Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2015

ONO PHARMACEUTICAL CO., LTD.

May 12, 2015

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results ended March 31, 2015.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Annual Flash Report 2015 (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 March 31, 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$
	2014	**2015**	**2015**
Revenue	¥ **143,247**	¥ **135,775**	$ **1,131,459**
Profit (Owners of the parent company)	**20,344**	**12,976**	**108,131**
Total equity	**451,724**	**475,213**	**3,960,111**
Total assets	**486,141**	**524,588**	**4,371,568**
	Yen		US$
Basic earnings per share	¥ **191.90**	¥ **122.40**	$ **1.02**

MANAGEMENT POLICY

(1) Corporate philosophy and policy

The Ono Pharmaceutical Group is "Dedicated to Man's Fight against Disease and Pain." Under this corporate philosophy, we are committed to fulfilling unmet medical needs and aim to create innovative drugs that deliver true benefit to patients.

We are highly aware of corporate responsibilities required as a pharmaceutical company dealing in medicinal drugs upon which human lives depend, working to further strengthen compliance to ensure that all of our actions are to not only fully comply with all legal regulations but also be based on higher ethical standards.

(2) Challenges for management

To realize sustainable growth as an innovative drug producing company, we have set our unique approach of drug discovery, which is the fundamental of our business and current tasks.

Drug discovery

Our drug discovery approach of innovative drugs has been very unique “compound-oriented” approach focusing on “lipids” and “enzyme inhibitors” but not on certain diseases as our strategic targets, through accumulating libraries of compounds acting on those targets and enabling discovery of innovative drug candidates. Our current drug discovery has been based on further improved “compound-oriented” approach of drug discovery, for example, by introducing cutting-edge technologies to find more druggable candidates faster and more efficiently. And our “open-innovation” of flexible alliances with research institutes and academia with state-of-art knowledge and technology allow more productivity and increase probability of success in drug discovery. To accelerate this effort, we are going to build up a new type of research network of industry-academia collaboration called “orientem innovation” inside and outside Japan under which we furnish our unique and novel compounds to academic institutions with cutting-edge knowledge and technologies so that we can explore pharmaceutical use of the compounds more rapidly than before.

Current challenges

Pharmaceutical industry faces severe environmental changes worldwide where productivity is decreasing and investment is increasing in R&D year by year while healthcare system reforms accelerate suppression of healthcare expenditures. Under such circumstances, our challenges are as follows:

(i) Enrichment of Development Pipeline

For sustainable growth, it is essential to launch new drugs into the market in a constant manner based on high quality of development pipeline. For this, we are in pursuit of continuous launch of new drugs, by accelerating in-house drug discovery of unique and innovative drug candidates with cutting-edge technologies as well as by focusing on in-licensing of drug candidates with strategic potential or high unmet medical needs. Further, we are also committed to earlier confirmation of efficacy and safety of compounds in clinical development to speed up the development of new drugs.

(ii) Acceleration of Overseas Operations

We are pushing forward global delivery of our innovative drugs to patients worldwide. We are aiming at launching our innovative drugs through proactively conducting clinical development overseas as well as out-licensing to foreign business partners. We have initiated building a base to sell by ourselves our specialty products such as anticancer drugs overseas and such attempts have already started in Asia. In South Korea and Taiwan, we have already established subsidiaries and built a base to sell by ourselves. In the future, we are going to strengthen our overseas infrastructures for such overseas business developments as mentioned above.

(iii) Enhancement of Company Infrastructure

We are in pursuit of speeding up of business and the fostering of human resources to enhance our competitiveness on a global basis. We are also seeking enhancement of diversity, including support system to enable women to utilize their ability at work, in order to align with environmental variations. Further, we are promoting Corporate Social Responsibility (CSR) activities to fulfill CSR to all stakeholders with a focus on “Corporate Governance”, “Innovative Drugs”, “Human Resources and Human Rights”, “Environment”, “Fair Business Environment", and “Society”. We are going to move ahead with these CSR activities and enhance company infrastructure.

(3) Basic policy concerning dividends

Distribution of profits to all our shareholders is one of our key management policies, and we place great importance on the maintenance of stable dividends based on business performance for each fiscal year.

The year-end dividend for Fiscal 2014 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2014 of JPY 180 per share including the interim dividend of JPY 90 per share. The annual dividend for the next fiscal term is projected to be JPY 180 per share, which is equivalent to the annual dividend for Fiscal 2014.

We actively utilize retained earnings for the future business development including research and development of new innovative drugs in Japan and abroad, alliance with bio-venture companies, and in-license of new drug candidate compounds for development risk reduction.

Gyo Sagara
President, Representative Director and CEO

Consolidated Financial Forecast for the Six Months Ending September 30, 2015 and for the Year Ending March 31,2016

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2015		Year ending March 31, 2016	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 64,100	$ 534,167	¥ 135,100	$ 1,125,833
Operating profit	7,500	62,500	14,000	116,667
Profit before tax	8,800	73,333	16,500	137,500
Profit (Owners of the parent company)	6,200	51,667	11,600	96,667
	Yen	US$	Yen	US$
Basic earnings per share	¥ 58.49	$ 0.49	¥ 109.43	$ 0.91

(*)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

	Millions of yen		Thousands of US$
ASSETS	2014	**2015**	**2015**
Current assets			
Cash and cash equivalents	¥ 104,898	¥ **104,222**	$ **868,520**
Trade and other receivables	42,240	**41,960**	**349,670**
Marketable securities	22,295	**22,746**	**189,550**
Other financial assets	905	**820**	**6,837**
Inventories	24,261	**25,805**	**215,039**
Other current assets	958	**2,311**	**19,260**
Total current assets	195,557	**197,865**	**1,648,878**
Noncurrent assets			
Property, plant and equipment	59,147	**70,754**	**589,613**
Intangible assets	22,690	**33,913**	**282,610**
Investment securities	188,360	**212,162**	**1,768,017**
Investments in associates	1,008	**1,023**	**8,522**
Other financial assets	5,913	**6,314**	**52,618**
Deferred tax assets	10,003	**45**	**374**
Retirement benefit assets	905	–	–
Other noncurrent assets	2,559	**2,512**	**20,935**
Total noncurrent assets	290,585	**326,723**	**2,722,690**
Total assets	¥ 486,141	¥ **524,588**	$ **4,371,568**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	2014	**2015**	**2015**
Current liabilities			
Trade and other payables	¥ 11,288	¥ **13,745**	$ **114,543**
Borrowings	508	**287**	**2,390**
Other financial liabilities	846	**2,585**	**21,544**
Income taxes payable	4,303	**6,587**	**54,895**
Provisions	1,063	**684**	**5,696**
Other current liabilities	10,264	**11,109**	**92,576**
Total current liabilities	28,272	**34,997**	**291,644**
Noncurrent liabilities			
Borrowings	468	**317**	**2,643**
Other financial liabilities	17	**21**	**175**
Retirement benefit liabilities	3,945	**5,426**	**45,213**
Provisions	87	**89**	**745**
Deferred tax liabilities	1,002	**1,156**	**9,632**
Long-term advances received	–	**6,724**	**56,033**
Other noncurrent liabilities	626	**645**	**5,379**
Total noncurrent liabilities	6,146	**14,378**	**119,813**
Total liabilities	34,418	**49,375**	**411,457**
Equity			
Share capital	17,358	**17,358**	**144,652**
Capital reserves	17,080	**17,080**	**142,332**
Treasury shares	(59,274)	**(59,308)**	**(494,235)**
Other components of equity	15,626	**45,756**	**381,300**
Retained earnings	456,537	**449,690**	**3,747,413**
Equity attributable to owners of the parent company	447,327	**470,575**	**3,921,462**
Non-controlling interests	4,397	**4,638**	**38,649**
Total equity	451,724	**475,213**	**3,960,111**
Total liabilities and equity	¥ 486,141	¥ **524,588**	$ **4,371,568**

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Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2014	**2015**	**2015**
Revenue	¥ 143,247	¥ **135,775**	$ **1,131,459**
Cost of sales	(32,746)	**(35,136)**	**(292,802)**
Gross profit	110,501	**100,639**	**838,657**
Selling, general and administrative expenses	(38,377)	**(42,222)**	**(351,849)**
Research and development costs	(44,413)	**(41,346)**	**(344,550)**
Other income	338	**368**	**3,069**
Other expenses	(1,620)	**(2,645)**	**(22,043)**
Operating profit	26,429	**14,794**	**123,284**
Finance income	3,107	**3,565**	**29,707**
Finance costs	(76)	**(67)**	**(557)**
Share of profit from investments in associates	4	**13**	**108**
Profit before tax	29,464	**18,305**	**152,541**
Income tax expense	(8,922)	**(5,089)**	**(42,407)**
Profit for the year	20,541	**13,216**	**110,134**
Profit for the year attributable to:			
Owners of the parent company	20,344	**12,976**	**108,131**
Non-controlling interests	198	**240**	**2,002**
Profit for the year	20,541	**13,216**	**110,134**
Earnings per share:	Yen		US$
Basic earnings per share	191.90	**122.40**	**1.02**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2014	**2015**	**2015**
Profit for the year	¥ 20,541	**¥ 13,216**	**$ 110,134**
Other comprehensive income:			
Items that will not be reclassified to profit or loss:			
Net gain on financial assets measured at fair value through other comprehensive income	7,106	**29,529**	**246,079**
Remeasurement of defined benefit plans	596	**(640)**	**(5,330)**
Share of net gain on financial assets measured at fair value through other comprehensive income of investments in associates	3	**4**	**35**
	7,706	**28,894**	**240,783**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	323	**505**	**4,210**
Net fair value gain (loss) on cash flow hedges	6	**(6)**	**(53)**
	330	**499**	**4,157**
Total other comprehensive income	8,036	**29,393**	**244,941**
Total comprehensive income for the year	28,577	**42,609**	**355,074**
Comprehensive income for the year attributable to:			
Owners of the parent company	28,367	**42,364**	**353,036**
Non-controlling interests	210	**245**	**2,038**
Total comprehensive income for the year	28,577	**42,609**	**355,074**

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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							
	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, 2013	17,358	17,080	(59,231)	8,198	454,681	438,086	4,190	442,276
Profit for the year					20,344	20,344	198	20,541
Other comprehensive income				8,023		8,023	12	8,036
Total comprehensive income for the year	–	–	–	8,023	20,344	28,367	210	28,577
Purchase of treasury shares			(43)			(43)		(43)
Cash dividends					(19,083)	(19,083)	(3)	(19,086)
Transfer from other components of equity to retained earnings				(595)	595	–		–
Total transactions with the owners	–	–	(43)	(595)	(18,487)	(19,126)	(3)	(19,129)
Balance at March 31, 2014	**17,358**	**17,080**	**(59,274)**	**15,626**	**456,537**	**447,327**	**4,397**	**451,724**
Profit for the year					**12,976**	**12,976**	**240**	**13,216**
Other comprehensive income				**29,389**		**29,389**	**4**	**29,393**
Total comprehensive income for the year	**–**	**–**	**–**	**29,389**	**12,976**	**42,364**	**245**	**42,609**
Purchase of treasury shares			**(34)**			**(34)**		**(34)**
Cash dividends					**(19,082)**	**(19,082)**	**(4)**	**(19,086)**
Transfer from other components of equity to retained earnings				**742**	**(742)**	**–**		**–**
Total transactions with the owners	**–**	**–**	**(34)**	**742**	**(19,823)**	**(19,116)**	**(4)**	**(19,119)**
Balance at March 31, 2015	**17,358**	**17,080**	**(59,308)**	**45,756**	**449,690**	**470,575**	**4,638**	**475,213**

	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 March 31, 2014	**144,652**	**142,332**	**(493,954)**	**130,215**	**3,804,477**	**3,727,723**	**36,643**	**3,764,366**
Profit for the year	–	–	–	–	**108,131**	**108,131**	**2,002**	**110,134**
Other comprehensive income	–	–	–	**244,905**	–	**244,905**	**36**	**244,941**
Total comprehensive income for the year	–	–	–	**244,905**	**108,131**	**353,036**	**2,038**	**355,074**
Purchase of treasury shares	–	–	**(281)**	–	–	**(281)**	–	**(281)**
Cash dividends	–	–	–	–	**(159,016)**	**(159,016)**	**(32)**	**(159,048)**
Transfer from other components of equity to retained earnings	–	–	–	**6,180**	**(6,180)**	–	–	–
Total transactions with the owners	–	–	**(281)**	**6,180**	**(165,196)**	**(159,297)**	**(32)**	**(159,329)**
Balance at March 31, 2015	**144,652**	**142,332**	**(494,235)**	**381,300**	**3,747,413**	**3,921,462**	**38,649**	**3,960,111**

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Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2014	**2015**	**2015**
Cash flows from operating activities			
Profit before tax	¥ 29,464	¥ **18,305**	$ **152,541**
Depreciation and amortization	5,109	**6,100**	**50,837**
Impairment losses	2,016	**560**	**4,668**
Interest and dividend income	(2,584)	**(2,528)**	**(21,069)**
Interest expense	14	**13**	**112**
Increase in inventories	(1,036)	**(1,541)**	**(12,839)**
Decrease in trade and other receivables	1,156	**282**	**2,353**
Increase in trade and other payables	990	**3,999**	**33,329**
Increase in retirement benefit liabilities	515	**526**	**4,387**
Decrease in retirement benefit assets	1,035	**915**	**7,629**
Increase in long-term advances received	–	**6,724**	**56,030**
Other	(93)	**327**	**2,729**
Subtotal	36,585	**33,685**	**280,707**
Interest received	667	**450**	**3,747**
Dividends received	2,046	**2,138**	**17,816**
Interest paid	(14)	**(13)**	**(112)**
Income taxes paid	(10,862)	**(4,680)**	**(38,997)**
Net cash provided by operating activities	28,422	**31,579**	**263,160**
Cash flows from investing activities			
Purchases of property, plant and equipment	(5,816)	**(17,540)**	**(146,168)**
Proceeds from sales of property, plant and equipment	7	**1**	**9**
Purchases of intangible assets	(7,041)	**(13,578)**	**(113,151)**
Purchases of investments	(31,353)	**(3,677)**	**(30,640)**
Proceeds from sales and redemption of investments	51,526	**22,396**	**186,634**
Other	(398)	**(358)**	**(2,984)**
Net cash provided by (used in) investing activities	6,926	**(12,756)**	**(106,300)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(19,073)	**(19,060)**	**(158,833)**
Dividends paid to non-controlling interests	(3)	**(4)**	**(34)**
Repayments of long-term borrowings	(515)	**(487)**	**(4,057)**
Net decrease in short-term borrowings	(2)	**(19)**	**(161)**
Purchases of treasury shares	(42)	**(33)**	**(272)**
Net cash used in financing activities	(19,636)	**(19,603)**	**(163,358)**
Net increase (decrease) in cash and cash equivalents	15,712	**(780)**	**(6,498)**
Cash and cash equivalents at the beginning of the year	89,117	**104,898**	**874,148**
Effects of exchange rate changes on cash and cash equivalents	69	**104**	**869**
Cash and cash equivalents at the end of the year	¥ 104,898	¥ **104,222**	$ **868,520**

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Sales of Major Products

Supplemental Data

For information purpose only

		2015			Year ending March 31,2016
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	**¥ 308**	¥ △ 49	△ 13.7 %	**¥ 320**
Opalmon	Circulatory system agent	**248**	△ 77	△ 23.6 %	**225**
Recalbon	Agent for osteoporosis	**103**	△ 8	△ 7.4 %	**110**
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**86**	△ 2	△ 1.8 %	**95**
Onon	Agent for bronchial asthma and allergic rhinitis	**102**	△ 32	△ 23.9 %	**90**
Rivastach	Agent for Alzheimer's disease	**68**	+4	+6.0 %	**85**
Forxiga	Agent for type II diabetes	**15**	—	—	**75**
Orencia SC	Agent for rheumatoid arthritis	**41**	+33	+419.2 %	**70**
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**58**	△ 11	△ 16.0 %	**55**
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**61**	△ 19	△ 24.2 %	**50**
Onoact	Agent for tachyarrhythmia during and post operation	**47**	+3	+6.3 %	**50**
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**53**	△ 12	△ 19.2 %	**45**
Kinedak	Agent for diabetic peripheral neuropathy	**48**	△ 26	△ 35.5 %	**45**
Opdivo	Agent for treatment of unresectable melanoma	**25**	—	—	**35**
Elaspol	Agent for acute lung injury associated with SIRS	**27**	△ 9	△ 24.1 %	**20**

Note: 1 Sales of products are shown in a gross sales basis.

2 Forxiga and Opdivo were launched in Fiscal year ended March 31, 2015 and year-on-year changes in value and percentage are therefore not available.

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Supplemental Information

Status of Development Pipeline
as of May 12, 2015

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **Onoact® Intravenous Infusion 150 mg (ONO-1101)*1**
  - **Additional formulation**
  - Intraoperative tachyarrhythmia, Post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function [Short acting beta 1 blocker]
  - Injection
  - ***In-house***

Filed

- **Rivastach® Patch (ONO-2540 / ENA713D)**
  - **Additional Dosing Regimen**
  - Alzheimer's disease [dual inhibitor of AChE and BuChE]
  - Transdermal patch
  - ***In-license (Novartis Pharma AG)***

Ongoing clinical studies

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**
  - **Additional indication for pediatric use**
  - Chemotherapy-induced nausea and vomiting in pediatric patients [NK_1 receptor antagonist] / Phase III
  - Injection
  - ***In-license (Merck & Co., Inc.)***
- **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)***
- **ONO-7057 / Carfilzomib**
  - **New chemical entities**
  - Multiple Myeloma [Proteasome inhibitor] / Phase III
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***
- **ONO-5163 / AMG-416**
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist] / Phase III
  - Injection
  - ***In-license (Amgen Inc.)***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)*2**
  - **Additional indication for pediatric use**
  - Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **ONO-7643 / RC-1291**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase II
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***
- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] / Phase II
  - Tablet
  - ***In-license (Les Laboratoires Servier)***

Ongoing clinical studies

- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **ONO-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **ONO-7056 / Salirasib**
  - **New chemical entities**
  - Solid tumor [Ras signal inhibitor] / Phase I
  - Tablet
  - ***In-license (Kadmon Corporation 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-2370 / Opicapone**
  - **New chemical entities**
  - Parkinson's disease [Long acting COMT inhibitor] / Phase I
  - Tablet
  - ***In-license (Bial)***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - ***In-house***
- **ONO-5371 / Metyrosine**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America LLC.)***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Onoact® Intravenous Infusion 150 mg (Short acting beta 1 blocker) (high content formulation) was obtained in Japan for the purpose of improvement in convenience.
*2: Phase II/III of Onoact® Intravenous Infusion 50 mg/150 mg (Short acting beta 1 blocker) was initiated for tachyarrhythmia in pediatric low cardiac function.

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-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist] / Phase II
  - Tablet
  - Europe
  - ***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
  - 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 *1**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
  - Capsule
  - Europe
  - ***In-house***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Phase I of ONO-4474 / Osteoarthritis (Tropomyosin receptor kinase (Trk) inhibitor) was initiated in healthy adult volunteers.
*2: Development of ONO-8539 (PG receptor (EP1) antagonist) was discontinued due to no expected treatment effect.

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 *1	Melanoma	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
Ipilimumab	Melanoma	Taiwan	In-license (Bristol-Myers Squibb Company)
	Melanoma	South Korea	In-license (Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Opdivo® Intravenous Infusion was obtained in South Korea for the treatment of unresectable or metastatic melanoma with disease progression.

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	Melanoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *2	Japan Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
Ipilimumab	Melanoma	Japan	In-license (Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*2: Opdivo® Intravenous Infusion was filed in Japan and Taiwan for the treatment of non-small cell lung cancer (except non-squamous 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	Renal cell cancer	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer	Phase III	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
	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 II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma*3	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (combination with Mogamulizumab) *4	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company and Kyowa Hakko Kirin)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*3: Phase I of Opdivo Intravenous Infusion was initiated for the treatment of hepatocellular carcinoma.
*4: Phase I was initiated for the treatment of Solid tumor (combination with Mogamulizumab) by Kyowa Hakko Kirin.

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

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Opdivo® Intravenous Infusion was obtained in USA for the treatment of squamous non-small cell lung cancer.

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-9365588	Non-small cell lung cancer	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Melanoma	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

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	Renal cell cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	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)
	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)
	Bladder cancer *2	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, bladder cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase I	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)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*2: Phase II was initiated for the treatment of bladder cancer by 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.

Supplemental Information

New Drugs in Development

as of May 12, 2015

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:

Opalmon® Tablets (OP-1206・α-CD)

Japan: J-NDA approved / thromboangitis obliterans, lumbar spinal canal stenosis (new formulation, co-development with Sumitomo Dainippon Pharma Co., Ltd.)

Onoact® Intravenous Infusion 150 mg (ONO-1101)

Japan: J-NDA approved / intraoperative tachyarrhythmia, post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function (additional formulation)

Rivastach® Patch(ONO-2540 / ENA713D)

Japan: J-NDA filed / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend® Intravenous Infusion (ONO-7847 / MK-0517)

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)
USA & Other Countries: Phase II / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication) (Merck & Co., Inc.)

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 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)

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: Phase III / multiple myeloma
Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-5163 / AMG-416 (injection)

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

Japan: Phase III / secondary hyperparathyroidism
USA & Other Countries: Phase III / secondary hyperparathyroidism (Amgen Inc.)

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

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

ONO-7643 / RC-1291 (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 II / cancer anorexia / cachexia
USA & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-1162 (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 II / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure (Les Laboratoires Servier)

ONO-6950 (tablet)

ONO-6950 is a leukotriene receptor antagonist, and is under clinical development for bronchial asthma. It is expected to improve symptoms associated with the disease by inhibiting airway inflammation.

Japan: Phase II / bronchial asthma
USA: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet)

ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor
USA: Phase I / pancreatic cancer (Kadmon Corporation, LLC), Phase II / non-small cell lung cancer (Kadmon Corporation, 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-4053 (tablet)

ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Japan: Phase II / allergic rhinitis
Europe: Phase II / allergic rhinitis

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 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 I / Parkinson's disease
Europe: Filed / Parkinson's disease (BIAL)

ONO-4059 (capsule)

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

Japan: Phase I / B cell lymphoma
Europe: Phase I / B cell lymphoma

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 / pheochromocytoma
USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

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 / IBS

ONO-9054 (eye drop)

ONO-9054 is a prostaglandin receptor (FP/EP3) agonist being developed for glaucoma and ocular hypertension.

USA: Phase II / glaucoma and ocular hypertension

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-1266 (capsule)

ONO-1266 is a sphingosine-1-phosphate receptor (S1P) antagonist being developed for the treatment of portal hypertension.

USA: Phase I /portal hypertension

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 I /osteoarthritis

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. Further,

Japan:
Launched in September 2014 / melanoma,
J-NDA filed / non-small cell lung cancer,
Phase III / renal cell cancer (global clinical trial),
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase II / esophageal cancer
Phase II / Hodgkin's lymphoma
Phase I / hepatocellular carcinoma

Overseas:
USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
Europe, Taiwan / Filed / melanoma,
USA / Approved in March 2015 / non-small cell lung cancer,
Europe, Taiwan / Filed / non-small cell lung cancer,
South Korea / Phase III / non-small cell lung cancer,
USA, Europe / Phase III / renal cell cancer,
USA, Europe, South Korea, Taiwan / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
USA, Europe / Phase II / Hodgkin's lymphoma,
USA, Europe / Phase II / bladder cancer,
USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer, bladder cancer),
USA, Europe / Phase I/II / colon cancer,
USA, Europe / Phase I / hepatocellular carcinoma,
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