profit	41.9	**52.4**	25.1%	77.5
Profit before tax	43.0	**53.7**	24.7%	79.7
Profit for the period (attributable to owners of the Company)	32.8	**39.8**	21.4%	59.7

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

1. Revenue ¥150.5 billion YoY an increase of 1.0% (FY 2019 2Q YTD ¥149.0 billion)

- While competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors expanded for the treatment of esophageal cancer while its use for the treatment of renal cell carcinoma and gastric cancer remained firm, resulting in sales of ¥49.1 billion, an increase of ¥2.3 billion (4.8%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.0 billion (2.3% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥10.9 billion (8.9% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥10.5 billion (20.5% increase year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥4.1 billion (7.0% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥3.9 billion (11.9% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥3.5 billion (19.8% 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 ¥2.9 billion (35.4% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥1.5 billion (41.3% decrease year-on-year), and sales of Emend Capsules for chemotherapy-induced nausea and vomiting were ¥1.5 billion (67.8% decrease year-on-year), respectively.
- Royalty and others increased by ¥1.7 billion (4.1%) year-on-year to ¥44.0 billion.

2. Operating profit ¥52.4 billion YoY an increase of 25.1% (FY 2019 2Q YTD ¥41.9 billion)

- Operating profit increased by ¥10.5 billion (25.1%) year-on-year to ¥52.4 billion.
- Cost of sales increased by ¥0.1 billion (0.2%) year-on-year to ¥41.8 billion.
- Research and development costs decreased by ¥5.2 billion (16.8%) year-on-year to ¥25.7 billion due to the decrease in clinical trial costs caused by the delay of registrations of subjects for new clinical trials and the suspension of registrations of subjects for continuing clinical trials as a result of the impact of the novel coronavirus disease (COVID-19), despite having resumed development activities including the registrations of subjects since June.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥3.9 billion (11.6%) year-on-year to ¥29.8 billion mainly due to the decrease in operating expenses caused by the revision of academic lectures and refraining from visiting medical institutions by MRs due to the impact of COVID-19.

3. Profit before tax ¥53.7 billion YoY an increase of 24.7% (FY 2019 2Q YTD ¥43.0 billion)

- Net financial income was ¥1.3 billion, an increase of ¥0.1 billion (9.3%) year-on-year.

4. Profit for the period ¥39.8 billion YoY an increase of 21.4% (FY 2019 2Q YTD ¥32.8 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥7.0 billion (21.4%) year-on-year to ¥39.8 billion in association with the increase of the profit before tax.

Sales Revenue Results and Forecasts of Major Products

(Billions of yen)

Product Name	Six months ended September 30, 2020 (April 1, 2020 to September 30, 2020)					FY 2020 Forecasts (April 1, 2020 to March 31, 2021)				
	Cumulative			YoY		Previous Forecasts	Change from Previous Forecasts	**Revised Forecasts**	YoY	
	Apr ~ Jun	Jul ~ Sep		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	24.4	24.6	**49.1**	2.3	4.8%	90.0	8.0	**98.0**	10.7	12.2%
Glactive Tablets	6.5	6.4	**13.0**	(0.3)	(2.3%)	25.0		**25.0**	(1.1)	(4.1%)
Forxiga Tablets	5.2	5.3	**10.5**	1.8	20.5%	22.5		**22.5**	4.4	24.6%
Orencia for Subcutaneous Injection	5.4	5.4	**10.9**	0.9	8.9%	21.5	0.5	**22.0**	2.2	11.0%
Rivastach Patches	2.0	2.0	**4.1**	(0.3)	(7.0%)	8.5	(1.0)	**7.5**	(1.0)	(12.0%)
Parsabiv Intravenous Injection	1.9	2.0	**3.9**	0.4	11.9%	7.5	0.5	**8.0**	0.9	13.1%
Kyprolis for Intravenous Infusion	1.7	1.8	**3.5**	0.6	19.8%	6.5	0.5	**7.0**	1.0	16.7%
Onoact for Intravenous Infusion	1.0	1.1	**2.2**	(0.3)	(11.2%)	6.0	(0.5)	**5.5**	0.6	13.1%
Opalmon Tablets	1.5	1.4	**2.9**	(1.6)	(35.4%)	5.0		**5.0**	(3.3)	(40.0%)
Proemend for Intravenous Infusion	0.7	0.7	**1.3**	(0.0)	(1.9%)	3.5	(1.0)	**2.5**	(0.1)	(4.8%)
Emend Capsules	0.8	0.7	**1.5**	(3.1)	(67.8%)	3.5	(1.0)	**2.5**	(5.6)	(69.1%)
Onon Capsules	0.7	0.5	**1.2**	(0.4)	(24.6%)	3.0	(0.5)	**2.5**	(1.0)	(27.6%)
Recalbon Tablets	0.8	0.7	**1.5**	(1.1)	(41.3%)	2.0	0.5	**2.5**	(2.2)	(47.3%)
Newly launched products during FY 2020	0.1	0.5	**0.5**	–	–	5.0	(2.0)	**3.0**	3.0	–

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecasts for the FY 2020, only currently approved indications are covered.
3. Cumulative results for newly launched products during FY 2020 include ¥0.5 billion in sales of Velexbru Tablets launched in May 2020 and ¥0.1 billion in sales of Ongentys Tablets launched in August 2020.

Details of Sales Revenue

(Billions of yen)

	Six months ended September 30, 2019	**Six months ended September 30, 2020**
Revenue of goods and products	106.8	**106.5**
Royalty and others	42.2	**44.0**
Total	149.0	**150.5**

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥30.7 billion for the second quarter (six months) ended September 30, 2019 and ¥29.2 billion for the second quarter (six months) ended September 30, 2020. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥8.5 billion for the second quarter (six months) ended September 30, 2019 and ¥11.4 billion for the second quarter (six months) ended September 30, 2020.

Revenue by Geographic Area

(Billions of yen)

	Six months ended September 30, 2019	**Six months ended September 30, 2020**
Japan	105.3	**105.0**
Americas	39.4	**41.3**
Asia	4.1	**3.8**
Europe	0.2	**0.3**
Total	149.0	**150.5**

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, 2021 (IFRS)

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**	YoY
Revenue	292.4	**305.0**	4.3%
Operating profit	77.5	**87.0**	12.3%
Profit before tax	79.7	**88.5**	11.0%
Profit for the year (attributable to owners of the Company)	59.7	**65.0**	8.9%

Details of Revenue (Forecasts)

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**
Revenue of goods and products	205.6	**214.0**
Royalty and others	86.8	**91.0**
Total	292.4	**305.0**

1. Revenue ¥305.0 billion YoY an increase of ¥12.6 billion (4.3%) (FY 2019 ¥292.4 billion)

- The severe business environment is forecasted to continue due to the impact of drug price revisions in April 2020 and the intensifying competition for market share with competing products. Sales of Opdivo Intravenous Infusion are forecasted to be ¥98.0 billion, an increase of ¥10.7 billion (12.2%) year-on-year, as we expect the expanded use in the treatment of esophageal cancer and entry into first-line treatment for non-small cell lung cancer. In other main new products, sales of Forxiga Tablets, Orencia SC, Parsabiv Intravenous Injection for Dialysis, Kyprolis for Intravenous Infusion etc. are expected to increase, and several new products are expected to be released. Furthermore, royalty and other revenue is expected to be ¥91.0 billion, an increase of ¥4.2 billion (4.8%) year-on-year. Therefore, revenue is forecasted to be ¥305.0 billion, an increase of ¥12.6 billion (4.3%) year-on-year.

2. Operating profit ¥87.0 billion YoY an increase of ¥9.5 billion (12.3%) (FY 2019 ¥77.5 billion)

- Cost of sales is forecasted to be ¥84.0 billion, an increase of ¥4.9 billion (6.2%) year-on-year.
- Research and development costs are forecasted to be ¥65.0 billion, a decrease of ¥1.5 billion (2.3%) year-on-year, due to the continued impact of COVID-19 despite having resumed development activities including the registrations of subjects.
- Selling, general, and administrative expenses (except for research and development costs) are forecasted to be ¥67.0 billion, a decrease of ¥0.7 billion (1.0%) year-on-year, due to the continued impact of COVID-19 despite the scheduled launch of new products and approval of several additional indications in the second half of the fiscal year and the strengthening of information provision activities.

Consequently, operating profit is forecasted to be ¥87.0 billion, an increase of ¥9.5 billion (12.3%) year-on-year.

3. Profit before tax ¥88.5 billion YoY an increase of ¥8.8 billion (11.0%) (FY 2019 ¥79.7 billion)

- Net financial income is forecasted to be ¥1.5 billion, a decrease of ¥0.7 billion (32.0%) year-on-year.

4. Profit for the year ¥65.0 billion YoY an increase of ¥5.3 billion (8.9%) (FY 2019 ¥59.7 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company is forecasted to be ¥65.0 billion, an increase of ¥5.3 billion (8.9%) year-on-year.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	**FY 2020 2Q YTD (April 1, 2020 to September 30, 2020)**	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**
Property, plant, and equipment	8.9	**4.7**	**9.6**
Intangible assets	5.3	**3.0**	**6.7**
Total	14.2	**7.8**	**16.3**
Ratio to sales revenue (%)	4.9%	**5.2%**	**5.3%**

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

(Billions of yen)

	FY 2019 (April 1, 2019 to March 31, 2020)	**FY 2020 2Q YTD (April 1, 2020 to September 30, 2020)**	**FY 2020 Forecasts (April 1, 2020 to March 31, 2021)**
Property, plant, and equipment	9.5	**4.2**	**9.9**
Intangible assets	11.4	**1.9**	**16.2**
Total	21.0	**6.2**	**26.1**

Number of Employees (Consolidated)

	FY 2019 2Q (as of September 30, 2019)	FY 2019 (as of March 31, 2020)	**FY 2020 2Q (as of September 30, 2020)**
Number of employees	3,604	3,560	**3,613**

Status of Shares (as of September 30, 2020)

Number of Shares

	As of September 30, 2020
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	528,341,400

Number of Shareholders

	As of September 30, 2020
Number of shareholders	70,882

Principal Shareholders

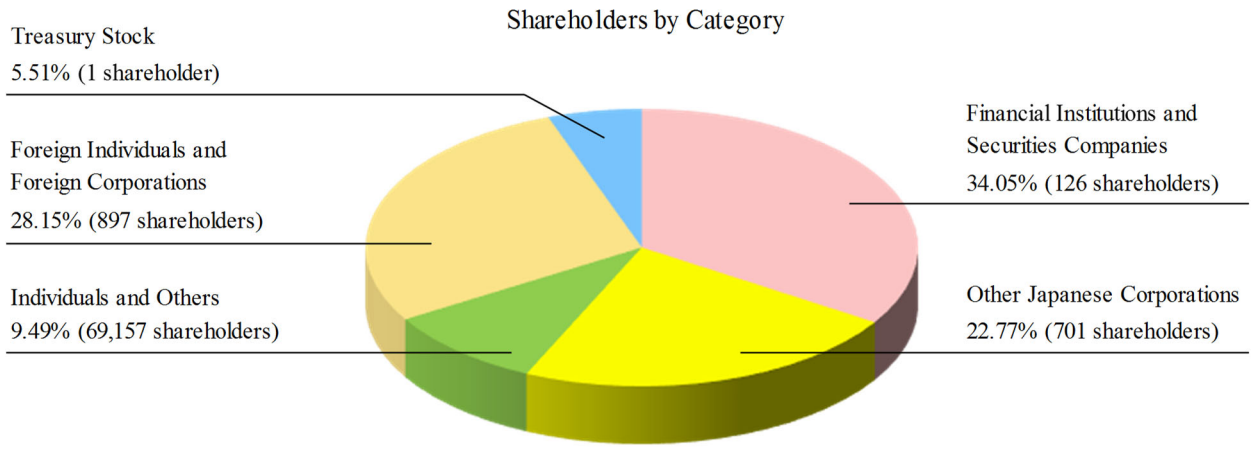
(As of September 30, 2020)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	43,002	8.61%
Custody Bank of Japan, Ltd. (Trust account)	27,050	5.41%
STATE STREET BANK AND TRUST COMPANY 505001	21,756	4.35%
Meiji Yasuda Life Insurance Company	18,594	3.72%
Ono Scholarship Foundation	16,428	3.29%
KAKUMEISOU Co., LTD	16,161	3.23%
Custody Bank of Japan, Ltd. (Trust account 5)	9,577	1.91%
MUFG Bank, Ltd.	8,640	1.73%
Aioi Nissay Dowa Insurance Co., Ltd.	8,313	1.66%
Custody Bank of Japan, Ltd. (Trust account 7)	7,563	1.51%

Note:1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,134 thousand shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (29,134 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 27, 2020

<Approved>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Colorectal cancer *1 (MSI-High)	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Waldenstorm macroglobulinemia, Lymphoplasmacytic lymphoma *2 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021

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

*2: An application was approved in Japan for Velexbru Tablets for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic lymphoma.

<Filed>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma *3	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021

*3: An approval application for combination therapy with Opdivo and Yervoy was filed in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.

<Clinical Trial Stage>

<Opdivo>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Ovarian cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	Japan S. Korea Taiwan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Biliary tract cancer	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-house (Co-development with Bristol-Myers Squibb)

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-license (Co-development with Bristol-Myers Squibb)

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7701 ★ (BMS-986205) / Linrodostat	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 ★ (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021

* Phase III of combination therapy of Opdivo and Yervoy for the treatment of small cell lung cancer was discontinued due to strategic reasons.
* Phase II of ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R antibody) for the treatment of pancreatic cancer was discontinued.

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

II. Main Status of Development Pipelines (Areas other than Oncology)

As of October 27, 2020

<Filed>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

<Clinical Trial Stage>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Orencia SC / Abatacept	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	Japan	III	In-license (Co-development with Bristol-Myers Squibb)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	Japan	I	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / S1P5 receptor agonist	Tablet	Europe	I	In-house
ONO-2910	New chemical entities	Peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	I	In-house
Foipan Tablets / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) / Protease enzyme inhibitor	Tablet	Japan	I	In-house

Profile for Main Development

Opdivo Intravenous Infusion (ONO-4538 / BMS-936558) / Nivolumab (injection)
Opdivo, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

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

ONO-4482 / BMS-986016 / Relatlimab (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of melanoma.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4686 / BMS-986207 (injection)
ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7701 / BMS-986205 / Linrodostat (capsule)
ONO-7701, IDO1 inhibitor, is being developed for the treatment of bladder cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4483 / BMS-986015/ Lirilumab (injection)
ONO-4483, a human anti-human KIR monoclonal antibody, is being developed for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7911 / BMS-986321 / Bempegaldesleukin (injection)
ONO-7911, PEGylated interleukin-2 formulation, is being developed for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7807 / BMS-986258 (injection)
ONO-7807, a human anti-human TIM-3 monoclonal antibody, is being developed for the treatment of solid tumor.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

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

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

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

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis is a proteasome inhibitor, being developed for change in dosage and administration after launched for multiple myeloma. It has become a new treatment option for multiple myeloma, which is a cancer of plasma cells (one of blood cells) and prognosis is considered poor.

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

Velexbru Tablets (ONO-4059) / Tirabrutinib (tablet)
Velexbru, a Btk inhibitor, has been marketed in Japan for the treatment of central nervous system lymphoma, and an additional indication was later approved for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic lymphoma. In addition, it is being developed for the treatment of B cell lymphoma and pemphigus.

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

ONO-7912 (CPI-613) / Devimistat (injection)
ONO-7912, a cancer metabolism inhibitor, is being developed for the treatment of pancreatic cancer and acute myeloid leukemia.

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

Orencia IV (ONO-4164 / BMS-188667) / Abatacept (injection)
Orencia IV is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, additionally approved for the treatment of active polyarticular juvenile idiopathic arthritis (JIA). Furthermore, an application was approved for the addition of prevention of the structural damage of the joints in rheumatoid arthritis.

Orencia SC (ONO-4164 / BMS-188667) / Abatacept (injection)
Orencia SC is marketed in Japan for use in patients of rheumatoid arthritis and psoriatic arthritis for whom other therapies have failed, after that, an application was approved for the addition of prevention of the structural damage of the joints in rheumatoid arthritis. Also, it is being developed for the treatment of polymyositis and dermatomyositis.

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

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

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

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

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

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

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

Foipan Tablets (FOY-305) / Camostat mesilate (tablet)
Foipan Tablets, a protease enzyme inhibitor, is marketed in Japan for the indication of chronic pancreatitis. It is currently being developed for the treatment of COVID-19.