

Third Quarter (April 1 – December 31, 2015) Flash Report (unaudited)
Nine months ended December 31, 2015

ONO PHARMACEUTICAL CO., LTD.

February 2, 2016

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for nine months ended December 31, 2015.

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs").

This Third Quarter Flash Report 2016 (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 120 to \$1, the approximate rate of exchange at December 30, 2015.

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, 2014	Annual 12 months ended Mar. 31, 2015	3rd Quarter 9 months ended Dec. 31, 2015	3rd Quarter 9 months ended Dec. 31, 2015	
Revenue	¥ 107,267	¥ 135,775	¥ 112,419	\$ 936,825	
Profit (Owners of the parent company)	15,708	12,976	19,181	159,845	
Total equity	463,873	475,213	483,313	4,027,608	
Total assets	505,630	524,588	531,365	4,428,039	
		Yen		US\$	
Basic earnings per share	¥ 148.17	¥ 122.40	¥ 180.95	\$ 1.51	
Diluted earnings per share	¥ -	¥ -	¥ 180.94	\$ 1.51	

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**Consolidated Financial Forecast
for the Year Ending March 31, 2016**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31, 2016	
	Millions of yen	Thousands of US\$
Revenue	¥ 156,000	\$ 1,300,000
Operating profit	24,000	200,000
Profit before tax	26,500	220,833
Profit	18,600	155,000
(Owners of the parent company)		
	Yen	US\$
Basic earnings per share	175.46	1.46

(*) The forecasts for the year ending March 31, 2016 are revised from November 4, 2015 for the following reasons.

The sales of “OPDIVO® Intravenous Infusion”, anti-cancer drug, are expected to exceed the previous forecast since an approval of its additional indication for the treatment of patients with unresectable, advanced or recurrent non-small cell lung cancer (NSCLC) was received in December, 2015.

With respect to the costs and expenses of the Company, it is estimated that the research and development expenditures will decrease compared to the previous forecast because a portion of investigational drug costs are recognized in the next fiscal year, and the selling, general, and administrative expenses will increase compared to the previous forecast due to an increase of operating expenses associated with such additional indication of OPDIVO®.

For the above reasons, the Company has upwardly revised its consolidated financial forecasts.

(*)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.

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Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US\$
	As of March 31, 2015	As of December 31, 2015	As of December 31, 2015
Current assets			
Cash and cash equivalents	¥ 104,222	¥ 101,105	\$ 842,538
Trade and other receivables	41,960	53,505	445,875
Marketable securities	22,746	20,631	171,927
Other financial assets	820	800	6,667
Inventories	25,805	22,842	190,354
Other current assets	2,311	3,686	30,717
Total current assets	197,865	202,569	1,688,078
Non-current assets			
Property, plant, and equipment	70,754	74,305	619,210
Intangible assets	33,913	37,385	311,544
Investment securities	212,162	206,573	1,721,446
Investments in associates	1,023	984	8,201
Other financial assets	6,314	6,686	55,716
Deferred tax assets	45	104	864
Retirement benefit assets	-	320	2,669
Other non-current assets	2,512	2,438	20,313
Total non-current assets	326,723	328,795	2,739,961
Total assets	¥ 524,588	¥ 531,365	\$ 4,428,039

LIABILITIES AND EQUITY	Millions of yen		Thousands of US\$
	As of March 31, 2015	As of December 31, 2015	As of December 31, 2015
Current liabilities			
Trade and other payables	¥ 13,745	¥ 16,549	\$ 137,912
Borrowings	287	393	3,279
Other financial liabilities	2,585	5,190	43,246
Income taxes payable	6,587	3,318	27,651
Provisions	684	1,059	8,821
Other current liabilities	11,109	7,639	63,662
Total current liabilities	34,997	34,149	284,571
Non-current liabilities			
Borrowings	317	489	4,074
Other financial liabilities	21	21	172
Retirement benefit liabilities	5,426	2,158	17,984
Provisions	89	97	807
Deferred tax liabilities	1,156	4,315	35,956
Long-term advances received	6,724	6,198	51,649
Other non-current liabilities	645	626	5,219
Total non-current liabilities	14,378	13,903	115,860
Total liabilities	49,375	48,052	400,431
Equity			
Share capital	17,358	17,358	144,652
Capital reserves	17,080	17,095	142,462
Treasury shares	(59,308)	(59,348)	(494,566)
Other components of equity	45,756	54,654	455,447
Retained earnings	449,690	448,791	3,739,923
Equity attributable to owners of the parent company	470,575	478,550	3,987,918
Non-controlling interests	4,638	4,763	39,690
Total equity	475,213	483,313	4,027,608
Total liabilities and equity	¥ 524,588	¥ 531,365	\$ 4,428,039

Third Quarter (April 1 – December 31, 2015) Flash Report (unaudited)

Nine months ended December 31, 2015

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	3rd Quarter 9 months ended Dec. 31, 2014	3rd Quarter 9 months ended Dec. 31, 2015	3rd Quarter 9 months ended Dec. 31, 2015
Revenue	¥ 107,267	¥ 112,419	\$ 936,825
Cost of sales	(26,753)	(29,981)	(249,838)
Gross profit	80,513	82,438	686,987
Selling, general, and administrative expenses	(32,510)	(30,391)	(253,262)
Research and development costs	(29,995)	(29,400)	(244,997)
Other income	335	341	2,846
Other expenses	(1,869)	(664)	(5,537)
Operating profit	16,474	22,324	186,037
Finance income	3,367	3,081	25,679
Finance costs	(55)	(257)	(2,145)
Share of profit (loss) from investments in associates	12	(37)	(304)
Profit before tax	19,799	25,112	209,266
Income tax expense	(3,974)	(5,829)	(48,576)
Profit for the period	<u>15,825</u>	<u>19,283</u>	<u>160,690</u>
Profit for the period attributable to:			
Owners of the parent company	15,708	19,181	159,845
Non-controlling interests	118	101	845
Profit for the period	<u>15,825</u>	<u>19,283</u>	<u>160,690</u>
Earnings per share:			
		Yen	US\$
Basic earnings per share	148.17	180.95	1.51
Diluted earnings per share	-	180.94	1.51

Third Quarter (April 1 – December 31, 2015) Flash Report (unaudited)

Nine months ended December 31, 2015

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, 2014	3rd Quarter 9 months ended Dec. 31, 2015	3rd Quarter 9 months ended Dec. 31, 2015
Profit for the period	¥ 15,825	¥ 19,283	\$ 160,690
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	14,522	9,662	80,513
Remeasurement of defined benefit plans	379	(1,704)	(14,199)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(4)	(1)	(9)
	<u>14,898</u>	<u>7,957</u>	<u>66,305</u>
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	563	(32)	(263)
Net fair value gain (loss) on cash flow hedges	(28)	-	-
	<u>535</u>	<u>(32)</u>	<u>(263)</u>
Total other comprehensive income (loss)	<u>15,432</u>	<u>7,925</u>	<u>66,043</u>
Total comprehensive income for the period	<u><u>31,258</u></u>	<u><u>27,208</u></u>	<u><u>226,733</u></u>
Comprehensive income for the period attributable to:			
Owners of the parent company	31,148	27,080	225,668
Non-controlling interests	110	128	1,065
Total comprehensive income for the period	<u>31,258</u>	<u>27,208</u>	<u>226,733</u>

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Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
Balance at April 1, 2014	¥17,358	¥17,080	(¥59,274)	¥15,626	¥456,537	¥447,327	¥4,397	¥451,724	
Profit for the period					15,708	15,708	118	15,825	
Other comprehensive income				15,440		15,440	(8)	15,432	
Total comprehensive income for the period	-	-	-	15,440	15,708	31,148	110	31,258	
Purchase of treasury shares			(23)			(23)		(23)	
Cash dividends					(19,082)	(19,082)	(4)	(19,086)	
Transfer from other components of equity to retained earnings				(277)	277	-		-	
Total transactions with the owners	-	-	(23)	(277)	(18,805)	(19,105)	(4)	(19,109)	
Balance at December 31, 2014	¥17,358	¥17,080	(¥59,297)	¥30,789	¥453,440	¥459,370	¥4,503	¥463,873	

	Millions of yen								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
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	

	Thousands of US \$								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
Balance at April 1, 2015	\$144,652	\$142,332	(\$494,235)	\$381,300	\$3,747,413	\$3,921,462	\$38,649	\$3,960,111	
Profit for the period					159,845	159,845	845	160,690	
Other comprehensive income				65,823		65,823	220	66,043	
Total comprehensive income for the period	-	-	-	65,823	159,845	225,668	1,065	226,733	
Purchase of treasury shares			(331)			(331)		(331)	
Cash dividends					(159,011)	(159,011)	(24)	(159,034)	
Share-based payments		130				130		130	
Transfer from other components of equity to retained earnings				8,324	(8,324)	-		-	
Total transactions with the owners	-	130	(331)	8,324	(167,335)	(159,212)	(24)	(159,236)	
Balance at December 31, 2015	\$144,652	\$142,462	(\$494,566)	\$455,447	\$3,739,923	\$3,987,918	\$39,690	\$4,027,608	

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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, 2014	3rd Quarter 9 months ended Dec. 31, 2015	3rd Quarter 9 months ended Dec. 31, 2015
Cash flows from operating activities			
Profit before tax	¥ 19,799	¥ 25,112	\$ 209,266
Depreciation and amortization	4,478	4,857	40,475
Impairment losses	559	1,182	9,849
Interest and dividend income	(2,397)	(2,668)	(22,229)
Interest expense	10	9	78
(Increase) Decrease in inventories	(2,091)	2,959	24,660
(Increase) Decrease in trade and other receivables	(15,812)	(11,553)	(96,271)
Increase (Decrease) in trade and other payables	4,646	1,940	16,163
Increase (Decrease) in retirement benefit liabilities	385	(6,013)	(50,110)
(Increase) Decrease in retirement benefit assets	812	(87)	(726)
Increase (Decrease) in long-term advances received	–	(526)	(4,381)
Other	(1,086)	(2,722)	(22,685)
Subtotal	9,303	12,491	104,089
Interest received	351	242	2,020
Dividends received	2,093	2,456	20,469
Interest paid	(10)	(9)	(78)
Income taxes paid	(4,615)	(9,922)	(82,685)
Net cash provided by (used in) operating activities	7,121	5,258	43,816
Cash flows from investing activities			
Purchases of property, plant, and equipment	(12,109)	(5,700)	(47,499)
Purchases of intangible assets	(13,420)	(5,811)	(48,422)
Purchases of investments	(1,036)	(250)	(2,085)
Proceeds from sales and redemption of investments	16,814	22,079	183,991
Other	(197)	(208)	(1,733)
Net cash provided by (used in) investing activities	(9,948)	10,110	84,252
Cash flows from financing activities			
Dividends paid to owners of the parent company	(18,174)	(18,223)	(151,855)
Dividends paid to non-controlling interests	(4)	(3)	(24)
Repayments of long-term borrowings	(372)	(274)	(2,286)
Net increase (decrease) in short-term borrowings	(45)	92	770
Purchases of treasury shares	(22)	(39)	(324)
Net cash provided by (used in) financing activities	(18,617)	(18,446)	(153,719)
Net increase (decrease) in cash and cash equivalents	(21,444)	(3,078)	(25,651)
Cash and cash equivalents at the beginning of the period	104,898	104,222	868,520
Effects of exchange rate changes on cash and cash equivalents	119	(40)	(331)
Cash and cash equivalents at the end of the period	¥ 83,572	¥ 101,105	\$ 842,538

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Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen					
		3rd Quarter 9 months ended December 31, 2015			Year ending March 31,2016		
		Results	Increase/Decrease		Forecast		
Glactiv	Agent for type II diabetes	¥ 253	¥ +6	+2.3 %	¥ 320		
Opalmon	Circulatory system agent	181	△ 15	△ 7.8 %	225		
Opdivo	Agent for treatment of unresectable melanoma and unresectable, advanced or recurrent non-small cell lung cancer (NSCLC)	57	+42	+288.2 %	175		
Recalbon	Agent for osteoporosis	88	+9	+11.7 %	110		
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	73	+6	+9.6 %	95		
Onon	Agent for bronchial asthma and allergic rhinitis	65	△ 7	△ 10.2 %	90		
Rivastach	Agent for Alzheimer's disease	61	+9	+16.6 %	85		
Orencia SC	Agent for rheumatoid arthritis	60	+31	+107.7 %	80		
Onoact	Agent for tachyarrhythmia during and post operation etc	46	+9	+23.0 %	60		
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	43	△ 0	△ 0.8 %	55		
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	42	△ 7	△ 14.0 %	50		
Forxiga	Agent for type II diabetes	30	+17	+123.2 %	45		
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	40	△ 0	△ 0.3 %	45		
Kinedak	Agent for diabetic peripheral neuropathy	33	△ 7	△ 17.8 %	45		
Elaspol	Agent for acute lung injury associated with SIRS	14	△ 8	△ 35.4 %	20		

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

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 the 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 the 1st quarter ended June 30, 2015, operating profit increased by 63 hundreds of millions of yen, for the reason of decrease of personnel expenses due to the effect of past service costs by the retirement benefits plan revision. The consolidated statement of income for the nine months ended December 31, 2015 excluding this impact is as follows.

	Hundreds of Millions of yen						Millions of US\$			
	3rd Quarter 9 months ended Dec. 31, 2014		3rd Quarter 9 months ended Dec. 31, 2015			3rd Quarter 9 months ended Dec. 31, 2015		3rd Quarter 9 months ended Dec. 31, 2015		
	Actual		Actual	Change (%)	Excluding the Impact of Retirement Benefits Plan Revision		Change (%)	Excluding the Impact of Retirement Benefits Plan Revision		
Revenue	¥	1,073	¥	1,124	4.8 %	¥	1,124	4.8 %	\$	937
Cost of sales		(268)		(300)	12.1 %		(304)	13.7 %		(253)
Gross profit		805		824	2.4 %		820	1.9 %		683
Selling, general, and administrative expenses		(325)		(304)	Δ 6.5 %		(340)	4.7 %		(284)
Research and development costs		(300)		(294)	Δ 2.0 %		(316)	5.4 %		(264)
Operating profit		165		223	35.5 %		160	Δ 2.7 %		134
Profit before tax		198		251	26.8 %		188	Δ 5.0 %		157
Income tax expense		(40)		(58)	46.7 %		(44)	10.2 %		(37)
Profit for the period		158		193	21.8 %		144	Δ 8.8 %		120
Profit for the period attributable to:										
Owners of the parent company		157		192	22.1 %		143	Δ 8.8 %		119

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Supplemental Information

Status of Development Pipeline

as of January 28, 2016

I. Main Pipelines Other than ONO-4538

i . Developments Status in Japan

Filed

- **Proemend®** for i.v. infusion (ONO-7847 / MK-0517)
 - **Additional indication for pediatric use**
 - Chemotherapy-induced nausea and vomiting in pediatric patients [NK1 receptor antagonist]
 - Injection
 - *In-license (Merck & Co., Inc.)*
- **ONO-7057 / Carfilzomib**
 - **New chemical entities**
 - Multiple Myeloma [Proteasome inhibitor]
 - Injection
 - *In-license (Onyx Pharmaceuticals, Inc.)*
- **ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride*1**
 - **New chemical entities**
 - Secondary hyperparathyroidism [Calcium sensing receptor agonist]
 - Injection
 - *In-license (Amgen 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)*
- **ONO-7057 / Carfilzomib**
 - **Additional Dosing Regimen**
 - 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)*
- **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*

Ongoing clinical studies

- **ONO-7643 / RC-1291**
 - **New chemical entities**
 - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase II
 - Tablet
 - *In-license (Helsinn Healthcare, S.A.)*
- **ONO-6950**
 - **New chemical entities**
 - Bronchial asthma [LT receptor antagonist] / Phase II
 - Tablet
 - *In-house*
- **ONO-2370 / Opicapone*2**
 - **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*

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015
*1: Manufacturing and Marketing Approval Application was filed for “etelcalcetide hydrochloride” (ONO-5163/AMG-416) , a calcimimetic agent, to seek an indication for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis.

*2: Phase II of ONO-2370 / Opicapone (Long acting COMT inhibitor) was initiated for Parkinson’s disease.

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-6950**
 - **New chemical entities**
 - Bronchial asthma [LT receptor antagonist] / Phase II
 - Tablet
 - USA
 - *In-house*
- **ONO-2952**
 - **New chemical entities**
 - Irritable bowel syndrome [TSPO antagonist] / Phase II
 - Tablet
 - USA
 - *In-house*
- **ONO-9054**
 - **New chemical entities**
 - Glaucoma, ocular hypertension [PG receptor (FP / EP3) agonist] / Phase II
 - Eye drop
 - USA
 - *In-house*
- **ONO-4059**
 - **New chemical entities**
 - B cell lymphoma [Bruton’s tyrosine kinase (Btk) inhibitor] / Phase I
 - Capsule
 - USA & Europe
 - *In-house*
- **ONO-8055**
 - **New chemical entities**
 - Underactive bladder [PG receptor (EP2 / EP3) agonist] / Phase I
 - Tablet
 - Europe
 - *In-house*
- **ONO-1266**
 - **New chemical entities**
 - Portal hypertension [S1P receptor antagonist] / Phase I
 - Capsule
 - USA
 - *In-house*
- **ONO-4232**
 - **New chemical entities**
 - Acute heart failure [PG receptor (EP4) agonist] / Phase I
 - Injection
 - USA
 - *In-house*
- **ONO-4474**
 - **New chemical entities**
 - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
 - Capsule
 - Europe
 - *In-house*

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	Non-small cell lung cancer*1	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*1: Manufacturing and marketing approval partial amendment approval of Opdivo[®] Intravenous Infusion was obtained in Japan for the treatment of patients with unresectable, advanced or recurrent non-small cell lung cancer (NSCLC).

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo [®] Intravenous Infusion (ONO-4538) /BMS-936558	Melanoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer	South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Renal cell carcinoma*2	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*2: Manufacturing and marketing approval partial amendment application of Opdivo[®] Intravenous Infusion was filed in Japan for the treatment of patients with unresectable or metastatic renal cell carcinoma.

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

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	Japan South Korea Taiwan	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)
	Small cell lung cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma*3	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma *4	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)

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Hodgkin's lymphoma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	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)
	Solid tumor (combination with Mogamulizumab)	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company and Kyowa Hakko Kirin Co., Ltd.)
	Solid tumor (combination with Urelumab)	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (combination with LAG3 immune Checkpoint inhibitor)	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*3: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Hepatocellular carcinoma.

*4: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Glioblastoma.

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

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*1: Manufacturing and marketing approval partial amendment approval of Opdivo[®] Intravenous Infusion was obtained in USA for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

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

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 Non-small cell lung cancer)	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Melanoma (combination)	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Renal cell carcinoma*2	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*2: Manufacturing and marketing approval partial amendment application of Opdivo[®] Intravenous Infusion was filed in Europe for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior therapy.

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

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	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	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)
	Urothelial cancer*3	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma*4	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer*5	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	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)
	Hodgkin's 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)	

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2016 announced on November 4, 2015

*3: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Urothelial cancer.

*4: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Hepatocellular carcinoma.

*5: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Esophageal 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.