Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2014

ONO PHARMACEUTICAL CO., LTD.

May 13, 2014

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results ended March 31, 2014.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs").
The Group has adopted IFRSs for the first time effective the current fiscal year, which commenced on April 1, 2013 and ended on March 31, 2014.

This Annual Flash Report 2014 (unaudited) is summary information extracted from the financial statements announced, and the financial statements 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.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All yen amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US$
	2014	2013	**2014**
Revenue	**¥ 143,247**	¥ 142,806	**$ 1,404,382**
Profit (Owners of the parent company)	**20,350**	22,919	**199,510**
Total equity	**451,996**	442,542	**4,431,333**
Total assets	**485,962**	475,068	**4,764,333**
	Yen		US$
Basic earnings per share	**¥ 191.96**	**¥ 216.18**	**$ 1.88**

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 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 development and activation of human resources for our competitiveness on a global basis. We are also seeking alignment to environmental variations and realization of innovation by diversity and alliances in and outside the company. Further, we are going to tackle the enhancement of CSR activities in the light of strengthening corporate governance including establishment of business ethics, promotion of contribution to society, environmental consciousness and respect for human rights.

(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 2013 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2013 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 2013.

Gyo Sagara
President, Representative Director and CEO

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Consolidated Financial Forecast for the Six Months Ending September 30, 2014 and for the Year Ending March 31,2015

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2014		Year ending March 31, 2015	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 68,100	$ 667,647	¥ 139,000	$ 1,362,745
Operating profit	10,300	100,980	19,200	188,235
Profit before tax	11,750	115,196	21,800	213,725
Profit	8,600	84,314	16,000	156,863
(Owners of the parent company)				
	Yen	US$	Yen	US$
Basic earnings per share	¥ 81.12	$ 0.80	¥ 150.93	$ 1.48

(*)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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Fiscal Year ended March 31, 2014

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US$
ASSETS	**2014**	2013	**2014**
Current assets			
Cash and cash equivalents	**¥ 104,898**	¥ 89,117	**$ 1,028,412**
Trade and other receivables	**42,240**	43,385	**414,118**
Marketable securities	**22,295**	40,022	**218,578**
Other financial assets	**905**	1,000	**8,873**
Inventories	**24,232**	23,195	**237,569**
Other current assets	**958**	721	**9,392**
Total current assets	**195,527**	197,439	**1,916,931**
Noncurrent assets			
Property, plant and equipment	**59,147**	55,781	**579,873**
Intangible assets	**22,690**	18,869	**222,451**
Investment securities	**188,360**	179,640	**1,846,667**
Investments accounted for using the equity method	**1,008**	1,001	**9,882**
Other financial assets	**5,913**	5,568	**57,971**
Deferred tax assets	**9,853**	13,415	**96,598**
Retirement benefit assets	**905**	1,050	**8,873**
Other noncurrent assets	**2,559**	2,303	**25,088**
Total noncurrent assets	**290,434**	277,628	**2,847,392**
Total assets	**¥ 485,962**	¥ 475,068	**$ 4,764,333**

(Note) All amounts are rounded off to the nearest million yen.

LIABILITIES AND EQUITY	Millions of yen 2014	Millions of yen 2013	Thousands of US$ 2014
Current liabilities			
Trade and other payables	**¥ 10,836**	¥ 9,007	**$ 106,235**
Borrowings	**508**	472	**4,980**
Other financial liabilities	**846**	1,092	**8,294**
Income taxes payable	**4,303**	5,606	**42,186**
Provisions	**1,063**	834	**10,422**
Other current liabilities	**10,264**	9,931	**100,627**
Total current liabilities	**27,820**	26,942	**272,745**
Noncurrent liabilities			
Borrowings	**468**	484	**4,588**
Other financial liabilities	**17**	14	**167**
Retirement benefit liabilities	**3,945**	3,467	**38,676**
Provisions	**87**	86	**853**
Deferred tax liabilities	**1,002**	898	**9,824**
Other noncurrent liabilities	**626**	634	**6,136**
Total noncurrent liabilities	**6,146**	5,584	**60,255**
Total liabilities	**33,966**	32,526	**333,000**
Equity			
Share capital	**17,358**	17,358	**170,176**
Capital reserves	**17,080**	17,080	**167,451**
Treasury shares	**(59,274)**	(59,231)	**(581,118)**
Other components of equity	**15,626**	8,198	**153,196**
Retained earnings	**456,809**	454,946	**4,478,520**
Equity attributable to the owners of the parent company	**447,599**	438,351	**4,388,225**
Non-controlling interests	**4,397**	4,190	**43,108**
Total equity	**451,996**	442,542	**4,431,333**
Total liabilities and equity	**¥ 485,962**	¥ 475,068	**$ 4,764,333**

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Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US$
	2014	2013	**2014**
Revenue	**¥ 143,247**	¥ 142,806	**$ 1,404,382**
Cost of sales	**(32,747)**	(31,479)	**(321,049)**
Gross profit	**110,500**	111,328	**1,083,333**
Selling, general and administrative expenses	**(38,381)**	(35,831)	**(376,284)**
Research and development costs	**(44,413)**	(44,763)	**(435,422)**
Other income	**338**	354	**3,314**
Other expenses	**(1,620)**	(1,153)	**(15,882)**
Operating profit	**26,423**	29,935	**259,049**
Finance income	**3,107**	3,029	**30,461**
Finance costs	**(76)**	(10)	**(745)**
Share of profit in investments accounted for using the equity	**4**	46	**39**
Profit before tax	**29,458**	33,001	**288,804**
Income tax expense	**(8,910)**	(9,811)	**(87,353)**
Profit for the year	**20,548**	23,190	**201,451**
Profit for the year attributable to			
Owners of the parent company	**20,350**	22,919	**199,510**
Non-controlling interests	**198**	270	**1,941**
Profit for the year	**20,548**	23,190	**201,451**
Earnings per share:	Yen		US$
Basic earnings per share	**191.96**	216.18	**1.88**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US$
	2014	2013	**2014**
Profit for the year	**¥ 20,548**	¥ 23,190	**$ 201,451**
Other comprehensive income			
Items that cannot be reclassified to profit or loss:			
Net gain on revaluation of financial assets measured at fair value through other comprehensive income	**7,106**	15,107	**69,667**
Remeasurement of defined benefit plans	**596**	(1,859)	**5,843**
Share of net gain on revaluation of financial assets measured at fair value through other comprehensive income of investments accounted for using the equity method	**3**	16	**29**
	7,706	13,264	**75,549**
Items that may be reclassified to profit or loss:			
Exchange differences on translation of foreign operations	**323**	344	**3,167**
Net gain on derivatives designated as cash flow hedges	**6**	–	**59**
Total other comprehensive income	**8,036**	13,608	**78,784**
Total comprehensive income for the year	**28,584**	36,798	**280,235**
Comprehensive income attributable to:			
Owners of the parent company	**28,374**	36,514	**278,176**
Non-controlling interests	**210**	283	**2,059**
Total comprehensive income for the year	**28,584**	36,798	**280,235**

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Fiscal Year ended March 31, 2014

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen							
	Capital and reserves attributable to the 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 as at April 1, 2012	17,358	17,080	(59,221)	(7,688)	453,401	420,930	3,911	424,841
Profit for the year	–	–	–	–	22,919	22,919	270	23,190
Other comprehensive income	–	–	–	13,595	–	13,595	13	13,608
Total comprehensive income for the year	–	–	–	13,595	22,919	36,514	283	36,798
Purchase of treasury shares	–	–	(10)	–	–	(10)	–	(10)
Cash dividends	–	–	–	–	(19,083)	(19,083)	(4)	(19,088)
Reclassification from other components of equity to retained earnings	–	–	–	2,291	(2,291)	–	–	–
Total transactions with the owners	–	–	(10)	2,291	(21,374)	(19,093)	(4)	(19,097)
Balance as at March 31, 2013	17,358	17,080	(59,231)	8,198	454,946	438,351	4,190	442,542
Profit for the year	–	–	–		20,350	20,350	198	20,548
Other comprehensive income	–	–	–	8,023	–	8,023	12	8,036
Total comprehensive income for the year	–	–	–	8,023	20,350	28,374	210	28,584
Purchase of treasury shares	–	–	(43)	–	–	(43)	–	(43)
Cash dividends	–	–	–	–	(19,083)	(19,083)	(3)	(19,086)
Reclassification 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 as at March 31, 2014	17,358	17,080	(59,274)	15,626	456,809	447,599	4,397	451,996

	Thousands of US $							
	Capital and reserves attributable to the 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 as at March 31, 2013	**170,176**	**167,451**	**(580,696)**	**80,373**	**4,460,255**	**4,297,559**	**41,078**	**4,338,647**
Profit for the year	–	–	–	–	**199,510**	**199,510**	**1,941**	**201,451**
Other comprehensive income	–	–	–	**78,657**	–	**78,657**	**118**	**78,784**
Total comprehensive income for the year	–	–	–	**78,657**	**199,510**	**278,176**	**2,059**	**280,235**
Purchase of treasury shares	–	–	**(422)**	–	–	**(422)**	–	**(422)**
Cash dividends	–	–	–	–	**(187,088)**	**(187,088)**	**(29)**	**(187,118)**
Reclassification from other components of equity to retained earnings	–	–	–	**(5,833)**	**5,833**	–	–	–
Total transactions with the owners	–	–	**(422)**	**(5,833)**	**(181,245)**	**(187,510)**	**(29)**	**(187,539)**
Balance as at March 31, 2014	**170,176**	**167,451**	**(581,118)**	**153,196**	**4,478,520**	**4,388,225**	**43,108**	**4,431,333**

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Fiscal Year ended March 31, 2014

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US$
	2014	2013	**2014**
Cash flows from operating activities			
Income before taxes	**¥ 29,458**	¥ 33,001	**$ 288,804**
Depreciation and amortization	**5,109**	4,765	**50,088**
Impairment losses	**2,016**	2,931	**19,765**
Interest and dividend income	**(2,584)**	(2,576)	**(25,333)**
Interest expense	**14**	8	**137**
Increase in inventories	**(1,038)**	(4,681)	**(10,176)**
(Increase) decrease in trade and other receivables	**1,156**	(777)	**11,333**
(Decrease) increase in trade and other payables	**997**	(825)	**9,775**
Increase in retirement benefit liabilities	**515**	496	**5,049**
Decrease in retirement benefit assets	**1,035**	793	**10,147**
Other	**(93)**	(1,582)	**(912)**
Subtotal	**36,585**	31,553	**358,676**
Interest received	**667**	963	**6,539**
Dividends received	**2,046**	1,786	**20,059**
Interest paid	**(14)**	(8)	**(137)**
Income taxes paid	**(10,862)**	(15,302)	**(106,490)**
Net cash provided by operating activities	**28,422**	18,992	**278,647**
Cash flows from investing activities			
Purchase of property, plant and equipment	**(5,816)**	(5,224)	**(57,020)**
Proceeds from sales of property, plant and equipment	**7**	0	**69**
Purchase of intangible assets	**(7,041)**	(2,383)	**(69,029)**
Purchase of investments	**(31,353)**	(43,015)	**(307,382)**
Proceeds from sales and redemption of investments	**51,526**	55,005	**505,157**
Other	**(398)**	(17)	**(3,902)**
Net cash provided by investing activities	**6,926**	4,365	**67,902**
Cash flows from financing activities			
Dividends paid to owners of the parent company	**(19,073)**	(19,056)	**(186,990)**
Dividends paid to non-controlling interests	**(3)**	(4)	**(29)**
Repayments of long-term borrowings	**(515)**	(400)	**(5,049)**
Proceeds from long-term borrowings	**—**	300	**—**
Decrease in short-term borrowings	**(2)**	(203)	**(20)**
Purchase of treasury shares	**(42)**	(9)	**(412)**
Net cash used in financing activities	**(19,636)**	(19,372)	**(192,510)**
Net increase in cash and cash equivalents	**15,712**	3,985	**154,039**
Cash and cash equivalents at the beginning of the year	**89,117**	85,067	**873,696**
Effects of exchange rate changes on cash and cash equivalents	**69**	65	**676**
Cash and cash equivalents at the end of the year	**¥ 104,898**	¥ 89,117	**$ 1,028,412**

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Note 1 This Annual Flash Report 2014 (unaudited) is summary information extracted from the financial statements announced by the Company on May 13, 2014.
The financial statements announced have been prepared and stated in accordance with International Financial Reporting Standards ("IFRSs").
The financial statements and figures contained in this Annual Flash Report 2014 (unaudited) 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.

Note 2 All amounts expressed herein in millions of Japanese yen are rounded off to the nearest million yen.

Note 3 U.S. Dollar amounts herein are given solely for the convenience of readers outside Japan and are stated, as a matter of arithmetical computation only, at the rate of Japanese yen 102 = US$ 1, the approximate exchange rate prevailing on March 31, 2014.

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Sales of Major Products

Supplemental Data

For information purpose only

(Note) All amounts are rounded off to the nearest hundred million yen.

		2014			Year ending March 31,2015
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	**¥ 357**	¥ +9	+2.6 %	**¥ 320**
Opalmon	Circulatory system agent	**325**	△ 14	△ 4.2 %	**285**
Onon	Agent for bronchial asthma and allergic rhinitis	**135**	△ 27	△ 16.6 %	**105**
Recalbon	Agent for osteoporosis	**111**	+34	+45.0 %	**120**
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**88**	+8	+10.5 %	**105**
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**80**	△ 8	△ 8.7 %	**70**
Kinedak	Agent for diabetic peripheral neuropathy	**74**	△ 13	△ 14.5 %	**60**
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**69**	△ 4	△ 6.0 %	**60**
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**65**	+1	+1.0 %	**65**
Rivastach	Agent for Alzheimer's disease	**64**	+25	+63.8 %	**80**
Onoact	Agent for tachyarrhythmia during and post operation	**44**	+7	+18.8 %	**60**
Elaspol	Agent for acute lung injury associated with SIRS	**35**	△ 4	△ 9.1 %	**30**
Orencia SC	Agent for rheumatoid arthritis	**8**	—	—	**30**

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

2 Orencia SC was launched in Fiscal 2013, 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 13, 2014

Developments in Japan

NDA filed (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection)**
  Melanoma [human anti-human PD-1 monoclonal antibody]

NDA filed (New Formulation):

- **Opalmon® Tablets (Co-development with Dainippon Sumitomo Pharma Co., Ltd.)**
  Thromboangitis obliterans and lumbar spinal canal stenosis [Blood vessel dilation]

NDA filed (Additional Formulation):

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

NDA filed (Additional Indication):

- **Glactiv® Tablets (ONO-5435 / MK-0431) (Co-development with Merck & Co., Inc.)**
  Type 2 diabetes: combination therapy with a rapid-acting insulin secretagogue [DPP-4 inhibitor]

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection)**
  Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-7057 / Carfilzomib (injection) *2 (In-licensed from Onyx Pharmaceuticals, Inc.)**
  Multiple Myeloma (Phase III) [Proteasome inhibitor]
- **ONO-2745 / CNS 7056 (injection) (In-licensed from PAION AG)**
  Short acting general anesthetic (Phase II / III) [$GABA_A$ receptor modulator]
- **ONO-7165 / EMD531444 (injection) (Co-development with Merck KGaA)**
  Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-4641 (tablet)**
  Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 / Methylnaltrexone bromide (injection) (In-licensed from Progenics Pharmaceuticals, Inc.)**
  Opioid-induced constipation (Phase II) [Mu-opioid receptor antagonist]
- **ONO-7643 / RC-1291 (tablet) (In-licensed from Helsinn Therapeutics (U.S.), Inc.)**
  Cancer anorexia / cachexia (Phase II) [Ghrelin mimetic]
- **ONO-4538 / BMS-936558 (injection)**
  Esophageal cancer (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**
  Non-small cell lung cancer (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-1162 / Ivabradine (tablet) (In-licensed from Les Laboratoires Servier)**
  Chronic heart failure (Phase II) [If channel inhibitor]
- **ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)**
  Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **ONO-6950 (tablet)**
  Bronchial asthma (Phase I) [LT receptor antagonist]
- **ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Corporation LLC)**
  Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-7268 MX1 (injection) (In-licensed from OncoTherapy Science, Inc.)**
  Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-7268 MX2 (injection) (In-licensed from OncoTherapy Science, Inc.)**
  Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-2160/CD (tablet)**
  Parkinson's disease (Phase I) [levodopa pro-drug]
- **ONO-4053 (tablet) *3**
  Allergic rhinitis (Phase I) [PGD2 receptor antagonist]

Ongoing clinical studies (Additional Indications):

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.)**
  Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK_1 receptor antagonist]
- **Orencia® IV (ONO-4164IV / BMS-188667IV) (Co-development with Bristol-Myers Squibb Company)**
  Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164IV / BMS-188667IV) (Co-development with Bristol-Myers Squibb Company)**
  Lupus nephritis (Phase III) [T-cell activation inhibitor]

Ongoing clinical studies (Additional Dosing Regimen):

- **Rivastach® Patch (ONO-2540 / ENA713D) (Co-development with Novartis Pharma AG)**
  Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**
  Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**
  Non-small cell lung cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**
  Melanoma (Phase III) [human anti-human PD-1 monoclonal antibody]

- **ONO-4538 / BMS-936558 (injection) *4**
  (Out-licensed to Bristol-Myers Squibb Company)
  Glioblastoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) *5**
  (Out-licensed to Bristol-Myers Squibb Company)
  Diffuse large B cell lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) *6**
  (Out-licensed to Bristol-Myers Squibb Company)
  Follicular lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4641 (tablet)**
  (Out-licensed to Merck KGaA)
  Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-6950 (tablet)**
  Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**
  Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet)**
  Irritable bowel syndrome (Phase II) [TSPO antagonist]
- **ONO-9054 (eye drop)**
  Glaucoma, ocular hypertension (Phase II) [PG receptor (FP / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection) *7**
  (Out-licensed to Bristol-Myers Squibb Company)
  Colon cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**
  (Out-licensed to Bristol-Myers Squibb Company)
  Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**
  (Out-licensed to Bristol-Myers Squibb Company)
  Hepatocellular carcinoma (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**
  (Out-licensed to Bristol-Myers Squibb Company)
  Hepatitis C (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4059 (capsule)**
  B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**
  Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-8539 (tablet)**
  Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-1266 (capsule)**
  Portal hypertension (Phase I) [S1P receptor antagonist]
- **ONO-4232 (injection)**
  Acute heart failure (Phase I) [PG receptor (EP4) agonist]

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2014 announced on February 4, 2014

- *1:High content formulation of Onoact® **Intravenous Infusion 150 mg (ONO-1101)** was filed for the purpose of improvement in convenience.
- *2:Phase III clinical study of ONO-7057 / Carfilzomib (proteasome inhibitor) was initiated for the treatment of multiple myeloma.
- *3: Phase I clinical study of ONO-4053 (PGD2 receptor antagonist) was initiated for the treatment of allergic rhinitis.
- *4:Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of glioblastoma.
- *5:Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of diffuse large B cell lymphoma.
- *6:Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of follicular lymphoma.
- *7:Phase I/II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of colon cancer.
- *:Phase I clinical study of ONO-7746 (TPO receptor agonist) for the treatment of thrombocytopenia was terminated from strategic points of view and the license was returned to Nissan Chemical Industries, Ltd..

Supplemental Information

New Drugs in Development

as of May 13, 2014

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:

Glactiv® Tablet (ONO-5435 / MK-0431)

Japan: J-NDA approved / type 2 diabetes with severe renal dysfunction (12.5 mg, new formulation, co-development with Merck & Co., Inc.), J-NDA filed / combination therapy with a rapid-acting insulin secretagogue for type 2 diabetes (additional indication, co-development with Merck & Co., Inc.)

Onoact® Intravenous Infusion 150 mg (ONO-1101)

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

Proemend® Intravenous Infusion (ONO-7847 / MK-0517) (*In-licensed from Merck & Co., Inc.)*

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

Rivastach® Patch(ONO-2540 / ENA713D)

Japan: Phase III / alzheimer' disease (administration change) (co-development with Novartis Pharma AG)

Opalmon® Tablets (OP-1206 ·α-CD)

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

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: J-NDA filed / melanoma, Phase III / renal cell cancer (global clinical trial), Phase II / non-small cell lung cancer, Phase II / esophageal cancer

Overseas: Phase III / renal cell cancer (Bristol-Myers Squibb Company, global clinical trial), Phase III / melanoma (Bristol-Myers Squibb Company), Phase II / follicular lymphoma (Bristol-Myers Squibb Company), Phase I/II / colon cancer (Bristol-Myers Squibb Company), Phase I/II / solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer)(Bristol-Myers Squibb Company)

US & Other Countries: Phase III / non-small cell lung cancer (Bristol-Myers Squibb Company), Phase II / glioblastoma (Bristol-Myers Squibb Company), Phase II / diffuse large B cell lymphoma (Bristol-Myers Squibb Company),

US: Phase I / Hepatitis C (Bristol-Myers Squibb Company), Phase I / Hepatocellular carcinoma (Bristol-Myers Squibb Company)

ONO-4164 / BMS-188667 (injection)(In-licensed from Bristol-Myers Squibb Company)

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)(In-licensed from Onyx Pharmaceuticals, Inc.)

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 poor prognosis multiple myeloma.

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

ONO-2745 / CNS 7056 (injection)(In-licensed from PAION AG)

ONO-2745 is a $GABA_A$ receptor modulator, an innovative short-acting general anaesthetic and sedative, and is under clinical development as a sedative agent during the induction and maintenance of general anesthesia. The sedative effects rapidly disappear after cessation of administration due to its metabolism by esterase enzymes, and therefore it is expected to be a drug with improved controllability and safety profile.

Japan: Phase II / III / general anesthesia,
Europe: Phase II / general anesthesia (PAION AG)
US: Phase II / procedural sedation (PAION AG)

ONO-7165 / EMD531444 (injection) (In-licensed from Merck KGaA)

ONO-7165 is a liposome vaccine being developed for non-small cell lung cancer. ONO-7165 is a cancer immunotherapy targeting the tumor antigen, MUC-1. It is thought that an immune cell recognizes MUC-1 as tumor antigen, and then attacks cancer cells expressing MUC-1.

Japan: Phase II / non-small cell lung cancer (co-development with Merck KGaA)
Overseas: Phase III / non-small cell lung cancer (Merck KGaA)

ONO-4641 (tablet)

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, being developed for the treatment of multiple sclerosis. ONO-4641 is a low molecular weight substance that keeps lymphocytes in lymph nodes and reduces the lymphocyte count in the blood, thereby inhibiting the infiltration of lymphocytes into lesions. ONO-4641 is therefore expected to be an innovative drug for the treatment of auto-immune diseases such as multiple sclerosis, which is regarded as an intractable disease.

Japan: Phase II / multiple sclerosis (global clinical trial)
US and Europe: Phase II / multiple sclerosis (Merck KGaA, global clinical trial)

ONO-3849 / Methylnaltrexone bromide (injection)(In-licensed from Progenics Pharmaceuticals, Inc.)

ONO-3849 is a peripherally acting mu-opioid receptor antagonist, and is developed for intractable opioid induced constipation. Opioid pain medications are often used for the treatment of pain in cancer and other advanced illnesses, but cause constipation in many of these patients. ONO-3849 is expected to decrease the constipating effects of opioid analgesics in the gastrointestinal tract without affecting their ability to relieve pain.

Japan: Phase II / opioid-induced constipation
Overseas: Marketed (Salix Pharmaceuticals, Inc.)

ONO-7643 / RC-1291 (tablet)(In-licensed from Helsinn Therapeutics (US), Inc.)

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
US & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)

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

Japan: Phase I / II / secondary hyperparathyroidism
US: Phase III / secondary hyperparathyroidism (Amgen Inc.)

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 I / bronchial asthma
US: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Pharmaceuticals, Inc.)

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
US: Phase I / pancreatic cancer (Kadmon Pharmaceuticals, Inc.)

ONO-7268MX1 / ONO-7268MX2 (injection) (In-licensed from OncoTherapy Science, Inc.)

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

Japan: Phase I / hepatocarcinoma

ONO-1162 (tablet) (In-licensed from Servier)

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 (Servier)

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 I / allergic rhinitis
Europe: Phase II / allergic rhinitis

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.

US: Phase II / IBS

ONO-8539 (tablet)

ONO-8539 is a prostaglandin receptor (EP1) antagonist being developed for the treatment of gastroesophageal reflux disease (GERD).

Europe: Phase I /GERD

ONO-9054 (eye drop)

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

US: Phase II / glaucoma and ocular hypertension

ONO-4059 (capsule)

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

Europe: Phase I / B cell lymphoma

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 (SIP) antagonist being developed for the treatment of portal hypertension.

US: Phase I /portal hypertension

ONO-4232 (injection)

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

US: Phase I /acute heart failure

ONO-2370/BIA9-1067 (tablet) (In-licensed from Bial)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. Bial is currently conducting the Phase III trials overseas 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.

Europe: Phase III /Parkinson's disease (Bial)