Consolidated Financial Results
for the Third Quarter of the Fiscal Year Ending March 31, 2019 (IFRS)

February 1, 2019

Company name : **Ono Pharmaceutical Co., Ltd.**
Stock exchange listing : Tokyo Stock Exchange
Code number : 4528
URL : https://www.ono.co.jp/
Representative : Gyo Sagara
President, Representative Director, and Chief Executive Officer
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Scheduled date of quarterly securities report submission : February 8, 2019
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 2018 (April 1, 2018 to December 31, 2018)

(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	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2018 Q3	223,197	11.3	52,146	(0.1)	55,234	(0.2)	43,212	4.0	43,133	4.1
FY 2017 Q3	200,570	6.2	52,191	(2.1)	55,333	(1.5)	41,539	(2.4)	41,439	(2.4)

	Total comprehensive income for the period		Basic earnings per share	Diluted earnings per share
	Million yen	%	Yen	Yen
FY 2018 Q3	37,419	(43.1)	83.90	83.89
FY 2017 Q3	65,744	23.5	79.74	79.74

(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, 2018	629,398	549,327	544,015	86.4
As of March 31, 2018	609,226	529,619	524,390	86.1

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2017	—	25.00	—	20.00	45.00
FY 2018	—	22.50	—		
FY 2018 (Forecast)				22.50	45.00

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

3. Forecasts of Consolidated Financial Results for FY 2018 (April 1, 2018 to March 31, 2019)

(% 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		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2018	280,000	6.9	63,500	4.6	67,000	4.8	52,100	3.4	52,000	3.4	101.14

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

Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies due to other than (2) – 1) above: None
3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the period (including treasury shares):
As of December 31, 2018 543,341,400 shares
As of March 31, 2018 543,341,400 shares
2) Number of treasury shares as of the end of the period:
As of December 31, 2018 29,220,621 shares
As of March 31, 2018 29,219,787 shares
3) Average number of shares outstanding during the period:
Nine months ended December 31, 2018 514,121,174 shares
Nine months ended December 31, 2017 519,671,572 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) Outlook for FY 2018" on page 3 for information regarding the forecast of consolidated financial results.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 3rd Quarter of FY 2018

The financial results for the third quarter (April–December 2018) were as follows.

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	Change	Change (%)
Revenue	200,570	223,197	22,627	11.3%
Operating profit	52,191	52,146	(46)	(0.1%)
Profit before tax	55,333	55,234	(98)	(0.2%)
Profit for the period (attributable to owners of the Company)	41,439	43,133	1,694	4.1%

[Revenue]

Revenue totaled ¥223.2 billion, which was an increase of ¥22.6 billion (11.3%) from the corresponding period of the previous fiscal year (year-on-year).

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction according to the drastic reform of NHI drug pricing system, its use was expanded for the treatment of renal cell carcinoma, and head and neck cancer approved in the fiscal year before last as well as gastric cancer etc. in the previous fiscal year, resulting in sales of ¥71.3 billion, an increase of ¥2.4 billion (3.4%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥21.2 billion (5.2% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥13.4 billion (23.5% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥11.1 billion (30.6% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥8.2 billion (5.8% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥7.0 billion (0.4% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥4.4 billion (77.6% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥3.9 billion (12.7% decrease year-on-year).
- Sales of long-term listed products were affected by the impact of NHI drug price reduction and generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥8.3 billion (28.7% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥6.1 billion (28.3% decrease year-on-year), respectively.
- Royalty and other revenue increased by ¥18.8 billion (46.2%) year-on-year to ¥59.4 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company and recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.

[Operating Profit]

Operating profit was ¥52.1 billion, a slight decrease of 0.1% year-on-year.

- Cost of sales was ¥66.6 billion, an increase of ¥16.4 billion (32.6%) year-on-year mainly due to the impact of applying IFRS 15 noted below (¥8.3 billion compared with the previous accounting standards) and one-time expense in order to ensure stable supply of ingredients for Opdivo.
- Research and development costs increased by ¥2.8 billion (5.8%) year-on-year to ¥51.2 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥2.7 billion (5.4%) year-on-year to ¥52.2 billion due to the rise in operating costs related to main new products such as Opdivo Intravenous Infusion and Forxiga Tablets.

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

Profit attributable to owners of the Company increased by ¥1.7 billion (4.1%) year-on-year to ¥43.1 billion due to the decrease of income tax expense (decrease of the forecasted annual tax rate).

Note: Our group has applied IFRS 15 "Revenue from Contracts with Customers" from the first quarter of the fiscal year ending March 31, 2019. For the condensed interim consolidated statement of income of the third quarter (nine months) ended December 31, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥8,297 million, cost of sales increased by ¥8,269 million, operating profit increased by ¥28 million, and profit before tax increased by ¥28 million.

(2) Overview of Financial Position for the 3rd Quarter of FY 2018

(Millions of yen)

	As of March 31, 2018	As of December 31, 2018	Change
Total Assets	609,226	629,398	20,172
Equity attributable to owners of the Company	524,390	544,015	19,625
Ratio of equity attributable owners of the Company to total assets	86.1%	86.4%	
Equity attributable to owners of the Company per share	1,019.97 yen	1,058.15 yen	

Total assets increased to ¥629.4 billion by ¥20.2 billion from the end of the previous fiscal year.
Current assets increased by ¥14.3 billion to ¥223.8 billion due to an increase of cash and cash equivalents etc.
Non-current assets increased by ¥5.8 billion to ¥405.6 billion due to an increase of property, plant, and equipment and intangible assets etc., despite a decrease in investment securities etc.
Liabilities increased by ¥0.5 billion to ¥80.1 billion due to an increase of trade and other payables etc., despite a decrease in income taxes payable etc.
Equity attributable to owners of the Company increased by ¥19.6 billion to ¥544.0 billion due to an increase in retained earnings etc., despite a decrease in other components of equity etc.

(3) Overview of Cash Flows for the 3rd Quarter of FY 2018

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	Change
Cash and cash equivalents at the beginning of the period	146,323	65,273	
Cash flows from operating activities	(8,537)	43,005	51,542
Cash flows from investing activities	(36,625)	(7,106)	29,519
Cash flows from financing activities	(61,595)	(21,418)	40,177
Net increase (decrease) in cash and cash equivalents	(106,757)	14,481	
Effects of exchange rate changes on cash and cash equivalents	142	(34)	
Cash and cash equivalents at the end of the period	39,708	79,720	

Net increase/decrease in cash and cash equivalents was an increase of ¥14.5 billion.
Net cash from operating activities was ¥43.0 billion, as a result of profit before tax of ¥55.2 billion etc.
Net cash used in investing activities was ¥7.1 billion, as a result of purchase of property, plant, and equipment of ¥15.4 billion etc., while proceeds from sales and redemption of investments amounted to ¥10.8 billion.
Net cash used in financing activities was ¥21.4 billion, as a result of dividends paid of ¥21.1 billion etc.

(4) Outlook for FY 2018

There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2019 announced on November 11, 2018.

2. Basic Approach to the Selection of Accounting Standards

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

3. Condensed Interim Consolidated Financial Statements and Major Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2018	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	65,273	79,720
Trade and other receivables	77,577	86,299
Marketable securities	9,670	1,737
Other financial assets	10,833	10,827
Inventories	31,290	33,745
Other current assets	14,821	11,462
Total current assets	209,464	223,791
Non-current assets:		
Property, plant, and equipment	94,321	108,383
Intangible assets	55,715	57,200
Investment securities	188,803	177,794
Investments in associates	116	112
Other financial assets	46,685	46,648
Deferred tax assets	10,192	11,783
Other non-current assets	3,929	3,686
Total non-current assets	399,761	405,607
Total assets	609,226	629,398

(Millions of yen)

	As of March 31, 2018	As of December 31, 2018
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,015	40,926
Borrowings	392	423
Other financial liabilities	3,756	2,904
Income taxes payable	8,742	3,072
Provisions	11,696	15,551
Other current liabilities	9,869	9,050
Total current liabilities	68,469	71,927
Non-current liabilities:		
Borrowings	320	1,834
Other financial liabilities	8	9
Retirement benefit liabilities	3,856	4,432
Provisions	30	30
Deferred tax liabilities	1,016	1,024
Long-term advances received	5,095	—
Other non-current liabilities	814	816
Total non-current liabilities	11,138	8,144
Total liabilities	79,607	80,071
Equity:		
Share capital	17,358	17,358
Capital reserves	17,175	17,195
Treasury shares	(38,148)	(38,150)
Other components of equity	68,021	61,355
Retained earnings	459,985	486,257
Equity attributable to owners of the Company	524,390	544,015
Non-controlling interests	5,228	5,312
Total equity	529,619	549,327
Total liabilities and equity	609,226	629,398

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Revenue	200,570	223,197
Cost of sales	(50,235)	(66,592)
Gross profit	150,336	156,605
Selling, general, and administrative expenses	(49,477)	(52,167)
Research and development costs	(48,366)	(51,172)
Other income	390	583
Other expenses	(691)	(1,703)
Operating profit	52,191	52,146
Finance income	3,158	3,225
Finance costs	(26)	(141)
Share of profit (loss) from investments in associates	9	5
Profit before tax	55,333	55,234
Income tax expense	(13,793)	(12,022)
Profit for the period	41,539	43,212
Profit for the period attributable to:		
Owners of the Company	41,439	43,133
Non-controlling interests	100	79
Profit for the period	41,539	43,212
Earnings per share:	*Yen*	
Basic earnings per share	79.74	83.90
Diluted earnings per share	79.74	83.89

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Profit for the period	41,539	43,212
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	23,363	(5,618)
Remeasurements of defined benefit plans	675	(208)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	(8)
Total of items that will not be reclassified to profit or loss	24,041	(5,835)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	158	51
Net fair value gain (loss) on cash flow hedges	6	(10)
Total of items that may be reclassified subsequently to profit or loss	164	42
Total other comprehensive income (loss)	24,205	(5,793)
Total comprehensive income (loss) for the period	65,744	37,419
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	65,620	37,330
Non-controlling interests	124	89
Total comprehensive income (loss) for the period	65,744	37,419

(3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 2017

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2017	17,358	17,144	(59,382)	51,752	492,237	519,110	5,101	524,211
Profit for the period					41,439	41,439	100	41,539
Other comprehensive income (loss)				24,181		24,181	24	24,205
Total comprehensive income (loss) for the period	–	–	–	24,181	41,439	65,620	124	65,744
Purchase of treasury shares			(38,772)			(38,772)		(38,772)
Retirement of treasury shares			60,007		(60,007)	–		–
Cash dividends					(23,453)	(23,453)	(3)	(23,457)
Share-based payments		24				24		24
Transfer from other components of equity to retained earnings				(2,078)	2,078	–		–
Total transactions with the owners	–	24	21,235	(2,078)	(81,382)	(62,202)	(3)	(62,205)
Balance as of December 31, 2017	17,358	17,168	(38,147)	73,855	452,294	522,528	5,222	527,750

Nine months ended December 31, 2018

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2018	17,358	17,175	(38,148)	68,021	459,985	524,390	5,228	529,619
Changes in Accounting Policies					4,127	4,127		4,127
Restated balance	17,358	17,175	(38,148)	68,021	464,112	528,517	5,228	533,746
Profit for the period					43,133	43,133	79	43,212
Other comprehensive income (loss)				(5,803)		(5,803)	10	(5,793)
Total comprehensive income (loss) for the period	–	–	–	(5,803)	43,133	37,330	89	37,419
Purchase of treasury shares			(2)			(2)		(2)
Cash dividends					(21,850)	(21,850)	(5)	(21,856)
Share-based payments		20				20		20
Transfer from other components of equity to retained earnings				(863)	863	–		–
Total transactions with the owners	–	20	(2)	(863)	(20,988)	(21,832)	(5)	(21,838)
Balance as of December 31, 2018	17,358	17,195	(38,150)	61,355	486,257	544,015	5,312	549,327

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Cash flows from operating activities		
Profit before tax	55,333	55,234
Depreciation and amortization	6,681	7,773
Impairment losses	—	24
Interest and dividend income	(2,885)	(3,054)
Interest expense	10	14
(Increase) decrease in inventories	(4,986)	(2,486)
(Increase) decrease in trade and other receivables	(19,581)	(8,746)
Increase (decrease) in trade and other payables	(2,965)	3,126
Increase (decrease) in provisions	3,985	4,678
Increase (decrease) in retirement benefit liabilities	282	276
Increase (decrease) in long-term advances received	(237)	–
Other	(10,683)	1,584
Subtotal	24,952	58,424
Interest received	66	51
Dividends received	2,817	3,002
Interest paid	(10)	(14)
Income taxes paid	(36,363)	(18,458)
Net cash provided by (used in) operating activities	(8,537)	43,005
Cash flows from investing activities		
Purchases of property, plant, and equipment	(11,989)	(15,372)
Purchases of intangible assets	(10,862)	(2,410)
Purchases of investments	(40)	–
Proceeds from sales and redemption of investments	16,761	10,844
Payments into time deposits	(30,600)	(10,600)
Proceeds from withdrawal of time deposits	600	10,600
Other	(495)	(168)
Net cash provided by (used in) investing activities	(36,625)	(7,106)
Cash flows from financing activities		
Dividends paid	(22,478)	(21,092)
Dividends paid to non-controlling interests	(3)	(5)
Repayments of long-term borrowings	(315)	(236)
Net increase (decrease) in short-term borrowings	(24)	(84)
Purchases of treasury shares	(38,775)	(1)
Net cash provided by (used in) financing activities	(61,595)	(21,418)
Net increase (decrease) in cash and cash equivalents	(106,757)	14,481
Cash and cash equivalents at the beginning of the period	146,323	65,273
Effects of exchange rate changes on cash and cash equivalents	142	(34)
Cash and cash equivalents at the end of the period	39,708	79,720

(5) Notes to Condensed Interim Consolidated Financial Statements

(Changes in Accounting Policies)

Our group has applied the following standards from the first quarter of the fiscal year ending March 31, 2019.

IFRS		Overview of establishment and amendments
IFRS 15	Revenue from Contracts with Customers	Issuance of a single and comprehensive model for accounting treatment for revenue from contracts with customers
IFRS 9 (amended in July 2014)	Financial Instruments	Impairment of financial assets and revision of hedge accounting
IFRIC 22	Foreign Currency Transactions and Advance Consideration	Clarification of the accounting for transactions that include the receipt or payment of advance consideration in a foreign currency

1) IFRS 15 “Revenue from Contracts with Customers”

Our group has applied IFRS 15 “Revenue from Contracts with Customers” (published in May 2014) and “Clarifications to IFRS 15” (published in April 2016) (hereinafter collectively referred to as “IFRS 15”) from the first quarter of the fiscal year ending March 31, 2019.
Along with application of IFRS 15, excluding the interest and dividend income etc. based on IFRS 9 “Financial Instruments”, revenue is recognized by applying the following five steps.

Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

(i) Sale of merchandise

For the sale of merchandise, revenue is recognized at the point where it is delivered, since material risks and economic value associated with ownership of said merchandise is transferred to customers at the time of its delivery, and customers acquire control over it, and thereby our group’s performance obligations are considered to be satisfied.
The revenue arising from sale of merchandise is calculated by deducting the amount of rebates and discounts based on the number and amount of sales from the consideration in the sales contract, and the consideration to be refunded to customers and the amounts to be collected on behalf of third-parties is recognized as a refund liability. The most likely amount method based on contractual conditions and past results is used to estimate rebates etc. Revenue is recognized only to the extent that it is highly probable that there will not be a significant reversal of revenue previously recognized.
Consideration related to sale of merchandise is mainly received within one year from the delivery of merchandise to customers. This does not include significant financing components.

(ii) Royalty revenue etc.

Royalty revenue is consideration for license contracts etc. calculated on the basis of revenue etc. of the other party in the contract, and it is recognized as revenue taking the time of occurrence into consideration.
The license revenue is upfront payment and milestone revenue received under license contracts etc. related to development or rights to develop or sell products etc. executed between our group and third-parties. For license contracts etc., when performance obligations are satisfied at a specific point in time, performance obligations under the contract are considered to be satisfied at the time of granting development or selling rights etc. for upfront payment and milestone revenue, and at this point the upfront payment and milestone revenue is recognized as revenue. When performance obligations are satisfied over a certain period of time, the consideration is recognized as contract liabilities, and upfront payment and milestone revenue is recognized as revenue over a certain period of time such as the estimated development period according to the method of measuring the degree of progress regarding satisfaction of the performance obligations determined for each individual contract.
For milestone revenue, considering the probability that there will be a significant reversal of revenue previously recognized, it is recognized as revenue from the time that milestones specified in the contract are achieved.
The royalty revenue etc. are mainly received within one year from the vesting under the contract. This does not include significant financing components.

Based on the five-step approach above, as a result of reviewing the revenue recognition period for license revenue such as upfront payment received under license contracts in light of satisfying performance obligations, upfront payment received from license contracts, which was recognized over time as deferred income under previous standard, is recognized as one-time income at the time of granting development or selling rights etc.. Also, as result of a review in light of the definition of customers, certain items which were formerly deducted from revenue are treated as cost of sales from the first quarter of the fiscal year ending March 31, 2019.
For the application of these standards, our group adopted a method to recognize the cumulative effect recognized as a transitional measure on the date of initial application.
Also, certain accounts payable formerly included and presented within trade and other payables, as well as certain provisions , are included and presented within trade and other payables as refund liabilities from the first quarter of the fiscal year ending March 31, 2019.

Consequently, compared with the case calculated using the previous accounting standards, at the beginning of the third quarter (nine months) of the fiscal year ending March 31, 2019, mainly trade and other payables increased by ¥618 million, retained earnings increased by ¥4,127 million, deferred tax assets decreased by ¥1,820 million, provisions decreased by ¥823 million, other current liabilities decreased by ¥646 million, and long-term advances received decreased by ¥5,095 million.
For the condensed interim consolidated statement of income of the third quarter (nine months) ended December 31, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥8,297 million, cost of sales increased by ¥8,269 million, operating profit increased by ¥28 million, and profit before tax increased by ¥28 million.
Also, for the condensed interim consolidated statement of financial position as at the end of the third quarter of the fiscal year ending March 31, 2019, compared with the case calculated using the previous accounting standards, mainly trade and other payables increased by ¥883 million, retained earnings increased by ¥4,146 million, deferred tax assets decreased by ¥1,828 million, provisions decreased by ¥1,193 million, other current liabilities decreased by ¥69 million, and long-term advances received decreased by ¥5,596 million.

2) IFRS 9 “Financial Instruments”

Our group has applied IFRS 9 “Financial Instruments” (amended in July 2014) from the first quarter of the fiscal year ending March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

3) IFRIC 22 “Foreign Currency Transactions and Advance Consideration”

Our group has applied IFRIC 22 “Foreign Currency Transactions and Advance Consideration” from the first quarter of the fiscal year ending March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

(Changes in Method of Presentation)

Condensed Interim Consolidated Statement of Cash Flows
“Proceeds from withdrawal of time deposits” included in “Other” in cash flows from investing activities for the third quarter (nine months) ended December 31, 2017 is separately listed from the second quarter (six months) ended September 30, 2018 due to the increased quantitative materiality. In order to reflect this change in the presentation method, the Condensed Interim Consolidated Financial Statements are classified for the third quarter (nine months) ended December 31, 2017.
As a result, ¥105 million for “Other,” which was shown in cash flows from investing activities in the Condensed Interim Consolidated Statement of Cash Flows for the third quarter (nine months) ended December 31, 2017, is classified into ¥600 million in “Proceeds from withdrawal of time deposits” and (¥495) million in “Other.”

(Significant Subsequent Events)

Not Applicable

(Notes Regarding Assumption of a Going Concern)

Not Applicable

4. Supplementary Information

(1) Sales revenue and forecast of Major Products

(Billions of yen)

	Nine months ended December 31, 2018 (From April 1, 2018 to December 31, 2018)						FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)		
	Actual				YoY		Forecasts	YoY	
Product	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)		Change	Change (%)
Opdivo	22.8	22.6	25.9	71.3	2.4	3.4%	90.0	(0.1)	(0.1%)
Glactive	7.1	6.6	7.4	21.2	(1.2)	(5.2%)	26.0	(1.4)	(5.1%)
Orencia	4.3	4.3	4.8	13.4	2.6	23.5%	17.0	2.9	20.3%
Forxiga	3.6	3.4	4.1	11.1	2.6	30.6%	14.5	3.4	31.0%
Opalmon	2.9	2.6	2.8	8.3	(3.3)	(28.7%)	10.5	(3.9)	(26.9%)
Emend / Proemend	2.7	2.6	2.9	8.2	0.5	5.8%	10.5	0.6	5.5%
Recalbon	2.7	1.7	1.7	6.1	(2.4)	(28.3%)	7.5	(3.4)	(31.3%)
Rivastach Patch	2.3	2.2	2.5	7.0	(0.0)	(0.4%)	9.0	0.1	1.3%
Kyprolis	1.3	1.2	1.3	3.9	(0.6)	(12.7%)	6.5	1.0	17.4%
Parsabiv	1.3	1.4	1.7	4.4	1.9	77.6%	5.5	2.1	60.4%
Onon Capsules	1.1	0.8	1.1	3.0	(0.9)	(22.6%)	4.5	(1.0)	(17.6%)
Onoact	1.1	1.0	1.5	3.6	(0.9)	(20.6%)	4.0	(1.6)	(28.8%)
Staybla	1.0	0.9	1.0	2.9	(0.4)	(11.2%)	3.5	(0.6)	(15.3%)
Onon Dry Syrup	0.7	0.5	0.8	2.0	(0.5)	(21.2%)	2.5	(0.8)	(25.0%)

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

2. Regarding sales revenue forecast for the FY 2018, only currently approved indications are covered.

(2) Details of Revenue

(Billions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Revenue of goods and products	159.9	163.8
Royalty and other revenue	40.6	59.4
Total	200.6	223.2

Notes: 1. In "Royalty and other revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥28.4 billion for the third quarter (nine months) ended December 31, 2017 and ¥43.3 billion for the third quarter (nine months) ended December 31, 2018. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥4.4 billion for the third quarter (nine months) ended December 31, 2017 and ¥9.0 billion for the third quarter (nine months) ended December 31, 2018.

2. Our group has applied IFRS 15 from the first quarter of the fiscal year ending March 31, 2019 as described in “Changes in Accounting Policies” on page 10. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the first quarter of the fiscal year ending March 31, 2019 according to the transitional option, the amount for the third quarter (nine months) ended December 31, 2017 is not restated.

(3) Revenue by geographic area

(Billions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Japan	159.1	163.0
Americas	38.1	53.1
Asia	3.2	5.6
Europe	0.1	1.4
Total	200.6	223.2

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

2. Our group has applied IFRS 15 from the first quarter of the fiscal year ending March 31, 2019 as described in “Changes in Accounting Policies” on page 10. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the first quarter of the fiscal year ending March 31, 2019 according to the transitional option, the amount for the third quarter (nine months) ended December 31, 2017 is not restated.

(4) Main Status of Development Pipelines (Oncology)

As of January 25, 2019

1. Development Status in Japan

<Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7702 *1 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	In-license (Array BioPharma Inc.)
ONO-7703 *1 / Binimetinib	New chemical entities	Melanoma / MEK inhibitor	Tablet	In-license (Array BioPharma Inc.)
ONO-5371 *2 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	In-license (Bausch Health Companies Inc.)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019

*1: A manufacturing and marketing approval for combination therapy with a BRAF inhibitor (ONO-7702) and a MEK inhibitor (ONO-7703) was obtained in Japan for the treatment of BRAF-mutant unresectable melanoma.

*2: A manufacturing and marketing approval for a tyrosine hydroxylase inhibitor (ONO-5371) was obtained in Japan for the improvement of status of catecholamine excess secretion in patients with pheochromocytoma.

Note: “In-house” compounds include a compound generated from collaborative research.

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

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7643 *3 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	In-license (Helsinn Healthcare, S.A.)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019

*3: A manufacturing and marketing approval application for a ghrelin receptor agonist (ONO-7643) was filed in Japan for the improvement of body weight loss and anorexia in patients with cancer cachexia.

Note: “In-house” compounds include a compound generated from collaborative research.

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer *4	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Colon cancer / BRAF inhibitor	Capsule	III	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer / MEK inhibitor	Tablet	III	In-license (Array BioPharma Inc.)
ONO-7701 ★ (BMS-986205)	New chemical entities	Melanoma / IDO1 inhibitor	Tablet	III	In-license (Co-development with Bristol-Myers Squibb)
	New chemical entities	Bladder cancer *4 / IDO1 inhibitor	Tablet	III	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Colon cancer	Injection	II / III	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary macroglobulinemia, Lymphoplasmacytic lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-4481 ★ (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house
ONO-7705 / Selinexor	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	I	In-house

★: Combination with Opdivo.

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019
*4: Phase III of combination therapy with IDO1 inhibitor (ONO-7701) and Opdivo was initiated for the treatment of bladder cancer.
*Phase II of Opdivo Intravenous Infusion for the treatment of multiple myeloma was discontinued due to the strategic reason.

Note: “In-house” compounds include a compound generated from collaborative research.

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

2. Development Status in South Korea and Taiwan

<Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★	Additional indication	Renal cell carcinoma *5	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019

*5: Approval for the partial change in approved items of the importing and marketing approval for combination therapy with Opdivo and Yervoy was obtained in Taiwan for the treatment of previously untreated intermediate and high risk advanced renal cell carcinoma.

Note: "In-house" compounds include a compound generated from collaborative research.

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer *4	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
ONO-7702 / Encorafenib	New chemical entities	Colon cancer / BRAF inhibitor	Capsule	III	South Korea	In-license (Array BioPharma Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Array BioPharma Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	III	South Korea	In-license (Array BioPharma Inc.)
ONO-7701 ★ (BMS-986205)	New chemical entities	Bladder cancer *4 / IDO1 inhibitor	Tablet	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Pancreatic cancer	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019
*4: Phase III of combination therapy with IDO1 inhibitor (ONO-7701) and Opdivo was initiated for the treatment of bladder cancer.

Note: “In-house” compounds include a compound generated from collaborative research.

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

3. Development Status in Europe and the United States

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer *4	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colon cancer	Injection	II / III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe	In-house (Out-license to Gilead Sciences, Inc.)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial cancer, Ovarian cancer)	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	I	USA	In-house

★: Combination with Opdivo.

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019
*4: Phase III of combination therapy with Opdivo and IDO1 inhibitor (ONO-7701) was initiated for the treatment of bladder cancer.

Note: "In-house" compounds include a compound generated from collaborative research.

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

(5) Main Status of Development Pipelines (Non-Oncology)

As of January 25, 2019

1. Development Status in Japan

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	Additional indication	Ventricular arrhythmia / β_1 blocker (short acting)	Injection	In-house
Rivastach Patch	Change of dosage form	Alzheimer's disease / Cholinesterase inhibitor	Patch	In-license (Novartis Pharma)
ONO-1162 *6 / Ivabradine	New chemical entities	Chronic heart failure / HCN channel inhibitor	Tablet	In-license (Les Laboratoires Servier)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019

*6: A manufacturing and marketing approval application for HCN channel inhibitor (ONO-1162) was filed in Japan for the treatment of chronic heart failure with a sinus rhythm resting heart beat of 75 beats per minute or higher.

Note: "In-house" compounds include a compound generated from collaborative research.

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary Sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	III	In-license (Seikagaku Corporation)
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / β_1 blocker (short acting)	Injection	II / III	In-house
	Additional indication	Tachyarrhythmia upon sepsis / β_1 blocker (short acting)	Injection	II / III	In-house
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
ONO-4059 *7 / Tirabrutinib	New chemical entities	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	I	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019

*7: Phase II of Btk inhibitor (ONO-4059) was initiated for the treatment of pemphigus.

*Phase III of Orencia IV for the treatment of lupus nephritis was discontinued due to the strategic reason.

*Phase I/II of Opdivo Intravenous Infusion for the treatment of sepsis was discontinued due to the strategic reason.

Note: "In-house" compounds include a compound generated from collaborative research.

2. Development Status in Overseas

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe, USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-5788	New chemical entities	Acromegaly / Growth hormone secretion inhibitor	Capsule	I	USA	In-house
ONO-7684 *8	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	I	Europe	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2019
*8: Phase I of FXIa inhibitor (ONO-7684) was initiated for healthy adult subjects.
*Phase I of Opdivo Intravenous Infusion for the treatment of hepatitis C and sepsis was discontinued due to the strategic reason.

Note: "In-house" compounds include a compound generated from collaborative research.