Third Quarter (April 1 – December 31, 2016) Flash Report (unaudited)
Nine months ended December 31, 2016

ONO PHARMACEUTICAL CO., LTD.

February 2, 2017

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for nine months ended December 31, 2016.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Third Quarter Flash Report 2017 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 116 to $1, the approximate rate of exchange at December 30, 2016.

Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen			Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2015	Annual 12 months ended Mar. 31, 2016	**3rd Quarter 9 months ended Dec. 31, 2016**	**3rd Quarter 9 months ended Dec. 31, 2016**
Revenue	¥ 112,419	¥ 160,284	**¥ 188,845**	**$ 1,627,977**
Profit (Owners of the parent company)	19,181	24,979	**42,472**	**366,140**
Total equity	483,313	476,255	**509,342**	**4,390,881**
Total assets	531,365	540,450	**583,405**	**5,029,353**
	Yen			US$
Basic earnings per share	¥ 36.19	¥ 47.13	**¥ 80.13**	**$ 0.69**
Diluted earnings per share	¥ 36.19	¥ 47.13	**¥ 80.13**	**$ 0.69**

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share” and “Diluted earnings per share”, it is calculated assuming that the stock split was conducted at April 1, 2015.

Revisions of Consolidated Financial Forecasts

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(1) Revisions to the full-year Consolidated Financial Forecasts Ending March 2017 (April 1, 2016 ~ March 31, 2017)

(Unit: Millions of yen, except basic earnings per share)

	Revenue	Operating Profit	Profit before Tax	Profit	Profit (Owners of the Parent Company)	Basic earnings per share (Owners of the Parent Company)
Previous Forecast (A) *	240,000	54,000	56,000	42,000	41,800	78.86
Revised Forecast (B)	240,000	68,500	70,500	52,500	52,300	98.68
Change (B – A)	—	14,500	14,500	10,500	10,500	—
Change (%)	—	26.9%	25.9%	25.0%	25.1%	—
(Reference) Results of the previous period	160,284	30,507	33,272	25,192	24,979	47.13

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for "Basic earnings per share", it is calculated assuming that the stock split was conducted at the beginning of the previous period.

* The previous forecast was announced on December 21, 2016

(2) Reasons for the revisions

Although there was a dispute by filing a patent infringement litigation against sale of the anti-PD-1 antibody product by Merck (USA) and its subsidiaries, it was settled in January 2017. Ono will receive an initial payment and estimates the amount of the initial payment after deducting litigation costs and others as "Other income".

Consequently, operating profit is forecasted to be ¥68.5 billion (an increase by ¥14.5 billion from the previous forecast), profit before tax to be ¥70.5 billion (an increase by ¥14.5 billion from the previous forecast), profit for the year attributable to owners of the parent company to be ¥52.3 billion (an increase by ¥10.5 billion from the previous forecast).

(Note) The financial forecasts and statements contained in this announcement are made based on information that are available as of the date the announcement is made. Actual results may differ materially from those set forth in the announcements due to various uncertain factors.

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US$
	As of March 31, 2016	**As of December 31, 2016**	**As of December 31, 2016**
Current assets			
Cash and cash equivalents	¥ 110,485	¥ **108,503**	$ **935,368**
Trade and other receivables	62,043	**88,007**	**758,680**
Marketable securities	21,583	**19,584**	**168,829**
Other financial assets	800	**800**	**6,897**
Inventories	23,232	**24,562**	**211,738**
Other current assets	5,430	**4,409**	**38,005**
Total current assets	223,573	**245,864**	**2,119,517**
Non-current assets			
Property, plant, and equipment	80,094	**82,151**	**708,198**
Intangible assets	38,324	**43,211**	**372,512**
Investment securities	182,396	**179,335**	**1,545,990**
Investments in associates	982	**1,008**	**8,693**
Other financial assets	6,753	**26,747**	**230,579**
Deferred tax assets	5,179	**1,802**	**15,538**
Other non-current assets	3,149	**3,286**	**28,327**
Total non-current assets	316,877	**337,541**	**2,909,836**
Total assets	¥ 540,450	¥ **583,405**	$ **5,029,353**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2016	**As of December 31, 2016**	**As of December 31, 2016**
Current liabilities			
Trade and other payables	¥ 31,250	¥ **31,182**	$ **268,809**
Borrowings	328	**403**	**3,474**
Other financial liabilities	3,068	**7,509**	**64,734**
Income taxes payable	6,585	**10,259**	**88,435**
Provisions	1,355	**1,409**	**12,144**
Other current liabilities	9,607	**11,697**	**100,836**
Total current liabilities	52,194	**62,458**	**538,432**
Non-current liabilities			
Borrowings	515	**631**	**5,440**
Other financial liabilities	19	**10**	**87**
Retirement benefit liabilities	4,093	**3,860**	**33,276**
Provisions	30	**30**	**259**
Deferred tax liabilities	885	**878**	**7,573**
Long-term advances received	5,814	**5,495**	**47,368**
Other non-current liabilities	643	**700**	**6,038**
Total non-current liabilities	12,000	**11,605**	**100,041**
Total liabilities	64,195	**74,063**	**638,472**
Equity			
Share capital	17,358	**17,358**	**149,640**
Capital reserves	17,103	**17,133**	**147,700**
Treasury shares	(59,358)	**(59,381)**	**(511,905)**
Other components of equity	43,307	**51,138**	**440,844**
Retained earnings	452,983	**478,122**	**4,121,739**
Equity attributable to owners of the parent company	471,393	**504,370**	**4,348,019**
Non-controlling interests	4,862	**4,972**	**42,862**
Total equity	476,255	**509,342**	**4,390,881**
Total liabilities and equity	¥ 540,450	¥ **583,405**	$ **5,029,353**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2015	**3rd Quarter 9 months ended Dec. 31, 2016**	**3rd Quarter 9 months ended Dec. 31, 2016**
Revenue	¥ 112,419	¥ **188,845**	$ **1,627,977**
Cost of sales	(29,981)	**(50,268)**	**(433,345)**
Gross profit	82,438	**138,577**	**1,194,632**
Selling, general, and administrative expenses	(30,391)	**(45,159)**	**(389,306)**
Research and development costs	(29,400)	**(38,980)**	**(336,035)**
Other income	341	**261**	**2,252**
Other expenses	(664)	**(1,396)**	**(12,032)**
Operating profit	22,324	**53,303**	**459,511**
Finance income	3,081	**2,937**	**25,320**
Finance costs	(257)	**(75)**	**(645)**
Share of profit (loss) from investments in associates	(37)	**27**	**232**
Profit before tax	25,112	**56,193**	**484,419**
Income tax expense	(5,829)	**(13,611)**	**(117,340)**
Profit for the period	19,283	**42,581**	**367,079**
Profit for the period attributable to:			
Owners of the parent company	19,181	**42,472**	**366,140**
Non-controlling interests	101	**109**	**940**
Profit for the period	19,283	**42,581**	**367,079**
Earnings per share:	Yen		US$
Basic earnings per share	36.19	**80.13**	**0.69**
Diluted earnings per share	36.19	**80.13**	**0.69**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2015	**3rd Quarter 9 months ended Dec. 31, 2016**	**3rd Quarter 9 months ended Dec. 31, 2016**
Profit for the period	¥ 19,283	**¥ 42,581**	**$ 367,079**
Other comprehensive income:			
Items that will not be reclassified to profit or loss:			
Net gain (loss) on financial assets measured at fair value through other comprehensive income	9,662	**10,246**	**88,326**
Remeasurement of defined benefit plans	(1,704)	**373**	**3,218**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(1)	**1**	**11**
	7,957	**10,620**	**91,555**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(32)	**23**	**199**
	(32)	**23**	**199**
Total other comprehensive income (loss)	7,925	**10,643**	**91,754**
Total comprehensive income for the period	27,208	**53,225**	**458,834**
Comprehensive income for the period attributable to:			
Owners of the parent company	27,080	**53,112**	**457,861**
Non-controlling interests	128	**113**	**972**
Total comprehensive income for the period	27,208	**53,225**	**458,834**

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2015	¥17,358	¥17,080	(¥59,308)	¥45,756	¥449,690	¥470,575	¥4,638	¥475,213
Profit for the period					19,181	19,181	101	19,283
Other comprehensive income				7,899		7,899	26	7,925
Total comprehensive income for the period	–	–	–	7,899	19,181	27,080	128	27,208
Purchase of treasury shares			(40)			(40)		(40)
Cash dividends					(19,081)	(19,081)	(3)	(19,084)
Share-based payments		16				16		16
Transfer from other components of equity to retained earnings				999	(999)	–		–
Total transactions with the owners	–	16	(40)	999	(20,080)	(19,105)	(3)	(19,108)
Balance at December 31, 2015	¥17,358	¥17,095	(¥59,348)	¥54,654	¥448,791	¥478,550	¥4,763	¥483,313

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2016	¥17,358	¥17,103	(¥59,358)	¥43,307	¥452,983	¥471,393	¥4,862	¥476,255
Profit for the period					42,472	42,472	109	42,581
Other comprehensive income				10,640		10,640	4	10,643
Total comprehensive income for the period	–	–	–	10,640	42,472	53,112	113	53,225
Purchase of treasury shares			(23)			(23)		(23)
Cash dividends					(20,142)	(20,142)	(3)	(20,145)
Share-based payments		30				30		30
Transfer from other components of equity to retained earnings				(2,809)	2,809	–		–
Total transactions with the owners	–	30	(23)	(2,809)	(17,333)	(20,135)	(3)	(20,138)
Balance at December 31, 2016	¥17,358	¥17,133	(¥59,381)	¥51,138	¥478,122	¥504,370	¥4,972	¥509,342

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2016	**$149,640**	**$147,442**	**($511,711)**	**$373,336**	**$3,905,024**	**$4,063,732**	**$41,917**	**$4,105,649**
Profit for the period					**366,140**	**366,140**	**940**	**367,079**
Other comprehensive income				**91,722**		**91,722**	**33**	**91,754**
Total comprehensive income for the period	–	–	–	**91,722**	**366,140**	**457,861**	**972**	**458,834**
Purchase of treasury shares			**(194)**			**(194)**		**(194)**
Cash dividends					**(173,638)**	**(173,638)**	**(27)**	**(173,665)**
Share-based payments		**258**				**258**		**258**
Transfer from other components of equity to retained earnings				**(24,214)**	**24,214**	–		–
Total transactions with the owners	–	**258**	**(194)**	**(24,214)**	**(149,425)**	**(173,574)**	**(27)**	**(173,601)**
Balance at December 31, 2016	**$149,640**	**$147,700**	**($511,905)**	**$440,844**	**$4,121,739**	**$4,348,019**	**$42,862**	**$4,390,881**

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2015	**3rd Quarter 9 months ended Dec. 31, 2016**	**3rd Quarter 9 months ended Dec. 31, 2016**
Cash flows from operating activities			
Profit before tax	¥ 25,112	**¥ 56,193**	**$ 484,419**
Depreciation and amortization	4,857	**5,651**	**48,716**
Impairment losses	1,182	**736**	**6,349**
Interest and dividend income	(2,668)	**(2,836)**	**(24,446)**
Interest expense	9	**10**	**89**
(Increase) Decrease in inventories	2,959	**(1,278)**	**(11,017)**
(Increase) Decrease in trade and other receivables	(11,553)	**(25,959)**	**(223,784)**
Increase (Decrease) in trade and other payables	1,940	**6,432**	**55,451**
Increase (Decrease) in retirement benefit liabilities	(6,013)	**304**	**2,624**
(Increase) Decrease in retirement benefit assets	(87)	–	–
Increase (Decrease) in long-term advances received	(526)	**(319)**	**(2,754)**
Other	(2,722)	**6,788**	**58,521**
Subtotal	12,491	**45,723**	**394,167**
Interest received	242	**114**	**985**
Dividends received	2,456	**2,732**	**23,553**
Interest paid	(9)	**(10)**	**(89)**
Income taxes paid	(9,922)	**(11,401)**	**(98,283)**
Net cash provided by (used in) operating activities	5,258	**37,159**	**320,333**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(5,700)	**(12,608)**	**(108,686)**
Purchases of intangible assets	(5,811)	**(6,719)**	**(57,923)**
Purchases of investments	(250)	**(2,437)**	**(21,009)**
Proceeds from sales and redemption of investments	22,079	**22,341**	**192,595**
Payments into time deposits	(600)	**(20,600)**	**(177,586)**
Other	392	**596**	**5,134**
Net cash provided by (used in) investing activities	10,110	**(19,427)**	**(167,476)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(18,223)	**(19,347)**	**(166,789)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(30)**
Repayments of long-term borrowings	(274)	**(290)**	**(2,499)**
Net increase (decrease) in short-term borrowings	92	**(37)**	**(319)**
Purchases of treasury shares	(39)	**(22)**	**(187)**
Net cash provided by (used in) financing activities	(18,446)	**(19,699)**	**(169,823)**
Net increase (decrease) in cash and cash equivalents	(3,078)	**(1,968)**	**(16,966)**
Cash and cash equivalents at the beginning of the period	104,222	**110,485**	**952,455**
Effects of exchange rate changes on cash and cash equivalents	(40)	**(14)**	**(121)**
Cash and cash equivalents at the end of the period	¥ 101,105	**¥ 108,503**	**$ 935,368**

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen					
		3rd Quarter 9 months ended December 31, 2016			Year ending March 31, 2017		
		Results	Increase/Decrease		Forecast	Increase/Decrease	
Opdivo	Agent for treatment of unresectable melanoma, unresectable, advanced or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, and relapsed or refractory classical Hodgkin lymphoma	**¥ 826**	**¥** +769	+1,360.4 %	**¥ 1,050**	**¥** +838	+396.4 %
Glactiv	Agent for type II diabetes	**227**	Δ 26	Δ 10.4 %	**295**	Δ 19	Δ 6.1 %
Opalmon	Circulatory system agent	**134**	Δ 48	Δ 26.3 %	**175**	Δ 52	Δ 22.9 %
Recalbon	Agent for osteoporosis	**87**	Δ 1	Δ 1.3 %	**115**	+2	+1.8 %
Orencia SC	Agent for rheumatoid arthritis	**87**	+27	+44.3 %	**115**	+35	+43.5 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**76**	+3	+3.9 %	**100**	+5	+5.6 %
Rivastach	Agent for Alzheimer's disease	**68**	+7	+12.1 %	**90**	+12	+14.9 %
Forxiga	Agent for type II diabetes	**58**	+28	+92.2 %	**85**	+42	+98.9 %
Onon	Agent for bronchial asthma and allergic rhinitis	**48**	Δ 17	Δ 26.2 %	**65**	Δ 25	Δ 27.4 %
Onoact	Agent for tachyarrhythmia during and post operation	**44**	Δ 1	Δ 3.2 %	**65**	+8	+13.9 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**37**	Δ 3	Δ 8.6 %	**50**	Δ 2	Δ 3.2 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**31**	Δ 12	Δ 27.3 %	**45**	Δ 11	Δ 19.7 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**30**	Δ 11	Δ 27.5 %	**40**	Δ 12	Δ 22.4 %
Kinedak	Agent for diabetic peripheral neuropathy	**23**	Δ 10	Δ 30.9 %	**30**	Δ 11	Δ 26.6 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**11**	Launched in August 2016		**20**	+20	—

Note: Sales of products are shown in a gross sales basis.

Breakdown of Revenue

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	3rd Quarter 9 months ended December 31, 2015	3rd Quarter 9 months ended December 31, 2016
Revenue of Goods and Products	1,041	1,671
Royalty and Other Revenue	83	218
Total	1,124	1,888

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 48 hundreds of millions of yen for 3rd quarter 9 months ended December 31, 2015 and 189 hundreds of millions of yen for 3rd quarter 9 months ended December 31, 2016.

Information about Revenue by Geographic Area

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	3rd Quarter 9 months ended December 31, 2015	3rd Quarter 9 months ended December 31, 2016
Japan	1,042	1,671
Americas	63	194
Asia	17	21
Europe	2	3
Total	1,124	1,888

Note: Revenue by geographic area is attributable to countries or regions based on the customer location.

Consolidated Statement of Income
excluding the Impact of Retirement Benefits Plan Revision

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Supplemental Data

For information purpose only

The Retirement Benefits Plan Revision was agreed between labor and management in April 2015. For previous 1st quarter ended June 30, 2015, the company computed actuarial calculations based on the revised retirement benefits plan and past service costs of retirement benefits obligations. As a result, for previous 1st quarter ended June 30, 2015, cost of sales decreased by 4 hundreds of millions of yen, research and development costs decreased by 22 hundreds of millions of yen, and selling, general, and administrative expenses decreased by 37 hundreds of millions of yen respectively, due to the effect of past service costs by the retirement benefits plan revision. Operating profit increased by 63 hundreds of millions of yen. The consolidated statement of income for the quarter ended December 31, 2015 excluding this impact and the quarter ended December 31, 2016 are as follows.

(Hundreds of Millions of yen)

	3rd Quarter 9 months ended December 31, 2015		3rd Quarter 9 months ended December 31, 2016		
	Actual	Actual excluding the Impact of Retirement Benefits Plan Revision	Actual	Changes	Changes excluding the Impact of Retirement Benefits Plan Revision in previous year
Revenue	¥ 1,124	¥ 1,124	¥ 1,888	68.0 %	68.0 %
Cost of sales	(300)	(304)	(503)	67.7 %	65.3 %
Gross profit	824	820	1,386	68.1 %	69.0 %
Selling, general, and administrative expenses	(304)	(340)	(452)	48.6 %	32.7 %
Research and development costs	(294)	(316)	(390)	32.6 %	23.3 %
Operating profit	223	160	533	138.8 %	232.6 %
Profit before tax	251	188	562	123.8 %	198.7 %
Income tax expense	(58)	(44)	(136)	133.5 %	210.7 %
Profit for the period	193	144	426	120.8 %	195.0 %
Profit for the period attributable to:					
Owners of the parent company	192	143	425	121.4 %	196.3 %

Supplemental Information

Status of Development Pipeline

as of January 31, 2017

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **PARSABIV® Intravenous Injection for Dialysis (ONO-5163) / AMG-416 / Etelcalcetide Hydrochloride *1**
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist]
  - Injection
  - ***In-license (Amgen Inc.)***

Filed

- **KYPROLIS® Intravenous Injection (ONO-7057) / Carfilzomib**
  - **Additional Dosage and Administration**
  - Multiple Myeloma [Proteasome inhibitor]
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***

Ongoing clinical studies

- **Orencia® IV (ONO-4164) / BMS-188667**
  - **Additional indication**
  - Juvenile Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® IV (ONO-4164) / BMS-188667**
  - **Additional indication**
  - Lupus nephritis[T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® SC (ONO-4164) / BMS-188667**
  - **Additional indication**
  - Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® SC (ONO-4164) / BMS-188667 *2**
  - **Additional indication**
  - Primary sjögren syndrome [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **KYPROLIS® Intravenous Injection (ONO-7057) / Carfilzomib**
  - **Additional Dosage and Administration**
  - Multiple Myeloma [Proteasome inhibitor] / Phase III
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***
- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] / Phase III
  - Tablet
  - ***In-license (Les Laboratoires Servier)***
- **ONO-7643 / Anamorelin**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase III
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***

Ongoing clinical studies

- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **Additional indication for pediatric use**
  - Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **Additional indication**
  - Ventricular arrhythmia [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **ONO-2370 / Opicapone**
  - **New chemical entities**
  - Parkinson's disease [Long acting COMT inhibitor] / Phase II
  - Tablet
  - ***In-license (Bial)***
- **ONO-5371 / Metyrosine**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I/II
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America LLC.)***
- **ONO-7268 MX1**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-7268 MX2**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-2160 / CD**
  - **New chemical entities**
  - Parkinson's disease [levodopa pro-drug] / Phase I
  - Tablet
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - ***In-house***
- **ONO-8577**
  - **New chemical entities**
  - Overactive bladder [bladder smooth muscle relaxant] / Phase I
  - Tablet
  - ***In-house***

Ongoing clinical studies

- **ONO-4578 *3**
  - **New chemical entities**
  - Solid tumor [PG receptor (EP4) antagonist] / Phase I
  - Tablet
  - ***In-house***

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*1: A manufacturing and marketing approval for PARSABIV® intravenous injection for dialysis (calcium sensing receptor agonist) was obtained in Japan for the treatment of secondary hyperparathyroidism in patients on hemodialysis
*2: Phase III of Orencia® SC (ONO-4164) / BMS-188667 (T-cell activation inhibitor) was initiated for primary sjögren syndrome.
*3: Phase I of ONO-4578 (PG receptor (EP4) antagonist) was initiated for solid tumor.

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.

ⅱ. Developments Status outside Japan

Ongoing clinical studies

- **ONO-4474**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase II
  - Capsule
  - Europe
  - ***In-house***
- **ONO-4059 *4**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase II
  - Capsule
  - USA & Europe
  - ***Out-license (Gilead Sciences, Inc.)***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist] / Phase I
  - Tablet
  - Europe
  - ***In-house***
- **ONO-7475 *5**
  - **New chemical entities**
  - Acute leukemia [Axl / Mer inhibitor] / Phase I
  - Tablet
  - USA
  - ***In-house***
- **ONO-7579 *6**
  - **New chemical entities**
  - Solid tumor [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
  - Tablet
  - USA & Europe
  - ***In-house***

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*4: Phase II of ONO-4059 (Bruton's tyrosine kinase (Btk) inhibitor) was initiated for B cell lymphoma.
*5: Phase I of ONO-7475 (Axl / Mer inhibitor) was initiated for acute leukemia.
*6: Phase I of ONO-7579 (Tropomyosin receptor kinase (Trk) inhibitor) was initiated for solid tumor.
* Development of ONO-2952 (TSPO antagonist) for the treatment of irritable bowel syndrome was discontinued due to the strategic reason considering differentiation among existing product and competing product under development and others comprehensively.
* Development of ONO-4232 (PG receptor (EP4) agonist) for the treatment of acute heart failure was discontinued due to the strategic reason considering future development period, development cost, and others comprehensively.

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.

II. Main Pipelines ONO-4538 etc

ⅰ. Developments Status in Japan, South Korea, and Taiwan

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Hodgkin's lymphoma *1	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Japan for the treatment of relapsed or refractory classical 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.

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Non-small cell lung cancer (Non- Squamous)	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Renal cell carcinoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Japan Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer *2	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*2: A supplemental application for Opdivo® Intravenous Infusion was filed in Japan for the treatment of unresectable advanced or recurrent gastric cancer for a partial change in the approved items of the manufacturing and marketing approval.

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.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Head and neck cancer	Phase III	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer	Phase III	South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophagogastric junction cancer and Esophageal cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Hepatocellular carcinoma	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial carcinoma	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Malignant pleural mesothelioma	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Ovarian cancer *3	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (Cervical cancer, Endometrial cancer, Soft tissue sarcoma)	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Primary central nervous system lymphoma / Testicular malignant lymphoma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Biliary tract cancer	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
Anti-TIGIT Antibody (ONO-4686 / BMS-986207)	Solid tumor *4	Phase I/II	Japan	In-license (Co-development with Bristol-Myers Squibb Company)
Urelumab (ONO-4481 / BMS-663513)	Solid tumor	Phase I	Japan	In-license (Co-development with Bristol-Myers Squibb Company)
Anti-LAG3 Antibody (ONO-4482 / BMS-986016)	Solid tumor	Phase I	Japan	In-license (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*3: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of ovarian cancer.
*4: Phase I/II of Anti-TIGIT Antibody (ONO-4686 / BMS-986207) was initiated for the treatment of solid tumor.

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.

ⅱ. Developments Status in Europe and the United States

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Head and neck cancer *5	USA	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma *6	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*5: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in USA for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.
*6: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Europe for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.

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.

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Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Head and neck cancer	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial carcinoma	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

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.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) / BMS-936558	Glioblastoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Multiple myeloma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophagogastric junction cancer and Esophageal cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Gastric cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Malignant pleural mesothelioma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Diffuse large B cell lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Follicular lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Primary central nervous system lymphoma / Testicular malignant lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Colon cancer	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Chronic myeloid leukemia	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatitis C	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Sepsis *7	Phase I	USA	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2017 announced on November 7, 2016
*7: Phase I of Opdivo® Intravenous Infusion was initiated for the treatment of Sepsis.

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.