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

August 1, 2018

Company name : **Ono Pharmaceutical Co., Ltd.**
Stock exchange listing : Tokyo Stock Exchange
Code number : 4528
URL : http://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 : August 9, 2018
Scheduled date of dividend payment commencement : —
Supplementary materials for quarterly financial results : Yes
Earnings announcement for quarterly financial results : Yes (for institutional investors and securities analysts)

(Note: Amounts of less than one million yen are rounded.)

1. Consolidated Financial Results for the First Quarter of FY 2018 (April 1, 2018 to June 30, 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 Q1	71,242	17.0	17,980	26.0	19,428	23.0	15,251	29.2	15,236	29.4
FY 2017 Q1	60,913	3.7	14,275	(17.2)	15,796	(13.4)	11,804	(13.9)	11,774	(13.9)

	Total comprehensive income for the period		Basic earnings per share	Diluted earnings per share
	Million yen	%	Yen	Yen
FY 2018 Q1	23,285	21.9	29.64	29.63
FY 2017 Q1	19,098	72.2	22.31	22.31

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets
	Million yen	Million yen	Million yen	%
As of June 30, 2018	618,659	546,749	541,508	87.5
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	—				
FY 2018 (Forecast)		22.50	—	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
Q2 (YTD)	134,500	10.7	28,500	6.4	30,000	5.7	23,100	8.5	23,000	8.4	44.74
FY 2018	277,000	5.8	61,500	1.3	65,000	1.7	50,600	0.4	50,500	0.4	98.23

(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 reasons: None
3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the period (including treasury shares):
As of June 30, 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 June 30, 2018 29,220,085 shares
As of March 31, 2018 29,219,787 shares
3) Average number of shares outstanding during the period:
Three months ended June 30, 2018 514,121,453 shares
Three months ended June 30, 2017 527,705,776 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 2 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 1st Quarter of FY 2018

The financial results for the first quarter (April–June 2018) were as follows.

(Millions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018	Change	Change (%)
Revenue	60,913	71,242	10,329	17.0%
Operating profit	14,275	17,980	3,705	26.0%
Profit before tax	15,796	19,428	3,632	23.0%
Profit for the period (attributable to owners of the Company)	11,774	15,236	3,462	29.4%

[Revenue]

Revenue totaled ¥71.2 billion, which was an increase of ¥10.3 billion (17.0%) 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 ¥22.8 billion, an increase of ¥3.0 billion (15.0%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥7.1 billion (0.7% increase year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥4.3 billion (32.9% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥3.6 billion (38.7% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥2.7 billion (8.4% increase year-on-year), sales of Recalbon Tablets for osteoporosis were ¥2.7 billion (0.1% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥2.3 billion (3.9% increase year-on-year), sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥1.3 billion (15.3% increase year-on-year), and sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥1.3 billion (132.5% increase 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 ¥2.9 billion (23.1% decrease year-on-year), and sales of Onon Capsules and Onon Dry Syrup for bronchial asthma and allergic rhinitis were ¥1.1 billion (14.6% decrease year-on-year) and ¥0.7 billion (14.3% decrease year-on-year), respectively.
- Royalty and Other Revenue increased by ¥4.9 billion (39.6%) year-on-year to ¥17.4 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company.

[Operating Profit]

Operating profit was ¥18.0 billion, an increase of ¥3.7 billion (26.0%) year-on-year.

- Cost of sales was ¥20.1 billion, an increase of ¥5.0 billion (33.1%) year-on-year.
- Research and development costs increased by ¥0.8 billion (5.2%) year-on-year to ¥15.7 billion due to an increase of Opdivo Intravenous Infusion-related expenses.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥0.8 billion (4.8%) year-on-year to ¥17.0 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 ¥3.5 billion (29.4%) year-on-year to ¥15.2 billion in association with the increase of the profit before tax.

Note: IFRS 15 "Revenue from Contracts with Customers" is applied from the fiscal year ending March 31, 2019. For the condensed interim consolidated statement of income of the first quarter (three months) ended June 30, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥2,519 million, cost of sales increased by ¥2,509 million, operating profit increased by ¥10 million, and profit before tax increased by ¥10 million.

(2) Overview of Financial Position for the 1st Quarter of FY 2018

(Millions of yen)

	As of March 31, 2018	As of June 30, 2018	Change
Total Assets	609,226	618,659	9,433
Equity attributable to owners of the Company	524,390	541,508	17,117
Ratio of equity attributable owners of the Company to total assets	86.1%	87.5%	
Equity attributable to owners of the Company per share	1,019.97 yen	1,053.27 yen	

Total assets increased to ¥618.7 billion by ¥9.4 billion from the end of the previous fiscal year.
Current assets decreased by ¥2.7 billion to ¥206.7 billion due to a decrease of cash and cash equivalents etc.
Non-current assets increased by ¥12.2 billion to ¥411.9 billion due to an increase of investment securities etc.
Liabilities decreased by ¥7.7 billion to ¥71.9 billion due to a decrease of long-term advances received etc.
Equity attributable to owners of the Company totaled ¥541.5 billion, which was an increase of ¥17.1 billion due to an increase in retained earnings and other components of equity etc.

(3) Overview of Cash Flows for the 1st Quarter of FY 2018

(Millions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018	Change
Cash and cash equivalents at the beginning of the period	146,323	65,273	
Cash flows from operating activities	(18,728)	14,261	32,989
Cash flows from investing activities	(3,229)	(6,887)	(3,658)
Cash flows from financing activities	(31,898)	(9,409)	22,489
Net increase (decrease) in cash and cash equivalents	(53,855)	(2,035)	
Effects of exchange rate changes on cash and cash equivalents	23	(8)	
Cash and cash equivalents at the end of the period	92,491	63,229	

Net increase/decrease in cash and cash equivalents was a decrease of ¥2.0 billion.
Net cash from operating activities was ¥14.3 billion, as a result of profit before tax of ¥19.4 billion, while income taxes paid amounted to ¥8.6 billion.
Net cash used in investing activities was ¥6.9 billion, as a result of purchase of property, plant, and equipment of ¥8.8 billion, while proceeds from sales and redemption of investments amounted to ¥2.1 billion.
Net cash used in financing activities was ¥9.4 billion, as a result of dividends paid of ¥9.2 billion.

(4) Outlook for FY 2018

There was no change in the second quarter (six months) ended September 30, 2018 and financial results for the full year from the financial forecast announced on May 10, 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 June 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	65,273	63,229
Trade and other receivables	77,577	81,533
Marketable securities	9,670	7,633
Other financial assets	10,833	10,808
Inventories	31,290	31,964
Other current assets	14,821	11,571
Total current assets	209,464	206,739
Non-current assets:		
Property, plant, and equipment	94,321	101,006
Intangible assets	55,715	55,708
Investment securities	188,803	200,094
Investments in associates	116	115
Other financial assets	46,685	46,650
Deferred tax assets	10,192	4,990
Other non-current assets	3,929	3,358
Total non-current assets	399,761	411,920
Total assets	609,226	618,659

(Millions of yen)

	As of March 31, 2018	As of June 30, 2018
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,015	33,578
Borrowings	392	322
Other financial liabilities	3,756	2,207
Income taxes payable	8,742	4,646
Provisions	11,696	12,354
Other current liabilities	9,869	12,857
Total current liabilities	68,469	65,964
Non-current liabilities:		
Borrowings	320	347
Other financial liabilities	8	10
Retirement benefit liabilities	3,856	3,746
Provisions	30	30
Deferred tax liabilities	1,016	1,018
Long-term advances received	5,095	—
Other non-current liabilities	814	796
Total non-current liabilities	11,138	5,946
Total liabilities	79,607	71,910
Equity:		
Share capital	17,358	17,358
Capital reserves	17,175	17,181
Treasury shares	(38,148)	(38,149)
Other components of equity	68,021	75,903
Retained earnings	459,985	469,214
Equity attributable to owners of the Company	524,390	541,508
Non-controlling interests	5,228	5,241
Total equity	529,619	546,749
Total liabilities and equity	609,226	618,659

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

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018
Revenue	60,913	71,242
Cost of sales	(15,140)	(20,145)
Gross profit	45,773	51,096
Selling, general, and administrative expenses	(16,240)	(17,025)
Research and development costs	(14,938)	(15,710)
Other income	62	219
Other expenses	(382)	(601)
Operating profit	14,275	17,980
Finance income	1,523	1,580
Finance costs	(8)	(132)
Share of profit (loss) from investments in associates	6	0
Profit before tax	15,796	19,428
Income tax expense	(3,992)	(4,177)
Profit for the period	11,804	15,251
Profit for the period attributable to:		
Owners of the Company	11,774	15,236
Non-controlling interests	29	15
Profit for the period	11,804	15,251
Earnings per share:	*Yen*	
Basic earnings per share	22.31	29.64
Diluted earnings per share	22.31	29.63

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018
Profit for the period	11,804	15,251
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	7,084	7,815
Remeasurements of defined benefit plans	185	148
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(0)	(0)
Total of items that will not be reclassified to profit or loss	7,269	7,963
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	19	67
Net fair value gain (loss) on cash flow hedges	6	5
Total of items that may be reclassified subsequently to profit or loss	26	71
Total other comprehensive income (loss)	7,294	8,034
Total comprehensive income (loss) for the period	19,098	23,285
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	19,052	23,267
Non-controlling interests	47	18
Total comprehensive income (loss) for the period	19,098	23,285

(3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 30, 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					11,774	11,774	29	11,804
Other comprehensive income (loss)				7,277		7,277	17	7,294
Total comprehensive income (loss) for the period	–	–	–	7,277	11,774	19,052	47	19,098
Purchase of treasury shares			(22,499)			(22,499)		(22,499)
Cash dividends					(10,600)	(10,600)	(3)	(10,604)
Share-based payments		11				11		11
Transfer from other components of equity to retained earnings				(185)	185	–		–
Total transactions with the owners	–	11	(22,499)	(185)	(10,415)	(33,088)	(3)	(33,091)
Balance as of June 30, 2017	17,358	17,155	(81,881)	58,844	493,596	505,073	5,145	510,218

Three months ended June 30, 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					15,236	15,236	15	15,251
Other comprehensive income (loss)				8,031		8,031	3	8,034
Total comprehensive income (loss) for the period	–	–	–	8,031	15,236	23,267	18	23,285
Purchase of treasury shares			(1)			(1)		(1)
Cash dividends					(10,282)	(10,282)	(5)	(10,288)
Share-based payments		6				6		6
Transfer from other components of equity to retained earnings				(148)	148	–		–
Total transactions with the owners	–	6	(1)	(148)	(10,134)	(10,277)	(5)	(10,282)
Balance as of June 30, 2018	17,358	17,181	(38,149)	75,903	469,214	541,508	5,241	546,749

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018
Cash flows from operating activities		
Profit before tax	15,796	19,428
Depreciation and amortization	2,217	2,559
Interest and dividend income	(1,488)	(1,580)
Interest expense	4	3
(Increase) decrease in inventories	(1,420)	(703)
(Increase) decrease in trade and other receivables	(1,186)	(3,994)
Increase (decrease) in trade and other payables	(3,243)	(414)
Increase (decrease) in provisions	1,048	1,481
Increase (decrease) in retirement benefit liabilities	120	104
Increase (decrease) in long-term advances received	(106)	–
Other	(7,259)	4,446
Subtotal	4,483	21,331
Interest received	22	13
Dividends received	1,464	1,565
Interest paid	(4)	(3)
Income taxes paid	(24,693)	(8,645)
Net cash provided by (used in) operating activities	(18,728)	14,261
Cash flows from investing activities		
Purchases of property, plant, and equipment	(2,844)	(8,762)
Purchases of intangible assets	(4,478)	(847)
Purchases of investments	(40)	–
Proceeds from sales and redemption of investments	4,000	2,060
Other	133	661
Net cash provided by (used in) investing activities	(3,229)	(6,887)
Cash flows from financing activities		
Dividends paid	(9,310)	(9,245)
Dividends paid to non-controlling interests	(3)	(5)
Repayments of long-term borrowings	(104)	(101)
Net increase (decrease) in short-term borrowings	18	(57)
Purchases of treasury shares	(22,499)	(0)
Net cash provided by (used in) financing activities	(31,898)	(9,409)
Net increase (decrease) in cash and cash equivalents	(53,855)	(2,035)
Cash and cash equivalents at the beginning of the period	146,323	65,273
Effects of exchange rate changes on cash and cash equivalents	23	(8)
Cash and cash equivalents at the end of the period	92,491	63,229

(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 and license revenue 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, regarding some license contracts, upfront payment received from an out-licensing contract, 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 first quarter 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 first quarter (three months) ended June 30, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥2,519 million, cost of sales increased by ¥2,509 million, operating profit increased by ¥10 million, and profit before tax increased by ¥10 million.
Also, for the condensed interim consolidated statement of financial position as at the end of the first 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 ¥874 million, retained earnings increased by ¥4,134 million, deferred tax assets decreased by ¥1,823 million, provisions decreased by ¥1,111 million, other current liabilities decreased by ¥637 million, and long-term advances received decreased by ¥5,083 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 or 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 or financial position.

(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)

	Three months ended June 30, 2018 (From April 1, 2018 to June 30, 2018)			FY 2018 (From April 1, 2018 to March 31, 2019)		
Product	Actual	Change from FY 2017 Q1	Change from FY 2017 Q1 (%)	Forecasts	Change from FY 2017	Change from FY 2017 (%)
Opdivo	22.8	3.0	15.0%	90.0	(0.1)	(0.1%)
Glactive	7.1	0.1	0.7%	26.0	(1.4)	(5.1%)
Orencia	4.3	1.1	32.9%	16.5	2.4	16.8%
Forxiga	3.6	1.0	38.7%	13.0	1.9	17.4%
Opalmon	2.9	(0.9)	(23.1%)	10.5	(3.9)	(26.9%)
Emend / Proemend	2.7	0.2	8.4%	10.5	0.6	5.5%
Recalbon	2.7	0.0	0.1%	9.5	(1.4)	(13.0%)
Rivastach Patch	2.3	0.1	3.9%	9.0	0.1	1.3%
Kyprolis	1.3	0.2	15.3%	6.5	1.0	17.4%
Parsabiv	1.3	0.7	132.5%	5.5	2.1	60.4%
Onon Capsules	1.1	(0.2)	(14.6%)	4.5	(1.0)	(17.6%)
Onoact	1.1	(0.3)	(21.3%)	4.0	(1.6)	(28.8%)
Staybla	1.0	(0.1)	(5.3%)	3.5	(0.6)	(15.3%)
Onon Dry Syrup	0.7	(0.1)	(14.3%)	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)

	Three months ended June 30, 2017	Three months ended June 30, 2018
Revenue of goods and products	48.5	53.9
Royalty and other revenue	12.4	17.4
Total	60.9	71.2

Notes: 1. In "Royalty and Other Revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥8.9 billion for the first quarter (three months) ended June 30, 2017 and ¥13.4 billion for the first quarter (three months) ended June 30, 2018. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥1.0 billion for the first quarter (three months) ended June 30, 2017 and ¥2.6 billion for the first quarter (three months) ended June 30, 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 9. 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 first quarter (three months) ended June 30, 2017 is not restated.

(3) Revenue by geographic area

(Billions of yen)

	Three months ended June 30, 2017	Three months ended June 30, 2018
Japan	48.4	53.1
Americas	11.5	16.5
Asia	1.1	1.6
Europe	0.0	0.1
Total	60.9	71.2

Notes: 1. Revenue of goods and products is presented on the basis of the place of destination for sales.

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 9. 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 first quarter (three months) ended June 30, 2017 is not restated.

(4) Main Status of Development Pipelines (Oncology)

As of July 31, 2018

1. Development Status in Japan

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Malignant pleural mesothelioma	Injection	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Renal cell carcinoma	Injection	In-license (Co-development with Bristol-Myers Squibb)
ONO-7702 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Melanoma / MEK inhibitor	Tablet	In-license (Array BioPharma Inc.)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	In-license (Valeant Pharmaceuticals North America LLC)

*1: Combination with Opdivo.

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)
Yervoy Injection*1	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.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)

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*1 (BMS-986205)	New chemical entities	Melanoma / IDO1 inhibitor	Capsule	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)
	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	Multiple myeloma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer*2	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687*1 (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer*2 / Anti-CSF-1R antibody	Injection	II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686*1 (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*1 (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807*1 (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-4481*1 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483*1 (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*3	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)

*1: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2018

*2: Phase II of Opdivo and ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R antibody) were initiated for the treatment of pancreatic cancer.

*3: Phase I of ONO-7705 (XPO1 inhibitor) was initiated for the treatment of multiple myeloma and non-hodgkin lymphoma.

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 S. Korea and Taiwan

<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)
Yervoy Injection*1	Additional indication	Renal cell carcinoma	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	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.)
	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.)
Opdivo Intravenous Infusion	Additional indication	Pancreatic cancer*2	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687*1 (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer*2 / 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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Yervoy Injection*1	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

*1: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2018

*2: Phase II of Opdivo and ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R antibody) were initiated in South Korea and Taiwan for the treatment of pancreatic 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

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Small cell lung cancer	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

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	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*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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Pancreatic cancer*5	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.)
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

Changes from the announcement of financial results for the fiscal year ended March 2018
*4: Phase III of Opdivo was initiated in Europe and USA for the treatment of ovarian cancer.
*5: Phase II of Opdivo was initiated in Europe and USA for the treatment of pancreatic cancer.
* Phase I / II of ONO-7579 (tropomyosin receptor kinase (Trk) inhibitor) for the treatment of solid tumor 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.

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

As of July 31, 2018

1. Development Status in Japan

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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[*6] / β_1 blocker (short acting)	Injection	In-house

Changes from the announcement of financial results for the fiscal year ended March 2018

*6: Application for the partial change in approved items of the manufacturing and marketing approval for Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101) was filed in Japan for the treatment of refractory and urgent fatal arrhythmia (ventricular fibrillation and hemodynamically unstable ventricular tachycardia).

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house[*)] / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
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-1162 / Ivabradine	New chemical entities	Chronic heart failure / If channel inhibitor	Tablet	III	In-license (Les Laboratoires Servier)
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)
Opdivo Intravenous Infusion	Additional indication	Sepsis	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Autoimmune disease / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	In-house

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.)
Opdivo Intravenous Infusion	Additional indication	Hepatitis C	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Sepsis	Injection	I	USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-5788*7	New chemical entities	Acromegaly / Growth hormone secretion inhibitor	Capsule	I	USA	In-house

Changes from the announcement of financial results for the fiscal year ended March 2018

*7: Phase I of ONO-5788 (growth hormone secretion inhibitor) was initiated in USA for the treatment of acromegaly.

* Phase I of ONO-8055 (PG receptor (EP2 / EP3) agonist) for the treatment of underactive bladder was discontinued due to strategic reason.

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