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

February 1, 2021

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	: February 12, 2021
Scheduled date of dividend payment commencement	: —
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 Third Quarter of FY 2020 (April 1, 2020 to December 31, 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 Q3	234,933	4.3	82,189	24.4	84,658	23.3	66,534	28.0	66,487	28.3	82,604	31.8
FY 2019 Q3	225,299	0.9	66,045	26.7	68,687	24.4	51,982	20.3	51,827	20.2	62,652	67.4

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2020 Q3	133.20	133.19
FY 2019 Q3	102.54	102.53

(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 December 31, 2020	718,991	628,185	622,608	86.6
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 dividend forecast most recently announced: None

3. Consolidated Financial Forecast 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	309,000	5.7	94,000	21.3	95,500	19.8	74,200	23.9	74,000	23.9	148.26

(Note) Revisions to financial forecast 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 December 31, 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 December 31, 2020	29,199,161	shares
As of March 31, 2020	29,222,272	shares

3) Average number of shares outstanding during the period:

Nine months ended December 31, 2020	499,135,713	shares
Nine months ended December 31, 2019	505,432,005	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 4 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 3rd Quarter of FY 2020

(Millions of yen)

	Nine months ended December 31, 2019	**Nine months ended December 31, 2020**	Change	Change (%)
Revenue	225,299	**234,933**	9,634	4.3%
Operating profit	66,045	**82,189**	16,144	24.4%
Profit before tax	68,687	**84,658**	15,971	23.3%
Profit for the period (attributable to owners of the Company)	51,827	**66,487**	14,659	28.3%

[Revenue]

Revenue totaled ¥234.9 billion, which was an increase of ¥9.6 billion (4.3%) 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 was expanded to include the treatment of esophageal cancer, resulting in sales of ¥76.3 billion, an increase of ¥8.3 billion (12.3%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥19.9 billion (3.2% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥16.8 billion (10.5% increase year-on-year), sales of Forxiga Tablets for diabetes and chronic heart failure were ¥16.6 billion (20.3% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥6.3 billion (14.9% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥5.4 billion (17.3% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Rivastach Patches for Alzheimer's disease were ¥6.0 billion (10.7% decrease year-on-year), sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.3 billion (35.5% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥2.3 billion (40.8% decrease year-on-year), and sales of Emend Capsules for chemotherapy-induced nausea and vomiting were ¥2.0 billion (70.2% decrease year-on-year), respectively.
- Royalty and others increased by ¥5.3 billion (8.2%) year-on-year to ¥69.5 billion.

[Operating profit]

Operating profit was ¥82.2 billion, an increase of ¥16.1 billion (24.4%) year-on-year.

- Cost of sales increased by ¥4.6 billion (7.5%) year-on-year to ¥66.2 billion mainly due to an increase in amortization of intangible assets, in addition to an increase in sales of goods and products.
- Research and development costs decreased by ¥1.5 billion (3.4%) year-on-year to ¥43.8 billion. Although development activities, including the registrations of subjects have resumed since June 2020, there has been a decrease in clinical trial costs caused by the impact of the novel coronavirus disease (COVID-19). That decrease outweighed increases in costs including joint research costs for joint research with universities and research institutions and milestone payments relating to drug discovery alliances with bio-venture companies.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥2.7 billion (5.3%) year-on-year to ¥48.2 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.
- Other income increased by ¥6.5 billion to ¥7.1 billion, due to the upfront payment received under the license agreement with Roche in November 2020 for the patent relating to the anti-PD-L1 antibody.

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

Profit attributable to owners of the Company increased by ¥14.7 billion (28.3%) year-on-year to ¥66.5 billion in association with the increase of the profit before tax.

(2) Overview of Financial Position for the 3rd Quarter of FY 2020

(Millions of yen)

	As of March 31, 2020	**As of December 31, 2020**	Change
Total Assets	673,444	**718,991**	45,547
Equity attributable to owners of the Company	562,484	**622,608**	60,124
Ratio of equity attributable to owners of the Company to total assets	83.5%	**86.6%**	
Equity attributable to owners of the Company per share	1,126.95 yen	**1,247.36 yen**	

Total assets increased to ¥719.0 billion by ¥45.5 billion from the end of the previous fiscal year.
Current assets increased by ¥14.5 billion to ¥239.8 billion mainly due to increases in cash and cash equivalents and trade and other receivables etc., despite a decrease in other financial assets.
Non-current assets increased by ¥31.0 billion to ¥479.2 billion mainly due to increases in other financial assets and investment securities etc., despite decreases in deferred tax assets etc.
Liabilities decreased by ¥14.6 billion to ¥90.8 billion mainly due to decreases in income taxes payable etc.
Equity attributable to owners of the Company increased by ¥60.1 billion to ¥622.6 billion mainly due to increases in retained earnings and other components of equity etc.

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

(Millions of yen)

	Nine months ended December 31, 2019	**Nine months ended December 31, 2020**	Change
Cash and cash equivalents at the beginning of the period	59,981	**69,005**	
Cash flows from operating activities	50,178	**48,032**	(2,147)
Cash flows from investing activities	10,349	**(5.980)**	(16,328)
Cash flows from financing activities	(53,391)	**(23,626)**	29,765
Net increase (decrease) in cash and cash equivalents	7,136	**18,426**	
Effects of exchange rate changes on cash and cash equivalents	(2)	**46**	
Cash and cash equivalents at the end of the period	67,116	**87,477**	

Net increase/decrease in cash and cash equivalents was an increase of ¥18.4 billion.
Net cash provided by operating activities was ¥48.0 billion, as a result of profit before tax of ¥84.7 billion etc., while income taxes paid amounted to ¥34.0 billion etc.
Net cash used in investing activities was ¥6.0 billion, as a result of purchases of intangible assets of ¥10.9 billion and purchases of property, plant, and equipment of ¥4.5 billion etc., while proceeds from sales and redemption of investments of ¥10.1 billion etc.
Net cash used in financing activities was ¥23.6 billion, as a result of dividends paid of ¥21.8 billion etc.

(4) Future outlook

The forecast of consolidated financial results for the fiscal year ending March 31, 2021, as announced on October 29, 2020, has been revised as follows:

Revisions to the forecast 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)	305,000	87,000	88,500	65,200	65,000	130.23 yen
Revised forecast (B)	309,000	94,000	95,500	74,200	74,000	148.26 yen
Amount of change (B-A)	4,000	7,000	7,000	9,000	9,000	
Change (%)	1.3	8.0	7.9	13.8	13.8	
(Reference) Consolidated results of FY 2019	292,420	77,491	79,696	59,888	59,704	118.47 yen

Revenue is forecasted to be ¥309.0 billion, an upward revision of ¥4.0 billion from the previously announced forecast. This reflects an expectation that revenue of royalty and others will exceed the previously announced forecast, despite assumptions regarding the impact of drug price revisions in April.
Cost of sales is forecasted to be ¥88.0 billion, an increase of ¥4.0 billion from the previously announced forecast.
The forecasts for research and development costs and selling, general, and administrative expenses (except for research and development costs) have not changed since the previously announced forecast.
Other income increased by ¥7.5 billion from the previously announced forecast, mainly due to the upfront payment received under the license agreement with Roche in November 2020 for the patent relating to the anti-PD-L1 antibody.
As a result, operating profit is forecasted to be ¥94.0 billion (up ¥7.0 billion from the previously announced forecast) and profit before tax is forecasted to be ¥95.5 billion (up ¥7.0 billion). By reassessing income tax expense, profit for the year is forecasted to be ¥74.2 billion (up ¥9.0 billion from the previously announced forecast) and profit attributable to owners of the Company is forecasted to be ¥74.0 billion (up ¥9.0 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 December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	69,005	87,477
Trade and other receivables	76,834	88,264
Marketable securities	614	2,943
Other financial assets	30,800	5,962
Inventories	32,906	38,620
Other current assets	15,063	16,490
Total current assets	225,222	239,756
Non-current assets:		
Property, plant, and equipment	114,628	114,043
Intangible assets	66,436	69,400
Investment securities	137,670	147,637
Investments in associates	108	113
Other financial assets	91,694	116,884
Deferred tax assets	34,817	29,025
Other non-current assets	2,871	2,132
Total non-current assets	448,222	479,235
Total assets	673,444	718,991

(Millions of yen)

	As of March 31, 2020	As of December 31, 2020
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,439	34,866
Lease liabilities	2,188	1,973
Other financial liabilities	450	3,007
Income taxes payable	20,346	5,568
Provisions	20,721	20,721
Other current liabilities	13,185	10,655
Total current liabilities	91,329	76,790
Non-current liabilities:		
Lease liabilities	6,173	7,076
Other financial liabilities	0	0
Retirement benefit liabilities	6,048	5,077
Deferred tax liabilities	1,059	1,040
Other non-current liabilities	813	823
Total non-current liabilities	14,093	14,017
Total liabilities	105,422	90,807
Equity:		
Share capital	17,358	17,358
Capital reserves	17,229	17,220
Treasury shares	(44,737)	(44,704)
Other components of equity	48,030	61,142
Retained earnings	524,605	571,592
Equity attributable to owners of the Company	562,484	622,608
Non-controlling interests	5,538	5,576
Total equity	568,022	628,185
Total liabilities and equity	673,444	718,991

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine months ended December 31, 2019	Nine months ended December 31, 2020
Revenue	225,299	234,933
Cost of sales	(61,555)	(66,151)
Gross profit	163,745	168,782
Selling, general, and administrative expenses	(50,938)	(48,216)
Research and development costs	(45,371)	(43,847)
Other income	584	7,097
Other expenses	(1,976)	(1,628)
Operating profit	66,045	82,189
Finance income	2,999	2,594
Finance costs	(362)	(131)
Share of profit (loss) from investments in associates	5	6
Profit before tax	68,687	84,658
Income tax expense	(16,705)	(18,124)
Profit for the period	51,982	66,534
Profit for the period attributable to:		
Owners of the Company	51,827	66,487
Non-controlling interests	155	47
Profit for the period	51,982	66,534
Earnings per share:		
Basic earnings per share (Yen)	102.54	133.20
Diluted earnings per share (Yen)	102.53	133.19

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2019	Nine months ended December 31, 2020
Profit for the period	51,982	66,534
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	10,288	15,199
Remeasurements of defined benefit plans	396	899
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	0
Total of items that will not be reclassified to profit or loss	10,687	16,098
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(36)	(16)
Net fair value gain (loss) on cash flow hedges	19	(11)
Total of items that may be reclassified subsequently to profit or loss	(17)	(27)
Total other comprehensive income (loss)	10,670	16,071
Total comprehensive income (loss) for the period	62,652	82,604
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	62,508	82,560
Non-controlling interests	145	44
Total comprehensive income (loss) for the period	62,652	82,604

(3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 2019

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2019	17,358	17,202	(38,151)	61,852	499,088	557,350	5,386	562,736
Profit for the period					51,827	51,827	155	51,982
Other comprehensive income (loss)				10,680		10,680	(10)	10,670
Total comprehensive income (loss) for the period	–	–	–	10,680	51,827	62,508	145	62,652
Purchase of treasury shares			(29,585)			(29,585)		(29,585)
Retirement of treasury shares			22,999		(22,999)	–		–
Cash dividends					(22,798)	(22,798)	(3)	(22,801)
Share-based payments		20				20		20
Transfer from other components of equity to retained earnings				(5,896)	5,896	–		–
Total transactions with the owners	–	20	(6,586)	(5,896)	(39,901)	(52,363)	(3)	(52,366)
Balance as of December 31, 2019	17,358	17,222	(44,736)	66,636	511,015	567,495	5,527	573,022

Nine months ended December 31, 2020

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
Profit for the period					66,487	66,487	47	66,534
Other comprehensive income (loss)				16,074		16,074	(3)	16,071
Total comprehensive income (loss) for the period	—	—	—	16,074	66,487	82,560	44	82,604
Purchase of treasury shares			(4)			(4)		(4)
Disposition of treasury shares		(38)	38			0		0
Cash dividends					(22,461)	(22,461)	(6)	(22,467)
Share-based payments		29				29		29
Transfer from other components of equity to retained earnings				(2,962)	2,962	—		—
Total transactions with the owners	—	(9)	33	(2,962)	(19,499)	(22,436)	(6)	(22,442)
Balance as of December 31, 2020	17,358	17,220	(44,704)	61,142	571,592	622,608	5,576	628,185

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2019	Nine months ended December 31, 2020
Cash flows from operating activities		
Profit before tax	68,687	84,658
Depreciation and amortization	10,426	11,814
Impairment losses	85	2,305
Interest and dividend income	(2,881)	(2,398)
Interest expense	57	53
(Increase) decrease in inventories	799	(5,672)
(Increase) decrease in trade and other receivables	(5,944)	(11,273)
Increase (decrease) in trade and other payables	(588)	1,743
Increase (decrease) in provisions	3,515	—
Increase (decrease) in retirement benefit liabilities	289	320
Other	1,294	(1,828)
Subtotal	75,739	79,722
Interest received	54	38
Dividends received	2,819	2,355
Interest paid	(57)	(53)
Income taxes paid	(28,377)	(34,030)
Net cash provided by (used in) operating activities	50,178	48,032
Cash flows from investing activities		
Purchases of property, plant, and equipment	(6,248)	(4,525)
Purchases of intangible assets	(12,677)	(10,878)
Purchases of investments	–	(760)
Proceeds from sales and redemption of investments	13,838	10,105
Payments into time deposits	(10,600)	(30,736)
Proceeds from withdrawal of time deposits	25,600	30,600
Other	437	215
Net cash provided by (used in) investing activities	10,349	(5,980)
Cash flows from financing activities		
Dividends paid	(22,066)	(21,757)
Dividends paid to non-controlling interests	(3)	(6)
Repayments of lease liabilities	(1,739)	(1,860)
Purchases of treasury shares	(29,584)	(3)
Net cash provided by (used in) financing activities	(53,391)	(23,626)
Net increase (decrease) in cash and cash equivalents	7,136	18,426
Cash and cash equivalents at the beginning of the period	59,981	69,005
Effects of exchange rate changes on cash and cash equivalents	(2)	46
Cash and cash equivalents at the end of the period	67,116	87,477

(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

4. Supplementary Information

(1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product Name	Nine months ended December 31, 2020 (April 1, 2020 to December 31, 2020)						FY 2020 Forecast (April 1, 2020 to March 31, 2021)		
	Cumulative				YoY		Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	24.4	24.6	27.3	**76.3**	8.3	12.3%	**98.0**	10.7	12.2%
Glactiv Tablets	6.5	6.4	6.9	**19.9**	(0.7)	(3.2%)	**25.0**	(1.1)	(4.1%)
Forxiga Tablets	5.2	5.3	6.1	**16.6**	2.8	20.3%	**22.5**	4.4	24.6%
Orencia for Subcutaneous Injection	5.4	5.4	5.9	**16.8**	1.6	10.5%	**22.0**	2.2	11.0%
Rivastach Patches	2.0	2.0	1.9	**6.0**	(0.7)	(10.7%)	**7.5**	(1.0)	(12.0%)
Parsabiv Intravenous Injection	1.9	2.0	2.4	**6.3**	0.8	14.9%	**8.0**	0.9	13.1%
Kyprolis for Intravenous Infusion	1.7	1.8	1.9	**5.4**	0.8	17.3%	**7.0**	1.0	16.7%
Onoact for Intravenous Infusion	1.0	1.1	1.4	**3.6**	(0.4)	(10.2%)	**5.5**	0.6	13.1%
Opalmon Tablets	1.5	1.4	1.5	**4.3**	(2.4)	(35.5%)	**5.0**	(3.3)	(40.0%)
Proemend for Intravenous Infusion	0.7	0.7	0.7	**2.0**	(0.0)	(1.9%)	**2.5**	(0.1)	(4.8%)
Emend Capsules	0.8	0.7	0.6	**2.0**	(4.8)	(70.2%)	**2.5**	(5.6)	(69.1%)
Onon Capsules	0.7	0.5	0.7	**1.9**	(0.6)	(23.1%)	**2.5**	(1.0)	(27.6%)
Recalbon Tablets	0.8	0.7	0.8	**2.3**	(1.6)	(40.8%)	**2.5**	(2.2)	(47.3%)
Newly launched products during FY 2020	0.1	0.5	0.9	**1.4**	-	-	**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 ¥1.2 billion in sales of Velexbru Tablets launched in May 2020 and ¥0.2 billion in sales of Ongentys Tablets launched in August 2020.

(2) Details of Sales Revenue

(Billions of yen)

	Nine months ended December 31, 2019	**Nine months ended December 31, 2020**
Revenue of goods and products	161.1	**165.4**
Royalty and others	64.2	**69.5**
Total	225.3	**234.9**

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥46.0 billion for the third quarter (nine months) ended December 31, 2019 and ¥44.7 billion for the third quarter (nine months) ended December 31, 2020. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥13.8 billion for the third quarter (nine months) ended December 31, 2019 and ¥17.6 billion for the third quarter (nine months) ended December 31, 2020.

(3) Revenue by Geographic Area

(Billions of yen)

	Nine months ended December 31, 2019	**Nine months ended December 31, 2020**
Japan	158.6	**163.4**
Americas	60.2	**63.3**
Asia	6.2	**5.8**
Europe	0.3	**2.5**
Total	225.3	**234.9**

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

(4) Main Status of Development Pipelines (Oncology)

As of January 25, 2021

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer *1	Injection	Japan S. Korea	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Colorectal cancer *2	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Colorectal cancer *2	Tablet	Japan	In-license (Pfizer Inc.)
Adlumiz Tablets / Anamorelin	New chemical entities	Cancer cachexia *3 / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)

★: Combination with Opdivo.

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

*1: Applications were approved in Japan and South Korea for combination therapy of Opdivo and Yervoy for the treatment of unresectable advanced or recurrent non-small cell lung cancer.

*2: Applications for Braftovi Capsules and Mektovi Tablets were approved in Japan for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer that has progressed following chemotherapy.

*3: An application was approved in Japan for Adlumiz / Anamorelin for the treatment of cancer cachexia in patients with malignant tumors (non-small cell lung cancer, gastric cancer, pancreatic cancer or colorectal cancer).

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

<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	Urothelial cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)

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	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 *4	Injection	Japan S. Korea Taiwan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-house (Co-development with Bristol-Myers Squibb)

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	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)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	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-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 ★ (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Colorectal cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor・Gastric cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Braftovi Capsules / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer *6 / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer *6 / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)

★: Combination with Opdivo.

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

*4: Phase II of Opdivo was initiated in Japan, South Korea, and Taiwan for the treatment of biliary tract cancer.

*5: Phase I of prostaglandin receptor (EP4) antagonist (ONO-4578) was initiated in Japan for the treatment of colorectal cancer, pancreatic cancer and non-small cell lung cancer.

*6: Phase II of combination therapy of Braftovi Capsules (BRAF inhibitor) and Mektovi Tablets (MEK inhibitor) was initiated in Japan for the treatment of thyroid cancer.

* Development of Opdivo for the treatment of glioblastoma has been removed from the development pipeline upon having deemed that it does not achieve the results anticipated.

* ONO-4059 was out-licensed to Gilead Sciences, Inc. (“Gilead,” based in USA) in 2014. However, Gilead returned the rights for oncology in all territories it holds rights for. Gilead retains the rights in those territories for all fields except oncology.

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

(5) Main Status of Development Pipelines (Areas other than Oncology)

As of January 25, 2021

<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)
Foipan Tablets / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) *7 / Protease enzyme inhibitor	Tablet	Japan	III	In-house
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
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-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / S1P5 receptor agonist	Tablet	Japan *8 Europe	I	In-house
ONO-2910	New chemical entities	Peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	I	In-house
ONO-2909	New chemical entities	Narcolepsy *9/Prostaglandin receptor (DP1) antagonist	Tablet	Japan	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic scleroderma *10 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	I	In-house

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

*7: Phase III of Foipan Tablets was initiated in Japan for the treatment of COVID-19.

*8: Phase I of S1P5 receptor agonist (ONO-2808) was initiated in Japan.

*9: Phase I of prostaglandin receptor (DP1) antagonist (ONO-2909) was initiated in Japan for healthy adult subjects and for the treatment of narcolepsy.

*10: Phase I of Velexbru Tablets (Btk inhibitor) was initiated in Japan for the treatment of systemic scleroderma.

* Development of FXIa inhibitor (ONO-7269) for the treatment of cerebral infarction was discontinued in Japan due to strategic reasons.