

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

January 31, 2023

Company name	: <b>ONO PHARMACEUTICAL CO., LTD.</b>
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: <a href="https://www.ono-pharma.com/en">https://www.ono-pharma.com/en</a>
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Scheduled date of quarterly securities report submission	: February 3, 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 Third Quarter of FY 2022 (April 1, 2022 to December 31, 2022)

#### (1) Consolidated Operating Results (cumulative)

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

	Revenue		Operating profit		Profit before tax		Profit for the period		Profit attributable to owners of the Company		Total comprehensive income for the period	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2022 Q3	339,020	24.9	122,590	49.2	124,379	47.5	95,827	48.2	95,656	48.0	95,297	39.5
FY 2021 Q3	271,430	15.5	82,167	(0.0)	84,349	(0.4)	64,669	(2.8)	64,620	(2.8)	68,303	(17.3)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2022 Q3	195.90	195.88
FY 2021 Q3	129.61	129.59

#### (2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets
	Million yen	Million yen	Million yen	%
As of December 31, 2022	830,539	727,307	721,385	86.9
As of March 31, 2022	739,203	661,674	655,906	88.7

### 2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2021	—	28.00	—	28.00	56.00
FY 2022	—	33.00	—		
FY 2022 (Forecast)				33.00	66.00

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

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

(% change from the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2022	440,000	21.8	149,000	44.4	150,000	42.8	114,200	41.5	114,000	41.6	233.47

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

## Notes

- (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None
- (2) Changes in accounting policies and changes in accounting estimates
  - 1) Changes in accounting policies required by IFRS: None
  - 2) Changes in accounting policies due to other than (2) – 1) above: None
  - 3) Changes in accounting estimates: None
- (3) Number of shares issued and outstanding (common stock)
  - 1) Number of shares issued and outstanding as of the end of the period (including treasury shares):

As of December 31, 2022	517,425,200	shares
As of March 31, 2022	528,341,400	shares
  - 2) Number of treasury shares as of the end of the period:

As of December 31, 2022	29,091,193	shares
As of March 31, 2022	40,096,713	shares
  - 3) Average number of shares outstanding during the period:

Nine months ended December 31, 2022	488,291,864	shares
Nine months ended December 31, 2021	498,583,112	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 3rd Quarter of FY 2022

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	Change	Change (%)
Revenue	271,430	<b>339,020</b>	67,590	24.9%
Operating profit	82,167	<b>122,590</b>	40,423	49.2%
Profit before tax	84,349	<b>124,379</b>	40,030	47.5%
Profit for the period (attributable to owners of the Company)	64,620	<b>95,656</b>	31,035	48.0%

#### [Revenue]

Revenue totaled ¥339.0 billion, which was an increase of ¥67.6 billion (24.9%) from the corresponding period of the previous fiscal year (year on year).

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded mainly to gastric cancer and esophageal cancer, resulting in sales of ¥109.1 billion, an increase of ¥24.1 billion (28.3%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥41.9 billion (58.0% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥19.1 billion (9.0% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥17.7 billion (8.5% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥6.8 billion (4.4% increase year on year). Sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥6.5 billion (5.6% decrease year on year). Sales of Velembro Tablets for malignant tumors were ¥6.5 billion (38.5% increase year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥3.8 billion (91.8% increase year on year).
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥3.4 billion (7.5% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥1.7 billion (34.9% decrease year on year).
- Royalty and others increased by ¥27.9 billion (32.7%) year on year to ¥113.5 billion.

#### [Operating profit]

Operating profit was ¥122.6 billion, an increase of ¥40.4 billion (49.2%) year on year.

- Cost of sales increased by ¥13.2 billion (18.6%) year on year to ¥83.8 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥16.5 billion (33.4%) year on year to ¥66.0 billion mainly due to increases in research costs, costs for drug discovery collaboration, development costs for early clinical trials, and expenses for collaborative development with alliance partners.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥8.7 billion (15.1%) year on year to ¥66.1 billion mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.
- Other expenses decreased by ¥11.4 billion year on year to ¥1.0 billion mainly due to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody recorded in the fiscal year ended March 2022.

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

Profit attributable to owners of the Company increased by ¥31.0 billion (48.0%) year on year to ¥95.7 billion in association with the increase of the profit before tax.

**(2) Overview of Financial Position for the 3rd Quarter of FY 2022**

(Millions of yen)

	As of March 31, 2022	As of December 31, 2022	Change
Total Assets	739,203	<b>830,539</b>	91,335
Equity attributable to owners of the Company	655,906	<b>721,385</b>	65,479
Ratio of equity attributable to owners of the Company to total assets	88.7%	<b>86.9%</b>	
Equity attributable to owners of the Company per share	1,343.40 yen	<b>1,477.26 yen</b>	

Total assets increased to ¥830.5 billion by ¥91.3 billion from the end of the previous fiscal year.

Current assets increased by ¥82.1 billion to ¥363.3 billion mainly due to increases in cash and cash equivalents and trade and other receivables.

Non-current assets increased by ¥9.3 billion to ¥467.2 billion mainly due to an increase in other financial assets, while decreases in investment securities and property, plant, and equipment.

Liabilities increased by ¥25.7 billion to ¥103.2 billion mainly due to an increase in income taxes payable.

Equity attributable to owners of the Company increased by ¥65.5 billion to ¥721.4 billion mainly due to the recording of the profit for the period despite there being cash dividends.

**(3) Overview of Cash Flows for the 3rd Quarter of FY 2022**

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	Change
Cash and cash equivalents at the beginning of the period	61,045	<b>69,112</b>	
Cash flows from operating activities	27,398	<b>115,064</b>	87,665
Cash flows from investing activities	18,056	<b>(44,852)</b>	(62,907)
Cash flows from financing activities	(44,234)	<b>(30,872)</b>	13,362
Net increase (decrease) in cash and cash equivalents	1,220	<b>39,340</b>	
Effects of exchange rate changes on cash and cash equivalents	211	<b>141</b>	
Cash and cash equivalents at the end of the period	62,476	<b>108,593</b>	

Net increase / decrease in cash and cash equivalents for the third quarter (nine months) of the fiscal year 2022 was an increase of ¥39.3 billion.

Net cash provided by operating activities was ¥115.1 billion, as a result of profit before tax of ¥124.4 billion, etc., while an increase in trade and other receivables of ¥23.8 billion, etc.

Net cash used in investing activities was ¥44.9 billion, as a result of payments into time deposits of ¥53.0 billion, while proceeds from withdrawal of time deposits of ¥12.8 billion, etc.

Net cash used in financing activities was ¥30.9 billion, as a result of dividends paid of ¥28.8 billion, etc.

#### **(4) Future Outlook**

There are no changes from the consolidated financial forecast for the year ending March 31, 2023 announced on October 31, 2022. As for the impact of the novel coronavirus disease (COVID-19) on business and financial results, we assume that restrictions on certain activities will continue, but we expect that the impact on operating profit will remain immaterial.

#### **2. Basic Approach to the Selection of Accounting Standards**

Our group has applied International Financial Reporting Standards (IFRSs) from the fiscal year ended March 31, 2014, for the purpose of improving comparability by disclosing financial information based on international standards and enhancing the convenience of various stakeholders such as shareholders, investors, and business partners.

### 3. Condensed Interim Consolidated Financial Statements and Major Notes

#### (1) Condensed Interim Consolidated Statements of Financial Position

	(Millions of yen)	
	As of March 31, 2022	As of December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	69,112	108,593
Trade and other receivables	99,788	124,024
Marketable securities	60	—
Other financial assets	47,797	68,442
Inventories	41,817	44,832
Other current assets	22,692	17,450
Total current assets	281,266	363,341
Non-current assets		
Property, plant, and equipment	112,131	108,804
Intangible assets	64,734	62,532
Investment securities	125,046	118,343
Investments in associates	108	117
Other financial assets	127,302	147,249
Deferred tax assets	25,074	26,720
Retirement benefit assets	377	334
Other non-current assets	3,165	3,099
Total non-current assets	457,937	467,198
Total assets	739,203	830,539

(Millions of yen)

	As of March 31, 2022	As of December 31, 2022
<b>Liabilities and Equity</b>		
<b>Current liabilities</b>		
Trade and other payables	49,689	49,198
Lease liabilities	2,301	2,443
Other financial liabilities	716	3,578
Income taxes payable	1,526	22,419
Other current liabilities	11,694	13,898
<b>Total current liabilities</b>	<b>65,926</b>	<b>91,536</b>
<b>Non-current liabilities</b>		
Lease liabilities	6,501	6,456
Other financial liabilities	0	0
Retirement benefit liabilities	3,322	3,532
Deferred tax liabilities	1,009	987
Other non-current liabilities	771	720
<b>Total non-current liabilities</b>	<b>11,603</b>	<b>11,696</b>
<b>Total liabilities</b>	<b>77,529</b>	<b>103,232</b>
<b>Equity</b>		
Share capital	17,358	17,358
Capital reserves	17,241	17,080
Treasury shares	(74,683)	(54,161)
Other components of equity	51,236	48,407
Retained earnings	644,754	692,702
<b>Equity attributable to owners of the Company</b>	<b>655,906</b>	<b>721,385</b>
Non-controlling interests	5,768	5,921
<b>Total equity</b>	<b>661,674</b>	<b>727,307</b>
<b>Total liabilities and equity</b>	<b>739,203</b>	<b>830,539</b>



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

**Condensed Interim Consolidated Statements of Income**

	(Millions of yen)	
	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Revenue	271,430	339,020
Cost of sales	(70,634)	(83,787)
Gross profit	200,796	255,233
Selling, general, and administrative expenses	(57,488)	(66,147)
Research and development costs	(49,464)	(65,974)
Other income	745	518
Other expenses	(12,422)	(1,041)
Operating profit	82,167	122,590
Finance income	2,537	2,409
Finance costs	(353)	(624)
Share of profit (loss) from investments in associates	(2)	4
Profit before tax	84,349	124,379
Income tax expense	(19,680)	(28,551)
Profit for the period	64,669	95,827
Profit for the period attributable to:		
Owners of the Company	64,620	95,656
Non-controlling interests	48	172
Profit for the period	64,669	95,827
Earnings per share:		
Basic earnings per share (Yen)	129.61	195.90
Diluted earnings per share (Yen)	129.59	195.88

**Condensed Interim Consolidated Statements of Comprehensive Income**

	(Millions of yen)	
	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Profit for the period	64,669	95,827
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	2,709	(743)
Remeasurements of defined benefit plans	556	(41)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(0)	3
Total of items that will not be reclassified to profit or loss	3,265	(781)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	344	377
Net fair value gain (loss) on cash flow hedges	25	(127)
Total of items that may be reclassified subsequently to profit or loss	369	250
Total other comprehensive income	3,634	(530)
Total comprehensive income for the period	68,303	95,297
Comprehensive income for the period attributable to:		
Owners of the Company	68,252	95,137
Non-controlling interests	51	160
Total comprehensive income for the period	68,303	95,297

**(3) Condensed Interim Consolidated Statements of Changes in Equity**

Nine months ended December 31, 2021

(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, 2021	17,358	17,231	(44,705)	62,299	581,950	634,133	5,610	639,743
Profit for the period					64,620	64,620	48	64,669
Other comprehensive income				3,631		3,631	2	3,634
Total comprehensive income for the period	—	—	—	3,631	64,620	68,252	51	68,303
Purchase of treasury shares			(15,460)			(15,460)		(15,460)
Disposition of treasury shares		(31)	31			0		0
Cash dividends					(27,703)	(27,703)	(4)	(27,707)
Share-based payments		31				31		31
Transfer from other components of equity to retained earnings				(7,827)	7,827	—		—
Total transactions with the owners	—	0	(15,429)	(7,827)	(19,876)	(43,132)	(4)	(43,136)
Balance as of December 31, 2021	17,358	17,231	(60,134)	58,104	626,694	659,253	5,657	664,910

Nine months ended December 31, 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					95,656	95,656	172	95,827
Other comprehensive income				(519)		(519)	(12)	(530)
Total comprehensive income for the period	—	—	—	(519)	95,656	95,137	160	95,297
Purchase of treasury shares			(2)			(2)		(2)
Retirement of treasury shares		(20,356)	20,356			—		—
Disposition of treasury shares		(168)	168			—		—
Cash dividends					(29,786)	(29,786)	(6)	(29,792)
Share-based payments		130				130		130
Transfer from retained earnings to capital reserves		20,233			(20,233)	—		—
Transfer from other components of equity to retained earnings				(2,311)	2,311	—		—
Total transactions with the owners	—	(161)	20,522	(2,311)	(47,708)	(29,658)	(6)	(29,665)
Balance as of December 31, 2022	17,358	17,080	(54,161)	48,407	692,702	721,385	5,921	727,307

**(4) Condensed Interim Consolidated Statements of Cash Flows**

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
<b>Cash flows from operating activities</b>		
Profit before tax	84,349	124,379
Depreciation and amortization	13,084	12,953
Impairment losses	345	1,154
Interest and dividend income	(2,285)	(2,327)
Interest expense	52	48
(Increase) decrease in inventories	187	(2,926)
(Increase) decrease in trade and other receivables	(17,857)	(23,818)
Increase (decrease) in trade and other payables	(621)	2,023
Increase (decrease) in provisions	(20,721)	–
Increase (decrease) in retirement benefit liabilities	129	171
(Increase) decrease in retirement benefit assets	97	22
Other	2,647	7,723
Subtotal	<u>59,406</u>	<u>119,402</u>
Interest received	29	27
Dividends received	2,265	2,305
Interest paid	(52)	(48)
Income taxes paid	<u>(34,250)</u>	<u>(6,622)</u>
Net cash provided by (used in) operating activities	<u>27,398</u>	<u>115,064</u>
<b>Cash flows from investing activities</b>		
Purchases of property, plant, and equipment	(3,928)	(3,944)
Purchases of intangible assets	(6,292)	(6,103)
Purchases of investments	(848)	(1,613)
Proceeds from sales and redemption of investments	16,927	7,367
Payments into time deposits	(7,267)	(52,975)
Proceeds from withdrawal of time deposits	20,600	12,811
Other	(1,137)	(395)
Net cash provided by (used in) investing activities	<u>18,056</u>	<u>(44,852)</u>
<b>Cash flows from financing activities</b>		
Dividends paid	(26,861)	(28,800)
Dividends paid to non-controlling interests	(4)	(6)
Repayments of lease liabilities	(1,911)	(2,065)
Purchases of treasury shares	(15,458)	(1)
Net cash provided by (used in) financing activities	<u>(44,234)</u>	<u>(30,872)</u>
Net increase (decrease) in cash and cash equivalents	1,220	39,340
Cash and cash equivalents at the beginning of the period	61,045	69,112
Effects of exchange rate changes on cash and cash equivalents	211	141
Cash and cash equivalents at the end of the period	<u>62,476</u>	<u>108,593</u>

**(5) Notes to Condensed Interim Consolidated Financial Statements**

**(Note Regarding Assumption of Going Concern)**

Not Applicable

**(Segment Information)**

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

**(Significant Subsequent Events)**

Not Applicable

#### 4. Supplementary Information

##### (1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product Name	Nine months ended December 31, 2022 (April 1, 2022 to December 31, 2022)						FY 2022 Forecast (April 1, 2022 to March 31, 2023)				
	Cumulative				YoY		Previous Forecast	Change from Previous Forecast	Revised Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	34.1	35.8	39.3	109.1	24.1	28.3%	155.0	(10.0)	145.0	32.6	28.9%
Forxiga Tablets	13.1	13.3	15.5	41.9	15.4	58.0%	47.0	8.0	55.0	18.3	50.1%
Orencia for Subcutaneous Injection	6.2	6.2	6.7	19.1	1.6	9.0%	23.0	1.5	24.5	1.6	7.0%
Glactiv Tablets	6.0	5.7	5.9	17.7	(1.6)	(8.5%)	23.0		23.0	(1.5)	(6.3%)
Kyprolis for Intravenous Infusion	2.2	2.2	2.4	6.8	0.3	4.4%	9.0		9.0	0.6	7.6%
Parsabiv Intravenous Injection	2.1	2.1	2.3	6.5	(0.4)	(5.6%)	8.0		8.0	(0.9)	(9.9%)
Velexbru Tablets	2.1	2.0	2.4	6.5	1.8	38.5%	7.0	1.5	8.5	2.2	35.6%
Ongentys Tablets	1.2	1.2	1.4	3.8	1.8	91.8%	5.0		5.0	2.1	73.6%
Onoact for Intravenous Infusion	1.1	1.0	1.4	3.6	(0.4)	(9.0%)	4.5		4.5	(0.4)	(7.6%)
Opalmon Tablets	1.1	1.1	1.2	3.4	(0.3)	(7.5%)	3.5	1.0	4.5	(0.2)	(4.9%)
Braftovi Capsules	0.9	0.8	0.9	2.5	0.4	20.7%	3.5		3.5	0.8	27.4%
Mektovi Tablets	0.7	0.6	0.7	2.0	0.3	15.5%	2.5		2.5	0.3	11.7%
Onon Capsules	0.7	0.5	0.6	1.7	(0.9)	(34.9%)	2.5		2.5	(1.1)	(29.7%)

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

2. Regarding sales revenue forecasts for the FY 2022, only currently approved indications are covered.

##### (2) Details of Sales Revenue

(Billions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Revenue of goods and products	185.9	225.5
Royalty and others	85.5	113.5
Total	271.4	339.0

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥52.1 billion for the third quarter (nine months) ended December 31, 2021 and ¥66.8 billion for the third quarter (nine months) ended December 31, 2022. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥22.4 billion for the third quarter (nine months) ended December 31, 2021 and ¥33.6 billion for the third quarter (nine months) ended December 31, 2022.

##### (3) Revenue by Geographic Area

(Billions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Japan	183.3	220.6
Americas	78.3	105.3
Asia	6.4	8.6
Europe	3.4	4.5
Total	271.4	339.0

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

(4) Main Status of Development Pipelines (Oncology)

As of January 23, 2023

<Clinical Trial Stage>

<b>&lt;Opdivo&gt;</b> *) : “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)
<b>&lt;Yervoy&gt;</b> *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Yervoy Injection * / Ipilimumab	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	S. Korea	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)

<b>&lt;I-O Related&gt;</b>						
*): "In-house" compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578 ★	New chemical entities	Colorectal cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor・Gastric cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 ★ /Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 ★ /Atamparib	New chemical entities	Solid tumor / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)
ONO-7122 ★	New chemical entities	Solid tumor / TGF-β inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 ★	New chemical entities	Solid tumor / STING agonist	Injection	Japan	I	In-house



<b>&lt;Others&gt;</b>						
*) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-7913 / Magrolimab	New chemical entities	TP53-mutant acute myeloid leukemia / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	EGFR-mutated non-small cell lung cancer / AxI/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.

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

**(5) Main Status of Development Pipelines (Areas other than Oncology)**

As of January 23, 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 <sub>A</sub> 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 <sub>A</sub> ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	III	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe	I	In-house
ONO-7684*1	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Japan Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / SIP5 receptor agonist	Tablet	Japan Europe	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house
ONO-1110*2	New chemical entities	Pain / Endocannabinoid regulation	Oral	Japan	I	In-house

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

\*1: Phase I of ONO-7684, FXIa inhibitor, was initiated in Japan for healthy adult subjects.

\*2: Phase I of ONO-1110, Endocannabinoid regulation, was initiated in Japan for healthy adult subjects.