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

January 31, 2022

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
Contact	: Yukio Tani Corporate Executive Officer / Head of Corporate Communications
Phone	: +81-(0)6-6263-5670
Scheduled date of quarterly securities report submission	: February 4, 2022
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 2021 (April 1, 2021 to December 31, 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 Q3	271,430	15.5	82,167	(0.0)	84,349	(0.4)	64,669	(2.8)	64,620	(2.8)	68,303	(17.3)
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

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2021 Q3	129.61	129.59
FY 2020 Q3	133.20	133.19

(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, 2021	740,057	666,324	660,667	89.3
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	360,000	16.4	107,000	8.8	109,000	8.0	83,100	10.1	83,000	10.0	166.47

(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, 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 December 31, 2021	34,904,925	shares
As of March 31, 2021	29,199,416	shares

3) Average number of shares outstanding during the period:

Nine months ended December 31, 2021	498,583,112	shares
Nine months ended December 31, 2020	499,135,713	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.

Index of the Attachment

1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 3rd Quarter of FY 2021

(Millions of yen)

	Nine months ended December 31, 2020	**Nine months ended December 31, 2021**	Change	Change (%)
Revenue	234,933	**271,430**	36,497	15.5%
Operating profit	82,189	**82,167**	(22)	(0.0%)
Profit before tax	84,658	**84,349**	(309)	(0.4%)
Profit for the period (attributable to owners of the Company)	66,487	**64,620**	(1,866)	(2.8%)

[Revenue]

Revenue totaled ¥271.4 billion, which was an increase of ¥36.5 billion (15.5%) 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 ¥85.1 billion, an increase of ¥8.7 billion (11.4%) year-on-year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥26.5 billion (59.9% increase year-on-year), sales of Glactiv Tablets for type-2 diabetes were ¥19.3 billion (2.9% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥17.5 billion (4.4% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥6.9 billion (10.1% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥6.5 billion (19.8% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥3.7 billion (14.2% decrease year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥2.3 billion (61.0% decrease year-on-year), respectively.
- Royalty and others increased by ¥16.0 billion (23.0%) year-on-year to ¥85.5 billion.

[Operating profit]

Operating profit was ¥82.2 billion, roughly even year-on-year.

- Cost of sales increased by ¥4.5 billion (6.8%) year-on-year to ¥70.6 billion mainly due to an increase in sales of goods and products.
- Research and development costs increased by ¥5.6 billion (12.8%) year-on-year to ¥49.5 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 ¥9.3 billion (19.2%) year-on-year to ¥57.5 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.
- Other income decreased by ¥6.4 billion year-on-year to ¥0.7 billion, due to the absence of the upfront payment received under the license agreement with Roche in the same period of the previous fiscal year for the patent relating to the anti-PD-L1 antibody.
- Other expenses increased by ¥10.8 billion year-on-year to ¥12.4 billion. The increase is attributable to factors that include the Company having recorded a ¥7.3 billion difference because the total consisting of ¥5.0 billion associated with settlement of litigation on patents relating to the PD-1 antibody and donations of ¥23.0 billion paid to Kyoto University exceeded the provision for royalties on patents of ¥20.7 billion that had already been recorded; along with the Company also having recorded expenses associated with the collaboration agreement relating to Opdivo with Bristol-Myers Squibb Company.

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

Profit attributable to owners of the Company decreased by ¥1.9 billion (2.8%) year-on-year to ¥64.6 billion.

(2) Overview of Financial Position for the 3rd Quarter of FY 2021

(Millions of yen)

	As of March 31, 2021	**As of December 31, 2021**	Change
Total Assets	746,842	**740,057**	(6,785)
Equity attributable to owners of the Company	635,547	**660,667**	25,120
Ratio of equity attributable to owners of the Company to total assets	85.1%	**89.3%**	
Equity attributable to owners of the Company per share	1,273.28 yen	**1,338.91 yen**	

Total assets decreased to ¥740.1 billion by ¥6.8 billion from the end of the previous fiscal year.
Current assets increased by ¥21.0 billion to ¥268.7 billion mainly due to increases in trade and other receivables and other financial assets.
Non-current assets decreased by ¥27.8 billion to ¥471.4 billion mainly due to decreases in other financial assets and investment securities.
Liabilities decreased by ¥32.0 billion to ¥73.7 billion mainly due to decreases in provisions and income taxes payable.

Equity attributable to owners of the Company increased by ¥25.1 billion to ¥660.7 billion mainly due to an increase in retained earnings, despite the purchase of treasury shares.

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

(Millions of yen)

	Nine months ended December 31, 2020	**Nine months ended December 31, 2021**	Change
Cash and cash equivalents at the beginning of the period	69,005	**61,045**	
Cash flows from operating activities	48,032	**27,398**	(20,633)
Cash flows from investing activities	(5,980)	**18,056**	24,035
Cash flows from financing activities	(23,626)	**(44,234)**	(20,608)
Net increase (decrease) in cash and cash equivalents	18,426	**1,220**	
Effects of exchange rate changes on cash and cash equivalents	46	**211**	
Cash and cash equivalents at the end of the period	87,477	**62,476**	

Net increase/decrease in cash and cash equivalents was an increase of ¥1.2 billion.
Net cash provided by operating activities was ¥27.4 billion, as a result of profit before tax of ¥84.3 billion, etc., while income taxes paid amounted to ¥34.2 billion and a decrease in provisions of ¥20.7 billion, etc.
Net cash provided by investing activities was ¥18.1 billion, as a result of proceeds from sales and redemption of investments of ¥16.9 billion, etc.
Net cash used in financing activities was ¥44.2 billion, as a result of dividends paid of ¥26.9 billion and purchases of treasury shares of ¥15.5 billion, etc.

(4) Future outlook

The forecast of consolidated financial results for the fiscal year ending March 31, 2022, as announced on May 13, 2021, has been revised as follows:

Revisions to the forecast of consolidated financial results for the fiscal year ending March 31, 2022
(April 1, 2021 to March 31, 2022)

(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)	345,000	103,000	105,000	81,600	81,500	163.28 yen
Revised forecast (B)	360,000	107,000	109,000	83,100	83,000	166.47 yen
Amount of change (B-A)	15,000	4,000	4,000	1,500	1,500	
Change (%)	4.3	3.9	3.8	1.8	1.8	
(Reference) Consolidated results of FY 2020	309,284	98,330	100,890	75,497	75,425	151.11 yen

Revenue is expected to exceed the previously announced forecast, particularly for major new products such as Forxiga Tablets with additional indication of chronic kidney disease. In addition, royalty revenue is expected to exceed the previously announced forecast due to higher-than-expected royalty revenue and a weaker-than-expected yen. Accordingly, revenue is forecasted to be ¥360.0 billion, an upward revision of ¥15.0 billion from the previously announced forecast.
Cost of sales is forecasted to be ¥93.0 billion, a downward revision of ¥2.0 billion from the previously announced forecast.
The forecast for research and development costs has not changed since the previously announced forecast.
Selling, general, and administrative expenses (except for research and development costs) are forecasted to be ¥77.0 billion, an increase of ¥3.0 billion from the previously announced forecast, anticipating an increase in co-promotion fees associated with expanding sales of Forxiga Tablets and an increase in digital and IT investment.
Other expenses are forecasted to be ¥12.5 billion, an increase of ¥10.5 billion from the previously announced forecast. The increase is attributable to factors that include the Company having recorded a ¥7.3 billion difference because the total consisting of ¥5.0 billion associated with settlement of litigation on patents relating to the PD-1 antibody and donations of ¥23.0 billion paid to Kyoto University exceeded the provision for royalties on patents of ¥20.7 billion that had already been recorded; along with the Company also having recorded expenses associated with the collaboration agreement relating to Opdivo with Bristol-Myers Squibb Company.
As a result, operating profit is forecasted to be ¥107.0 billion (up ¥4.0 billion from the previously announced forecast), profit before tax is forecasted to be ¥109.0 billion (up ¥4.0 billion), profit for the year is forecasted to be ¥83.1 billion (up ¥1.5 billion), and profit attributable to owners of the Company is forecasted to be ¥83.0 billion (up ¥1.5 billion) for the fiscal year ending March 31, 2022.

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, 2021	As of December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	61,045	62,476
Trade and other receivables	84,269	102,197
Marketable securities	2,978	60
Other financial assets	40,952	47,717
Inventories	39,151	39,036
Other current assets	19,246	17,203
Total current assets	247,642	268,690
Non-current assets		
Property, plant, and equipment	113,866	112,515
Intangible assets	70,322	70,255
Investment securities	146,796	137,556
Investments in associates	112	111
Other financial assets	131,888	112,113
Deferred tax assets	33,619	35,058
Retirement benefit assets	7	745
Other non-current assets	2,590	3,013
Total non-current assets	499,200	471,367
Total assets	746,842	740,057

(Millions of yen)

	As of March 31, 2021	As of December 31, 2021
Liabilities and Equity		
Current liabilities		
Trade and other payables	39,163	38,901
Lease liabilities	2,023	2,330
Other financial liabilities	616	3,279
Income taxes payable	19,047	7,220
Provisions	20,721	—
Other current liabilities	12,163	10,168
Total current liabilities	93,733	61,898
Non-current liabilities		
Lease liabilities	7,030	6,767
Other financial liabilities	0	0
Retirement benefit liabilities	3,056	3,219
Deferred tax liabilities	1,052	1,032
Other non-current liabilities	813	817
Total non-current liabilities	11,952	11,835
Total liabilities	105,685	73,733
Equity		
Share capital	17,358	17,358
Capital reserves	17,231	17,231
Treasury shares	(44,705)	(60,134)
Other components of equity	62,299	58,104
Retained earnings	583,363	628,108
Equity attributable to owners of the Company	635,547	660,667
Non-controlling interests	5,610	5,657
Total equity	641,157	666,324
Total liabilities and equity	746,842	740,057

(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, 2020	Nine months ended December 31, 2021
Revenue	234,933	271,430
Cost of sales	(66,151)	(70,634)
Gross profit	168,782	200,796
Selling, general, and administrative expenses	(48,216)	(57,488)
Research and development costs	(43,847)	(49,464)
Other income	7,097	745
Other expenses	(1,628)	(12,422)
Operating profit	82,189	82,167
Finance income	2,594	2,537
Finance costs	(131)	(353)
Share of profit (loss) from investments in associates	6	(2)
Profit before tax	84,658	84,349
Income tax expense	(18,124)	(19,680)
Profit for the period	66,534	64,669
Profit for the period attributable to:		
Owners of the Company	66,487	64,620
Non-controlling interests	47	48
Profit for the period	66,534	64,669
Earnings per share:		
Basic earnings per share (Yen)	133.20	129.61
Diluted earnings per share (Yen)	133.19	129.59

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Profit for the period	66,534	64,669
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	15,199	2,709
Remeasurements of defined benefit plans	899	556
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	0	(0)
Total of items that will not be reclassified to profit or loss	16,098	3,265
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(16)	344
Net fair value gain (loss) on cash flow hedges	(11)	25
Total of items that may be reclassified subsequently to profit or loss	(27)	369
Total other comprehensive income (loss)	16,071	3,634
Total comprehensive income (loss) for the period	82,604	68,303
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	82,560	68,252
Non-controlling interests	44	51
Total comprehensive income (loss) for the period	82,604	68,303

(3) Condensed Interim Consolidated Statement of Changes in Equity

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

Nine months ended December 31, 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					64,620	64,620	48	64,669
Other comprehensive income (loss)				3,631		3,631	2	3,634
Total comprehensive income (loss) for the period	—	—	—	3,631	64,620	68,252	51	68,303
Purchase of treasury shares			(15,460)			(15,460)		(15,460)
Disposition of treasury shares		(31)	31			0		0
Cash dividends					(27,703)	(27,703)	(4)	(27,707)
Share-based payments		31				31		31
Transfer from other components of equity to retained earnings				(7,827)	7,827	—		—
Total transactions with the owners	—	0	(15,429)	(7,827)	(19,876)	(43,132)	(4)	(43,136)
Balance as of December 31, 2021	17,358	17,231	(60,134)	58,104	628,108	660,667	5,657	666,324

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Cash flows from operating activities		
Profit before tax	84,658	84,349
Depreciation and amortization	11,814	13,084
Impairment losses	2,305	345
Interest and dividend income	(2,398)	(2,285)
Interest expense	53	52
(Increase) decrease in inventories	(5,672)	187
(Increase) decrease in trade and other receivables	(11,273)	(17,857)
Increase (decrease) in trade and other payables	1,743	(621)
Increase (decrease) in provisions	—	(20,721)
Increase (decrease) in retirement benefit liabilities	320	129
(Increase) decrease in retirement benefit assets	—	97
Other	(1,828)	2,647
Subtotal	79,722	59,406
Interest received	38	29
Dividends received	2,355	2,265
Interest paid	(53)	(52)
Income taxes paid	(34,030)	(34,250)
Net cash provided by (used in) operating activities	48,032	27,398
Cash flows from investing activities		
Purchases of property, plant, and equipment	(4,525)	(3,928)
Purchases of intangible assets	(10,878)	(6,292)
Purchases of investments	(760)	(848)
Proceeds from sales and redemption of investments	10,105	16,927
Payments into time deposits	(30,736)	(7,267)
Proceeds from withdrawal of time deposits	30,600	20,600
Other	215	(1,137)
Net cash provided by (used in) investing activities	(5,980)	18,056
Cash flows from financing activities		
Dividends paid	(21,757)	(26,861)
Dividends paid to non-controlling interests	(6)	(4)
Repayments of lease liabilities	(1,860)	(1,911)
Purchases of treasury shares	(3)	(15,458)
Net cash provided by (used in) financing activities	(23,626)	(44,234)
Net increase (decrease) in cash and cash equivalents	18,426	1,220
Cash and cash equivalents at the beginning of the period	69,005	61,045
Effects of exchange rate changes on cash and cash equivalents	46	211
Cash and cash equivalents at the end of the period	87,477	62,476

(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

4. Supplementary Information

(1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product Name	Nine months ended December 31, 2021 (April 1, 2021 to December 31, 2021)						FY 2021 Forecast (April 1, 2021 to March 31, 2022)				
	Cumulative				YoY		Previous Forecast	Change from Previous Forecast	**Revised Forecast**	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	29.0	27.1	28.9	**85.1**	8.7	11.4%	110.0		**110.0**	11.2	11.3%
Forxiga Tablets	7.5	8.2	10.9	**26.5**	9.9	59.9%	35.0	1.5	**36.5**	14.1	63.3%
Glactiv Tablets	6.5	6.3	6.6	**19.3**	(0.6)	(2.9%)	24.5		**24.5**	(1.0)	(3.9%)
Orencia for Subcutaneous Injection	5.7	5.5	6.3	**17.5**	0.7	4.4%	22.5		**22.5**	0.6	2.7%
Parsabiv Intravenous Injection	2.2	2.3	2.4	**6.9**	0.6	10.1%	8.0	1.0	**9.0**	0.9	11.8%
Kyprolis for Intravenous Infusion	2.0	2.2	2.3	**6.5**	1.1	19.8%	7.5	1.0	**8.5**	1.4	19.4%
Velexbru Tablets	1.4	1.4	1.8	**4.7**	3.5	289.4%	5.0	1.0	**6.0**	3.9	191.2%
Onoact for Intravenous Infusion	1.2	1.1	1.6	**3.9**	0.3	8.4%	4.0	1.0	**5.0**	0.3	7.3%
Opalmon Tablets	1.2	1.2	1.3	**3.7**	(0.6)	(14.2%)	4.0	1.0	**5.0**	(0.5)	(8.4%)
Rivastach Patches	0.8	0.7	0.8	**2.3**	(3.7)	(61.0%)	3.0		**3.0**	(3.6)	(54.6%)
Braftovi Capsules	0.7	0.7	0.7	**2.1**	1.5	271.0%	3.0		**3.0**	1.9	180.6%
Mektovi Tablets	0.5	0.6	0.6	**1.7**	1.2	210.3%	2.5		**2.5**	1.5	150.9%
Onon Capsules	1.1	0.7	0.9	**2.7**	0.8	39.9%	2.5	1.5	**4.0**	1.1	37.2%
Ongentys Tablets	0.2	0.7	1.1	**2.0**	1.8	955.2%	2.5	0.5	**3.0**	2.7	777.3%
Newly launched products during FY 2021	0.3	0.2	0.3	**0.8**	0.8	—	2.5	(1.5)	**1.0**	1.0	—

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.

(2) Details of Sales Revenue

(Billions of yen)

	Nine months ended December 31, 2020	**Nine months ended December 31, 2021**
Revenue of goods and products	165.4	**185.9**
Royalty and others	69.5	**85.5**
Total	234.9	**271.4**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥44.7 billion for the third quarter (nine months) ended December 31, 2020 and ¥52.1 billion for the third quarter (nine months) ended December 31, 2021. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥17.6 billion for the third quarter (nine months) ended December 31, 2020 and ¥22.4 billion for the third quarter (nine months) ended December 31, 2021.

(3) Revenue by Geographic Area

(Billions of yen)

	Nine months ended December 31, 2020	**Nine months ended December 31, 2021**
Japan	163.4	**183.3**
Americas	63.3	**78.3**
Asia	5.8	**6.4**
Europe	2.5	**3.4**
Total	234.9	**271.4**

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

(4) Main Status of Development Pipelines (Oncology)

As of January 26, 2022

<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
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Cancer of unknown primary *1	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Velexbru Tablets / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma *2 / BTK inhibitor	Tablet	S. Korea	In-house

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2022
*1: An application for Opdivo was approved in Japan for the treatment of cancer of unknown primary.
*2: An application for Velexbru Tablets (BTK inhibitor) was approved in South Korea for the treatment of recurrent or refractory B-cell primary central nervous system 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)
Yervoy Injection ★ / Ipilimumab	Additional indication	Esophageal cancer	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	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 ★ /Atamparib	New chemical entities	Solid tumor /PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-7122 ★	New chemical entities	Solid tumor *3 / TGF-beta inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 ★	New chemical entities	Solid tumor *4 / STING agonist	Injection	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
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 /Magrolimab	New chemical entities	TP53-mutant Acute Myeloid Leukemia *5 / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia *6 / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, 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 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma / PD-1 x CD3 bispecific antibody	Injection	USA	I	In-house

★: Combination with Opdivo.

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

*3: Phase I of TGF-beta inhibitor (ONO-7122) was initiated in Japan for the treatment of solid tumor.

*4: Phase I of STING agonist (ONO-7914) was initiated in Japan for the treatment of solid tumor.

*5: Phase III of anti-CD47 antibody (ONO-7913) was initiated in Japan for the treatment of TP53-mutant acute myeloid leukemia.

*6: Phase III of anti-CD47 antibody (ONO-7913) was initiated in South Korea and Taiwan for the treatment of acute myeloid leukemia.

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 26, 2022

<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
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function *7 / Short-acting selective β_1 blocker	Injection	Japan	In-house

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

*7: An approval application for Onoact for Intravenous Infusion was filed for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

<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
ONO-2017 / Cenobamate	New chemical entities	Primary generalized tonic-clonic seizures *8 / Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
	New chemical entities	Partial-onset seizures *9 / Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
Joyclu Intra-articular Injection / Diclofenac Etalhyaluronate Sodium	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	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 second quarter of the fiscal year ending March 2022

*8: Phase III of inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel (ONO-2017) was initiated for the treatment of primary generalized tonic-clonic seizures.

*9: Phase III of inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel (ONO-2017) is being conducted for the treatment of partial-onset seizures.

* Phase III of T-cell activation inhibitor Orencia SC for the treatment of polymyositis and dermatomyositis was discontinued due to the results not being able to confirm anticipated efficacy.

* ONO-4059 was out-licensed to Gilead Sciences, Inc. in 2014. However, Gilead returned the rights, except for oncology, in all territories it held rights for. The rights for oncology were already returned.