Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2013

ONO PHARMACEUTICAL CO., LTD.

May 13, 2013

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2013.

This Annual Flash Report 2013 (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$
	2013	2012	**2013**
Net sales	¥ **145,393**	¥ 145,779	$ **1,546,734**
Net income	**24,120**	24,361	**256,596**
Total Net assets	**423,291**	400,968	**4,503,096**
Total assets	**455,573**	436,414	**4,846,521**
	Yen		US$
Net income per common share	¥ **227.51**	¥ **229.78**	$ **2.42**

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.

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 enriching our development pipeline, leading to continuous launch of new drugs, by commitment to enhance in-house drug discovery of unique and innovative drug candidates with cutting-edge technologies as well as by dedication to licensing activities taking into account potential synergy in already relevant therapeutic areas with our own current product line-up and/or development pipeline or focusing on attractive drug candidates for the treatment of high unmet medical needs. Further, we are also committed to earlier “proof of concept” in clinical development.

(ii) Acceleration of Overseas Operations

We are pushing forward global delivery of our innovative drugs to patients worldwide. We are aiming at launching of our innovative drugs through proactively conducting clinical development overseas, including not only in US and Europe but also in Asian regions, as well as out-licensing to foreign business partners. We are also promoting human resource development for such foreign business operations and strengthening our overseas infrastructures as needed.

(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 driving CSR activities forward in the light of business ethics, contribution to society, environmental consciousness and risk countermeasures, etc.

(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 2012 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2012 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 2012.

Gyo Sagara
President, Representative Director and CEO

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Consolidated Financial Forecast for the Year Ending March 31,2014

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2014	
	Millions of yen	Thousands of US$
Net sales	¥ 148,300	$ 1,577,660
Operating income	27,900	296,809
Ordinary income	29,000	308,511
Net income	20,400	217,021
	Yen	US$
Net income per common share	192.42	2.05

(*)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.

Consolidated Balance Sheets

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	**2013**	2012	**2013**
Current assets			
Cash and bank deposits	**¥ 24,261**	¥ 20,960	**$ 258,096**
Notes and accounts receivable	**37,823**	37,853	**402,372**
Marketable securities	**105,877**	104,814	**1,126,351**
Inventories	**23,409**	18,638	**249,032**
Deferred taxes	**17,153**	14,809	**182,479**
Others	**6,225**	5,168	**66,223**
Allowance for doubtful receivables	**(6)**	(6)	**(64)**
Total current assets	**214,742**	202,236	**2,284,489**
Property, plant and equipment			
Land	**23,479**	22,550	**249,777**
Buildings and structures	**66,934**	66,173	**712,064**
Machinery,equipment and others	**26,375**	25,593	**280,585**
Construction in progress	**1,438**	262	**15,298**
Accumulated depreciation	**(68,596)**	(66,598)	**(729,745)**
Net property, plant and equipment	**49,630**	47,980	**527,979**
Investments and other assets			
Investment securities	**180,201**	168,691	**1,917,031**
Deferred taxes	**35**	4,579	**372**
Intangible assets	**1,383**	995	**14,713**
Prepaid pension cost	**3,366**	5,774	**35,809**
Others	**6,216**	6,159	**66,128**
Total investments and other assets	**191,201**	186,198	**2,034,053**
Total assets	**¥ 455,573**	¥ 436,414	**$ 4,846,521**

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen 2013	2012	Thousands of US$ 2013
Current liabilities			
Current portion of long-term debt	**¥ 102**	¥ 2	**$ 1,085**
Notes and accounts payable	**4,243**	5,767	**45,138**
Income taxes payable	**5,606**	8,876	**59,638**
Others	**15,836**	16,397	**168,469**
Total current liabilities	**25,787**	31,042	**274,330**
Long-term liabilities			
Long-term debt, less current portion	**135**	11	**1,436**
Long-term payable	**73**	73	**777**
Liability for retirement benefits	**1,076**	1,628	**11,447**
Deferred tax liabilities	**5,070**	2,593	**53,936**
Asset retirement obligations	**54**	53	**574**
Others	**87**	46	**925**
Total long-term liabilities	**6,495**	4,404	**69,095**
Equity			
Shareholders' equity			
Common stock	**17,358**	17,358	**184,660**
Capital surplus	**17,080**	17,080	**181,702**
Retained earnings	**430,825**	425,787	**4,583,245**
Treasury stock	**(59,215)**	(59,204)	**(629,947)**
Total shareholders' equity	**406,048**	401,021	**4,319,660**
Accumulated other comprehensive income			
Unrealized gain on securities (*)	**22,451**	5,725	**238,841**
Land revaluation surplus	**(8,577)**	(8,577)	**(91,245)**
Foreign currency translation adjustments	**67**	(277)	**713**
Total Accumulated other comprehensive income	**13,941**	(3,129)	**148,309**
Minority interests	**3,302**	3,076	**35,127**
Total equity	**423,291**	400,968	**4,503,096**
Total liabilities and equity	**¥ 455,573**	¥ 436,414	**$ 4,846,521**

(*) Unrealized gain on securities classified as available for sale, net of tax

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Consolidated Statements 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$
	2013	2012	**2013**
Net sales	**¥ 145,393**	¥ 145,779	**$ 1,546,734**
Cost of sales	**33,983**	28,987	**361,521**
Gross profit	**111,410**	116,792	**1,185,213**
Selling, general and administrative expenses	**79,489**	78,888	**845,628**
Operating income	**31,921**	37,904	**339,585**
Other income (expenses)			
Interest and dividend income	**2,574**	2,800	**27,383**
Interest expenses	**(2)**	(1)	**(21)**
Other, net	**165**	(693)	**1,755**
	2,737	2,106	**29,117**
Income before income taxes and minority interests	**34,658**	40,010	**368,702**
Income taxes			
Current	**11,859**	15,526	**126,159**
Deferred	**(1,542)**	(150)	**(16,404)**
	10,317	15,376	**109,755**
Income before minority interests	**24,341**	24,634	**258,947**
Minority interests	**(221)**	(273)	**(2,351)**
Net income	**¥ 24,120**	¥ 24,361	**$ 256,596**

	Yen		US$
Amounts per common share			
Net income	**¥ 227.51**	¥ 229.78	**$ 2.42**
Cash dividends applicable to the period	**¥ 180.00**	¥ 180.00	**$ 1.91**

Consolidated Statements 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$
	2013	2012	**2013**
Net income before minority interests	**¥ 24,341**	¥ 24,634	**$ 258,947**
Other comprehensive income			
Unrealized loss on available-for-sale securities	**16,723**	1,578	**177,904**
Revaluation reserve for land	**—**	361	**—**
Foreign currency translation adjustments	**344**	(10)	**3,660**
Share of other comprehensive income in associates	**16**	4	**170**
Total other comprehensive income	**17,083**	1,933	**181,734**
Comprehensive income	**41,424**	26,567	**440,681**
Total comprehensive income attributable to			
Owners of the parent	**41,190**	26,274	**438,192**
Minority interests	**234**	293	**2,489**

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Fiscal Year ended March 31, 2013

Consolidated Statements of Changes in Net Asset

(Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2013 (Note) All amounts are rounded off to the nearest million yen.

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the beginning of previous period	17,358	17,080	425,787	(59,204)	401,021
Changes of items during the period					
Cash dividends paid			(19,082)		(19,082)
Net income			24,120		24,120
Purchase of treasury stock				(11)	(11)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	5,038	(11)	5,027
Balance at the end of current period	17,358	17,080	430,825	(59,215)	406,048

	Accumulated other comprehensive income				Minority interests	Total net assets
	Unrealized gain on available-for - sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Accumulated other comprehensive income		
Balance at the beginning of previous period	5,725	(8,577)	(277)	(3,129)	3,076	400,968
Changes of items during the period						
Cash dividends paid						(19,082)
Net income						24,120
Purchase of treasury stock						(11)
Net changes of items other than shareholder's equity during the period	16,726	—	344	17,070	226	17,296
Total changes of items during the period	16,726	—	344	17,070	226	22,323
Balance at the end of current period	22,451	(8,577)	67	13,941	3,302	423,291

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Fiscal Year ended March 31, 2013

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2013 (Note) All amounts are rounded off to the nearest thousands of US$

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the beginning of previous period	184,660	181,702	4,529,649	(629,830)	4,266,181
Changes of items during the period					
Cash dividends paid			(203,000)		(203,000)
Net income			256,596		256,596
Purchase of treasury stock				(117)	(117)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	53,596	(117)	53,479
Balance at the end of current period	184,660	181,702	4,583,245	(629,947)	4,319,660

	Accumulated other comprehensive income				Minority interests	Total net assets
	Unrealized gain on available-for - sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Accumulated other comprehensive income		
Balance at the beginning of previous period	60,904	(91,245)	(2,947)	(33,288)	32,723	4,265,616
Changes of items during the period						
Cash dividends paid						(203,000)
Net income						256,596
Purchase of treasury stock						(117)
Net changes of items other than shareholder's equity during the period	177,937	—	3,660	181,597	2,404	184,001
Total changes of items during the period	177,937	—	3,660	181,597	2,404	237,480
Balance at the end of current period	238,841	(91,245)	713	148,309	35,127	4,503,096

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Consolidated Statements of Changes in Net Asset

(Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2012 (Note) All amounts are rounded off to the nearest million yen.

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the beginning of previous period	17,358	17,080	435,536	(74,219)	395,755
Changes of items during the period					
Cash dividends paid			(19,084)		(19,084)
Net income			24,361		24,361
Purchase of treasury stock				(11)	(11)
Retirement of treasury stock			(15,026)	15,026	—
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	(9,749)	15,015	5,266
Balance at the end of current period	17,358	17,080	425,787	(59,204)	401,021

	Accumulated other comprehensive income				Minority interests	Total net assets
	Unrealized gain on available-for - sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Accumulated other comprehensive income		
Balance at the beginning of previous period	4,163	(8,938)	(267)	(5,042)	3,860	394,573
Changes of items during the period						
Cash dividends paid						(19,084)
Net income						24,361
Purchase of treasury stock						(11)
Retirement of treasury stock						—
Net changes of items other than shareholder's equity during the period	1,562	361	(10)	1,913	(784)	1,129
Total changes of items during the period	1,562	361	(10)	1,913	(784)	6,395
Balance at the end of current period	5,725	(8,577)	(277)	(3,129)	3,076	400,968

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Consolidated Statements 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$
	2013	2012	**2013**
Operating activities:			
Income before income taxes and minority interests	**¥ 34,658**	¥ 40,010	**$ 368,702**
Adjustments:			
Depreciation and amortization	**2,845**	3,005	**30,266**
Increase(decrease) in allowance for doubtful receivables	**0**	(0)	**0**
Increase(decrease) in provision for retirement benefits, net	**(569)**	1,123	**(6,053)**
Decrease(Increase) in prepaid pension costs	**2,408**	(1,983)	**25,617**
Interest and dividend income	**(2,575)**	(2,800)	**(27,394)**
Loss(gain) on sales of investment securities	**(771)**	491	**(8,202)**
Loss on valuation of investment securities	**66**	226	**702**
Interest expenses	**2**	1	**21**
Increase(decrease) in notes and accounts receivable	**31**	(1,147)	**330**
Increase in inventories	**(4,772)**	(5,589)	**(50,766)**
Decrease (increase) in trade notes and accounts payable	**(1,660)**	450	**(17,660)**
Others	**(1,651)**	(1,010)	**(17,564)**
Interest and dividend income received	**2,749**	2,962	**29,245**
Interest paid	**(2)**	(1)	**(21)**
Income taxes paid	**(15,097)**	(14,103)	**(160,606)**
Net cash (used in) provided by operating activities	**15,662**	21,635	**166,617**
Investing activities:			
Payments for purchases of marketable securities	**(23,012)**	(33,002)	**(244,808)**
Proceeds from sales and redemption of marketable securities	**50,591**	66,370	**538,203**
Payments for purchases of property, plant and equipment	**(4,578)**	(2,023)	**(48,702)**
Payments for purchases of investment securities	**(20,004)**	(30,882)	**(212,809)**
Proceeds from sales of investment securities	**4,414**	469	**46,957**
Other payments	**(241)**	(1,065)	**(2,564)**
Net cash generated from provided by investment activities	**7,170**	(133)	**76,277**
Financing activities:			
Repayment of current portion of long-term loans payable	**(77)**	(2)	**(819)**
Proceeds from long-term loans payable	**300**	—	**3,191**
Payments for obtaining treasury stock	**(9)**	(10)	**(96)**
Cash dividends	**(19,056)**	(19,057)	**(202,723)**
Cash dividends to minority shareholders	**(4)**	(4)	**(42)**
Others	**(1)**	—	**(11)**
Net cash used in financing activities	**(18,847)**	(19,073)	**(200,500)**
Foreign currency translation adjustments on cash and cash equivalents	**65**	61	**691**
Net decrease in cash and cash equivalents	**4,050**	2,490	**43,085**
Cash and cash equivalents, beginning	**85,067**	82,577	**904,968**
Cash and cash equivalents, ending	**¥ 89,117**	¥ 85,067	**$ 948,053**

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Note 1 This Annual Flash Report 2013 (unaudited) is summary information extracted from the financial statements announced by the Company on May 13, 2013.
The financial statements announced have been prepared and stated in accordance with accounting principles generally accepted in Japan.
The financial statements and figures contained in this Annual Flash Report 2013 (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 94 = US$ 1, the approximate exchange rate prevailing on March 31, 2013.

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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.

		2013			Year ending March 31,2014
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	**¥ 348**	¥ +69	24.7 %	**¥ 400**
Opalmon	Circulatory system agent	**339**	Δ 56	Δ 14.1 %	**310**
Onon	Agent for bronchial asthma and allergic rhinitis	**161**	Δ 30	Δ 15.6 %	**125**
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**88**	Δ 14	Δ 13.7 %	**80**
Kinedak	Agent for diabetic peripheral neuropathy	**87**	Δ 25	Δ 22.6 %	**80**
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**79**	+12	18.0 %	**95**
Recalbon	Agent for osteoporosis	**77**	+41	117.6 %	**105**
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**73**	Δ 3	Δ 3.7 %	**70**
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**64**	+3	5.3 %	**70**
Rivastach	Agent for Alzheimer's disease	**39**	+27	216.9 %	**65**
Elaspol	Agent for acute lung injury associated with SIRS	**39**	Δ 5	Δ 10.9 %	**35**
Onoact	Agent for tachyarrhythmia during and post operation	**37**	+4	10.5 %	**45**

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

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Supplemental Information

Status of Development Pipeline

as of May 13, 2013

Developments in Japan

NDA filed (New Formulations):

- **Orencia® SC (ONO-4164 SC / BMS-188667SC)**
  (Co-development with Bristol-Myers Squibb Company)
  Rheumatoid Arthritis [T-cell activation inhibitor]

- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431)**
  (Co-development with Merck & Co., Inc.)
  Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

NDA filed (Additional Indication):

- **Onoact® 50 for Injection (ONO-1101) *1**
  Tachyarrhythmia in low cardiac function
  [Short acting beta-1 blocker]

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection)**
  Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]

- **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)**
  Melanoma (Phase II) [Fully human anti-PD-1 antibody]

- **ONO-4538 / BMS-936558 (injection)**
  Non-small cell lung cancer (Phase II) [Fully human anti-PD-1 antibody]

- **ONO-2745 / CNS 7056 (injection)**
  (In-licensed from PAION AG)
  ICU sedation (Phase II)
  [$GABA_A$ receptor modulator]

- **ONO-7057 / Carfilzomib (injection)**
  (In-licensed from Onyx Pharmaceuticals, Inc.)
  Multiple Myeloma (Phase I / II) [Proteasome 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-1162 / Ivabradine (tablet)**
  (In-licensed from Les Laboratoires Servier)
  Chronic heart failure (Phase I) [If channel inhibitor]

- **ONO-2160/CD (tablet) *2**
  Parkinson's disease (Phase I) [levodopa pro-drug]

Ongoing clinical studies (Additional Indications):

- **Glactiv® Tablets (ONO-5435 / MK-0431)**
  (Co-development with MSD KK)
  Type II diabetes: combination therapy with a rapid-acting insulin secretagogue (Phase III) [DPP-4 inhibitor]

- **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) [NK1 receptor antagonist]

- **Orencia® IV (ONO-4164IV / BMS-188667IV) *3**
  (Co-development with Bristol-Myers KK)
  Juvenile idiopathic arthritis [T-cell activation inhibitor]

- **Orencia® IV (ONO-4164IV / BMS-188667IV) *4**
  (Co-development with Bristol-Myers Squibb Company)
  Lupus nephritis [T-cell activation inhibitor]

Ongoing clinical studies (Additional Dosing Regimen):

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

Ongoing clinical studies (New Formulations):

- **Glactiv® and Metformin Combination Tablets (ONO-5435A / MK-0431A)**
  (Co-development with MSD KK)
  Type II diabetes (Phase III) / Combination product with Glacitiv and biguanide

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) [Fully human anti-PD-1 antibody]

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

- **ONO-4538 / BMS-936558 (injection)**
  (Out-licensed to Bristol-Myers Squibb Company)
  Melanoma (Phase III) [Fully human anti-PD-1 antibody]

- **ONO-4641 (tablet)**
  (Out-licensed to Merck KGaA)
  Multiple sclerosis (Phase II) [S1P receptor agonist]

Supplemental Information

New Drugs in Development

as of May 13, 2013

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:

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

ONO-4164SC is a subcutaneous formulation of Orencia® which is under development for rheumatoid arthritis. ONO-4164SC is a biologic therapy that works by inhibiting the T cell activation and suppressing the production of pro-inflammatory cytokines, which leads to the amelioration of the inflammation in joints of patients.

Japan: J-NDA filed / rheumatoid arthritis (co-development with Bristol-Myers KK)
Overseas: Approved / rheumatoid arthritis (Bristol-Myers Squibb Company)

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

ONO-4164IV 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.

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

Onoact® for Injection (ONO-1101)

Japan: J-NDA filed / tachyarrhythmia in low cardiac function

Glactiv® Tablets (ONO-5435 / MK-0431)

Japan: Phase III / combination therapy with a rapid-acting insulin secretagogue for type II diabetes (co-development with MSD K.K.)

Glactiv® and metformin Combination Tablets (ONO-5435A / MK-0431A)

Japan: Phase III / combination product with Glacitiv and biguanide for type II diabetes (co-development with MSD K.K.)

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 KK)

ONO-4538 / BMS-936558 (injection)

ONO-4538, a fully human anti-PD-1 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: Phase III / renal cell cancer (being conducted as global clinical trial), Phase II / melanoma, Phase II / non-small cell lung cancer
Overseas: Phase III / melanoma (Bristol-Myers Squibb Company), Phase III / renal cell cancer (Bristol-Myers Squibb Company, global clinical trial),
US & Other Countries: Phase III / non-small cell lung cancer, Phase I /hematological cancer (Bristol-Myers Squibb Company)
US: Phase I / Hepatocellular carcinoma, Phase I / Hepatitis C (Bristol-Myers Squibb Company)

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 (being conducted as 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-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 and during mechanical ventilation in the Intensive Care Unit (ICU). 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,
Phase II / ICU sedation
US: Phase II / procedural sedation (PAION AG)

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 I / II / 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-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 (injection) (In-licensed from OncoTherapy Science, Inc.)
ONO-7268 is a peptide vaccine and is 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 I / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure

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.

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-7746 (capsule) (In-licensed from Nissan Chemical Industries, Ltd.)
ONO-7746 is an orally active low molecule compound which may increase platelet count by activating a receptor of thrombopoietin, which is a hematopoietic factor to accelerate platelet production. It is therefore expected to be developed as a new drug which may reduce the risk of bleeding in various diseases with thrombocytopenia and overcome the risk of infection associated with platelet transfusion. Nissan Chemical is participating in co-development by process development and manufacture of the drug substance.

US: Phase I / thrombocytopenia

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

US: Phase I / glaucoma and ocular hypertension

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

Europe: Phase I / B cell lymphoma

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-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-6950 (tablet)**
  Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**
  Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet) *5**
  Irritable bowel syndrome (Phase II) [TSPO antagonist]
- **ONO-8539 (tablet)**
  Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-4538 / BMS-936558 (injection)**
  (Out-licensed to Bristol-Myers Squibb Company)
  Hepatitis C (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-7746 (capsule)**
  (In-licensed from Nissan Chemical Industries, Ltd.)
  Thrombocytopenia (Phase I) [TPO receptor agonist]
- **ONO-9054 (eye drop)**
  Glaucoma, ocular hypertension (Phase I) [PG receptor (FP / EP3) agonist]
- **ONO-4059 (tablet)**
  B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**
  Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection) *6**
  (Out-licensed to Bristol-Myers Squibb Company)
  Hematological cancer (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection) *7**
  (Out-licensed to Bristol-Myers Squibb Company)
  Hepatocellular carcinoma (Phase I) [Fully human anti-PD-1 antibody]

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2013 announced on February 4, 2013

- *1: J-NDA of Onoact® 50 for Injection was filed for additional indication of tachyarrhythmia in low cardiac function.
- *2:Phase I clinical study of ONO-2160, levodopa pro-drug was commenced for Parkinson's disease.
- *3: Phase III clinical study of Orencia IV® IV, RA therapeutic agent was commenced for juvenile rheumatoid arthritis.
- *4: Phase III clinical study of Orencia IV® IV, RA therapeutic agent was commenced for lupus nephritis.
- *5: Phase II clinical study of ONO-2952, TSPO (translocator protein) antagonist was commenced for IBS.
- *6: Phase I clinical study of ONO-4538, fully human anti-PD-1 antibody was commenced for hematological cancer.
- *7: Phase I clinical study of ONO-4538, fully human anti-PD-1 antibody was commenced for hepatocellular carcinoma.
- *: Further development of ONO-3951 for irritable bowel syndrome was discontinued because expected efficacy was not confirmed in Phase II clinical study.