Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2023 (IFRS)

October 31, 2022

Company name	: **ONO PHARMACEUTICAL CO., LTD.**
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: https://www.ono-pharma.com/en
Representative	: Gyo Sagara President, Representative Director, and Chief Executive Officer
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Phone	: +81-(0)6-6263-5670
Scheduled date of quarterly securities report submission	: November 4, 2022
Scheduled date of dividend payment commencement	: December 1, 2022
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 2022 (April 1, 2022 to September 30, 2022)

(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 2022 Q2	216,701	24.5	80,270	38.0	81,019	36.8	62,442	34.8	62,339	34.7	62,263	19.2
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)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2022 Q2	127.67	127.66
FY 2021 Q2	92.74	92.73

(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, 2022	805,008	710,375	704,518	87.5
As of March 31, 2022	739,203	661,674	655,906	88.7

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 2021	—	28.00	—	28.00	56.00
FY 2022	—	33.00			
FY 2022 (Forecast)			—	33.00	66.00

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

3. Consolidated Financial Forecast for FY 2022 (April 1, 2022 to March 31, 2023)

(% 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 2022	440,000	21.8	149,000	44.4	150,000	42.8	114,200	41.5	114,000	41.6	233.47

(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 September 30, 2022	517,425,200	shares
As of March 31, 2022	528,341,400	shares

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

As of September 30, 2022	29,091,133	shares
As of March 31, 2022	40,096,713	shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2022	488,277,710	shares
Six months ended September 30, 2021	499,153,142	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 consolidated financial forecasts.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of FY 2022

(Millions of yen)

	Six months ended September 30, 2021	**Six months ended September 30, 2022**	Change	Change (%)
Revenue	174,077	**216,701**	42,624	24.5%
Operating profit	58,171	**80,270**	22,099	38.0%
Profit before tax	59,231	**81,019**	21,788	36.8%
Profit for the period (attributable to owners of the Company)	46,290	**62,339**	16,049	34.7%

[Revenue]

Revenue totaled ¥216.7 billion, which was an increase of ¥42.6 billion (24.5%) 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 mainly to gastric cancer and esophageal cancer, resulting in sales of ¥69.9 billion, an increase of ¥13.8 billion (24.6%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥26.4 billion (68.8% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥12.5 billion (11.0% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥11.7 billion (8.0% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.4 billion (6.5% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.3 billion (5.3% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥4.1 billion (43.4% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥2.4 billion.
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥2.3 billion (5.9% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥1.2 billion (35.3% decrease year on year).
- Royalty and others increased by ¥16.9 billion (30.8%) year on year to ¥71.8 billion.

[Operating profit]

Operating profit was ¥80.3 billion, an increase of ¥22.1 billion (38.0%) year on year.

- Cost of sales increased by ¥8.1 billion (17.9%) year on year to ¥53.7 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥7.1 billion (21.7%) year on year to ¥39.6 billion mainly due to increases in research costs and development costs for early clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥5.3 billion (14.0%) year on year to ¥42.9 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.

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

Profit attributable to owners of the Company increased by ¥16.0 billion (34.7%) year on year to ¥62.3 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 etc., and development is proceeding. Among these, the area of cancer treatment is positioned as an important strategic field because 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 extensively investigate biology of human disease in the respective domains, and make efforts to enhance our drug discovery capabilities aiming to discover and develop new drugs that meet medical needs. To that end, by actively promoting our strategy of “Open Innovation,” which is one of our strengths, we are finding 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 and outside the company, in fields such as informatics, human disease modeling, and synthesis of new drug candidate compounds.

A total of eight new drug candidate compounds in our priority therapeutic areas have proceeded to the clinical stage, and we are also continuing 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 informatics and research tools such as human genome data and human iPS cells in the early stages of research, we analyze the relationship between target molecules and diseases and make efforts to find physiological indicators (biomarkers) to predict and evaluate the efficacy of new drug candidate compounds in humans more accurately.

In order to boost development speed and success rates, we are working on initiatives to improve the accuracy of efficacy and safety predictions by using accumulated clinical trial data. Moreover, to maximize the value of new drug candidate compounds, we will collaborate with the Discovery & Research from the research stage and begin drawing up development strategies early on, with the aim of commencing early clinical trials for multiple diseases. By working to enhance our clinical development functions in Europe and the USA, we will build a framework that enables early clinical trials to be implemented flexibly in Japan, the USA, and Europe.

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, 2022 (including those on and after September 30, 2022) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

“Opdivo / Nivolumab”

Non-small cell lung cancer

- In April 2022, an approval application was filed in Japan for the neoadjuvant treatment of resectable non-small cell lung cancer in combination therapy with chemotherapy.

Renal cell carcinoma

- In May 2022, an application was approved in Taiwan for the treatment of untreated advanced renal cell carcinoma in combination therapy with Cabometyx tablets / Cabozantinib s-malate, a tyrosine kinase inhibitor of Takeda Pharmaceutical Company Limited.

Esophageal cancer

- In May 2022, applications were approved in Japan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.
- In July 2022, applications were approved in Taiwan for combination therapy with Yervoy and combination therapy with chemotherapy for the treatment of advanced or metastatic esophageal squamous cell carcinoma.

Urothelial carcinoma / Bladder cancer

- In April 2022, an application was approved in Taiwan for the adjuvant treatment in patients with muscle-invasive urothelial carcinoma at a high risk of recurrence after radical surgery.

Biliary tract cancer

- In April 2022, phase II for the treatment of biliary tract cancer was conducted in Japan, but the project was removed from the development pipeline as the application was abandoned due to strategic reasons.

Pancreatic cancer

- In July 2022, phase II of Opdivo for the treatment of pancreatic cancer was conducted in Japan, but the project was discontinued.

Virus positive / negative solid carcinoma

- In July 2022, phase I / II of combination therapy with Opdivo and Yervoy for the treatment of virus positive / negative solid carcinoma was conducted in Japan, South Korea and Taiwan, but the project was discontinued due to strategic reasons.

“ONO-7018”

- In August 2022, phase I of ONO-7018 (MALT1 inhibitor) was initiated in the USA for the treatment of non-Hodgkin lymphoma or chronic lymphocytic leukemia.

"ONO-7911"

- In April 2022, phase I of combination therapy with Opdivo and ONO-7911 (PEGylated IL-2) for the treatment of solid tumor was conducted in Japan, but the project was discontinued due to strategic reasons.

"ONO-7475"

- In September 2022, phase I / II of ONO-7475 (Axl / Mer inhibitor) for the treatment of acute leukemia was conducted in the USA, but the project was discontinued due to strategic reasons.

<Areas other than Oncology>

"Onoact for Intravenous Infusion / Landiolol Hydrochloride"

- In August 2022, an application for Onoact for Intravenous Infusion (a short-acting selective β_1 blocker) was approved in Japan for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

"Velexbru Tablets / Tirabrutinib Hydrochloride / ONO-4059"

- In April 2022, phase III of Velexbru Tablets (BTK inhibitor) was initiated in Japan for the treatment of pemphigus.

"ONO-2020"

- In July 2022, phase I of ONO-2020 (Epigenetic Regulation) was initiated in the USA for the treatment of neurodegenerative disease.

"ONO-2909"

- In October 2022, phase I of ONO-2909 (Prostaglandin receptor (DP1) antagonist) for the treatment of narcolepsy was conducted in Japan, but the project was discontinued due to the results not being able to confirm anticipated efficacy.

[Status of Drug Discovery / Research Alliance Activities]

- In April 2022, the Company entered into a drug discovery collaboration agreement with Domain Therapeutics S.A. in France and Université de Montréal in Canada to discover novel small molecules against a G-Protein Coupled Receptor (GPCR) selected as therapeutic target by the Company in a metabolic disease area, utilizing their unique GPCR drug discovery platform and expertise in medicinal chemistry and pharmacology for GPCR drug discovery.
- In June 2022, the Company entered into an agreement to expand the drug discovery collaboration agreement with Fate Therapeutics, Inc. in the USA for the discovery of iPSC-derived chimeric antigen receptor (CAR)-T cell therapies signed in September 2018, to include the discovery of iPSC-derived chimeric antigen receptor (CAR)-NK cell therapies.
- In August 2022, the Company entered into an agreement to expand the research collaboration with Knowledge Palette, Inc., aiming to build a data-driven new drug discovery platform using Knowledge Palette's large-scale transcriptome analysis technology.

(2) Overview of Financial Position for the 2nd Quarter of FY 2022

(Millions of yen)

	As of March 31, 2022	**As of September 30, 2022**	Change
Total Assets	739,203	**805,008**	65,804
Equity attributable to owners of the Company	655,906	**704,518**	48,611
Ratio of equity attributable to owners of the Company to total assets	88.7%	**87.5%**	
Equity attributable to owners of the Company per share	1,343.40 yen	**1,442.73 yen**	

Total assets increased to ¥805.0 billion by ¥65.8 billion from the end of the previous fiscal year.
Current assets increased by ¥57.9 billion to ¥339.2 billion mainly due to increases in cash and cash equivalents and other financial assets.
Non-current assets increased by ¥7.9 billion to ¥465.8 billion mainly due to an increase in other financial assets, while decreases in investment securities and intangible assets.
Liabilities increased by ¥17.1 billion to ¥94.6 billion mainly due to an increase in income taxes payable.
Equity attributable to owners of the Company increased by ¥48.6 billion to ¥704.5 billion mainly due to the recording of the profit for the period despite there being cash dividends.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2022

(Millions of yen)

	Six months ended September 30, 2021	**Six months ended September 30, 2022**	Change
Cash and cash equivalents at the beginning of the period	61,045	**69,112**	
Cash flows from operating activities	40,369	**80,977**	40,607
Cash flows from investing activities	(5,385)	**(37,925)**	(32,540)
Cash flows from financing activities	(14,968)	**(15,065)**	(97)
Net increase (decrease) in cash and cash equivalents	20,016	**27,987**	
Effects of exchange rate changes on cash and cash equivalents	56	**653**	
Cash and cash equivalents at the end of the period	81,117	**97,752**	

Net increase / decrease in cash and cash equivalents for the second quarter (six months) of the fiscal year 2022 was an increase of ¥28.0 billion.
Net cash provided by operating activities was ¥81.0 billion, as a result of profit before tax of ¥81.0 billion, etc., while an increase in trade and other receivables of ¥11.7 billion, etc.
Net cash used in investing activities was ¥37.9 billion, as a result of payments into time deposits of ¥50.1 billion, while proceeds from withdrawal of time deposits of ¥12.1 billion, etc.
Net cash used in financing activities was ¥15.1 billion, as a result of dividends paid of ¥13.7 billion, etc.

(4) Future Outlook

The forecast of consolidated financial results for the fiscal year ending March 31, 2023, as announced on May 11, 2022, has been revised as follows:

Revisions to the forecast of consolidated financial results for the fiscal year ending March 31, 2023
(April 1, 2022 to March 31, 2023)

(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)	425,000	145,000	146,000	110,100	110,000	225.30 yen
Revised forecast (B)	440,000	149,000	150,000	114,200	114,000	233.47 yen
Change (B-A)	15,000	4,000	4,000	4,100	4,000	
Change (%)	3.5%	2.8%	2.7%	3.7%	3.6%	
(Reference) Consolidated results of FY 2021	361,361	103,195	105,025	80,684	80,519	162.19 yen

Note: The previous forecast was based on an assumed foreign exchange rate of 1 USD=110 yen, which has been revised to 1 USD =130 yen in the revised forecast for the second half.

Revenue is expected to exceed the previously announced forecast mainly due to a weaker-than-expected yen exchange rate in the royalty revenue. Accordingly, revenue is forecasted to be ¥440.0 billion, an upward revision of ¥15.0 billion from the previously announced forecast.
Cost of sales is forecasted to be ¥109.0 billion, an upward revision of ¥5.0 billion from the previously announced forecast.
Research and development costs are forecasted to be ¥91.0 billion, an upward revision of ¥4.0 billion from the previously announced forecast, mainly due to the effect of foreign exchange rates, etc.
Selling, general, and administrative expenses (except for research and development costs) are forecasted to be ¥90.0 billion, an upward revision of ¥2.0 billion from the previously announced forecast, anticipating an increase in digital and IT investments.
As a result, operating profit is forecasted to be ¥149.0 billion (up ¥4.0 billion from the previously announced forecast). Profit before tax is forecasted to be ¥150.0 billion (up ¥4.0 billion). Profit for the year is forecasted to be ¥114.2 billion (up ¥4.1 billion). Profit attributable to owners of the Company is forecasted to be ¥114.0 billion (up ¥4.0 billion) for the fiscal year ending March 31, 2023.

Note: The financial forecasts and statements contained in this announcement are prepared 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 Statements of Financial Position

(Millions of yen)

	As of March 31, 2022	As of September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	69,112	97,752
Trade and other receivables	99,788	111,545
Marketable securities	60	20
Other financial assets	47,797	66,009
Inventories	41,817	43,887
Other current assets	22,692	19,963
Total current assets	281,266	339,176
Non-current assets		
Property, plant, and equipment	112,131	109,119
Intangible assets	64,734	61,614
Investment securities	125,046	117,445
Investments in associates	108	112
Other financial assets	127,302	147,209
Deferred tax assets	25,074	26,813
Retirement benefit assets	377	348
Other non-current assets	3,165	3,172
Total non-current assets	457,937	465,831
Total assets	739,203	805,008

(Millions of yen)

	As of March 31, 2022	As of September 30, 2022
Liabilities and Equity		
Current liabilities		
Trade and other payables	49,689	46,518
Lease liabilities	2,301	2,205
Other financial liabilities	716	881
Income taxes payable	1,526	19,978
Other current liabilities	11,694	13,828
Total current liabilities	65,926	83,409
Non-current liabilities		
Lease liabilities	6,501	6,081
Other financial liabilities	0	0
Retirement benefit liabilities	3,322	3,429
Deferred tax liabilities	1,009	1,005
Other non-current liabilities	771	707
Total non-current liabilities	11,603	11,223
Total liabilities	77,529	94,632
Equity		
Share capital	17,358	17,358
Capital reserves	17,241	17,080
Treasury shares	(74,683)	(54,161)
Other components of equity	51,236	48,841
Retained earnings	644,754	675,400
Equity attributable to owners of the Company	655,906	704,518
Non-controlling interests	5,768	5,858
Total equity	661,674	710,375
Total liabilities and equity	739,203	805,008

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

Condensed Interim Consolidated Statements of Income

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Revenue	174,077	216,701
Cost of sales	(45,567)	(53,712)
Gross profit	128,510	162,990
Selling, general, and administrative expenses	(37,656)	(42,945)
Research and development costs	(32,552)	(39,628)
Other income	669	457
Other expenses	(800)	(602)
Operating profit	58,171	80,270
Finance income	1,422	1,224
Finance costs	(361)	(478)
Share of profit (loss) from investments in associates	(2)	3
Profit before tax	59,231	81,019
Income tax expense	(12,897)	(18,577)
Profit for the period	46,334	62,442
Profit for the period attributable to:		
Owners of the Company	46,290	62,339
Non-controlling interests	43	103
Profit for the period	46,334	62,442
Earnings per share:		
Basic earnings per share (Yen)	92.74	127.67
Diluted earnings per share (Yen)	92.73	127.66

Condensed Interim Consolidated Statements of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Profit for the period	46,334	62,442
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	5,524	(1,394)
Remeasurements of defined benefit plans	324	(26)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	1	1
Total of items that will not be reclassified to profit or loss	5,849	(1,418)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	70	1,206
Net fair value gain (loss) on cash flow hedges	—	32
Total of items that may be reclassified subsequently to profit or loss	70	1,239
Total other comprehensive income (loss)	5,918	(180)
Total comprehensive income (loss) for the period	52,252	62,263
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	52,208	62,166
Non-controlling interests	44	96
Total comprehensive income (loss) for the period	52,252	62,263

(3) Condensed Interim Consolidated Statements of Changes in Equity

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	581,950	634,133	5,610	639,743
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	616,256	672,634	5,650	678,285

Six months ended September 30, 2022

(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, 2022	17,358	17,241	(74,683)	51,236	644,754	655,906	5,768	661,674
Profit for the period					62,339	62,339	103	62,442
Other comprehensive income (loss)				(173)		(173)	(7)	(180)
Total comprehensive income (loss) for the period	—	—	—	(173)	62,339	62,166	96	62,263
Purchase of treasury shares			(2)			(2)		(2)
Retirement of treasury shares		(20,356)	20,356			—		—
Disposition of treasury shares		(168)	168			—		—
Cash dividends					(13,671)	(13,671)	(6)	(13,677)
Share-based payments		118				118		118
Transfer from retained earnings to capital reserves		20,245			(20,245)	—		—
Transfer from other components of equity to retained earnings				(2,223)	2,223	—		—
Total transactions with the owners	—	(161)	20,522	(2,223)	(31,693)	(13,555)	(6)	(13,562)
Balance as of September 30, 2022	17,358	17,080	(54,161)	48,841	675,400	704,518	5,858	710,375

(4) Condensed Interim Consolidated Statements of Cash Flows

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Cash flows from operating activities		
Profit before tax	59,231	81,019
Depreciation and amortization	8,686	8,629
Impairment losses	124	–
Interest and dividend income	(1,177)	(1,218)
Interest expense	35	32
(Increase) decrease in inventories	577	(2,024)
(Increase) decrease in trade and other receivables	(5,375)	(11,671)
Increase (decrease) in trade and other payables	(6,523)	45
Increase (decrease) in retirement benefit liabilities	115	81
(Increase) decrease in retirement benefit assets	65	18
Other	1,587	3,967
Subtotal	57,345	78,878
Interest received	25	22
Dividends received	1,157	1,206
Interest paid	(35)	(32)
Income taxes refund (paid)	(18,124)	904
Net cash provided by (used in) operating activities	40,369	80,977
Cash flows from investing activities		
Purchases of property, plant, and equipment	(3,045)	(3,267)
Purchases of intangible assets	(5,587)	(2,138)
Purchases of investments	(382)	(1,143)
Proceeds from sales and redemption of investments	6,407	7,062
Payments into time deposits	(6,847)	(50,100)
Proceeds from withdrawal of time deposits	5,200	12,110
Other	(1,130)	(450)
Net cash provided by (used in) investing activities	(5,385)	(37,925)
Cash flows from financing activities		
Dividends paid	(13,707)	(13,650)
Dividends paid to non-controlling interests	(4)	(6)
Repayments of lease liabilities	(1,256)	(1,407)
Purchases of treasury shares	(0)	(1)
Net cash provided by (used in) financing activities	(14,968)	(15,065)
Net increase (decrease) in cash and cash equivalents	20,016	27,987
Cash and cash equivalents at the beginning of the period	61,045	69,112
Effects of exchange rate changes on cash and cash equivalents	56	653
Cash and cash equivalents at the end of the period	81,117	97,752

(5) Notes to Condensed Interim Consolidated Financial Statements

(Note Regarding Assumption of 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 2022 (Ending March 31, 2023)
(April 1, 2022 to September 30, 2022)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【Consolidated Financial Results for the 2nd Quarter of Fiscal Year 2022 (Ending March 31, 2023) (IFRS)】

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

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2022 (IFRS)

(Billions of yen)

	Six months ended September 30, 2021	**Six months ended September 30, 2022**	YoY	Full year ended March 31, 2022
Revenue	174.1	**216.7**	24.5%	361.4
Operating profit	58.2	**80.3**	38.0%	103.2
Profit before tax	59.2	**81.0**	36.8%	105.0
Profit for the period (attributable to owners of the Company)	46.3	**62.3**	34.7%	80.5

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

1. Revenue ¥216.7 billion YoY an increase of 24.5% (FY 2021 2Q YTD ¥174.1 billion)

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded mainly to gastric cancer and esophageal cancer, resulting in sales of ¥69.9 billion, an increase of ¥13.8 billion (24.6%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥26.4 billion (68.8% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥12.5 billion (11.0% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥11.7 billion (8.0% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.4 billion (6.5% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.3 billion (5.3% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥4.1 billion (43.4% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥2.4 billion.
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥2.3 billion (5.9% decrease year on year), and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥1.2 billion (35.3% decrease year on year).
- Royalty and others increased by ¥16.9 billion (30.8%) year on year to ¥71.8 billion.

2. Operating profit ¥80.3 billion YoY an increase of 38.0% (FY 2021 2Q YTD ¥58.2 billion)

- Operating profit was ¥80.3 billion, an increase of ¥22.1 billion (38.0%) year on year.
- Cost of sales increased by ¥8.1 billion (17.9%) year on year to ¥53.7 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥7.1 billion (21.7%) year on year to ¥39.6 billion mainly due to increases in research costs and development costs for early clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥5.3 billion (14.0%) year on year to ¥42.9 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.

3. Profit before tax ¥81.0 billion YoY an increase of 36.8% (FY 2021 2Q YTD ¥59.2 billion)

- Net financial income, etc. was ¥0.7 billion, a decrease of ¥0.3 billion (29.3%) year on year.

4. Profit for the period ¥62.3 billion YoY an increase of 34.7% (FY 2021 2Q YTD ¥46.3 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥16.0 billion (34.7%) year on year to ¥62.3 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, 2022 (April 1, 2022 to September 30, 2022)					FY 2022 Forecast (April 1, 2022 to March 31, 2023)		
	Cumulative			YoY		Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	34.1	35.8	**69.9**	13.8	24.6%	**155.0**	42.6	37.8%
Forxiga Tablets	13.1	13.3	**26.4**	10.8	68.8%	**47.0**	10.3	28.2%
Orencia for Subcutaneous Injection	6.2	6.2	**12.5**	1.2	11.0%	**23.0**	0.1	0.5%
Glactiv Tablets	6.0	5.7	**11.7**	(1.0)	(8.0%)	**23.0**	(1.5)	(6.3%)
Kyprolis for Intravenous Infusion	2.2	2.2	**4.4**	0.3	6.5%	**9.0**	0.6	7.6%
Parsabiv Intravenous Injection	2.1	2.1	**4.3**	(0.2)	(5.3%)	**8.0**	(0.9)	(9.9%)
Velexbru Tablets	2.1	2.0	**4.1**	1.2	43.4%	**7.0**	0.7	11.7%
Ongentys Tablets	1.2	1.2	**2.4**	1.5	156.1%	**5.0**	2.1	73.6%
Onoact for Intravenous Infusion	1.1	1.0	**2.1**	(0.2)	(9.6%)	**4.5**	(0.4)	(7.6%)
Opalmon Tablets	1.1	1.1	**2.3**	(0.1)	(5.9%)	**3.5**	(1.2)	(26.0%)
Braftovi Capsules	0.9	0.8	**1.6**	0.3	21.8%	**3.5**	0.8	27.4%
Mektovi Tablets	0.7	0.6	**1.3**	0.2	17.5%	**2.5**	0.3	11.7%
Onon Capsules	0.7	0.5	**1.2**	(0.6)	(35.3%)	**2.5**	(1.1)	(29.7%)

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecasts for the FY 2022, only currently approved indications are covered.

Details of Sales Revenue

(Billions of yen)

	Six months ended September 30, 2021	**Six months ended September 30, 2022**
Revenue of goods and products	119.2	**144.9**
Royalty and others	54.9	**71.8**
Total	174.1	**216.7**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥33.9 billion for the second quarter (six months) ended September 30, 2021 and ¥42.1 billion for the second quarter (six months) ended September 30, 2022. In addition, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥14.2 billion for the second quarter (six months) ended September 30, 2021 and ¥21.4 billion for the second quarter (six months) ended September 30, 2022.

Revenue by Geographic Area

(Billions of yen)

	Six months ended September 30, 2021	**Six months ended September 30, 2022**
Japan	117.6	**141.9**
Americas	50.3	**66.5**
Asia	4.0	**5.5**
Europe	2.2	**2.9**
Total	174.1	**216.7**

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, 2023 (IFRS)

Consolidated Financial Forecast

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 Forecast (April 1, 2022 to March 31, 2023)**	YoY
Revenue	361.4	**440.0**	21.8%
Operating profit	103.2	**149.0**	44.4%
Profit before tax	105.0	**150.0**	42.8%
Profit for the year (attributable to owners of the Company)	80.5	**114.0**	41.6%

Details of Revenue (Forecast)

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 Forecast (April 1, 2022 to March 31, 2023)**
Revenue of goods and products	246.0	**290.0**
Royalty and others	115.4	**150.0**
Total	361.4	**440.0**

1. Revenue ¥440.0 billion YoY an increase of ¥78.6 billion (21.8%)

- Revenue of goods and products are expected to be ¥290.0 billion, an increase of ¥44.0 billion (17.9%) year on year. Sales of Opdivo Intravenous Infusion, one of the new main products, are expected to be ¥155.0 billion, an increase of ¥42.6 billion year on year mainly due to its expanded use in treatment of gastric cancer and esophageal cancer, despite the intensifying competitive environment. In other main new products, the Company anticipates increases in sales of products that include Forxiga Tablets approved for additional indications of chronic kidney disease last year, Velexbru Tablets, and Ongentys Tablets. Furthermore, royalty and others are expected to increase by ¥34.6 billion (30.0%) year on year to ¥150.0 billion, anticipating that royalty revenue would grow continuously with the positive effect of the yen's weakening. Therefore, revenue is expected to be ¥440.0 billion, an increase of ¥78.6 billion (21.8%) year on year.

2. Operating profit ¥149.0 billion YoY an increase of ¥45.8 billion (44.4%)

- Cost of sales is forecasted to be ¥109.0 billion, an increase of ¥15.5 billion (16.6%) year on year, due to an increase in revenue of goods and products, etc.
- Research and development costs are expected to be ¥91.0 billion, an increase of ¥15.1 billion (19.9%) year on year, providing for active investments to achieve sustainable growth, such as further expansion of joint research projects with academic institutions and advanced companies having the latest technologies and themes, global development trials, and joint development, etc., in addition to the effect of foreign exchange rates.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥90.0 billion, an increase of ¥12.9 billion (16.8%) year on year, due to an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, and active investments in information infrastructure related to IT and digital technologies and global business in the USA, etc.
- Other expenses are expected to be ¥1.5 billion, a decrease of ¥11.2 billion year on year, due in part to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody recorded in the fiscal year ended March 2022, etc.

  Consequently, operating profit is forecasted to be ¥149.0 billion, an increase of ¥45.8 billion (44.4%) year on year.

3. Profit before tax ¥150.0 billion YoY an increase of ¥45.0 billion (42.8%)

- Net financial income, etc. is forecasted to be ¥1.0 billion, a decrease of ¥0.8 billion (45.3%) year on year.

4. Profit for the year ¥114.0 billion YoY an increase of ¥33.5 billion (41.6%) (attributable to owners of the Company)

- Profit attributable to owners of the Company is forecasted to be ¥114.0 billion, an increase of ¥33.5 billion (41.6%) year on year.

Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets

Depreciation and Amortization

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 2Q YTD (April 1, 2022 to September 30, 2022)**	**FY 2022 Forecast (April 1, 2022 to March 31, 2023)**
Property, plant, and equipment	9.9	**4.9**	**9.7**
Intangible assets	7.8	**3.8**	**7.6**
Total	17.7	**8.6**	**17.3**
Ratio to sales revenue	4.9%	**4.0%**	**3.9%**

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

(Billions of yen)

	FY 2021 (April 1, 2021 to March 31, 2022)	**FY 2022 2Q YTD (April 1, 2022 to September 30, 2022)**	**FY 2022 Forecast (April 1, 2022 to March 31, 2023)**
Property, plant, and equipment	9.3	**1.7**	**7.5**
Intangible assets	7.2	**1.0**	**11.0**
Total	16.5	**2.7**	**18.5**

Number of Employees (Consolidated)

	FY 2021 2Q (as of September 30, 2021)	FY 2021 (as of March 31, 2022)	**FY 2022 2Q (as of September 30, 2022)**
Number of employees	3,685	3,687	**3,765**

Status of Shares (as of September 30, 2022)

Number of Shares

	As of September 30, 2022
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	517,425,200

Number of Shareholders

	As of September 30, 2022
Number of shareholders	58,246

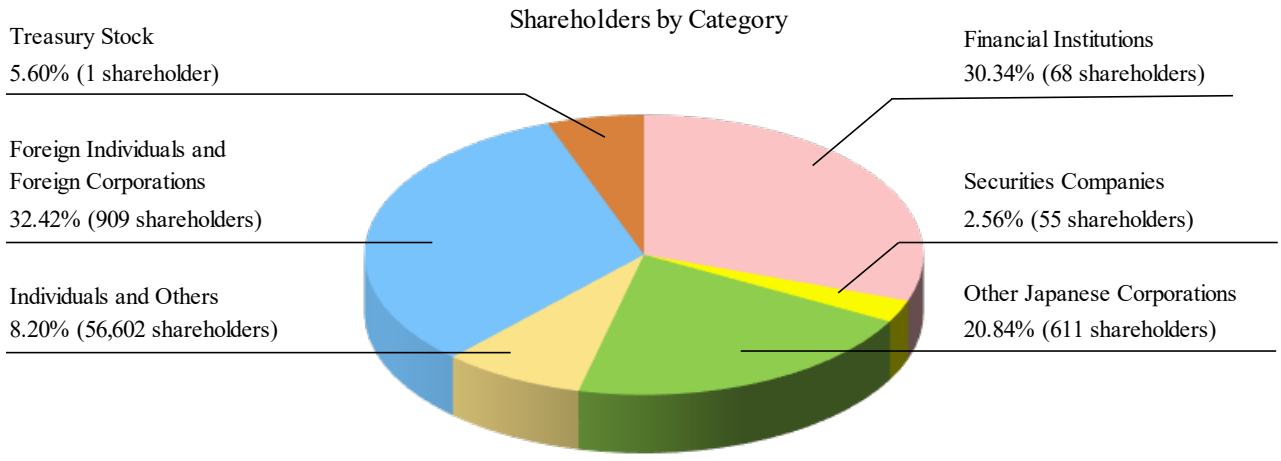
Principal Shareholders

(As of September 30, 2022)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	67,401	13.80
Custody Bank of Japan, Ltd. (Trust account)	25,225	5.16
STATE STREET BANK AND TRUST COMPANY 505001	21,704	4.44
Meiji Yasuda Life Insurance Company	18,594	3.80
Ono Scholarship Foundation	16,428	3.36
KAKUMEISOU Co., LTD.	16,161	3.30
STATE STREET BANK WEST CLIENT – TREATY 505234	8,986	1.84
MUFG Bank, Ltd.	8,640	1.76
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.59
NORTHERN TRUST CO. (AVFC) SUB A/C NON TREATY	7,098	1.45

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,025 thousand shares of treasury stock.
2. The shareholding percentage is calculated by deducting treasury stock (29,025 thousand shares).

Ownership and Distribution of Shares



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

I. Main Status of Development Pipelines (Oncology)

As of October 24, 2022

<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)

<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	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial carcinoma	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)

<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-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-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578 ★	New chemical entities	Colorectal cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor・Gastric cancer / Prostaglandin 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.)
ONO-7122 ★	New chemical entities	Solid tumor / TGF-β inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 ★	New chemical entities	Solid tumor / 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-7913 / Magrolimab	New chemical entities	TP53-mutant acute myeloid leukemia / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia / 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	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
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 / Prostaglandin 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
ONO-7018 *1	New chemical entities	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia / MALT1 inhibitor	Tablet	USA	I	In-license (Chordia Therapeutics Inc.)

★: Combination with Opdivo.

The changes from the announcement of financial results for the first quarter of the fiscal year ending March 2023 are as follows:

*1: Phase I of ONO-7018, MALT1 inhibitor, was initiated in the USA for the treatment of non-Hodgkin lymphoma or chronic lymphocytic leukemia.

* Phase II of Opdivo for the treatment of pancreatic cancer was conducted in Japan, but the project was discontinued.

* Phase I/II of combination therapy with Opdivo and Yervoy for the treatment of virus positive / negative solid carcinoma was conducted in Japan, South Korea and Taiwan, but the project was discontinued due to strategic reasons.

* Phase I/II of ONO-7475, Axl / Mer inhibitor, for the treatment of acute leukemia was conducted in the USA, but the project was discontinued 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 24, 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
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function*2 / Short-acting selective β_1 blocker	Injection	Japan	In-house

The change from the announcement of financial results for the first quarter of the fiscal year ending March 2023 is as follows:

*2: An application of Onoact for Intravenous Infusion, short-acting selective β_1 blocker, was approved in Japan 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 / 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 / Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	III	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
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house

The change from the announcement of financial results for the first quarter of the fiscal year ending March 2023 is as follows:

*Phase I of ONO-2909, Prostaglandin receptor (DP1) antagonist, for the treatment of narcolepsy was conducted in Japan, but the project was discontinued due to the results not being able to confirm anticipated efficacy.

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 mainly for the treatment of cancer. PD-1 (programmed death-1), one of the receptors expressed on the surface of activated lymphocytes, plays a role in a regulatory pathway that suppresses activated lymphocytes in the body (negative signal). Available evidence suggests that cancer cells exploit this pathway to escape from immune responses. Opdivo is thought to provide benefit by blocking PD-1-mediated negative regulation of lymphocytes, thereby enhancing the ability of the immune system to recognize cancer cells as foreign and eliminate them.
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-4578 (tablet)
ONO-4578, a Prostaglandin receptor (EP4) antagonist, is 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 untreated BRAF-mutant colorectal cancer. Also, it is being developed in Japan 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 in Japan 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.

Velexbru Tablets (ONO-4059) / Tirabrutinib (tablet)
Velexbru, a BTK inhibitor, has been marketed in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma, and additional indications were later approved for the treatment of waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma. After that, applications were approved in South Korea and Taiwan for the treatment of recurrent or refractory B-cell primary central nervous system lymphoma. Furthermore, it is being developed in the USA for the treatment of primary central nervous system lymphoma. Also, it is being developed in Japan for the treatment of pemphigus and systemic sclerosis.

ONO-7475 (tablet)
ONO-7475, Axl/Mer inhibitor, is being developed in Japan for the treatment of EGFR-mutated non-small cell lung cancer and solid tumor.

ONO-7913 / Magrolimab (injection)
ONO-7913, an anti-CD47 antibody, is being developed in Japan for the treatment of pancreatic cancer, colorectal cancer, TP53-mutant acute myeloid leukemia, solid tumor and myelodysplastic syndromes (MDS). In addition, it is being developed in South Korea and Taiwan for the treatment of acute myeloid leukemia.

ONO-7119 / Atamparib
ONO-7119, PARP7 inhibitor, is being developed in Japan for the treatment of solid tumor.

ONO-7122 (injection)
ONO-7122, a TGF-β inhibitor, is being developed in Japan 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-7914 (injection)
ONO-7914, STING agonist, is being developed in Japan for the treatment of solid tumor.

ONO-4685 (injection)

ONO-4685, PD-1 x CD3 bispecific antibody, is being developed in Japan and Europe for the treatment of autoimmune disease. In addition, it is being developed in the USA for the treatment of T-cell lymphoma.

ONO-7018 (tablet)

ONO-7018, MALT1 inhibitor, is being developed in the USA for the treatment of non-Hodgkin lymphoma or chronic lymphocytic leukemia.

Onoact for Intravenous Infusion (ONO-1101) / Landiolol Hydrochloride (injection)

An application was approved for the treatment of tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in pediatric patients with low cardiac function.

ONO-2017 / Cenobamate (tablet)

ONO-2017, an inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel, is being developed in Japan for the treatment of primary generalized tonic-clonic seizures and partial-onset seizures.

ONO-7684 (tablet)

ONO-7684, a FXIa inhibitor, is being developed in Europe for the treatment of thrombosis.

ONO-2808 (tablet)

ONO-2808, a S1P5 receptor agonist, is being developed in Japan and Europe for the treatment of neurodegenerative disease.

ONO-2910 (tablet)

ONO-2910, a Schwann cell differentiation promoter, is being developed in Japan for the treatment of diabetic polyneuropathy.

ONO-2020 (tablet)

ONO-2020, an Epigenetic regulation, is being developed in the USA for the treatment of neurodegenerative disease.