Second Quarter (April 1 – September 30, 2016) Flash Report (unaudited)
Six months ended September 30, 2016

ONO PHARMACEUTICAL CO., LTD.

November 7, 2016

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for six months ended September 30, 2016.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Second 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 101 to $1, the approximate rate of exchange at September 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$
	2nd Quarter 6 months ended Sep. 30, 2015	Annual 12 months ended Mar. 31, 2016	**2nd Quarter 6 months ended Sep. 30, 2016**	**2nd Quarter 6 months ended Sep. 30, 2016**
Revenue	¥ 70,303	¥ 160,284	**¥ 117,726**	**$ 1,165,604**
Profit (Owners of the parent company)	11,873	24,979	**23,119**	**228,896**
Total equity	469,973	476,255	**490,548**	**4,856,913**
Total assets	516,637	540,450	**557,753**	**5,522,305**
		Yen		US$
Basic earnings per share	¥ 22.40	¥ 47.13	**¥ 43.62**	**$ 0.43**
Diluted earnings per share	¥ 22.40	¥ 47.13	**¥ 43.62**	**$ 0.43**

(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.

Consolidated Financial Forecast for the Year Ending March 31, 2017

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31, 2017	
	Millions of yen	Thousands of US$
Revenue	¥ 259,000	$ 2,564,356
Operating profit	72,500	717,822
Profit before tax	75,000	742,574
Profit (Owners of the parent company)	55,800	552,475
	Yen	US$
Basic earnings per share	105.28	1.04

(*)The foregoing are forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and are subject to risks and uncertainties. Actual financial results may differ materially depending on a number of economic factors, including conditions and currency exchange rate fluctuations.
(*)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 based on the number of shares after the stock split.

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 September 30, 2016**	**As of September 30, 2016**
Current assets			
Cash and cash equivalents	¥ 110,485	¥ **95,584**	$ **946,374**
Trade and other receivables	62,043	**73,077**	**723,535**
Marketable securities	21,583	**18,507**	**183,241**
Other financial assets	800	**837**	**8,286**
Inventories	23,232	**25,777**	**255,217**
Other current assets	5,430	**4,993**	**49,438**
Total current assets	223,573	**218,775**	**2,166,090**
Non-current assets			
Property, plant, and equipment	80,094	**81,804**	**809,940**
Intangible assets	38,324	**43,277**	**428,482**
Investment securities	182,396	**177,954**	**1,761,917**
Investments in associates	982	**997**	**9,876**
Other financial assets	6,753	**26,771**	**265,062**
Deferred tax assets	5,179	**4,859**	**48,104**
Other non-current assets	3,149	**3,316**	**32,834**
Total non-current assets	316,877	**338,978**	**3,356,215**
Total assets	¥ 540,450	¥ **557,753**	$ **5,522,305**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2016	**As of September 30, 2016**	**As of September 30, 2016**
Current liabilities			
Trade and other payables	¥ 31,250	¥ **29,002**	$ **287,147**
Borrowings	328	**415**	**4,107**
Other financial liabilities	3,068	**4,493**	**44,488**
Income taxes payable	6,585	**8,275**	**81,928**
Provisions	1,355	**1,245**	**12,325**
Other current liabilities	9,607	**11,787**	**116,704**
Total current liabilities	52,194	**55,217**	**546,700**
Non-current liabilities			
Borrowings	515	**596**	**5,897**
Other financial liabilities	19	**17**	**168**
Retirement benefit liabilities	4,093	**4,366**	**43,224**
Provisions	30	**30**	**297**
Deferred tax liabilities	885	**881**	**8,719**
Long-term advances received	5,814	**5,466**	**54,114**
Other non-current liabilities	643	**634**	**6,273**
Total non-current liabilities	12,000	**11,988**	**118,693**
Total liabilities	64,195	**67,205**	**665,392**
Equity			
Share capital	17,358	**17,358**	**171,864**
Capital reserves	17,103	**17,122**	**169,527**
Treasury shares	(59,358)	**(59,380)**	**(587,921)**
Other components of equity	43,307	**43,879**	**434,448**
Retained earnings	452,983	**466,640**	**4,620,201**
Equity attributable to owners of the parent company	471,393	**485,620**	**4,808,118**
Non-controlling interests	4,862	**4,928**	**48,795**
Total equity	476,255	**490,548**	**4,856,913**
Total liabilities and equity	¥ 540,450	¥ **557,753**	$ **5,522,305**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2015	**2nd Quarter 6 months ended Sep. 30, 2016**	**2nd Quarter 6 months ended Sep. 30, 2016**
Revenue	¥ 70,303	¥ **117,726**	$ **1,165,604**
Cost of sales	(18,555)	**(32,227)**	**(319,082)**
Gross profit	51,749	**85,499**	**846,523**
Selling, general, and administrative expenses	(18,212)	**(29,286)**	**(289,959)**
Research and development costs	(19,097)	**(25,323)**	**(250,726)**
Other income	294	**226**	**2,235**
Other expenses	(331)	**(980)**	**(9,705)**
Operating profit	14,404	**30,135**	**298,369**
Finance income	1,833	**1,623**	**16,071**
Finance costs	(280)	**(648)**	**(6,418)**
Share of profit (loss) from investments in associates	(52)	**17**	**165**
Profit before tax	15,904	**31,127**	**308,186**
Income tax expense	(3,964)	**(7,938)**	**(78,593)**
Profit for the period	11,940	**23,189**	**229,593**
Profit for the period attributable to:			
Owners of the parent company	11,873	**23,119**	**228,896**
Non-controlling interests	66	**70**	**697**
Profit for the period	11,940	**23,189**	**229,593**
Earnings per share:	Yen		US$
Basic earnings per share	22.40	**43.62**	**0.43**
Diluted earnings per share	22.40	**43.62**	**0.43**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2015	**2nd Quarter 6 months ended Sep. 30, 2016**	**2nd Quarter 6 months ended Sep. 30, 2016**
Profit for the period	¥ 11,940	**¥ 23,189**	**$ 229,593**
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	(5,666)	**1,237**	**12,246**
Remeasurement of defined benefit plans	(1,912)	**(46)**	**(453)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(7)	**0**	**4**
	(7,585)	**1,191**	**11,796**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(44)	**(541)**	**(5,357)**
	(44)	**(541)**	**(5,357)**
Total other comprehensive income (loss)	(7,629)	**650**	**6,439**
Total comprehensive income for the period	4,310	**23,839**	**236,032**
Comprehensive income for the period attributable to:			
Owners of the parent company	4,227	**23,770**	**235,349**
Non-controlling interests	83	**69**	**684**
Total comprehensive income for the period	4,310	**23,839**	**236,032**

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					11,873	11,873	66	11,940
Other comprehensive income				(7,647)		(7,647)	17	(7,629)
Total comprehensive income for the period	–	–	–	(7,647)	11,873	4,227	83	4,310
Purchase of treasury shares			(15)			(15)		(15)
Cash dividends					(9,541)	(9,541)	(3)	(9,544)
Share-based payments		8				8		8
Transfer from other components of equity to retained earnings				1,207	(1,207)	–		–
Total transactions with the owners	–	8	(15)	1,207	(10,747)	(9,548)	(3)	(9,551)
Balance at September 30, 2015	¥17,358	¥17,088	(¥59,323)	¥39,316	¥450,816	¥465,254	¥4,718	¥469,973

	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					23,119	23,119	70	23,189
Other comprehensive income				652		652	(1)	650
Total comprehensive income for the period	–	–	–	652	23,119	23,770	69	23,839
Purchase of treasury shares			(22)			(22)		(22)
Cash dividends					(9,540)	(9,540)	(3)	(9,544)
Share-based payments		19				19		19
Transfer from other components of equity to retained earnings				(79)	79	–		–
Total transactions with the owners	–	19	(22)	(79)	(9,461)	(9,543)	(3)	(9,546)
Balance at September 30, 2016	¥17,358	¥17,122	(¥59,380)	¥43,879	¥466,640	¥485,620	¥4,928	¥490,548

	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	**$171,864**	**$169,340**	**($587,707)**	**$428,782**	**$4,484,978**	**$4,667,256**	**$48,142**	**$4,715,399**
Profit for the period					**228,896**	**228,896**	**697**	**229,593**
Other comprehensive income				**6,452**		**6,452**	**(13)**	**6,439**
Total comprehensive income for the period	–	–	–	**6,452**	**228,896**	**235,349**	**684**	**236,032**
Purchase of treasury shares			**(214)**			**(214)**		**(214)**
Cash dividends					**(94,460)**	**(94,460)**	**(31)**	**(94,491)**
Share-based payments		**187**				**187**		**187**
Transfer from other components of equity to retained earnings				**(786)**	**786**	–		–
Total transactions with the owners	–	**187**	**(214)**	**(786)**	**(93,674)**	**(94,487)**	**(31)**	**(94,518)**
Balance at September 30, 2016	**$171,864**	**$169,527**	**($587,921)**	**$434,448**	**$4,620,201**	**$4,808,118**	**$48,795**	**$4,856,913**

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2015	**2nd Quarter 6 months ended Sep. 30, 2016**	**2nd Quarter 6 months ended Sep. 30, 2016**
Cash flows from operating activities			
Profit before tax	¥ 15,904	¥ **31,127**	$ **308,186**
Depreciation and amortization	3,226	**3,598**	**35,623**
Impairment losses	1,000	**674**	**6,677**
Interest and dividend income	(1,575)	**(1,622)**	**(16,059)**
Interest expense	6	**7**	**66**
(Increase) Decrease in inventories	255	**(2,563)**	**(25,377)**
(Increase) Decrease in trade and other receivables	(1,585)	**(11,035)**	**(109,255)**
Increase (Decrease) in trade and other payables	929	**4,362**	**43,190**
Increase (Decrease) in retirement benefit liabilities	(6,174)	**207**	**2,054**
Increase (Decrease) in long-term advances received	(350)	**(349)**	**(3,452)**
Other	(2,776)	**4,385**	**43,415**
Subtotal	8,860	**28,792**	**285,067**
Interest received	185	**87**	**866**
Dividends received	1,423	**1,547**	**15,319**
Interest paid	(6)	**(7)**	**(66)**
Income taxes paid	(6,728)	**(6,557)**	**(64,917)**
Net cash provided by (used in) operating activities	3,733	**23,863**	**236,269**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(1,725)	**(11,174)**	**(110,638)**
Purchases of intangible assets	(5,394)	**(6,016)**	**(59,563)**
Purchases of investments	(250)	**(2,437)**	**(24,130)**
Proceeds from sales and redemption of investments	18,079	**11,406**	**112,929**
Payments into time deposits	(200)	**(20,200)**	**(200,000)**
Other	66	**80**	**795**
Net cash provided by (used in) investing activities	10,575	**(28,341)**	**(280,606)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(9,530)	**(9,534)**	**(94,393)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(34)**
Repayments of long-term borrowings	(188)	**(192)**	**(1,897)**
Net increase (decrease) in short-term borrowings	15	**4**	**39**
Purchases of treasury shares	(15)	**(21)**	**(209)**
Net cash provided by (used in) financing activities	(9,719)	**(9,746)**	**(96,493)**
Net increase (decrease) in cash and cash equivalents	4,589	**(14,224)**	**(140,830)**
Cash and cash equivalents at the beginning of the period	104,222	**110,485**	**1,093,908**
Effects of exchange rate changes on cash and cash equivalents	(37)	**(677)**	**(6,705)**
Cash and cash equivalents at the end of the period	¥ 108,775	¥ **95,584**	$ **946,374**

Second Quarter (April 1 – September 30, 2016) Flash Report (unaudited)

Six months ended September 30, 2016

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen				
		2nd Quarter 6 months ended September 30, 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 and unresectable or metastatic renal cell carcinoma	¥ **533**	¥ +503	+1,714.0 %	¥ **1,260**	¥ +1,048	+495.7 %
Glactiv	Agent for type II diabetes	**148**	Δ 12	Δ 7.4 %	**295**	Δ 19	Δ 6.1 %
Opalmon	Circulatory system agent	**88**	Δ 31	Δ 25.9 %	**175**	Δ 52	Δ 22.9 %
Recalbon	Agent for osteoporosis	**56**	Δ 0	Δ 0.7 %	**115**	+2	+1.8 %
Orencia SC	Agent for rheumatoid arthritis	**54**	+17	+46.1 %	**115**	+35	+43.5 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**50**	+2	+4.8 %	**100**	+5	+5.6 %
Rivastach	Agent for Alzheimer's disease	**44**	+5	+13.3 %	**90**	+12	+14.9 %
Forxiga	Agent for type II diabetes	**36**	+19	+118.4 %	**85**	+42	+98.9 %
Onon	Agent for bronchial asthma and allergic rhinitis	**30**	Δ 10	Δ 25.6 %	**65**	Δ 25	Δ 27.4 %
Onoact	Agent for tachyarrhythmia during and post operation	**27**	Δ 1	Δ 3.4 %	**65**	+8	+13.9 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**24**	Δ 2	Δ 7.9 %	**50**	Δ 2	Δ 3.2 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**18**	Δ 6	Δ 25.5 %	**45**	Δ 11	Δ 19.7 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**20**	Δ 7	Δ 27.0 %	**40**	Δ 12	Δ 22.4 %
Kinedak	Agent for diabetic peripheral neuropathy	**16**	Δ 7	Δ 29.7 %	**30**	Δ 11	Δ 26.6 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**2**	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)

	2nd Quarter 6 months ended September 30, 2015	2nd Quarter 6 months ended September 30, 2016
Revenue of Goods and Products	658	1,073
Royalty and Other Revenue	45	104
Total	703	1,177

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 22 hundreds of millions of yen for 2nd quarter 6 months ended September 30, 2015 and 87 hundreds of millions of yen for 2nd quarter 6 months ended September 30, 2016.

Information about Revenue by Geographic Area

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	2nd Quarter 6 months ended September 30, 2015	2nd Quarter 6 months ended September 30, 2016
Japan	658	1,073
Americas	33	90
Asia	11	13
Europe	1	2
Total	703	1,177

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 September 30, 2015 excluding this impact and the quarter ended September 30, 2016 are as follows.

(Hundreds of Millions of yen)

	2nd Quarter 6 months ended September 30, 2015		2nd Quarter 6 months ended September 30, 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	¥ 703	¥ 703	¥ 1,177	67.5 %	67.5 %
Cost of sales	(186)	(190)	(322)	73.7 %	69.7 %
Gross profit	517	513	855	65.2 %	66.6 %
Selling, general, and administrative expenses	(182)	(219)	(293)	60.8 %	34.0 %
Research and development costs	(191)	(213)	(253)	32.6 %	18.8 %
Operating profit	144	81	301	109.2 %	271.7 %
Profit before tax	159	96	311	95.7 %	224.0 %
Income tax expense	(40)	(24)	(79)	100.2 %	233.0 %
Profit for the period	119	72	232	94.2 %	221.0 %
Profit for the period attributable to:					
Owners of the parent company	119	72	231	94.7 %	223.0 %

Supplemental Information

Status of Development Pipeline

as of October 31, 2016

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Filed

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

- **KYPROLIS® Intravenous Injection (ONO-7057) / Carfilzomib *1**
  - **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)***

- **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 *2**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase III
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***

- **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***

Ongoing clinical studies

- **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***

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 2016
*1: Application for the partial change in approved items of the manufacturing and marketing approval for KYPROLIS® for Intravenous Injection, which is a proteasome inhibitor, was filed in Japan for additional dosage and administration.
*2: Phase III of ONO-7643 (Ghrelin mimetic) was initiated for cancer anorexia/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.

ⅱ. Developments Status outside Japan

Ongoing clinical studies

- **ONO-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-4474 *3**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase II
  - Capsule
  - Europe
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - 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-4232**
  - **New chemical entities**
  - Acute heart failure [PG receptor (EP4) agonist] / Phase I
  - Injection
  - USA
  - ***In-house***

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 2016
*3: Phase II of ONO-4474 (Tropomyosin receptor kinase (Trk) inhibitor) was initiated for osteoarthritis.

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	Renal cell carcinoma *1	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 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 unresectable or metastatic 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.

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)
	Hodgkin's lymphoma	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Japan Taiwan	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	Head and neck cancer	Phase III	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer	Phase III	Japan 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 *2	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)
	Hepatocellular carcinoma	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	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 *3	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Ovarian cancer	Phase II	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 *4	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)
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 *5	Phase I	Japan	In-license (Co-development with Bristol-Myers Squibb Company)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 2016
*2: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Esophagogastric junction cancer and Esophageal cancer.
*3: Phase III of Opdivo® Intravenous Infusion in combination with Yervoy was initiated for the treatment of Malignant pleural mesothelioma.
*4: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Primary central nervous system lymphoma / Testicular malignant lymphoma.
*5: Phase I of Anti-LAG3 Antibody (ONO-4482 / BMS-986016) 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

Filed

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

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 2016
*6: A supplemental application for Opdivo® Intravenous Infusion was filed in USA and Europe for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy for a partial change to 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	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)
	Gastric cancer *7	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Malignant pleural mesothelioma *8	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)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Follicular lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Primary central nervous system lymphoma / Testicular malignant lymphoma *9	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)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2017 announced on August 2, 2016
*7: Phase III of Opdivo® Intravenous Infusion in combination with Yervoy was initiated for the treatment of Gastric cancer.
*8: Phase III of Opdivo® Intravenous Infusion in combination with Yervoy was initiated for the treatment of Malignant pleural mesothelioma.
*9: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Primary central nervous system lymphoma / Testicular malignant 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.

Supplemental Information

New Drugs in Development

as of October 31, 2016

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following main drugs:

KYPROLIS® Intravenous Injection (ONO-7057) / Carfilzomib (injection)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for multiple myeloma of which prognosis is considered poor.

Japan: Launched in August 2016 / multiple myeloma, J-NDA filed / multiple myeloma (additional dosing regimen), Phase III / multiple myeloma (additional indication)
Overseas: Approved in the United States / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

Orencia® IV (ONO-4164) / BMS-188667 (injection)

ONO-4164 is an intravenous preparation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and overseas where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and with juvenile idiopathic arthritis.

Japan: Phase III / juvenile idiopathic arthritis (additional indication) (co-development with Bristol-Myers Squibb Company), Phase III / lupus nephritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Phase III / lupus nephritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

Orencia® SC (ONO-4164) / BMS-188667 (injection)

ONO-4164 is a subcutaneous formulation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed.

Japan: Launched in May 2016 / Orencia® SC 125 mg Auto-injector 1 mL, Phase III / rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Approved in September 2016 / rheumatoid arthritis

ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride (injection)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism.

Japan: J-NDA filed / secondary hyperparathyroidism
Overseas (USA & Europe): Filed / secondary hyperparathyroidism (Amgen Inc.)

ONO-1162 / Ivabradine (tablet)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase III / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure (Les Laboratoires Servier)

Onoact® Intravenous Infusion 50mg/150 mg (ONO-1101) (injection)

Japan: Phase II/III / tachyarrhythmia in low cardiac function in pediatric patients (additional indication), Phase II/III / ventricular arrhythmia (additional indication)

ONO-7643 / Anamorelin (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase III / cancer anorexia / cachexia
USA: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)
Europe: Filed / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-2370 / Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. ONO-2370 is filed in Europe by Bial and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

Japan: Phase II / Parkinson's disease
Europe: Approved in July 2016 / Parkinson's disease (Bial)

ONO-5371 / Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

Japan: Phase I/II / pheochromocytoma
USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

ONO-7268MX1 / ONO-7268MX2 (injection)

ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocellular carcinoma.

Japan: Phase I / hepatocellular carcinoma

ONO-2160/CD (tablet)

ONO-2160 is a combination product with levodopa pro-drug and carbidopa which is currently developed for Parkinson's disease.

Japan: Phase I / Parkinson's disease

ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

Japan: Phase I / B cell lymphoma
USA & Europe: Phase I / B cell lymphoma (Gilead Sciences, Inc.)

ONO-8577 (tablet)

ONO-8577 is a bladder smooth muscle relaxant being developed for the treatment of overactive bladder.

Japan: Phase I / overactive bladder

ONO-2952 (tablet)

ONO-2952 is an antagonist of translocator protein (TSPO) that is involved in neurosteroid production mainly in central nervous system, and is under clinical development for irritable bowel syndrome. It is expected to improve various symptoms of the disease by blocking the mechanism eliciting abnormality of brain-gut interactions under stress.

USA: Phase II / Irritable bowel syndrome

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

ONO-4232 (injection)

ONO-4232 is a prostaglandin receptor (EP4) agonist being developed for the treatment of acute heart failure.

USA: Phase I /acute heart failure

ONO-4474 (capsule)

ONO-4474 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of osteoarthritis.

Europe: Phase II /osteoarthritis

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

ONO-4538, a human anti-human PD-1 monoclonal antibody, is expected to be a potential treatment for cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.

Japan:

Launched in September 2014 / melanoma,
J-NDA approved in December 2015 / non-small cell lung cancer,
J-NDA approved in August 2016 / renal cell cancer,
J-NDA filed / hodgkin's lymphoma,
J-NDA filed / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / esophagogastric junction cancer and esophageal cancer (global clinical trial),
Phase III / small cell lung cancer (global clinical trial),
Phase III / urothelial cancer (global clinical trial),
Phase III / hepatocellular carcinoma (global clinical trial),
Phase III / glioblastoma (global clinical trial),
Phase III / malignant pleural mesothelioma (global clinical trial),
Phase II / ovarian cancer,
Phase II / solid tumor (cervical cancer, endometrial cancer, soft tissue sarcoma),
Phase II / primary central nervous system lymphoma / testicular malignant lymphoma (global clinical trial),
Phase I/II / virus-positive/negative solid tumor (global clinical trial),
Phase I / biliary tract cancer,

Overseas:

USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
USA / Approved in March 2015 / squamous non-small cell lung cancer,
Europe / Approved in June 2015 / melanoma,
Europe / Approved in July 2015 / squamous non-small cell lung cancer,
USA / Approved in September 2015 / melanoma (combination with Yervoy),
USA / Approved in October 2015 / non-squamous non-small cell lung cancer,
USA / Approved in November 2015 / renal cell cancer,
Europe / Approved in April 2016 / non-squamous non-small cell lung cancer,
South Korea / Approved in April 2016 / non-small cell lung cancer,
Europe / Approved in April 2016 / renal cell cancer,
USA / Approved in May 2016 / hodgkin's lymphoma,
Europe / Approved in May 2016 / melanoma (combination with Yervoy),
Taiwan / Approved in May 2016 / melanoma,
Taiwan / Approved in May 2016 / squamous non-small cell lung cancer,
USA, Europe / Filed / urothelial cancer,
Taiwan / Filed / non-squamous non-small cell lung cancer,
USA, Europe / Filed / hodgkin's lymphoma,
Taiwan / Filed / renal cell cancer,
USA, Europe / Phase III / multiple myeloma,
USA, Europe, South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe, South Korea, Taiwan / Phase III / esophageal cancer,
USA, Europe, South Korea, Taiwan / Phase III / esophagogastric junction cancer and esophageal cancer,
South Korea / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
South Korea, Taiwan / Phase III / urothelial cancer,
USA, Europe, South Korea, Taiwan / Phase III / hepatocellular carcinoma,
USA, Europe / Phase III / malignant pleural mesothelioma,
USA, Europe / Phase II / primary central nervous system lymphoma / testicular malignant lymphoma,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
USA, Europe / Phase I/II / colon cancer,
USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer),
USA, Europe, South Korea, Taiwan / Phase I/II / virus-positive/negative solid tumor,
USA, Europe / Phase I / hematological cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),
USA, Europe / Phase I / chronic myelocytic leukemia,
USA, Europe / Phase I / hepatitis C

ONO-4481 / BMS-663513 (injection)

ONO-4481, a human anti-human CD-137 monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor

ONO-4482 / BMS-986016 (injection)

ONO-4482, a human anti-human LAG-3 monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor