

Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2024 (IFRS)

July 31, 2023

Company name : **ONO PHARMACEUTICAL CO., LTD.**
 Stock exchange listing : Tokyo Stock Exchange
 Code number : 4528
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 Scheduled date of quarterly securities report submission : August 4, 2023
 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 First Quarter of FY 2023 (April 1, 2023 to June 30, 2023)

(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 2023 Q1	120,016	12.5	41,348	8.3	42,378	8.5	31,818	7.8	31,818	7.9	38,701	30.3
FY 2022 Q1	106,722	22.2	38,162	28.1	39,041	26.7	29,528	22.5	29,477	22.4	29,697	30.8

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2023 Q1	65.16	65.15
FY 2022 Q1	60.37	60.36

(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 June 30, 2023	871,878	768,449	762,487	87.5
As of March 31, 2023	882,437	747,812	741,869	84.1

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 2022	—	33.00	—	37.00	70.00
FY 2023	—				
FY 2023 (Forecast)		40.00	—	40.00	80.00

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

3. Consolidated Financial Forecast for FY 2023 (April 1, 2023 to March 31, 2024)

(% 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 2023	475,000	6.2	153,000	7.8	154,000	7.3	115,200	2.0	115,000	2.0	235.49

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

Notes

- (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None
- (2) Changes in accounting policies and changes in accounting estimates
 - 1) Changes in accounting policies required by IFRS: Yes
 - 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 June 30, 2023	517,425,200 shares
As of March 31, 2023	517,425,200 shares
 - 2) Number of treasury shares as of the end of the period:

As of June 30, 2023	29,091,238 shares
As of March 31, 2023	29,091,218 shares
 - 3) Average number of shares outstanding during the period:

Three months ended June 30, 2023	488,332,722 shares
Three months ended June 30, 2022	488,244,535 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 consolidated financial forecasts.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 1st Quarter of FY 2023

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023	Change	Change (%)
Revenue	106,722	120,016	13,293	12.5%
Operating profit	38,162	41,348	3,186	8.3%
Profit before tax	39,041	42,378	3,337	8.5%
Profit for the period (attributable to owners of the Company)	29,477	31,818	2,341	7.9%

[Revenue]

Revenue totaled ¥120.0 billion, which was an increase of ¥13.3 billion (12.5%) 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 treatments for gastric cancer, esophageal cancer, urothelial carcinoma, etc., resulting in sales of ¥37.8 billion, an increase of ¥3.7 billion (10.9%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥17.5 billion (34.0% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥6.6 billion (5.6% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥5.6 billion (7.2% decrease year on year). Sales of Velexbro Tablets for malignant tumors were ¥2.6 billion (23.7% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥2.2 billion (0.1% decrease year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.1 billion (3.0% decrease year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥1.6 billion (28.8% increase year on year).
- Royalty and others increased by ¥4.9 billion (14.2%) year on year to ¥39.5 billion.

[Operating Profit]

Operating profit was ¥41.3 billion, an increase of ¥3.2 billion (8.3%) year on year.

- Cost of sales increased by ¥3.2 billion (12.0%) year on year to ¥30.2 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥5.2 billion (26.6%) year on year to ¥24.6 billion mainly due to increases in research costs, costs for drug discovery collaboration, development costs for clinical trials and expenses for collaborative development with alliance partners.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥1.8 billion (8.1%) year on year to ¥23.5 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and expenses associated with IT and digital related information infrastructure enhancements.

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

Profit attributable to owners of the Company increased by ¥2.3 billion (7.9%) year on year to ¥31.8 billion in association with the increase of the profit before tax.

(2) Overview of Financial Position for the 1st Quarter of FY 2023

(Millions of yen)

	As of March 31, 2023	As of June 30, 2023	Change
Total assets	882,437	871,878	(10,559)
Equity attributable to owners of the Company	741,869	762,487	20,619
Ratio of equity attributable to owners of the Company to total assets	84.1%	87.5%	
Equity attributable to owners of the Company per share	1,519.19 yen	1,561.41 yen	

Total assets decreased to ¥871.9 billion by ¥10.6 billion from the end of the previous fiscal year.

Current assets decreased by ¥19.0 billion to ¥326.1 billion mainly due to a decrease in cash and cash equivalents, despite there being increases in trade and other receivables and inventories.

Non-current assets increased by ¥8.4 billion to ¥545.7 billion mainly due to an increase in investment securities, despite there being decreases in deferred tax assets and intangible assets.

Liabilities decreased by ¥31.2 billion to ¥103.4 billion mainly due to decreases in income taxes payable and trade and other payables. Equity attributable to owners of the Company increased by ¥20.6 billion to ¥762.5 billion mainly due to the recording of the profit for the period, despite there being cash dividends.

(3) Overview of Cash Flows for the 1st Quarter of FY 2023

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023	Change
Cash and cash equivalents at the beginning of the period	69,112	96,135	
Cash flows from operating activities	33,078	(9,638)	(42,716)
Cash flows from investing activities	(1,320)	(9,190)	(7,870)
Cash flows from financing activities	(13,355)	(17,536)	(4,181)
Net increase (decrease) in cash and cash equivalents	18,403	(36,364)	
Effects of exchange rate changes on cash and cash equivalents	424	661	
Cash and cash equivalents at the end of the period	87,940	60,433	

Net increase/decrease in cash and cash equivalents for the first quarter (three months) of the fiscal year 2023 was a decrease of ¥36.4 billion.

Net cash used in operating activities was ¥9.6 billion, as a result of profit before tax of ¥42.4 billion, etc., while there were income taxes paid of ¥34.3 billion and decreases in trade and other payables of ¥8.6 billion, etc.

Net cash used in investing activities was ¥9.2 billion, as a result of purchases of intangible assets of ¥6.1 billion and purchases of property, plant, and equipment of ¥1.7 billion, etc.

Net cash used in financing activities was ¥17.5 billion, as a result of dividends paid of ¥16.8 billion, etc.

(4) Future Outlook

There are no changes from the consolidated financial forecast for the year ending March 31, 2024, announced on May 10, 2023. The impact of the settlement with AstraZeneca UK Limited regarding the PD-L1 and CTLA-4 antibody patents announced on July 25, 2023, on the consolidated financial results for the fiscal year ending March 31, 2024, will be disclosed at the announcement of the financial results for the second quarter of the fiscal year ending March 31, 2024.

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, 2023	As of June 30, 2023
Assets		
Current assets		
Cash and cash equivalents	96,135	60,433
Trade and other receivables	114,396	123,518
Marketable securities	20	20
Other financial assets	68,134	68,341
Inventories	44,814	50,390
Other current assets	21,602	23,444
Total current assets	345,101	326,145
Non-current assets		
Property, plant, and equipment	108,420	107,466
Intangible assets	69,134	67,518
Investment securities	123,308	136,701
Investments in associates	115	118
Other financial assets	197,441	197,418
Deferred tax assets	35,604	33,875
Other non-current assets	3,314	2,636
Total non-current assets	537,336	545,732
Total assets	882,437	871,878

(Millions of yen)

	As of March 31, 2023	As of June 30, 2023
Liabilities and Equity		
Current liabilities		
Trade and other payables	66,794	51,898
Lease liabilities	2,490	2,433
Other financial liabilities	661	7,738
Income taxes payable	34,575	11,036
Other current liabilities	18,409	18,408
Total current liabilities	122,929	91,513
Non-current liabilities		
Lease liabilities	6,678	6,954
Other financial liabilities	0	0
Retirement benefit liabilities	3,350	3,404
Deferred tax liabilities	983	1,005
Other non-current liabilities	684	552
Total non-current liabilities	11,695	11,916
Total liabilities	134,625	103,429
Equity		
Share capital	17,358	17,358
Capital reserves	17,080	17,092
Treasury shares	(54,161)	(54,161)
Other components of equity	51,701	58,457
Retained earnings	709,890	723,741
Equity attributable to owners of the Company	741,869	762,487
Non-controlling interests	5,944	5,961
Total equity	747,812	768,449
Total liabilities and equity	882,437	871,878

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

Condensed Interim Consolidated Statement of Income

	(Millions of yen)	
	Three months ended June 30, 2022	Three months ended June 30, 2023
Revenue	106,722	120,016
Cost of sales	(26,937)	(30,171)
Gross profit	79,785	89,844
Selling, general, and administrative expenses	(21,726)	(23,483)
Research and development costs	(19,413)	(24,579)
Other income	106	118
Other expenses	(590)	(553)
Operating profit	38,162	41,348
Finance income	1,159	1,273
Finance costs	(279)	(241)
Share of profit (loss) from investments in associates	0	(2)
Profit before tax	39,041	42,378
Income tax expense	(9,513)	(10,560)
Profit for the period	29,528	31,818
Profit for the period attributable to:		
Owners of the Company	29,477	31,818
Non-controlling interests	51	0
Profit for the period	29,528	31,818
Earnings per share:		
Basic earnings per share (Yen)	60.37	65.16
Diluted earnings per share (Yen)	60.36	65.15

Condensed Interim Consolidated Statement of Comprehensive Income

	(Millions of yen)	
	Three months ended June 30, 2022	Three months ended June 30, 2023
Profit for the period	29,528	31,818
Other comprehensive income:		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	(845)	8,479
Remeasurements of defined benefit plans	(10)	(24)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	4	5
Total of items that will not be reclassified to profit or loss	(850)	8,460
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	875	1,331
Net fair value gain (loss) on cash flow hedges	144	(2,908)
Total of items that may be reclassified subsequently to profit or loss	1,019	(1,577)
Total other comprehensive income	169	6,883
Total comprehensive income for the period	29,697	38,701
Comprehensive income for the period attributable to:		
Owners of the Company	29,650	38,675
Non-controlling interests	47	26
Total comprehensive income for the period	29,697	38,701

(3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 30, 2022

(Millions of yen)

	Equity attributable to owners of the Company							Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
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					29,477	29,477	51	29,528
Other comprehensive income				173		173	(4)	169
Total comprehensive income for the period	–	–	–	173	29,477	29,650	47	29,697
Purchase of treasury shares			(1)			(1)		(1)
Retirement of treasury shares		(171)	20,356		(20,185)	–		–
Cash dividends					(13,671)	(13,671)	(6)	(13,677)
Share-based payments		10				10		10
Transfer from other components of equity to retained earnings				(1,127)	1,127	–		–
Total transactions with the owners	–	(161)	20,355	(1,127)	(32,729)	(13,662)	(6)	(13,669)
Balance as of June 30, 2022	17,358	17,080	(54,328)	50,282	641,501	671,894	5,808	677,702

Three months ended June 30, 2023

(Millions of yen)

	Equity attributable to owners of the Company							Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
Balance as of April 1, 2023	17,358	17,080	(54,161)	51,701	709,890	741,869	5,944	747,812
Profit for the period					31,818	31,818	0	31,818
Other comprehensive income				6,857		6,857	26	6,883
Total comprehensive income for the period	–	–	–	6,857	31,818	38,675	26	38,701
Purchase of treasury shares			(0)			(0)		(0)
Cash dividends					(18,068)	(18,068)	(9)	(18,077)
Share-based payments		12				12		12
Transfer from other components of equity to retained earnings				(101)	101	–		–
Total transactions with the owners	–	12	(0)	(101)	(17,967)	(18,056)	(9)	(18,065)
Balance as of June 30, 2023	17,358	17,092	(54,161)	58,457	723,741	762,487	5,961	768,449

(4) Condensed Interim Consolidated Statement of Cash Flows

	(Millions of yen)	
	Three months ended June 30, 2022	Three months ended June 30, 2023
Cash flows from operating activities		
Profit before tax	39,041	42,378
Depreciation and amortization	4,303	4,530
Impairment losses	—	19
Interest and dividend income	(1,158)	(1,271)
Interest expense	22	23
(Increase) decrease in inventories	(674)	(5,316)
(Increase) decrease in trade and other receivables	(10,124)	(8,111)
Increase (decrease) in trade and other payables	(5,937)	(8,569)
Increase (decrease) in retirement benefit liabilities	24	21
(Increase) decrease in retirement benefit assets	12	—
Increase (decrease) in accrued consumption tax	3,231	(2,783)
Other	4,254	2,495
Subtotal	32,995	23,415
Interest received	8	8
Dividends received	1,157	1,233
Interest paid	(22)	(23)
Income taxes paid	(1,060)	(34,270)
Net cash provided by (used in) operating activities	33,078	(9,638)
Cash flows from investing activities		
Purchases of property, plant, and equipment	(2,166)	(1,674)
Proceeds from sales of property, plant, and equipment	0	840
Purchases of intangible assets	(1,608)	(6,068)
Purchases of investments	(88)	(1,187)
Proceeds from sales and redemption of investments	2,880	315
Other	(339)	(1,416)
Net cash provided by (used in) investing activities	(1,320)	(9,190)
Cash flows from financing activities		
Dividends paid	(12,652)	(16,827)
Dividends paid to non-controlling interests	(6)	(9)
Repayments of lease liabilities	(696)	(700)
Purchases of treasury shares	(1)	(0)
Net cash provided by (used in) financing activities	(13,355)	(17,536)
Net increase (decrease) in cash and cash equivalents	18,403	(36,364)
Cash and cash equivalents at the beginning of the period	69,112	96,135
Effects of exchange rate changes on cash and cash equivalents	424	661
Cash and cash equivalents at the end of the period	87,940	60,433

(5) Notes to Condensed Interim Consolidated Financial Statements

(Note Regarding Assumption of Going Concern)

Not Applicable

(Changes in Accounting Policies)

Our Group has applied the following standard from the first quarter of the fiscal year ending March 31, 2024.

IFRS		Overview of establishment and amendments
IAS 12	Income Taxes	Clarification of accounting treatment for deferred taxes on lease and decommissioning obligations

Application of this standard does not have a material impact on the our group's condensed interim consolidated financial statements.

(Segment Information)

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

(Significant Subsequent Events)

<Settlement of Significant Lawsuits and Disputes>

The Company and Bristol Myers Squibb (USA: hereinafter referred to as "BMS") signed an agreement with AstraZeneca UK Limited and MedImmune Ltd. (UK) and certain of their affiliates to completely and globally settle the infringement lawsuits and disputes over the PD-L1 and CTLA-4 antibody patents owned by the Company and BMS on July 24, 2023.

The Company will receive approximately 140 Million US dollars in total as a result of this settlement.

The impact on the consolidated financial results for the fiscal year ending March 31, 2024, will be disclosed at the announcement of the financial results for the second quarter of the fiscal year ending March 31, 2024.

<Acquisition and Retirement of Treasury Shares>

On July 25, 2023, in accordance with Article 370 (resolution by documents instead of resolution by board meetings) of the Companies Act, the Company resolved to acquire treasury shares under the provisions of Article 156 of the Companies Act, applied by the replacing terms pursuant to the provisions of Paragraph 3, Article 165 of the Companies Act, and retire treasury shares pursuant to the provisions of Article 178 of the Companies Act.

1. Reasons for the Acquisition and Retirement of Treasury Shares

The Company will acquire treasury shares for the purpose of shareholder return, future financial condition, common stock price and etc.

2. Contents of the Acquisition

- (1) Class of shares to be acquired : Common stock of the Company
- (2) Total number of shares to be acquired: 19 million shares (maximum)
(3.89% of the total outstanding shares excluding treasury shares)
- (3) Aggregate amount of acquisition cost: ¥50.0 billion (maximum)
- (4) Period of acquisition : August 1, 2023 to March 22, 2024
- (5) Method for acquisition : Purchase on the Tokyo Stock Exchange
- (6) Schedule after acquisition : All the common stock acquired will be retired.

3. Contents of the Retirement

- (1) Class of shares to be retired : Common stock of the Company
- (2) Total number of shares to be retired : All the common stock acquired in accordance with Section 2 above
- (3) Scheduled date of retirement : March 29, 2024 (planned)

(Reference) Number of treasury shares held by the Company as of June 30, 2023

Total number of shares issued (excluding treasury shares): 488,399,226 shares

Total number of treasury shares : 29,025,974 shares

4. Supplementary Information

(1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product name	Three months ended June 30, 2023 (April 1, 2023 to June 30, 2023)			FY 2023 Forecast (April 1, 2023 to March 31, 2024)		
	Result	YoY		Forecast	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	37.8	3.7	10.9%	155.0	12.7	8.9%
Forxiga Tablets	17.5	4.4	34.0%	65.0	8.5	15.0%
Orencia for Subcutaneous Injection	6.6	0.4	5.6%	25.5	0.7	3.0%
Glactiv Tablets	5.6	(0.4)	(7.2%)	21.0	(1.5)	(6.7%)
Velexbru Tablets	2.6	0.5	23.7%	9.5	1.0	11.3%
Kyprolis for Intravenous Infusion	2.2	(0.0)	(0.1%)	8.5	(0.2)	(2.3%)
Parsabiv Intravenous Injection	2.1	(0.1)	(3.0%)	8.0	(0.4)	(4.8%)
Ongentys Tablets	1.6	0.3	28.8%	6.5	1.5	30.5%
Onoact for Intravenous Infusion	1.0	(0.1)	(7.5%)	4.5	0.0	0.4%
Braftovi Capsules	0.9	0.0	1.7%	4.0	0.8	23.2%
Opalmon Tablets	1.0	(0.2)	(13.5%)	3.5	(0.9)	(19.9%)
Mektovi Tablets	0.7	0.0	0.5%	3.0	0.5	18.1%

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).

2. Regarding sales revenue forecasts for the fiscal year ending March 31, 2024, only currently approved indications are covered.

(2) Details of Sales Revenue

(Billions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Revenue of goods and products	72.2	80.5
Royalty and others	34.6	39.5
Total	106.7	120.0

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥20.8 billion for the first quarter (three months) ended June 30, 2022, and ¥22.6 billion for the first quarter (three months) ended June 30, 2023. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥9.8 billion for the first quarter (three months) ended June 30, 2022, and ¥12.2 billion for the first quarter (three months) ended June 30, 2023.

(3) Revenue by Geographic Area

(Billions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Japan	70.8	78.2
Americas	32.3	37.1
Asia	2.7	3.5
Europe	1.0	1.1
Total	106.7	120.0

Notes: 1. Revenue by geographic area is presented on the basis of the place of customers.

2. Due to the change in the place of a customer, we revised the classification of revenue by geographic area.

Therefore, revenue by geographic area is reclassified for the three months ended June 30, 2022.

(4) Main Status of Development Pipelines (Oncology)

As of July 21, 2023

<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	Malignant mesothelioma (excluding malignant pleural mesothelioma)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant epithelial tumors *1	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer *2 / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer *2 / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

The change from the announcement of financial results for the fiscal year ended March 31, 2023, is as follows:

*1: An application for approval of Opdivo was filed in Japan for the treatment of malignant epithelial tumors.

*2: Applications for approval of Braftovi Capsules and Mektovi Tablets were filed for the treatment of radically unresectable BRAF-mutant thyroid cancer in doublet combination therapy.

<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	Urothelial carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	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 * / Tamnorzatinib	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
ONO-7226 * *3	New chemical entities	Solid tumor / Anti-ILT4 antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)

<Others>						
*): “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-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.)
ONO-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475 / Tammorzinib	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	New chemical entities	Non-Hodgkin lymphoma, chronic lymphocytic leukemia / MALT1 inhibitor	Tablet	USA	I	In-license (Chordia Therapeutics Inc.)

★: Combination with Opdivo

The change from the announcement of financial results for the fiscal year ended March 31, 2023, is as follows:

*3: Phase I of ONO-7226 (Anti-ILT4 antibody) in combination therapy with Opdivo was initiated in Japan for the treatment of solid tumor.

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 July 21, 2023

<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
	New chemical entities	Chemotherapy-induced peripheral neuropathy *4 / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-2808	New chemical entities	Multiple system atrophy *5 / S1P5 receptor agonist	Tablet	USA	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	Japan Europe	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house
ONO-1110	New chemical entities	Pain / Endocannabinoid regulation	Oral	Japan	I	In-house

The change from the announcement of financial results for the fiscal year ended March 31, 2023, is as follows:

*4: Phase II of ONO-2910 (Schwann cell differentiation promoter) was initiated in Japan for the treatment of chemotherapy-induced peripheral neuropathy.

*5: Phase II of ONO-2808 (S1P5 receptor agonist) was initiated in the USA for the treatment of multiple system atrophy.