Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2025 (IFRS)

October 31, 2024

Company name

Listing

Securities Code

URL

Representative

Inquiries

Telephone

Scheduled date of semi-annual securities report submission Scheduled date of dividend payment commencement Supplementary materials for the quarterly financial results

Earnings announcement for the quarterly financial results

: ONO PHARMACEUTICAL CO., LTD.

: Tokyo Stock Exchange

: 4528

: https://www.ono-pharma.com/en

: Toichi Takino

Representative Director, President and Chief Operating Officer

: Ryuta Imura

Senior Director of Corporate Communications

: +81-(0)6-6263-5670 : November 6, 2024

: December 2, 2024

: Yes

: 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 2024 (From April 1, 2024 to September 30, 2024)

(1) Consolidated Operating Results (cumulative)

(% change from the same period of the previous fiscal year)

	Rever	nue	Operating	g profit	Profit bef	ore tax	Profit for th	ne period	Profit attrib owners	of the	Total comprincome for to	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2024 Q2	240,339	(7.1)	55,881	(42.4)	54,637	(45.0)	41,647	(44.1)	41,641	(44.1)	8,196	(89.8)
FY 2023 Q2	258,713	19.4	97,036	20.9	99,296	22.6	74,520	19.3	74,491	19.5	80,632	29.5

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2024 Q2	88.66	88.61
FY 2023 Q2	153.33	153.32

(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, 2024	1,046,406	788,110	782,463	74.8	
As of March 31, 2024	913,668	798,604	792,961	86.8	

2. Dividends

		Annual dividends per share				
	End of	End of	End of	End of	Total	
	First quarter	Second quarter	Third quarter	fiscal year		
	Yen	Yen	Yen	Yen	Yen	
FY 2023	_	40.00	_	40.00	80.00	
FY 2024	_	40.00	_	_	_	
FY 2024 (Forecast)	1	-		40.00	80.00	

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

3. Consolidated Financial Forecast for FY 2024 (From April 1, 2024 to March 31, 2025)

(% change from the previous fiscal year)

	Reve	enue	Operatir	ng profit	Profit be	efore tax	Profit for	the year	Profit attri owners Com	of the	Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2024	485,000	(3.5)	82,000	(48.7)	81,500	(50.2)	58,100	(54.6)	58,000	(54.7)	123.49

(Note) Revisions to financial forecast most recently announced: Yes

Consolidated financial forecasts on a core basis are as follows;

(% change from the previous fiscal year)

	Revenu	е	Core operat	ting profit	Core profit for the year		
EX/2024	Million yen	%	Million yen	%	Million yen	%	
FY2024	485,000	_	110,000	_	80,000	_	

Note) From the fiscal year 2024, we will disclose core-basis financial results to present our performance in our core business.

The full-year financial forecast on a core basis for the fiscal year ending March 2025 includes provisional forecasts, and starting from the third quarter of the fiscal year ending March 2025, we plan to disclose our financial results on a full basis and core basis. For more information, please refer to page 4 of the supplemental materials.

Notes

(1) Significant changes in scope of consolidation during the period: Yes

Newly included: 12 companies (Company name) Deciphera Pharmaceuticals, Inc.
Other subsidiaries (11 companies)

(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, 2024 498,692,800 shares As of March 31, 2024 498,692,800 shares

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

As of September 30, 2024 28,984,855 shares As of March 31, 2024 29,045,346 shares

3) Average number of shares outstanding during the period:

Six months ended September 30, 2024
Six months ended September 30, 2023
469,661,929 shares
485,813,059 shares

- * Review of the attached consolidated semi-annual financial statements by certified public accountants or an audit firm: None
- * Note to ensure appropriate use of forecast, and other comments in particular
 Forecast 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 forecast.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of FY 2024

(1) Overview of Financial Results

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024	Change	Change (%)
Revenue	258,713	240,339	(18,374)	(7.1)%
Operating profit	97,036	55,881	(41,155)	(42.4)%
Profit before tax	99,296	54,637	(44,659)	(45.0)%
Profit for the period (attributable to owners of the Company)	74,491	41,641	(32,850)	(44.1)%

[Revenue]

Revenue totaled \(\frac{\pma}{2}\)40.3 billion, which was a decrease of \(\frac{\pma}{1}\)8.4 billion (7.1%) from the corresponding period of the previous fiscal year (year on year).

<Sales of Domestic Products>

- Sales of Opdivo Intravenous Infusion for malignant tumors were decreased by \(\xi\$12.4 billion (16.5%) year on year to \(\xi\$62.6 billion, mainly due to the revision of the National Health Insurance (NHI) drug price.
- Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were increased by \(\xi\)7.8 billion (21.7%) year on year to \(\xi\)43.7 billion, mainly due to its expanded use, particularly in treatment for chronic kidney disease.
- With respect to other main products, sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.5 billion (3.5% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥9.6 billion (11.2% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥5.2 billion (3.7% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.6 billion (1.0% decrease year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.2 billion (0.7% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥3.8 billion (21.4% increase year on year).

<Sales of Overseas Products>

• Sales of Qinlock for gastrointestinal stromal tumor, acquired through the acquisition of Deciphera Pharmaceuticals, Inc., were ¥8.1 billion for the period from July 2024 to September 2024.

<Royalty and Others>

Royalty and others decreased by \(\frac{\pmathbf{\text{\te}\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texitex{\text{\tex{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tex

[Operating Profit]

Operating profit was ¥55.9 billion, a decrease of ¥41.2 billion (42.4%) year on year.

- Cost of sales decreased by \(\frac{\pmathbf{\qmandbf{\pmathbf{\pmathbf{\pmathbf{\pmathbf{\pmathbf{\pmathbf{\q}\pmathbf
- Research and development costs increased by ¥19.4 billion (39.4%) year on year to ¥68.8 billion mainly due to increases in research costs and development costs for clinical trials, as well as the recording of the impairment loss of ¥3.5 billion on intangible assets related to development compounds and the inclusion of research and development expenses from Deciphera Pharmaceuticals, Inc.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥10.8 billion (22.7%) year
 on year to ¥58.4 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets, as well
 as the recording of business operating costs and acquisition-related expenses for Deciphera Pharmaceuticals, Inc.

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

Profit attributable to owners of the Company decreased by ¥32.9 billion (44.1%) year on year to ¥41.6 billion in association with the decrease of the profit before tax.

2 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 of anticancer drugs including antibody drugs in addition to Opdivo, candidates for treatment of autoimmune disease and neurological disorder, all of which are under development. Among these, the area of oncology is positioned as a key strategic field due to its high medical needs, and we are working to further enhance the pipeline with the addition of Deciphera Pharmaceuticals' pipeline.

In drug discovery research, we focus on the areas of oncology, immunology, neurology and specialties; all of which include diseases with high medical needs. In each of these areas, we are working to strengthen our drug discovery capabilities by delving into the biology of human disease with the aim of discovering new drugs that can satisfy medical needs. To that end, by actively promoting "open innovation", which is one of our strengths, we aim to discover original drug discovery seeds and create breakthrough new drugs with medical impact by utilizing a variety of cutting-edge internal and external technologies, such as informatics, human disease modeling, and the discovery of new drug candidate.

In our priority therapeutic areas, there have been 14 new drug candidates (including two candidates from Deciphera) that were made in-house in 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 are working to analyze the relationship between target molecules and diseases to find physiological indicators (biomarkers) that can more accurately predict and evaluate the efficacy of new drug candidates in humans.

In order to improve the speed and success rates of clinical development, we strive to formulate the best and most appropriate development strategy in strong collaboration with the Discovery & Research from an earlier stage. Additionally, using many of the clinical trial data accumulated so far and samples gained through actual clinical trials, we are carrying out various types of analysis to increase the resolution of data in clinical trial results. To maximize the value of new drug candidate, we are conducting multiple clinical trials in parallel, while at the same time accelerating the enhancement of clinical development functions in Europe and the USA in order to build a framework that enables international collaborative trials to be conducted globally (Japan, the USA, and Europe).

We are also striving for the introduction of promising new drug candidates 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, 2024 (including those on and after September 30, 2024) are as follows.

[Main Progress of Development Pipelines]

<Oncology>

"Opdivo / Nivolumab"

Hepatocellular carcinoma

- In August 2024, an application for approval of combination therapy with Opdivo and Yervoy was filed in Japan for the treatment of unresected hepatocellular carcinoma.

Urothelial carcinoma

- In July 2024, an application of Opdivo was approved in South Korea for the treatment of radically unresectable or metastatic urothelial carcinoma (in combination with chemotherapy in the first-line treatment).
- In October 2024, an application of Opdivo was approved in Taiwan for the treatment of radically unresectable or metastatic urothelial carcinoma (in combination with chemotherapy in the first-line treatment).

Colorectal cancer

- In September 2024, an application for approval of Opdivo was filed in Japan for the treatment of unresectable advanced or recurrent microsatellite instability-high (MSI-High) or mismatch repair deficient (dMMR) colorectal cancer.

Rhabdoid tumor

- In July 2024, phase II of Opdivo was initiated in Japan for the treatment of rhabdoid tumor.

Ovarian cancer

- Regarding the combination therapy of Opdivo and Rucaparib, a PARP inhibitor, the Group participated in a global cooperative phase III trial from Japan, South Korea, and Taiwan, targeting maintenance therapy after initial chemotherapy for ovarian cancer, which was led by Pharmaand GmbH. However, the trial was unable to achieve the primary endpoint of progression-free survival (PFS) in June 2024.

"Braftovi Capsules / Encorafenib" and "Mektovi Tablets / Binimetinib"

- Approvals were obtained in Japan for Braftovi Capsules and Mektovi Tablets in May 2024, for their indications and effects in doublet combination therapy for the treatment of radically unresectable BRAF-mutant thyroid cancer that has progressed after chemotherapy, as well as for the treatment of radically unresectable anaplastic BRAF-mutant thyroid cancer.

"ONO-7018"

- In August 2024, phase I of ONO-7018 (MALT1 inhibitor) was initiated in Japan for the treatment of Non-Hodgkin lymphoma, chronic lymphocytic leukemia.

"ONO-7122"

- In April 2024, the Company had participated in collaborative international phase I trials of combination therapy of ONO-7122 (TGF-β inhibitor) and Opdivo under the leadership of Bristol-Myers Squibb Company from Japan for the treatment of solid tumor. However, it was discontinued due to strategic reasons.

"ONO-7226"

- In April 2024, the Company had participated in collaborative international phase I trials of combination therapy of ONO-7226 (anti-ILT4 antibody) and Opdivo under the leadership of Bristol-Myers Squibb Company from Japan for the treatment of solid tumor. However, it was discontinued due to strategic reasons.

<Areas other than Oncology>

"ONO-4915"

-In September 2024, phase I of ONO-4915 (PD-1/CD19 bispecific antibody) was initiated in Japan aimed at healthy adults.

"ONO-2910"

- In July 2024, the Company participated in phase II trials of ONO-2910 (Schwann cell differentiation) from Japan for the treatment of diabetic polyneuropathy, but the projects were discontinued due to not being able to confirm expected efficacy.

<Development Pipelines of Deciphera>

"DCC-3014"

- In July 2024, an application for approval of DCC-3014/Vimseltinib (CSF-1R inhibitor) was accepted in Europe for the treatment of tenosynovial giant cell tumor.
- In August 2024, an application for approval of the CSF-1R inhibitor DCC-3014/Vimseltinib for the treatment of tenosynovial giant cell tumor was accepted for priority review in the United States.

[Status of Drug Discovery / Research Alliance Activities]

- In April 2024, the Company entered into a drug discovery collaboration agreement with PRISM BioLab in Japan to generate novel drug candidates in the oncology area.
- In August 2024, the Company entered into a new option and drug discovery collaboration agreement with Monash University in Australia to discover and create new antibodies targeting at G protein-coupled receptors (GPCRs) in autoimmune and inflammatory areas.

[Status of Licensing Activities]

- In October 2024, the Company entered into a licensing agreement with LigaChem Bioscience, Inc. (LCB) in South Korea for LCB97, a pre-clinical stage antibody-drug conjugate (ADC), as well as a research collaboration and license agreement to generate novel ADC candidates by leveraging LCB's proprietary ConjuAllTM ADC platform.
- In October 2024, the Company decided not to exercise the exclusive option and asset purchase agreement for "itolizumab" signed with Equillium, Inc. in the United States in December 2022, for strategic reasons.

(2) Overview of Financial Position for the 2nd Quarter of FY 2024

(Millions of yen)

	As of March 31, 2024	As of September 30, 2024	Change
Total assets	913,668	1,046,406	132,738
Equity attributable to owners of the Company	792,961	782,463	(10,498)
Ratio of equity attributable to owners of the Company to total assets	86.8%	74.8%	
Equity attributable to owners of the Company per share	1,688.43 yen	1,665.91 yen	

Total assets increased to \\(\frac{\pma}{1}\),046.4 billion by \\(\frac{\pma}{1}\)32.7 billion from the end of the previous fiscal year.

Current assets decreased by \\$12.2 billion to \\$401.4 billion mainly due to a decrease in other financial assets, despite increases in marketable securities and other current assets.

Non-current assets increased by ¥144.9 billion to ¥645.0 billion mainly due to the recording of goodwill associated with the acquisition of Deciphera Pharmaceuticals, Inc., despite a decrease in other financial assets.

Liabilities increased by ¥143.2 billion to ¥258.3 billion mainly due to the loans from financial institutions to finance the acquisition of Deciphera Pharmaceuticals, Inc.

Equity attributable to owners of the Company decreased by ¥10.5 billion to ¥782.5 billion mainly due to cash dividends and a decrease in other components of equity, despite there being the recording of the profit for the period.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2024

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024	Change
Cash and cash equivalents at the beginning of the period	96,135	166,141	
Cash flows from operating activities	36,721	34,723	(1,998)
Cash flows from investing activities	20,713	(160,930)	(181,643)
Cash flows from financing activities	(46,647)	129,687	176,334
Net increase (decrease) in cash and cash equivalents	10,787	3,480	
Effects of exchange rate changes on cash and cash equivalents	782	(2,530)	
Cash and cash equivalents at the end of the period	107,704	167,090	

Net increase/decrease in cash and cash equivalents for the second quarter (six months) of the fiscal year ending March 31, 2025, was an increase of ¥3.5 billion.

Net cash provided by operating activities was ¥34.7 billion, as a result of profit before tax of ¥54.6 billion, etc., while there were income taxes paid of ¥22.2 billion, etc.

Net cash used by investing activities was ¥160.9 billion, as a result of the acquisition of subsidiaries of ¥364.8 billion, etc., while there were proceeds from withdrawal of time deposits of ¥200.6 billion, etc.

Net cash provided by financing activities was ¥129.7 billion, as a result of proceeds from long-term loans of ¥150.0 billion, while there were dividends paid of ¥18.8 billion, etc.

(4) Future Outlook

- Introduction of Core-Basis Results

Previously, our IFRS full-basis financial results have included the impact of transactions that are not related to our core business or are temporary in nature. Additionally, due to the acquisition of Deciphera Pharmaceuticals, Inc., we anticipate amortization expenses for intangible assets acquired through the acquisition in the future.

Therefore, starting from the fiscal year 2024, we will disclose core-basis financial results to present our performance in our core business. For the definition of core-based results, please refer to the "Definition of Core-Basis Results" on page 4 of the Supplementary Materials.

The forecast of consolidated financial results for the fiscal year ending March 31, 2025, as announced on May 9, 2024, has been revised as follows.

(Millions of ven)

	Revenue	Operating profit	Core operating profit	Profit before tax	Profit for the year	Profit for the year attributable to owners of the Company	Core profit for the year
Previous forecast (A)	450,000	122,000	ı	123,000	91,200	91,000	
Revised forecast (B)	485,000	82,000	110,000	81,500	58,100	58,000	81,000
Change (B-A)	35,000	(40,000)		(41,500)	(33,100)	(33,000)	1
Change (%)	7.8%	(32.8%)	_	(33.7%)	(36.3%)	(36.3%)	
(Reference) Consolidated result of FY2023	502,672	159,935	_	163,734	128,040	127,977	_

Note: The annual exchange rate assumed in this forecast is 1 USD=145 yen.

Revenue is forecasted to be ¥485.0 billion, an upward revision of ¥35.0 billion from the previously announced forecast. This increase is mainly due to several factors: expected sales of Forxiga Tablets are forecasted to be ¥89.0 billion, an upward revision of ¥6.0 billion from the previously announced forecast; the expected sales of Qinlock, a gastrointestinal stromal tumor treatment acquired through the acquisition of Deciphera Pharmaceuticals, Inc., are forecasted to be ¥23.5 billion; and royalty income from Bristol-Myers Squibb Company is expected to exceed the previously announced forecast due to the impact of yen depreciation.

Operating profit is forecasted to be \pmu 82.0 billion, a decrease of \pmu 40.0 billion year on year, mainly due to the inclusion of the cost of sales, research and development costs, and selling, general and administrative expenses from Deciphera Pharmaceuticals, Inc., as well as the costs associated with the licensing agreement with LigaChem Biosciences, Inc., etc. Research and development costs are forecasted to be \pmu 147.0 billion, an increase of \pmu 35.0 billion compared to the previously announced forecast, and selling, general, and administrative expenses are forecasted to be \pmu 123.0 billion, an increase of \pmu 23.0 billion compared to the previously announced forecast.

Core operating profit is forecasted to be ¥110.0 billion, after adjusting full-basis operating profit for the amortization of intangible assets related to Qinlock (cost of sales), acquired through the acquisition of Deciphera Pharmaceuticals, Inc., and the impairment losses on intangible assets related to development compounds (research and development expenses).

As a result, profit before tax is forecasted to decrease by ± 41.5 billion to ± 81.5 billion. Profit for the year is forecasted to decrease by ± 33.1 billion to ± 58.1 billion, and profit attributable to owners of the Company is forecasted to decrease by ± 33.0 billion to ± 58.0 billion. Core profit for the year is forecasted to be ± 81.0 billion.

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 (IFRS) 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, 2024	As of September 30, 2024
Assets		
Current assets		
Cash and cash equivalents	166,141	167,090
Trade and other receivables	136,066	137,291
Marketable securities	_	9,952
Other financial assets	38,454	4,092
Inventories	48,629	52,154
Other current assets	24,306	30,830
Total current assets	413,596	401,410
Non-current assets		
Property, plant, and equipment	104,752	107,074
Goodwill	_	315,138
Intangible assets	57,288	51,679
Investment securities	121,147	117,325
Investments in associates	115	119
Other financial assets	173,113	7,936
Deferred tax assets	40,863	41,383
Other non-current assets	2,795	4,342
Total non-current assets	500,072	644,996
Total assets	913,668	1,046,406

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	As of March 31, 2024	As of September 30, 2024
Liabilities and Equity		
Current liabilities		
Trade and other payables	60,691	58,887
Short-term loans	_	30,000
Lease liabilities	2,310	2,869
Other financial liabilities	2,273	761
Income taxes payable	22,093	14,150
Other current liabilities	16,257	17,992
Total current liabilities	103,624	124,660
Non-current liabilities		
Long-term loans	_	120,000
Lease liabilities	6,552	8,788
Other financial liabilities	0	0
Retirement benefit liabilities	3,294	3,253
Deferred tax liabilities	1,013	1,035
Other non-current liabilities	580	558
Total non-current liabilities	11,439	133,635
Total liabilities	115,063	258,295
Equity		
Share capital	17,358	17,358
Capital reserves	17,458	17,458
Treasury shares	(63,233)	(63,096)
Other components of equity	53,194	17,767
Retained earnings	768,183	792,976
Equity attributable to owners of the Company	792,961	782,463
Non-controlling interests	5,644	5,647
Total equity	798,604	788,110
Total liabilities and equity	913,668	1,046,406

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

Condensed Interim Consolidated Statement of Income

		(Millions of yen)
	Six months ended September 30, 2023	Six months ended September 30, 2024
Revenue	258,713	240,339
Cost of sales	(64,765)	(56,877)
Gross profit	193,948	183,462
Selling, general, and administrative expenses	(47,604)	(58,424)
Research and development costs	(49,360)	(68,803)
Other income	894	572
Other expenses	(842)	(928)
Operating profit	97,036	55,881
Finance income	2,321	2,276
Finance costs	(64)	(3,522)
Share of profit (loss) from investments in associates	4	2
Profit before tax	99,296	54,637
Income tax expense	(24,776)	(12,990)
Profit for the period	74,520	41,647
Profit for the period attributable to:		
Owners of the Company	74,491	41,641
Non-controlling interests	29	6
Profit for the period	74,520	41,647
Earnings per share:		
Basic earnings per share (Yen)	153.33	88.66
Diluted earnings per share (Yen)	153.32	88.61

Condensed Interim Consolidated Statement of Comprehensive Income

		(Millions of yen)
	Six months ended September 30, 2023	Six months ended September 30, 2024
Profit for the period	74,520	41,647
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	7,630	291
Remeasurements of defined benefit plans	(50)	(107)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	4	0
Total of items that will not be reclassified to profit or loss	7,584	184
Items that may be reclassified subsequently to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	_	70
Exchange differences on translation of foreign operations	1,709	(34,516)
Net fair value gain (loss) on cash flow hedge	(3,182)	811
Total of items that may be reclassified subsequently to profit or loss	(1,472)	(33,635)
Total other comprehensive income	6,112	(33,451)
Total comprehensive income for the period	80,632	8,196
Comprehensive income for the period attributable to:		
Owners of the Company	80,569	8,181
Non-controlling interests	63	15
Total comprehensive income for the period	80,632	8,196

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 2023

Six months ended September							(Million	ns 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, 2023	17,358	17,080	(54,161)	51,701	709,890	741,869	5,944	747,812
Profit for the period					74,491	74,491	29	74,520
Other comprehensive income				6,078		6,078	34	6,112
Total comprehensive income for the period	_	_	_	6,078	74,491	80,569	63	80,632
Purchase of treasury shares			(27,187)			(27,187)		(27,187)
Disposition of treasury shares		(1)	86			86		86
Cash dividends					(18,068)	(18,068)	(9)	(18,077)
Share-based payments		23				23		23
Transfer from other components of equity to retained earnings				(1,022)	1,022	_		_
Total transactions with the owners	_	22	(27,101)	(1,022)	(17,047)	(45,148)	(9)	(45,156)
Balance as of September 30, 2023	17,358	17,102	(81,262)	56,757	767,335	777,290	5,998	783,288

Six months ended September 30, 2024

Six months ended september	30, 2024						(Million	ns 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, 2024	17,358	17,458	(63,233)	53,194	768,183	792,961	5,644	798,604
Profit for the period					41,641	41,641	6	41,647
Other comprehensive income				(33,460)		(33,460)	9	(33,451)
Total comprehensive income for the period	_	_	_	(33,460)	41,641	8,181	15	8,196
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(53)	138			85		85
Cash dividends					(18,786)	(18,786)	(11)	(18,797)
Share-based payments		23				23		23
Transfer from retained earnings to capital reserves		30			(30)	_		_
Transfer from other components of equity to retained earnings				(1,968)	1,968	_		_
Total transactions with the owners	_	_	138	(1,968)	(16,848)	(18,679)	(11)	(18,690)
Balance as of September 30, 2024	17,358	17,458	(63,096)	17,767	792,976	782,463	5,647	788,110

(4) Condensed Interim Consolidated Statement of Cash Flows

(4) Condensed Internit Consondated Statement of Ca	(Millions of yen)	
	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash flows from operating activities		
Profit before tax	99,296	54,637
Depreciation and amortization	9,086	8,996
Impairment losses	5,440	3,510
Interest and dividend income	(1,607)	(2,259)
Interest expense	46	293
(Increase) decrease in inventories	(3,476)	207
(Increase) decrease in trade and other receivables	(25,992)	4,539
Increase (decrease) in trade and other payables	(7,538)	(7,906)
Increase (decrease) in retirement benefit liabilities	(2)	(195)
Increase (decrease) in accrued consumption tax	(4,451)	(2,204)
Other	(595)	(3,988)
Subtotal	70,206	55,630
Interest received	66	279
Dividends received	1,271	1,264
Interest paid	(46)	(293)
Income taxes refund (paid)	(34,776)	(22,157)
Net cash provided by (used in) operating activities	36,721	34,723
Cash flows from investing activities		
Purchase of property, plant, and equipment	(2,510)	(2,806)
Proceeds from sales of property, plant, and equipment	842	6
Purchase of intangible assets	(6,381)	(1,975)
Purchase of investments	(1,918)	(906)
Proceeds from sales and redemption of investments	2,820	10,098
Payments into time deposits	(30,455)	(591)
Proceeds from withdrawal of time deposits	60,455	200,591
Payments of the acquisition of subsidiaries	_	(364,816)
Other	(2,140)	(532)
Net cash provided by (used in) investing activities	20,713	(160,930)
Cash flows from financing activities		
Dividends paid	(18,049)	(18,754)
Dividends paid to non-controlling interests	(9)	(11)
Proceeds from long-term loans	_	150,000
Repayments of lease liabilities	(1,402)	(1,547)
Purchase of treasury shares	(27,187)	(1)
Net cash provided by (used in) financing activities	(46,647)	129,687
Net increase (decrease) in cash and cash equivalents	10,787	3,480
Cash and cash equivalents at the beginning of the period	96,135	166,141
Effects of exchange rate changes on cash and cash equivalents	782	(2,530)
Cash and cash equivalents at the end of the period	107,704	167,090
and table equilibrium at the end of the period	107,701	107,000

(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.

(Business Combination)

In April 2024, ONO Pharmaceutical, Co, Ltd. ("the Company") and Deciphera Pharmaceuticals, Inc. ("Deciphera") entered into a definitive merger agreement through a tender offer, followed by a merger of a wholly owned subsidiary of the Company with Deciphera, with Deciphera surviving as a wholly owned subsidiary of the Company (the "Acquisition"). The Acquisition was completed under the agreement on June 11, 2024 (New York City Time), making Deciphera a wholly owned subsidiary of the Company.

(1) Overview of the business combination

1. Overview of the acquired company

Company name	Deciphera Pharmaceuticals, Inc.
Business description	R&D and Commercialization of pharmaceuticals

2. Acquisition date

June 11, 2024 (New York City Time)

3. Percentage of voting equity interest acquired

100%

4. Process of obtaining control of the acquired company

Acquisition of outstanding shares in cash

5. Main objectives of the Acquisition

The Company, as a global specialty pharma company, is committed to delivering innovative new drugs to patients around the world. As a part of our medium-term management plan, the Company aims to reinforce our pipeline and accelerate global development, as well as realize direct sales in the United States and Europe. In addition, the Company has designated oncology, immunological diseases, central nervous system diseases, and specialty areas with high medical needs as priority research areas, and we accumulate disease know-how in each area to create new drugs that will bring innovation to medicine on-site. Through this Acquisition, the Company is pleased to welcome Deciphera as a partner with commercial capabilities in the United States and Europe and excellent research and development capabilities in the field of cancer. This combination will further enhance the Group's pipeline and accelerate its globalization.

Deciphera focuses on the discovery, development, and commercialization of innovative medicines for cancer and has deep expertise in kinase biology. QINLOCK® (Ripretinib), a KIT inhibitor, is approved in over 40 countries and marketed globally, including in the US, Europe, and China, for the treatment of fourth-line gastrointestinal stromal tumor (GIST). Vimseltinib, a CSF-1R inhibitor, demonstrated statistically significant and clinically meaningful efficacy across all primary and secondary endpoints in the Phase III MOTION trial in patients with tenosynovial giant cell tumor (TGCT). Data from the MOTION trial will be used to support marketing applications in the US and EU in 2024. Deciphera has established highly successful commercial operations in the United States and key European countries, which could be immediately leveraged for vimseltinib, if approved.

With this Acquisition, the Group will expand its oncology pipeline with near-term revenue growth, notably through the immediate addition of QINLOCK® and potential addition of vimseltinib. Moreover, acquiring Deciphera's commercial capabilities in the United States and Europe will strengthen the Group's global commercial presence. By leveraging Deciphera's drug discovery capabilities, the Group will further accelerate its research and development capabilities in the field of oncology.

(2) Fair value of assets acquired, liabilities assumed and purchase consideration transferred at the acquisition date are as follows:

(Millions of yen)

	(Millions of yell)
Cash and cash equivalents	15,433
Trade and other receivables	6,729
Marketable securities	16,650
Inventories	4,478
Property, plant, and equipment	5,182
Investment securities	1,156
Other assets	4,332
Trade and other payables	(8,941)
Lease liabilities	(3,890)
Other liabilities	(5,790)
Fair value of assets acquired and liabilities assumed (Net)	35,338
Basis adjustments	1,886
Goodwill *2	344,911
Total	382,135
Total fair value of purchase consideration transferred	382,135

- Notes: 1. As of September 30, 2024, the amount of generated goodwill and the assets acquired and liabilities assumed at the acquisition date are provisionally accounted for because the review to verify the identifiable assets and liabilities at the acquisition date is still in progress and the allocation of consideration for acquisition has not been finalized.
 - 2. Goodwill was mainly attributable to expected future earnings potential. No portion of the recognized goodwill is expected to be deductible for tax purposes.

(3) Cash flow information

(Millions of ven)

	(Willions of yell)
Total fair value of purchase consideration transferred	382,135
Cash and cash equivalents held by the acquiree	(15,433)
Basis adjustments	(1,886)
Payments for the acquisition of subsidiaries	364,816

(4) Acquisition-related costs

3,382 million yen

Acquisition-related costs have been recorded as "selling, general, and administrative expenses" in the consolidated statement of income for the fiscal year ended March 31, 2024, and for the six months ended September 30, 2024.

(5) Impact on the condensed interim consolidated statement of income

1. Revenue and profit for the year of the acquired company after the acquisition date that are recognized in the condensed interim consolidated statement of income for the six months ended September 30, 2024

Revenue 8,275 million yen Profit for the year (loss) (4,875) million yen

2. Impact on revenue and profit for the period in the condensed interim consolidated statement of income for the six months ended September 30, 2024 assuming that this business combination had been conducted at the beginning of the fiscal year

Revenue 16,727 million yen Profit for the year (loss) (9,739) million yen

(Significant Subsequent Events)

Not applicable.

2nd Quarter of Fiscal Year 2024 (Ending March 31, 2025) (April 1, 2024 to September 30, 2024)

Supplementary Materials (Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

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	(Reference) Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2025 (Core Basis)
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Note: "(Billions of yen)" are rounded.

Summary of Consolidated Financial Results for the 2nd Quarter of FY 2024 (Full Basis)

(Billions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024	YoY	Full year ended March 31, 2024
Revenue	258.7	240.3	(7.1)%	502.7
Operating profit	97.0	55.9	(42.4)%	159.9
Profit before tax	99.3	54.6	(45.0)%	163.7
Profit for the year (attributable to owners of the Company)	74.5	41.6	(44.1)%	128.0

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

1. Revenue \(\frac{\pma}{2}40.3\) billion YoY a decrease of 7.1% (FY 2023 2Q YTD \(\frac{\pma}{2}58.7\) billion)

<Sales of Domestic Products>

- Sales of Opdivo Intravenous Infusion for malignant tumors were decreased by ¥12.4 billion (16.5%) year on year to ¥62.6 billion, mainly due to the revision of the National Health Insurance (NHI) drug price.
- Sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were increased by ¥7.8 billion (21.7%) year on year to ¥43.7 billion, mainly due to its expanded use, particularly in treatment for chronic kidney disease.
- With respect to other main products, sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.5 billion (3.5% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥9.6 billion (11.2% decrease year on year). Sales of Velexbru Tablets for malignant tumors were ¥5.2 billion (3.7% increase year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥4.6 billion (1.0% decrease year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.2 billion (0.7% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥3.8 billion (21.4% increase year on year).

<Sales of Overseas Products>

• Sales of Qinlock for gastrointestinal stromal tumor, acquired through the acquisition of Deciphera Pharmaceuticals, Inc., were ¥8.1 billion for the period from July 2024 to September 2024.

<Royalty and others>

Royalty and others decreased by \(\frac{\pmathbf{\text{\te}\text{

2. Operating profit ¥55.9 billion YoY a decrease of 42.4% (FY 2023 2Q YTD ¥97.0 billion)

- Operating profit decreased by ¥41.2 billion (42.4%) year on year to ¥55.9 billion.
- Cost of sales decreased by \(\pm\)7.9 billion (12.2%) year on year to \(\pm\)56.9 billion, mainly due to the absence of impairment losses of \(\pm\)5.4 billion on sales licenses recorded in the same period of the previous year.
- Research and development costs increased by ¥19.4 billion (39.4%) year on year to ¥68.8 billion, mainly due to increases in research costs and development costs for clinical trials, as well as the recording of the impairment loss of ¥3.5 billion on intangible assets related to development compounds and the inclusion of research and development expenses from Deciphera Pharmaceuticals, Inc.
- Selling, general, and administrative expenses (except for research and development costs) increased by \(\pm\)10.8 billion (22.7%) year on year to \(\pm\)58.4 billion, mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets, as well as the recording of business operating costs and acquisition-related expenses for Deciphera Pharmaceuticals, Inc.

3. Profit before tax ¥54.6 billion YoY a decrease of 45.0% (FY 2023 2Q YTD ¥99.3 billion)

• Net financial income, etc., was a loss of ¥1.2 billion, a decrease of ¥3.5 billion year on year.

4. Profit for the period \$\frac{\pmathbf{4}}{4}1.6\$ billion YoY a decrease of 44.1% (FY 2023 2Q YTD \frac{\pmathbf{7}}{7}4.5\$ billion) (attributable to owners of the Company)

• Profit attributable to owners of the Company decreased by ¥32.9 billion (44.1%) year on year to ¥41.6 billion in association with the decrease of the profit before tax.

Sales Revenue Result and Forecast of Major Products

(Billions of Yen)

	Six months ended September 30, 2024 (April 1, 2024 to September 30, 2024)			FY 2024 Forecast (April 1, 2024 to March 31, 2025)						
	Cumulative		YoY			Change		YoY		
Product Name	Apr ~ Jun	Jul ~ Sep		Change	Change (%)	Previous Forecast	from Previous Forecast	Revised Forecast	Change	Change (%)
<domestic></domestic>										
Opdivo Intravenous Infusion	32.1	30.6	62.6	(12.4)	(16.5%)	125.0		125.0	(20.5)	(14.1%)
Forxiga Tablets	22.2	21.5	43.7	7.8	21.7%	83.0	6.0	89.0	12.9	16.9%
Orencia for Subcutaneous Injection	6.9	6.6	13.5	0.5	3.5%	27.0		27.0	1.2	4.5%
Glactiv Tablets	5.0	4.6	9.6	(1.2)	(11.2%)	18.5		18.5	(2.7)	(12.7%)
Velexbru Tablets	2.7	2.5	5.2	0.2	3.7%	10.0		10.0	(0.2)	(2.1%)
Kyprolis for Intravenous Infusion	2.3	2.2	4.6	(0.0)	(1.0%)	9.5		9.5	0.4	3.9%
Parsabiv Intravenous Injection	2.1	2.1	4.2	0.0	0.7%	8.5		8.5	0.3	3.3%
Ongentys Tablets	1.9	1.8	3.8	0.7	21.4%	7.5		7.5	1.2	18.8%
<overseas></overseas>										
Opdivo	3.1	3.4	6.5	0.4	6.9 %			13.5		
Qinlock		8.1	8.1					23.5		

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

- 2. Sales revenue of overseas products is shown in a net sales basis.
- 3. Regarding sales revenue forecast for the fiscal year ending March 31, 2025, only currently approved indications are covered

Details of Sales Revenue (Billions of yen)

	Six months ended	Six months ended
	September 30, 2023	September 30, 2024
Revenue of goods and products	159.9	163.3
Royalty and others	98.8	77.0
Total	258.7	240.3

Note: In "Royalty and others", royalty revenue from Opdivo Intravenous Infusion by Bristol-Myers Squibb Company is included, amounting to ¥47.4 billion for the second quarter (six months) ended September 30, 2023, and ¥56.4 billion for the second quarter (six months) ended September 30, 2024. In addition, royalty revenue from Keytruda® by Merck & Co., Inc. is included, amounting to ¥25.6 billion for the second quarter (six months) ended September 30, 2023, and ¥12.8 billion for the second quarter (six months) ended September 30, 2024.

Revenue by Geographic Area (Billions of yen)

	Six months ended	Six months ended
	September 30, 2023	September 30, 2024
Japan	155.4	150.7
USA	77.0	79.2
Asia	7.0	7.5
Europe	19.4	2.8
Others	_	0.2
Total	258.7	240.3

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

2. Due to the inclusion of revenue from Deciphera Pharmaceuticals, Inc., the Company has revised the classification of revenue by geographic area, starting from this interim consolidated accounting period.

Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2025 (Full Basis)

Consolidated Financial Forecast

(Billions of yen)

			(Difficilly of yell)
	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 Forecast (April 1, 2024 to March 31, 2025)	YoY
Revenue	502.7	485.0	(3.5)%
Operating profit	159.9	82.0	(48.7)%
Profit before tax	163.7	81.5	(50.2)%
Profit for the year (attributable to owners of the Company)	128.0	58.0	(54.7)%

Details of Sales Revenue (Forecast)

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 Forecast (April 1, 2024 to March 31, 2025)
Revenue of goods and products	317.0	333.0
Royalty and others	185.7	152.0
Total	502.7	485.0

1. Revenue ¥485.0 billion YoY a decrease of ¥17.7 billion (3.5%)

• Revenue of goods and products are expected to be \(\frac{\pmax}{33.0}\) billion, an increase of \(\frac{\pmax}{16.0}\) billion (5.1%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be \(\frac{\pmax}{125.0}\) billion, a decrease of \(\frac{\pmax}{20.5}\) billion (14.1%) year on year, due to the revision of the National Health Insurance (NHI) drug price, and sales of Forxiga Tablets are expected to increase by \(\frac{\pmax}{12.9}\) billion (16.9%) year on year to \(\frac{\pmax}{89.0}\) billion. Sales of Qinlock for gastrointestinal stromal tumor, acquired through the acquisition of Deciphera Pharmaceuticals, Inc., are expected to be \(\frac{\pmax}{23.5}\) billion for the fiscal year ending March 2025. Furthermore, royalty and others are expected to decrease by \(\frac{\pmax}{33.7}\) billion (18.1%) year on year to \(\frac{\pmax}{152.0}\) billion mainly due to a decrease in royalty revenue from Merck & Co., Inc., and others in line with a decrease in royalty rates, and the absence of the lump-sum income of \(\frac{\pmax}{17.0}\) billion recorded in the same period of the previous year associated with the settlement of the litigation on patents with AstraZeneca UK Limited. Revenue is therefore expected to be \(\frac{\pmax}{4485.0}\) billion, a decrease of \(\frac{\pmax}{17.7}\) billion (3.5%) year on year.

2. Operating profit \quad \quad \text{\$\frac{4}{8}}\text{2.0 billion} \quad \text{YoY a decrease of \$\frac{4}{7}}\text{7.9 billion (48.7%)}

• Profit attributable to owners of the Company is expected to decrease by ¥70.0 billion (54.7%) year on year to ¥58.0 billion in association with the decrease of the profit before tax.

Introduction of Core-Basis Results and Definition of Core-Basis Results

Previously, our IFRS full-basis result has included the impact of transactions that are not related to our core business or are temporary in nature. Additionally, due to the acquisition of Deciphera Pharmaceuticals, Inc., we anticipate amortization expenses for intangible assets acquired through the acquisition in the future. Therefore, starting from the FY 2024, we will disclose the core-basis result to present our performance in our core business.

<Definition of Core-Basis Results>

Core-basis results are calculated by deducting items not related to the essential performance of our business and temporary items such as those occurring in a single fiscal year from the IFRS full-basis results:

Examples of specific adjustment items include amortization expenses arising from intangible assets acquired through acquisitions or in-licensing, impairment losses, and compensation or settlement from litigation, losses due to disasters, etc.

(Reference) Consolidated Financial Forecast for the Fiscal Year Ending March 31, 2025 (Core Basis)

(Billions of yen)

	FY 2024 Forecast (April 1, 2024 to March 31, 2025)
Revenue	485.0
Core operating profit	110.0
Core profit for the year	81.0

1. Revenue ¥485.0 billion

• There are no adjustments from IFRS full-basis revenue.

2. Core operating profit ¥110.0 billion

Core operating profit is calculated by deducting amortization expenses arising from Qinlock, acquired through the acquisition of
Deciphera Pharmaceuticals, Inc., amortization expenses for intangible assets acquired through in-licensing (cost of sales),
impairment losses on intangible assets related to development compounds (research and development expenses), and expenses
associated with the acquisition of Deciphera Pharmaceuticals, Inc. (selling, general, and administrative expenses) from the fullbasis operating profit.

3. Core profit for the period ¥81.0 billion

• Depreciation and Amortization, Capital Expenditure and Investments on Intangible Assets Depreciation and Amortization

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 2Q YTD (April 1, 2024 to September 30, 2024)	FY 2024 Forecast (April 1, 2024 to March 31, 2025)
Property, plant, and equipment	10.1	5.1	10.4
Intangible assets	8.1	3.9	7.9
Total	18.1	9.0	18.3
Ratio to sales revenue	3.6%	3.7%	3.8%

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

(Billions of yen)

	FY 2023 (April 1, 2023 to March 31, 2024)	FY 2024 2Q YTD (April 1, 2024 to September 30, 2024)	FY 2024 Forecast (April 1, 2024 to March 31, 2025)
Property, plant, and equipment	6.5	3.1	9.0
Intangible assets	11.3	1.8	17.0
Total	17.8	4.9	26.0

Number of Employees (Consolidated)

	FY 2023 2Q (as of September 30, 2023)	FY 2023 (as of March 31, 2024)	FY 2024 2Q (as of September 30, 2024)
Number of employees	3,843	3,853	4,258

Status of Shares (as of September 30, 2024)

Number of Shares

	As of September 30, 2024
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	498,692,800

Number of Shareholders

	As of September 30, 2024	
Number of shareholders	84,291	

Principal Shareholders

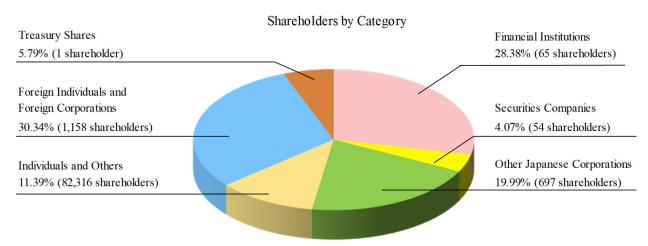
(As of September 30, 2024)

Name of shareholder	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	61,858	13.16
Custody Bank of Japan, Ltd. (Trust account)	20,238	4.30
Meiji Yasuda Life Insurance Company	18,594	3.95
Ono Scholarship Foundation	16,428	3.49
KAKUMEISOU Co., LTD.	16,153	3.43
STATE STREET BANK AND TRUST COMPANY 505001	10,090	2.14
STATE STREET BANK WEST CLIENT – TREATY 505234	9,835	2.09
MUFG Bank, Ltd.	8,640	1.83
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.65
JP Morgan Securities Japan Co., Ltd	7,061	1.50

Notes: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 28,919 thousand shares of treasury shares.

2. The shareholding percentage is calculated by deducting treasury shares (28,919 thousand shares).

Ownership and Distribution of Shares



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

I. Main Status of Development Pipelines (Oncology)

As of October 24, 2024

<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	Hepatocellular carcinoma *1	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)	
Yervoy Injection * / Ipilimumab	Additional indication	Hepatocellular carcinoma *1	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)	

^{★:} Combination with Opdivo

The change from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2025, is as follows:

<Clinical Trial Stage>

<opdivo></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			
	Additional indication	Hepatocellular carcinoma	Injection	S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)			
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)			
	Additional indication	Rhabdoid tumor*2	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)			
<yervoy></yervoy>		*) : "In-house" compou	nds include a	compound g	enerated fr	om 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	S. Korea	III	In-license (Co-development with Bristol-Myers Squibb)			
<ono-4538 subcuta<="" td=""><td>neous Injectior</td><td>> *): "In-house" compo</td><td>ınds include a</td><td>ı compound ş</td><td>generated f</td><td>rom collaborative research.</td></ono-4538>	neous Injectior	> *): "In-house" compo	ınds include a	ı compound ş	generated f	rom collaborative research.			
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license			
ONO-4538 HSC	New chemical entities	Solid tumor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)			

^{★:} Combination with Opdivo

The changes from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2025, are as follows:

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

^{*1:} An application for approval of combination therapy with Opdivo and Yervoy was filed in Japan for the treatment of hepatocellular carcinoma.

^{*2:} Phase II of Opdivo was initiated in Japan for the treatment of rhabdoid tumor.

<i-o related=""></i-o>	*): "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	e In-house*) / In-license			
ONO-4578 *	New chemical entities	Gastric cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan S. Korea Taiwan	II	In-house			
ONO-4482 *	New chemical entities	Hepatocellular carcinoma / Anti-LAG-3 antibody	Injection	Japan S. Korea Taiwan	II	In-license (Co-development with Bristol-Myers Squibb)			
(BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)			
ONO-7427 *	New chemical entities	Solid tumor / Anti-CCR8 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)			
ONO-7475 * / Tamnorzatinib	New chemical entities	Pancreatic cancer / 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			
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-7914 *	New chemical entities	Solid tumor / STING agonist	Injection	Japan	I	In-house			

^{★:} Combination with Opdivo

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

<others></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-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house			
ONO-7475 / Tamnorzatinib	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house			
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	Japan USA	I	In-house			
ONO-7018	New chemical entities	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia / MALT1 inhibitor	Tablet	Japan*3 USA	I	In-license (Chordia Therapeutics Inc.			
ONO-8250	New chemical entities	HER2-expressing solid tumors / iPS cell-derived HER2-targeted CAR-T cell therapeutics	Injection	USA	I	In-house (Co-development with Fate Therapeutics, Inc.)			

The changes from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2025, are as follows:

*3: Phase I of ONO-7018 (MALT1 inhibitor) was initiated in Japan for the treatment of Non-Hodgkin lymphoma, chronic lymphocytic leukemia.

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, 2024

<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 GABAA 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	Chemotherapy-induced peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-2808	New chemical entities	Multiple system atrophy /S1P5 receptor agonist	Tablet	Japan USA	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	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
ONO-4915*4	New chemical entities	Autoimmune disease / PD-1/CD19 bispecific antibody	Injection	Japan	I	In-house

The change from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2025, is as follows:

^{*4:} Phase I of ONO-4915 (PD-1/CD19 bispecific antibody) was initiated in Japan aimed at healthy adults.

^{*}Phase II of ONO-2910 (Schwann cell differentiation promoter) for the treatment of diabetic polyneuropathy was conducted in Japan, but the project was discontinued due to not being able to confirm expected efficacy.

III. Main Status of Development Pipelines (Deciphera Pharmaceuticals, Inc.)

As of October 24, 2024

<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
QINLOCK / Ripretinib	New chemical entities	Gastrointestinal stromal tumor (fourth line or fourth line plus) / KIT inhibitor	Tablet	North America, Europe, Australia, etc.,	Approved	In-house (Deciphera Pharmaceuticals Inc.)
	Additional indication	Gastrointestinal stromal tumor (second line) KIT exon 11+17/18 / KIT inhibitor	Tablet	North America, South America, Europe, Australia, etc.,	III	In-house (Deciphera pharmaceuticals Inc.)
DCC-3014 ^{*5} / Vimseltinib	New chemical entities	Tenosynovial giant cell tumor / CSF-1R inhibitor	Tablet	North America, Europe,	Filed	In-house (Deciphera pharmaceuticals Inc.)
DCC-3116	New chemical entities	Solid tumor (in combination with Sotorasib) / ULK inhibitor	Tablet	USA	I/ II	In-house (Deciphera pharmaceuticals Inc.)
	New chemical entities Solid tumor (in combination with Ripretinib) / ULK inhibitor	Tablet	USA	I/ II	In-house (Deciphera pharmaceuticals Inc.)	
DCC-3084	New chemical entities	Solid tumor / Pan-RAF inhibitor	Tablet	USA	I/ II	In-house (Deciphera pharmaceuticals Inc.)

The change from the announcement of financial results for the first quarter of the fiscal year ending March 31, 2025, is as follows:

^{*5:} An application of approval for DCC-3014 (CSF-1R inhibitor) was accepted in Europe and the United States for the treatment of tenosynovial giant cell tumor.

Profile for Main Development

Opdivo Intravenous Infusion (ONO-4538 / BMS-936558) / Nivolumab (injection)

Opdivo, a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer, etc. PD-1 is a receptor expressed on the surface of activated lymphocytes, and plays a role in a regulatory pathway that suppresses the 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 and hepatocellular carcinoma.

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 gastric cancer, colorectal cancer, pancreatic cancer, non-small cell lung cancer, and hormone receptor-positive HER2-negative breast cancer.

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, approvals were obtained in Japan for Braftovi Capsules and Mektovi Tablets, for their indications and effects in doublet combination therapy for the treatment of radically unresectable BRAF-mutant thyroid cancer that has progressed after chemotherapy, as well as for the treatment of radically unresectable anaplastic BRAF-mutant thyroid cancer. Also, it is being developed for the treatment of untreated BRAF-mutant colorectal 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, approvals were obtained in Japan for Braftovi Capsules and Mektovi Tablets, for their indications and effects in doublet combination therapy for the treatment of radically unresectable BRAF-mutant thyroid cancer that has progressed after chemotherapy, as well as for the treatment of radically unresectable anaplastic BRAF-mutant thyroid cancer.

Velexbru Tablets (ONO-4059) / Tirabrutinib Hydrochloride (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. Applications were approved in South Korea and Taiwan for the treatment of recurrent or refractory B-cell primary central nervous system lymphoma. In addition, it is being developed in the USA for the treatment of primary central nervous system lymphoma, and in Japan for the treatment of pemphigus.

ONO-7475 / Tamnorzatinib (tablet)

ONO-7475, an Axl/Mer inhibitor, is being developed in Japan for the treatment of EGFR-mutated non-small cell lung cancer and pancreatic cancer.

ONO-7913 / Magrolimab (injection)

ONO-7913, an anti-CD47 antibody, is being developed in Japan for the treatment of pancreatic cancer and colorectal cancer.

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 the oncology area, it is being developed in Japan and the USA for the treatment of T-cell lymphoma.

ONO-7018 (tablet)

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

ONO-7121 (injection)

ONO-7121, combination drugs with Opdivo and ONO-4482 (anti LAG-3 antibody / Relatlimab), is being developed. 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-4538HSC (subcutaneous injection)

ONO-4538HSC, a combination drug comprising nivolumab and volhyaluronidase alfa, is being developed in Japan for the treatment of solid tumor.

ONO-8250 (injection)

ONO-8250, an iPS cell-derived HER2-targeted CAR-T cell therapeutics, is being developed in the USA for the treatment of HER2-expressing solid tumor.

ONO-7427 (injection)

ONO-7427, an anti-CCR8 antibody, 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-2017 / Cenobamate (tablet)

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

ONO-2808 (tablet)

ONO-2808, a S1P5 receptor agonist, is being developed in Japan and the USA for the treatment of multiple system atrophy.

ONO-2910 (tablet)

ONO-2910, a Schwann cell differentiation promoter, is being developed in Japan for the treatment of chemotherapy-induced peripheral neuropathy.

ONO-2020 (tablet)

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

ONO-1110 (oral)

ONO-1110, an endocannabinoid regulation, is being developed in Japan for the treatment of pain.

ONO-4915 (injection)

ONO-4915, a PD-1/CD19 bispecific antibody, is being developed in Japan for the treatment of autoimmune disease.

<Development Pipelines (Deciphera Pharmaceuticals Inc.,)>

QINLOCK / Ripretinib (tablet)

QINLOCK is a KIT inhibitor that has been approved by the US FDA for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have a history of treatment with three or more kinase inhibitors, including imatinib. It is based on the favorable results in fourth-line treatment and fourth-line treatment + GIST patients in the Phase 3 INVICTUS trial, and has been approved in regions such as North America, Europe, and Australia. In addition, it is being developed as a second-line treatment for KIT exon 11+17/18 mutation-positive GIST patients.

DCC-3014/Vimseltinib

DCC-3014 is a CSF-1R inhibitor being developed globally as a treatment for tenosynovial giant cell tumor (TGCT). In addition, the New Drug Application (NDA) for TGCT treatment has been accepted in Europe and the United States.

DCC-3116

DCC-3116, a ULK inhibitor, is being developed in combination with sotorasib and in combination with ripretinib for the treatment of solid tumor in the USA.

DCC-3084

DCC-3084, a Pan-RAF inhibitor, is being developed in the USA for the treatment of solid tumor.