Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2022 (IFRS)

November 1, 2021

Company name : **ONO PHARMACEUTICAL CO., LTD.**
Stock exchange listing : Tokyo Stock Exchange
Code number : 4528
URL : https://www.ono-pharma.com/
Representative : Gyo Sagara
President, Representative Director, and Chief Executive Officer
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Corporate Executive Officer / Head of Corporate Communications
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Scheduled date of quarterly securities report submission : November 5, 2021
Scheduled date of dividend payment commencement : December 1, 2021
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 2021 (April 1, 2021 to September 30, 2021)

(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 2021 Q2	174,077	15.7	58,171	11.0	59,231	10.4	46,334	16.2	46,290	16.2	52,252	(2.9)
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

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2021 Q2	92.74	92.73
FY 2020 Q2	79.84	79.83

(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, 2021	772,900	679,698	674,048	87.2
As of March 31, 2021	746,842	641,157	635,547	85.1

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2020	—	22.50	—	27.50	50.00
FY 2021	—	28.00			
FY 2021 (Forecast)			—	28.00	56.00

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

3. Consolidated Financial Forecast for FY 2021 (April 1, 2021 to March 31, 2022)

(% 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 2021	345,000	11.5	103,000	4.7	105,000	4.1	81,600	8.1	81,500	8.1	163.28

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

Notes

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

(2) Changes in accounting policies and changes in accounting estimates
1) Changes in accounting policies required by IFRS: 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, 2021	528,341,400	shares
As of March 31, 2021	528,341,400	shares

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

As of September 30, 2021	29,179,954	shares
As of March 31, 2021	29,199,416	shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2021	499,153,142	shares
Six months ended September 30, 2020	499,132,780	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 2021

(Millions of yen)

	Six months ended September 30, 2020	**Six months ended September 30, 2021**	Change	Change (%)
Revenue	150,474	**174,077**	23,603	15.7%
Operating profit	52,401	**58,171**	5,770	11.0%
Profit before tax	53,674	**59,231**	5,557	10.4%
Profit for the period (attributable to owners of the Company)	39,849	**46,290**	6,441	16.2%

[Revenue]

Revenue totaled ¥174.1 billion, which was an increase of ¥23.6 billion (15.7%) from the corresponding period of the previous fiscal year (year-on-year).

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to first-line treatment for non-small cell lung cancer and second-line treatment for esophageal cancer, resulting in sales of ¥56.1 billion, an increase of ¥7.0 billion (14.3%) year-on-year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥15.6 billion (49.3% increase year-on-year), sales of Glactiv Tablets for type-2 diabetes were ¥12.7 billion (1.7% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥11.2 billion (3.3% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.5 billion (15.6% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.2 billion (18.6% increase year-on-year), respectively.
- 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 ¥2.4 billion (16.8% decrease year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥1.6 billion (61.7% decrease year-on-year), respectively.
- Royalty and others increased by ¥10.9 billion (24.8%) year-on-year to ¥54.9 billion.

[Operating profit]

Operating profit was ¥58.2 billion, an increase of ¥5.8 billion (11.0%) year-on-year.

- Cost of sales increased by ¥3.8 billion (9.1%) year-on-year to ¥45.6 billion mainly due to an increase in sales of goods and products.
- Research and development costs increased by ¥6.8 billion (26.5%) year-on-year to ¥32.6 billion. The increase is largely attributable to higher costs associated with development amid a situation where development activities including the registrations of subjects mounted a gradual recovery, as well as higher costs associated with research.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.8 billion (26.3%) year-on-year to ¥37.7 billion, despite MRs refraining from visiting medical institutions and other restrictions on activities due to the impact of the novel coronavirus disease (COVID-19). The increase is partly attributable to an increase in operating expenses largely associated with actively implementing online lectures, an increase in expenses pertaining to the launch of new products and additional indication, and an increase in co-promotion fees associated with expanding sales of Forxiga Tablets.

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

Profit attributable to owners of the Company increased by ¥6.4 billion (16.2%) year-on-year to ¥46.3 billion in association with the increase of the profit before tax.

(Research & Development Activities)

Upholding the corporate philosophy "Dedicated to the 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 autoimmune disease and neurological disorder, and so on, and development is proceeding. Among these, the area of cancer treatment is positioned as an important strategic field because unmet medical needs are high.

In drug discovery research, having designated oncology, immunology, neurology, and specialty domains with high medical needs as our priority areas of research, we accordingly promote initiatives to accurately identify medical needs by extensively investigating biology of human disease with the aim of enhancing our competitive strengths with respect to drug discovery in the respective domains. Through our strategy of "Open Innovation," we are acquiring original drug seeds and are pursuing the discovery and development of innovative new drugs with a significant medical impact by exploiting the latest technologies in fields such as informatics, human disease modeling, and compound synthesis.

A total of seven new drug candidate compounds in our priority therapeutic areas have proceeded to the clinical stage, and we will also continue to bolster our efforts in translational research bridging the gap between basic and clinical research to accelerate drug discovery timelines and boost success rates. By organically leveraging bioinformatics technologies and research tools such as human genome data and human iPS cells in the early stages of research, we intend to garner a deeper understanding of the relationship between target molecules and diseases to more accurately predict the efficacy of new drug candidate compounds in humans, and to develop physiological indicators (biomarkers) for evaluating efficacy against disease in clinical trials. 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, 2021 (including those on and after September 30, 2021) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

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

Gastric cancer

- In June 2021, an application was approved in South Korea for combination therapy with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma.
- In October 2021, an application was approved in Taiwan for combination therapy with fluoropyrimidine- and platinum- containing chemotherapy for the treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma without human epidermal growth factor receptor 2 (HER2) overexpression.

Esophageal cancer

- In September 2021, approval applications were filed in Japan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.

Malignant pleural mesothelioma

- In May 2021, an application for combination therapy with Yervoy was approved in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.
- In June 2021, an application for combination therapy with Yervoy was approved in South Korea for the treatment of unresectable malignant pleural mesothelioma.
- In September 2021, an application for combination therapy with Yervoy was approved in Taiwan for the treatment of unresectable malignant pleural mesothelioma.

Renal cell carcinoma

- In August 2021, an application for combination therapy with CABOMETYX Tablets was approved in Japan for the treatment of unresectable or metastatic renal cell carcinoma.

Pancreatic cancer

- In April 2021, phase I of combination therapy with ONO-7913 was initiated in Japan for the treatment of pancreatic cancer.

Colorectal cancer

- In April 2021, phase I of combination therapy with ONO-7913 was initiated in Japan for the treatment of colorectal cancer.

Non-small cell lung cancer

- In June 2021, the package insert was revised in Japan for combination therapy with bevacizumab and chemotherapy for the treatment of unresectable advanced or recurrent non-small cell lung cancer.

Cancer of unknown primary

- In April 2021, an approval application was filed in Japan for the treatment of cancer of unknown primary.

Hodgkin lymphoma

- In September 2021, an approval was obtained in Japan to expand the use for the treatment of pediatric patients with recurrent or refractory classical hodgkin lymphoma.

Solid tumor

- In August 2021, phase I of combination therapy with ONO-7119 was initiated in Japan for the treatment of solid tumor.
- In April 2021, development for the treatment of solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma) was discontinued in Japan due to strategic reasons.

Central nervous system lymphoma / Primary testicular lymphoma

- In April 2021, development for the treatment of central nervous system lymphoma / primary testicular lymphoma was discontinued in Japan due to strategic reasons.

Head and neck cancer
- In July 2021, development involving combination therapy with Yervoy for the treatment of head and neck cancer was discontinued because it did not meet primary endpoints.

"Velexbru Tablets / Tirabrutinib Hydrochloride"
- In July 2021, phase II of ONO-4059 was initiated in the USA for the treatment of primary central nervous system lymphoma.

"Braftovi Capsules / Encorafenib" "Mektovi Tablets / Binimetinib"
- In August 2021, an application was approved in South Korea for Braftovi Capsules / Encorafenib for use in combination therapy with cetuximab for the treatment of adult patients with advanced or recurrent $BRAF^{V600E}$-mutant colorectal cancer after prior therapy.
- In August 2021, phase III of Braftovi Capsules and Mektovi Tablets for the treatment of melanoma was discontinued in South Korea due to strategic reasons.
- In August 2021, phase III of Mektovi Tablets for the treatment of colorectal cancer was discontinued in South Korea due to strategic reasons.

"ONO-7475"
- In April 2021, phase I of ONO-7475 was initiated in Japan for the treatment of EGFR-mutated non-small cell lung cancer.

"ONO-7913"
- In April 2021, phase I of combination therapy of Opdivo and ONO-7913 was initiated in Japan for the treatment of pancreatic cancer and colorectal cancer.
- In April 2021, phase I of ONO-7913 was initiated in Japan for the treatment of myelodysplastic syndromes (MDS).

"ONO-7119"
- In August 2021, phase I of combination therapy of Opdivo and ONO-7119 was initiated in Japan for the treatment of solid tumor.

"ONO-4578"
- In July 2021, phase I of ONO-4578 was initiated in Japan for the treatment of hormone receptor-positive, HER2-negative breast cancer.

"ONO-4483"
- In July 2021, development of ONO-4483 for the treatment of solid tumor was discontinued in Japan due to strategic reasons.

"ONO-4685"
- In October 2021, phase I of ONO-4685 was initiated in the USA for the treatment of T-cell lymphoma.

<Areas other than Oncology>

"Forxiga Tablets / Dapagliflozin propylene glycolate hydrate"
- In August 2021, an application was approved in Japan for Forxiga Tablets for the treatment of chronic kidney disease (excluding patients with end-stage renal disease or undergoing dialysis), with and without type-2 diabetes.

"Foipan Tablets / Camostat mesilate"
- In June 2021, phase III of Foipan Tablets for the treatment of COVID-19 in Japan was discontinued because the clinical trial did not demonstrate efficacy.

"ONO-2910"
- In April 2021, phase II of ONO-2910 was initiated in Japan for the treatment of diabetic polyneuropathy.

"ONO-4685"
-In September 2021, phase I of ONO-4685 was initiated in Europe for the treatment of autoimmune disease.

[Status of Drug Discovery / Research Alliance Activities]
- In August 2021, the Company entered into a research collaboration agreement with Healx Limited in the UK to jointly discover and develop innovative drugs that meet unmet medical needs utilizing Healx's artificial intelligence (AI) technology.
- In August 2021, the Company entered into a drug discovery collaboration agreement with MiraBiologics, Inc. to discover and create the next generation of biopharmaceuticals utilizing MiraBiologics' proprietary LassoGraft Technology®, a new technology that combines cyclic peptide searching method and protein engineering.

(2) Overview of Financial Position for the 2nd Quarter of FY 2021

(Millions of yen)

	As of March 31, 2021	**As of September 30, 2021**	Change
Total Assets	746,842	**772,900**	26,058
Equity attributable to owners of the Company	635,547	**674,048**	38,501
Ratio of equity attributable to owners of the Company to total assets	85.1%	**87.2%**	
Equity attributable to owners of the Company per share	1,273.28 yen	**1,350.36 yen**	

Total assets increased to ¥772.9 billion by ¥26.1 billion from the end of the previous fiscal year.
Current assets increased by ¥28.5 billion to ¥276.1 billion mainly due to increases in cash and cash equivalents and other financial assets.
Non-current assets decreased by ¥2.4 billion to ¥496.8 billion mainly due to a decrease in other financial assets.
Liabilities decreased by ¥12.5 billion to ¥93.2 billion mainly due to decreases in trade and other payables and income taxes payable.
Equity attributable to owners of the Company increased by ¥38.5 billion to ¥674.0 billion mainly due to an increase in retained earnings.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2021

(Millions of yen)

	Six months ended September 30, 2020	**Six months ended September 30, 2021**	Change
Cash and cash equivalents at the beginning of the period	69,005	**61,045**	
Cash flows from operating activities	31,314	**40,369**	9,055
Cash flows from investing activities	(4,033)	**(5,385)**	(1,352)
Cash flows from financing activities	(12,488)	**(14,968)**	(2,480)
Net increase (decrease) in cash and cash equivalents	14,793	**20,016**	
Effects of exchange rate changes on cash and cash equivalents	3	**56**	
Cash and cash equivalents at the end of the period	83,800	**81,117**	

Net increase/decrease in cash and cash equivalents was an increase of ¥20.0 billion.
Net cash provided by operating activities was ¥40.4 billion, as a result of profit before tax of ¥59.2 billion, etc., while income taxes paid amounted to ¥18.1 billion, etc.
Net cash used in investing activities was ¥5.4 billion, as a result of purchases of intangible assets of ¥5.6 billion, etc.
Net cash used in financing activities was ¥15.0 billion, as a result of dividends paid of ¥13.7 billion, etc.

(4) Future outlook

There are no changes from the forecast of consolidated financial results for the year ending March 31, 2022 announced on May 13, 2021. As for the impact of COVID-19 on business and financial results, we assume that restrictions on certain activities will continue, but we expect that the impact on operating profit will remain immaterial.

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, 2021	As of September 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	61,045	81,117
Trade and other receivables	84,269	89,596
Marketable securities	2,978	640
Other financial assets	40,952	47,629
Inventories	39,151	38,594
Other current assets	19,246	18,538
Total current assets	247,642	276,115
Non-current assets:		
Property, plant, and equipment	113,866	112,050
Intangible assets	70,322	71,682
Investment securities	146,796	151,043
Investments in associates	112	111
Other financial assets	131,888	127,119
Deferred tax assets	33,619	31,289
Retirement benefit assets	7	431
Other non-current assets	2,590	3,060
Total non-current assets	499,200	496,785
Total assets	746,842	772,900

(Millions of yen)

	As of March 31, 2021	As of September 30, 2021
Liabilities and Equity		
Current liabilities:		
Trade and other payables	39,163	31,556
Lease liabilities	2,023	2,004
Other financial liabilities	616	889
Income taxes payable	19,047	14,060
Provisions	20,721	20,721
Other current liabilities	12,163	11,986
Total current liabilities	93,733	81,217
Non-current liabilities:		
Lease liabilities	7,030	6,954
Other financial liabilities	0	0
Retirement benefit liabilities	3,056	3,192
Deferred tax liabilities	1,052	1,037
Other non-current liabilities	813	802
Total non-current liabilities	11,952	11,986
Total liabilities	105,685	93,202
Equity:		
Share capital	17,358	17,358
Capital reserves	17,231	17,221
Treasury shares	(44,705)	(44,676)
Other components of equity	62,299	66,475
Retained earnings	583,363	617,669
Equity attributable to owners of the Company	635,547	674,048
Non-controlling interests	5,610	5,650
Total equity	641,157	679,698
Total liabilities and equity	746,842	772,900

(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, 2020	Six months ended September 30, 2021
Revenue	150,474	174,077
Cost of sales	(41,760)	(45,567)
Gross profit	108,714	128,510
Selling, general, and administrative expenses	(29,817)	(37,656)
Research and development costs	(25,733)	(32,552)
Other income	365	669
Other expenses	(1,127)	(800)
Operating profit	52,401	58,171
Finance income	1,403	1,422
Finance costs	(137)	(361)
Share of profit (loss) from investments in associates	6	(2)
Profit before tax	53,674	59,231
Income tax expense	(13,786)	(12,897)
Profit for the period	39,888	46,334
Profit for the period attributable to:		
Owners of the Company	39,849	46,290
Non-controlling interests	38	43
Profit for the period	39,888	46,334
Earnings per share:		
Basic earnings per share (Yen)	79.84	92.74
Diluted earnings per share (Yen)	79.83	92.73

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Profit for the period	39,888	46,334
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	13,417	5,524
Remeasurements of defined benefit plans	515	324
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(0)	1
Total of items that will not be reclassified to profit or loss	13,932	5,849
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(23)	70
Total of items that may be reclassified subsequently to profit or loss	(23)	70
Total other comprehensive income (loss)	13,909	5,918
Total comprehensive income (loss) for the period	53,797	52,252
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	53,754	52,208
Non-controlling interests	43	44
Total comprehensive income (loss) for the period	53,797	52,252

(3) Condensed Interim Consolidated Statement of Changes in Equity

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

Six months ended September 30, 2021

(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, 2021	17,358	17,231	(44,705)	62,299	583,363	635,547	5,610	641,157
Profit for the period					46,290	46,290	43	46,334
Other comprehensive income (loss)				5,918		5,918	0	5,918
Total comprehensive income (loss) for the period	—	—	—	5,918	46,290	52,208	44	52,252
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(31)	31			0		0
Cash dividends					(13,726)	(13,726)	(4)	(13,730)
Share-based payments		21				21		21
Transfer from other components of equity to retained earnings				(1,742)	1,742	—		—
Total transactions with the owners	—	(10)	29	(1,742)	(11,984)	(13,707)	(4)	(13,711)
Balance as of September 30, 2021	17,358	17,221	(44,676)	66,475	617,669	674,048	5,650	679,698

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Cash flows from operating activities		
Profit before tax	53,674	59,231
Depreciation and amortization	7,764	8,686
Impairment losses	-	124
Interest and dividend income	(1,317)	(1,177)
Interest expense	36	35
(Increase) decrease in inventories	(4,215)	577
(Increase) decrease in trade and other receivables	(3,747)	(5,375)
Increase (decrease) in trade and other payables	(76)	(6,523)
Increase (decrease) in retirement benefit liabilities	211	115
(Increase) decrease in retirement benefit assets	-	65
Other	(2,478)	1,587
Subtotal	49,852	57,345
Interest received	34	25
Dividends received	1,285	1,157
Interest paid	(36)	(35)
Income taxes paid	(19,822)	(18,124)
Net cash provided by (used in) operating activities	31,314	40,369
Cash flows from investing activities		
Purchases of property, plant, and equipment	(3,307)	(3,045)
Purchases of intangible assets	(2,998)	(5,587)
Purchases of investments	(450)	(382)
Proceeds from sales and redemption of investments	2,915	6,407
Payments into time deposits	(30,335)	(6,847)
Proceeds from withdrawal of time deposits	30,200	5,200
Other	(59)	(1,130)
Net cash provided by (used in) investing activities	(4,033)	(5,385)
Cash flows from financing activities		
Dividends paid	(11,221)	(13,707)
Dividends paid to non-controlling interests	(6)	(4)
Repayments of lease liabilities	(1,260)	(1,256)
Purchases of treasury shares	(2)	(0)
Net cash provided by (used in) financing activities	(12,488)	(14,968)
Net increase (decrease) in cash and cash equivalents	14,793	20,016
Cash and cash equivalents at the beginning of the period	69,005	61,045
Effects of exchange rate changes on cash and cash equivalents	3	56
Cash and cash equivalents at the end of the period	83,800	81,117

(5) Notes to Condensed Interim Consolidated Financial Statements

(Notes Regarding Assumption of a Going Concern)

Not Applicable

(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

2nd Quarter of Fiscal Year 2021 (Ending March 31, 2022)
(April 1, 2021 to September 30, 2021)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2021 (Ending March 31, 2022) (IFRS)】

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

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2021 (IFRS)

(Billions of yen)

	Six months ended September 30, 2020	**Six months ended September 30, 2021**	YoY	Full year ended March 31, 2021
Revenue	150.5	**174.1**	15.7%	309.3
Operating profit	52.4	**58.2**	11.0%	98.3
Profit before tax	53.7	**59.2**	10.4%	100.9
Profit for the period (attributable to owners of the Company)	39.8	**46.3**	16.2%	75.4

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

1. Revenue ¥174.1 billion YoY an increase of 15.7% (FY 2020 2Q YTD ¥150.5 billion)

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to first-line treatment for non-small cell lung cancer and second-line treatment for esophageal cancer, resulting in sales of ¥56.1 billion, an increase of ¥7.0 billion (14.3%) year-on-year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥15.6 billion (49.3% increase year-on-year), sales of Glactiv Tablets for type-2 diabetes were ¥12.7 billion (1.7% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥11.2 billion (3.3% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.5 billion (15.6% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.2 billion (18.6% increase year-on-year), respectively.
- 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 ¥2.4 billion (16.8% decrease year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥1.6 billion (61.7% decrease year-on-year), respectively.
- Royalty and others increased by ¥10.9 billion (24.8%) year-on-year to ¥54.9 billion.

2. Operating profit ¥58.2 billion YoY an increase of 11.0% (FY 2020 2Q YTD ¥52.4 billion)

- Operating profit was ¥58.2 billion, an increase of ¥5.8 billion (11.0%) year-on-year.
- Cost of sales increased by ¥3.8 billion (9.1%) year-on-year to ¥45.6 billion mainly due to an increase in sales of goods and products.
- Research and development costs increased by ¥6.8 billion (26.5%) year-on-year to ¥32.6 billion. The increase is largely attributable to higher costs associated with development amid a situation where development activities including the registrations of subjects mounted a gradual recovery, as well as higher costs associated with research.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.8 billion (26.3%) year-on-year to ¥37.7 billion, despite MRs refraining from visiting medical institutions and other restrictions on activities due to the impact of the novel coronavirus disease (COVID-19). The increase is partly attributable to an increase in operating expenses largely associated with actively implementing online lectures, an increase in expenses pertaining to the launch of new products and additional indication, and an increase in co-promotion fees associated with expanding sales of Forxiga Tablets.

3. Profit before tax ¥59.2 billion YoY an increase of 10.4% (FY 2020 2Q YTD ¥53.7 billion)

- Net financial income, etc. was ¥1.1 billion, a decrease of ¥0.2 billion (16.8%) year-on-year.

4. Profit for the period ¥46.3 billion YoY an increase of 16.2% (FY 2020 2Q YTD ¥39.8 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥6.4 billion (16.2%) year-on-year to ¥46.3 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, 2021 (April 1, 2021 to September 30, 2021)					FY 2021 Forecast (April 1, 2021 to March 31, 2022)		
	Cumulative			YoY		Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	29.0	27.1	**56.1**	7.0	14.3%	110.0	11.2	11.3%
Forxiga Tablets	7.5	8.2	**15.6**	5.2	49.3%	35.0	12.6	56.6%
Glactiv Tablets	6.5	6.3	**12.7**	(0.2)	(1.7%)	24.5	(1.0)	(3.9%)
Orencia for Subcutaneous Injection	5.7	5.5	**11.2**	0.4	3.3%	22.5	0.6	2.7%
Parsabiv Intravenous Injection	2.2	2.3	**4.5**	0.6	15.6%	8.0	(0.1)	(0.6%)
Kyprolis for Intravenous Infusion	2.0	2.2	**4.2**	0.7	18.6%	7.5	0.4	5.3%
Velexbru Tablets	1.4	1.4	**2.9**	2.4	497.2%	5.0	2.9	142.6%
Onoact for Intravenous Infusion	1.2	1.1	**2.3**	0.2	8.8%	4.0	(0.7)	(14.1%)
Opalmon Tablets	1.2	1.2	**2.4**	(0.5)	(16.8%)	4.0	(1.5)	(26.7%)
Rivastach Patches	0.8	0.7	**1.6**	(2.5)	(61.7%)	3.0	(3.6)	(54.6%)
Braftovi Capsules	0.7	0.7	**1.4**	1.0	301.0%	3.0	1.9	180.6%
Mektovi Tablets	0.5	0.6	**1.1**	0.8	234.9%	2.5	1.5	150.9%
Onon Capsules	1.1	0.7	**1.8**	0.6	49.6%	2.5	(0.4)	(14.2%)
Ongentys Tablets	0.2	0.7	**0.9**	0.9	1,477.7%	2.5	2.2	631.1%
Newly launched products during FY 2021	0.3	0.2	**0.5**	0.5	–	2.5	2.5	–

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecasts for the FY 2021, only currently approved indications are covered.
3. Cumulative results for newly launched products during FY 2021 include sales of Adlumiz Tablets launched in April 2021 and Joyclu Intra-articular Injection launched in May 2021.

Details of Sales Revenue

(Billions of yen)

	Six months ended September 30, 2020	**Six months ended September 30, 2021**
Revenue of goods and products	106.5	**119.2**
Royalty and others	44.0	**54.9**
Total	150.5	**174.1**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥29.2 billion for the second quarter (six months) ended September 30, 2020 and ¥33.9 billion for the second quarter (six months) ended September 30, 2021. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥11.4 billion for the second quarter (six months) ended September 30, 2020 and ¥14.2 billion for the second quarter (six months) ended September 30, 2021.

Revenue by Geographic Area

(Billions of yen)

	Six months ended September 30, 2020	**Six months ended September 30, 2021**
Japan	105.0	**117.6**
Americas	41.3	**50.3**
Asia	3.8	**4.0**
Europe	0.3	**2.2**
Total	150.5	**174.1**

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

Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2022 (IFRS)

Consolidated Financial Forecast

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 Forecast (April 1, 2021 to March 31, 2022)**	YoY
Revenue	309.3	**345.0**	11.5%
Operating profit	98.3	**103.0**	4.7%
Profit before tax	100.9	**105.0**	4.1%
Profit for the year (attributable to owners of the Company)	75.4	**81.5**	8.1%

Details of Revenue (Forecast)

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 Forecast (April 1, 2021 to March 31, 2022)**
Revenue of goods and products	214.5	**240.0**
Royalty and others	94.7	**105.0**
Total	309.3	**345.0**

1. Revenue ¥345.0 billion YoY an increase of ¥35.7 billion (11.5%)

- The severe business environment is expected to continue due to the impact of drug price revisions and the intensifying competition for market share with competing products. Sales of Opdivo Intravenous Infusion are expected to be ¥110.0 billion, an increase of ¥11.2 billion year-on-year, due to its expanded use in first-line treatment for non-small cell lung cancer and treatment of esophageal cancer, and also due to the likelihood of entry into first-line treatment for gastric cancer, despite the intensifying competitive environment. In other main new products, the Company anticipate increases in sales of products that include Forxiga Tablets approved for additional indications of chronic kidney disease, Velexbru Tablets, Braftovi Capsules, Mektovi Tablets and Ongentys Tablets. Furthermore, royalty and others are expected to grow continuously and to increase by ¥10.3 billion (10.8%) year-on-year to ¥105.0 billion. Therefore, revenue is forecasted to be ¥345.0 billion, an increase of ¥35.7 billion (11.5%) year-on-year.

2. Operating profit ¥103.0 billion YoY an increase of ¥4.7 billion (4.7%)

- Cost of sales is forecasted to be ¥95.0 billion, an increase of ¥9.4 billion (11.0%) year-on-year, due to an increase in sales of goods and products.
- Research and development costs are expected to be ¥72.0 billion, an increase of ¥9.6 billion (15.4%) year-on-year, providing for active investments to achieve sustainable growth.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥74.0 billion, an increase of ¥4.8 billion (6.9%) year-on-year, due to an increase in operating expenses pertaining to the launch of new products and additional indications, and also due to active investment to strengthen information infrastructure related to IT and digital technologies.
- Consequently, operating profit is forecasted to be ¥103.0 billion, an increase of ¥4.7 billion (4.7%) year-on-year.

3. Profit before tax ¥105.0 billion YoY an increase of ¥4.1 billion (4.1%)

- Net financial income, etc. is forecasted to be ¥2.0 billion, a decrease of ¥0.6 billion (21.8%) year-on-year.

4. Profit for the year ¥81.5 billion YoY an increase of ¥6.1 billion (8.1%) (attributable to owners of the Company)

- Profit attributable to owners of the Company is forecasted to be ¥81.5 billion, an increase of ¥6.1 billion (8.1%) year-on-year.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 2Q YTD (April 1, 2021 to September 30, 2021)**	**FY 2021 Forecast (April 1, 2021 to March 31, 2022)**
Property, plant, and equipment	9.5	**4.8**	**9.6**
Intangible assets	6.3	**3.9**	**7.9**
Total	15.8	**8.7**	**17.5**
Ratio to sales revenue	5.1%	**5.0%**	**5.0%**

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

(Billions of yen)

	FY 2020 (April 1, 2020 to March 31, 2021)	**FY 2021 2Q YTD (April 1, 2021 to September 30, 2021)**	**FY 2021 Forecast (April 1, 2021 to March 31, 2022)**
Property, plant, and equipment	9.1	**3.6**	**12.9**
Intangible assets	12.6	**5.4**	**13.9**
Total	21.7	**9.0**	**26.8**

Number of Employees (Consolidated)

	FY 2020 2Q (as of September 30, 2020)	FY 2020 (as of March 31, 2021)	**FY 2021 2Q (as of September 30, 2021)**
Number of employees	3,613	3,607	**3,685**

Status of Shares (as of September 30, 2021)

Number of Shares

	As of September 30, 2021
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, 2021
Number of shareholders	73,938

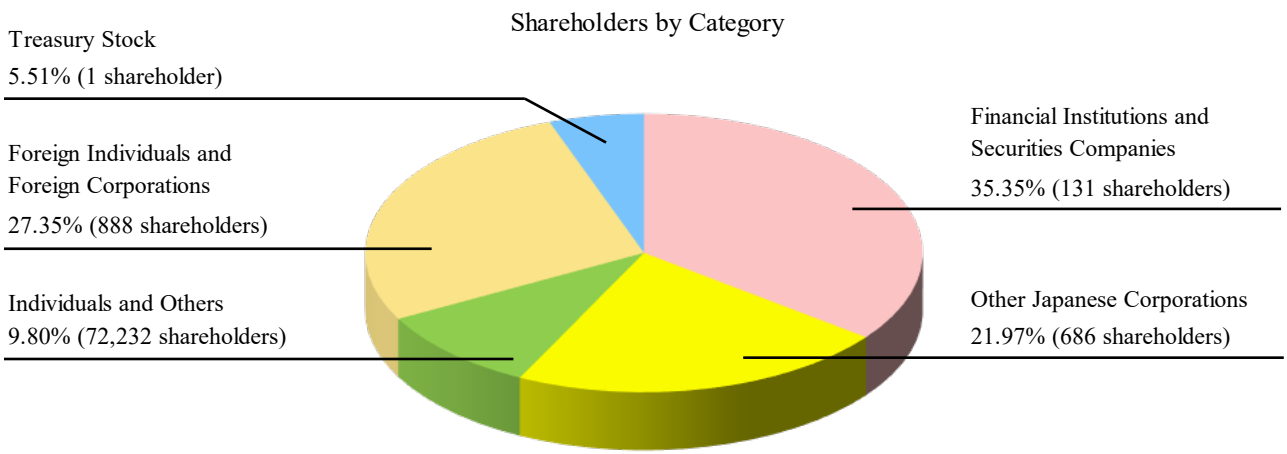
Principal Shareholders

(As of September 30, 2021)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	67,531	13.52
Custody Bank of Japan, Ltd. (Trust account)	28,578	5.72
STATE STREET BANK AND TRUST COMPANY 505001	21,295	4.26
Meiji Yasuda Life Insurance Company	18,594	3.72
Ono Scholarship Foundation	16,428	3.29
KAKUMEISOU Co., LTD.	16,161	3.23
MUFG Bank, Ltd.	8,640	1.73
Aioi Nissay Dowa Insurance Co., Ltd.	8,193	1.64
Custody Bank of Japan, Ltd. (Trust account 7)	7,740	1.55
STATE STREET BANK WEST CLIENT – TREATY 505234	7,388	1.47

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,115 thousand shares of treasury stock.
2. The shareholding percentage is calculated by deducting treasury stock (29,115 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 22, 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	Malignant pleural mesothelioma *1	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Colorectal cancer *2 / BRAF inhibitor	Capsule	S. Korea	In-license (Pfizer Inc.)
Opdivo Intravenous Infusion / Nivolumab	Additional indication for pediatric use	Hodgkin lymphoma *3	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022

*1: An application was approved in Taiwan for combination therapy of Opdivo and Yervoy for the treatment of unresectable malignant pleural mesothelioma.

*2: An application was approved in South Korea for Braftovi Capsules / Encorafenib for use in combination therapy with cetuximab for the treatment of adult patients with advanced or recurrent $BRAF^{V600E}$-mutant colorectal cancer after prior therapy.

*3: An approval for Opdivo was obtained in Japan to expand the use for the treatment of pediatric patients with recurrent or refractory classical hodgkin 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
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Cancer of unknown primary	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★ / Ipilimumab	Additional indication	Esophageal cancer *4	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022

*4: Approval applications were filed in Japan for combination therapy of Opdivo and Yervoy and combination therapy of Opdivo and chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.

<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	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan S. Korea Taiwan	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	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	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	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)
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-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 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / 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
ONO-7913 ★ /Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 ★	New chemical entities	Solid tumor *5 / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)

<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-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 / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 /Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	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.)
	New chemical entities	Myelodysplastic syndromes (MDS) / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-4578	New chemical entities	Hormone receptor-positive, HER2-negative breast cancer[*6] ／PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma[*7] ／PD-1 x CD3 bispecific antibody	Injection	USA	I	In-house

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022
*5: Phase I of combination therapy of Opdivo and ONO-7119 was initiated in Japan for the treatment of solid tumor.
*6: Phase I of ONO-4578 was initiated in Japan for the treatment of hormone receptor-positive, HER2-negative breast cancer.
*7: Phase I of ONO-4685 was initiated in the USA for the treatment of T-cell lymphoma.
* Phase III of Braftovi Capsules and Mektovi Tablets for the treatment of melanoma was discontinued in South Korea due to strategic reasons.
* Phase III of Mektovi Tablets for the treatment of colorectal cancer was discontinued in South Korea due to strategic reasons.

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 22, 2021

<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
Joyclu Intra-articular Injection / ONO-5704 / SI-613	Additional indication	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	II	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe*8	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / S1P5 receptor agonist	Tablet	Japan Europe	I	In-house
ONO-2909	New chemical entities	Narcolepsy / PG receptor (DP1) antagonist	Tablet	Japan	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022

*8: Phase I of ONO-4685 was initiated in Europe for the treatment of autoimmune disease.

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-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 PG receptor (EP4) antagonist being developed for the treatment of colorectal cancer, pancreatic cancer, non-small cell lung cancer, gastric cancer, hormone receptor-positive HER2-negative breast cancer and solid tumor.

Braftovi Capsules (ONO-7702) / Encorafenib (capsule)
Braftovi, a BRAF inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved in Japan and South Korea for the treatment of BRAF-mutant colorectal cancer. In addition, it is being developed for the treatment of BRAF-mutant thyroid cancer.

Mektovi Tablets (ONO-7703) / Binimetinib (tablet)
Mektovi, a MEK inhibitor, has been marketed in Japan for the treatment of melanoma, and an additional indication was later approved for the treatment of BRAF-mutant colorectal cancer. In addition, it is being developed for the treatment of BRAF-mutant thyroid cancer.

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis, a proteasome inhibitor, has been marketed for the treatment of multiple myeloma, and an additional twice-weekly regimen was later made available for a new DKd combination therapy with dexamethasone plus Darzalex (generic name: daratumumab) Intravenous Infusion, a human anti-CD38 monoclonal antibody. 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.

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

ONO-7475 (tablet)
ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia, EGFR-mutated non-small cell lung cancer 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.

ONO-7119
ONO-7119 is a PARP7 inhibitor being developed for the treatment of solid tumor.

Orencia SC (ONO-4164 / BMS-188667) / Abatacept (injection)
Orencia SC is marketed in Japan for use in patients of rheumatoid 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.

Joyclu Intra-articular Injection (ONO-5704 / SI-613) / Diclofenac Etalhyaluronate Sodium (injection)
Joyclu is a hyaluronic acid-NSAID. An application was approved for the treatment of osteoarthritis (knee joint and hip joint). Also, it is being developed for the treatment of enthesopathy.

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

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 disease.

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

ONO-2909 (tablet)
ONO-2909, a PG receptor (DP1) antagonist, is being developed for the treatment of narcolepsy.