

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2012

ONO PHARMACEUTICAL CO., LTD.

May 9, 2012

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2012.

This Annual Flash Report 2012 (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\$		
	2012	2011	2012			
Net sales	¥ 145,779	¥ 135,255	\$ 1,777,793			
Net income	24,361	24,222	297,085			
Total Net assets	400,968	394,573	4,889,854			
Total assets	436,414	424,443	5,322,122			
		Yen			US\$	
Net income per common share	¥ 229.78	¥ 223.88	\$ 2.80			

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MANAGEMENT PHILOSOPHY

(1) Mission and Basic management policy

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

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

(2) Management challenges

To realize continuous prosperity as a new drug oriented company, we have set the drug discovery policy, which is a fundamental part of business and the current tasks.

(Drug discovery policy)

Our discovery process of new drugs called compound-orient aims to identify lipids and enzyme inhibitors as important area, accumulates libraries of compounds that act on those targets and finds new drugs that cure diseases. We are currently discovering new drugs with further improved discovery process by introducing technology to find new drugs faster and more precisely. And flexible alliances with research institutes and universities with cutting-edge knowledge and technology give more efficiency in drug discovery and increase success rate of drug discovery.

(Current tasks)

Pharmaceutical industry sees severe environment where success rate of drug discovery is on the decrease and R&D cost is on the increase worldwide while reforming healthcare system advances policy to lower medical cost. We have decided to tackle the current tasks as follows:

(i) Expansion of Development Pipeline

For continuous growth of pharmaceutical company, it is essential to launch a new drug in the market in a constant manner by expanding its development pipeline. For this, we are in pursuit of expansion of our development pipeline which will lead to the continuous launch of a new drug, by making efforts to accelerate the discovery and development of unique and innovative pharmaceutical products with leading-edge technologies as well as by

focusing on licensing activities in a constant and proactive way toward in-license of attractive compounds which we expect to meet the unmet medical needs.

(ii) Enhancement of Marketing Base in Japanese Market

We envision that the NHI price revision and implementation of various healthcare cost containment policies may significantly and adversely affect our business, mainly long-term listed products, and therefore it is important for us to increase the portion of new products in our sales. In order to address this issue, we strive to attain enhancement of sales of new products by establishing the reputation of new products as early as possible and to strengthen our marketing base in Japanese market. In particular, we are in pursuit of increase of sales of new products such as Glactive® Tabelets for type II diabetes and Emend® Capsules for Chemotherapy-induced nausea and vomiting (both of which were launched in 2009), Rivastach® Patch for Alzheimer's disease and Recalbon® Tablets 50mg for osteoporosis (both of which were launched in 2011), by fostering them through dissemination of appropriate and scientific information.

(iii) Obtainment of Marketing Approval and Launch of In-house Compounds outside Japan

We are driving our global business development in order for patients in the world to use our own new drugs. First, we expect that our in-house compound will be granted the marketing approval and be launched outside Japan through our out-licensed partners or alliance with overseas entities. Further, we are actively conducting clinical development of our compound in overseas including Europe and Asia in order to add value to our compounds. For this purpose, we implement the development of human resources toward such overseas business development and improve our business activities based in the overseas affiliated companies.

(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.

The year-end dividend for Fiscal 2011 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2011 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 2011.

*Gyo Sagara
President, Representative
Director and CEO*

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Consolidated Financial Forecast for the Year Ending March 31,2013

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2013	
	Millions of yen	Thousands of US\$
Net sales	¥ 146,200	\$ 1,782,927
Operating income	32,700	398,780
Ordinary income	34,100	415,854
Net income	23,000	280,488
	Yen	US\$
Net income per common share	216.94	2.65

(*)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 Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

ASSETS	Millions of yen		Thousands of US\$
	2012	2011	2012
Current assets			
Cash and bank deposits	¥ 20,960	¥ 22,446	\$ 255,610
Notes and accounts receivable	37,853	36,704	461,622
Marketable securities	104,814	103,524	1,278,220
Inventories	18,638	13,048	227,293
Deferred taxes	14,809	13,641	180,598
Others	5,168	2,016	63,024
Allowance for doubtful receivables	(6)	(9)	(74)
Total current assets	202,236	191,370	2,466,293
Property, plant and equipment			
Land	22,550	22,552	275,000
Buildings and structures	66,173	65,246	806,988
Machinery, equipment and others	25,593	25,722	312,110
Construction in progress	262	658	3,195
Accumulated depreciation	(66,598)	(65,562)	(812,171)
Net property, plant and equipment	47,980	48,616	585,122
Investments and other assets			
Investment securities	168,691	167,953	2,057,207
Deferred taxes	4,579	5,764	55,841
Intangible assets	995	956	12,134
Prepaid pension cost	5,774	3,790	70,415
Others	6,159	5,994	75,110
Total investments and other assets	186,198	184,457	2,270,707
Total assets	¥ 436,414	¥ 424,443	\$ 5,322,122

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2012	2011	2012
Current liabilities			
Current portion of long-term debt	¥ 2	¥ 2	\$ 24
Notes and accounts payable	5,767	5,325	70,329
Income taxes payable	8,876	7,422	108,244
Others	16,397	13,449	199,964
Total current liabilities	31,042	26,198	378,561
Long-term liabilities			
Long-term debt, less current portion	11	12	134
Long-term payable	73	84	890
Liability for retirement benefits	1,628	547	19,854
Deferred tax liabilities	2,593	2,933	31,622
Asset retirement obligations	53	52	646
Others	46	44	561
Total long-term liabilities	4,404	3,672	53,707
Equity			
Shareholders' equity			
Common stock	17,358	17,358	211,683
Capital surplus	17,080	17,080	208,293
Retained earnings	425,787	435,536	5,192,525
Treasury stock	(59,204)	(74,219)	(722,000)
Total shareholders' equity	401,021	395,755	4,890,501
Accumulated other comprehensive income			
Unrealized gain on securities (*)	5,725	4,163	69,817
Land revaluation surplus	(8,577)	(8,938)	(104,598)
Foreign currency translation adjustments	(277)	(267)	(3,378)
Total Accumulated other comprehensive income	(3,129)	(5,042)	(38,159)
Minority interests	3,076	3,860	37,512
Total equity	400,968	394,573	4,889,854
Total liabilities and equity	¥ 436,414	¥ 424,443	\$ 5,322,122

(*) 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\$
	2012	2011	2012
Net sales	¥ 145,779	¥ 135,255	\$ 1,777,793
Cost of sales	28,987	24,759	353,500
Gross profit	116,792	110,496	1,424,293
Selling, general and administrative expenses	78,888	75,295	962,049
Operating income	37,904	35,201	462,244
Other income (expenses)			
Interest and dividend income	2,800	2,947	34,146
Interest expenses	(1)	(1)	(12)
Other, net	(693)	(1,247)	(8,451)
	2,106	1,699	25,683
Income before income taxes and minority interests	40,010	36,900	487,927
Income taxes			
Current	15,525	12,669	189,329
Deferred	(150)	(249)	(1,828)
	15,375	12,420	187,501
Income before minority interests	24,635	24,480	300,426
Minority interests	(274)	(258)	(3,341)
Net income	¥ 24,361	¥ 24,222	\$ 297,085
		Yen	US\$
Amounts per common share			
Net income	¥ 229.78	¥ 223.88	\$ 2.80
Cash dividends applicable to the period	¥ 180.00	¥ 180.00	\$ 2.20

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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\$
	2012	2011	2012
Net income before minority interests	¥ 24,635	¥ 24,480	\$ 300,426
Other comprehensive income			
Unrealized loss on available-for-sale securities	1,577	(5,563)	19,233
Revaluation reserve for land	361	—	4,402
Foreign currency translation adjustments	(10)	(93)	(122)
Share of other comprehensive income in associates	4	(4)	49
Total other comprehensive income	1,932	(5,660)	23,562
Comprehensive income	26,567	18,820	323,988
Total comprehensive income attributable to			
Owners of the parent	26,274	18,585	320,415
Minority interests	293	235	3,573

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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 end 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 end 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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Fiscal Year ended March 31, 2012

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2012

(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 end of previous period	211,683	208,293	5,311,415	(905,110)	4,826,281
Changes of items during the period					
Cash dividends paid			(232,731)		(232,731)
Net income			297,085		297,085
Purchase of treasury stock				(134)	(134)
Retirement of treasury stock			(183,244)	183,244	—
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	(118,890)	183,110	64,220
Balance at the end of current period	211,683	208,293	5,192,525	(722,000)	4,890,501

	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 end of previous period	50,768	(109,000)	(3,256)	(61,488)	47,073	4,811,866
Changes of items during the period						
Cash dividends paid						(232,731)
Net income						297,085
Purchase of treasury stock						(134)
Retirement of treasury stock						—
Net changes of items other than shareholder's equity during the period	19,049	4,402	(122)	23,329	(9,561)	13,768
Total changes of items during the period	19,049	4,402	(122)	23,329	(9,561)	77,988
Balance at the end of current period	69,817	(104,598)	(3,378)	(38,159)	37,512	4,889,854

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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, 2011

(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 end of previous period	17,358	17,080	430,870	(63,439)	401,869
Changes of items during the period					
Cash dividends paid			(19,572)		(19,572)
Net income			24,222		24,222
Purchase of treasury stock				(10,780)	(10,780)
Reversal of revaluation reserve for land			16		16
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	4,666	(10,780)	(6,114)
Balance at the end of current period	17,358	17,080	435,536	(74,219)	395,755

	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 end of previous period	9,707	(8,923)	(174)	610	3,630	406,109
Changes of items during the period						
Cash dividends paid						(19,572)
Net income						24,222
Purchase of treasury stock						(10,780)
Reversal of revaluation reserve for land						16
Net changes of items other than shareholder's equity during the period	(5,544)	(15)	(93)	(5,652)	230	(5,422)
Total changes of items during the period	(5,544)	(15)	(93)	(5,652)	230	(11,536)
Balance at the end of current period	4,163	(8,938)	(267)	(5,042)	3,860	394,573

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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\$
	2012	2011	2012
Cash flows from operating activities:			
Income before income taxes and minority interests	¥ 40,010	¥ 36,900	\$ 487,927
Adjustments:			
Depreciation and amortization	3,005	3,052	36,646
Decrease in allowance for doubtful receivables	(0)	(4)	(0)
Increase (decrease) in provision for retirement benefits, net	1,123	(57)	13,695
Increase in prepaid pension costs	(1,983)	(3,790)	(24,183)
Interest and dividend income	(2,800)	(2,947)	(34,146)
Interest expenses	1	1	12
Loss on sales of investment securities	491	—	5,988
Loss on valuation of investment securities	226	614	2,756
Increase in notes and accounts receivable	(1,147)	(5,082)	(13,988)
(Increase) decrease in inventories	(5,589)	1,580	(68,159)
Increase in trade notes and accounts payable	450	2,953	5,488
Others	(1,010)	7,071	(12,316)
Interest and dividend income received	2,962	3,178	36,122
Interest paid	(1)	(1)	(12)
Income taxes paid	(14,103)	(13,672)	(171,988)
Net cash provided by operating activities	21,635	29,796	263,841
Cash flows from investing activities:			
Payments for purchases of marketable securities	(33,001)	(35,548)	(402,451)
Proceeds from sales and redemption of marketable securities	66,370	63,550	809,390
Payments for purchases of property, plant and equipment	(2,023)	(1,294)	(24,671)
Payments for purchases of investment securities	(30,883)	(15,321)	(376,622)
Proceeds from sales and redemption of investment securities	469	14	5,720
Other payments	(1,065)	(286)	(12,988)
Net cash generated from (used in) investment activities	(133)	11,115	(1,622)
Cash flows from financing activities:			
Repayment of current portion of long-term debt	(2)	(2)	(24)
Payments for obtaining treasury stock	(10)	(10,779)	(122)
Cash dividends	(19,057)	(19,552)	(232,403)
Cash dividends to minority shareholders	(4)	(3)	(49)
Net cash used in financing activities	(19,073)	(30,336)	(232,598)
Foreign currency translation adjustments			
on cash and cash equivalents	61	(95)	744
Net increase in cash and cash equivalents	2,490	10,480	30,365
Cash and cash equivalents, beginning	82,577	72,097	1,007,037
Cash and cash equivalents, ending	¥ 85,067	¥ 82,577	\$ 1,037,402

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Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2012 (unaudited) is summary information extracted from the financial statements announced by the Company on May 9, 2012.
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 2012 (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 82 = US\$ 1, the approximate exchange rate prevailing on March 31, 2012.

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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.

		2012		
		Results	Increase/Decrease	
Opalmon	Circulatory system agent	¥ 395	¥ ▲6	▲1.5%
Glactiv	Agent for type II diabetes	279	+168	+150.7%
Onon	Agent for bronchial asthma and allergic rhinitis	191	▲24	▲11.2%
Kinedak	Agent for diabetic peripheral neuropathy	112	▲20	▲15.1%
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	102	▲8	▲7.2%
Onon dry syrup	Agent for pediatric bronchial asthma	76	▲9	▲11.0%
Emend	Agent for Chemotherapy-induced nausea and vomiting	66	+18	+38.5%
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	61	+3	+4.8%
Elaspol	Agent for acute lung injury associated with SIRS	44	▲6	▲12.5%
Recalbon	Agent for osteoporosis	35	+16	+80.3%
Onoact	Agent for tachyarrhythmia during and post operation	33	▲2	▲5.9%
Rivastach	Agent for Alzheimer's disease	12	—	—

Note: Rivastach was launched in Fiscal 2011, 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 9, 2012

Developments in Japan

NDA filed (Additional Indications):

- **Emend® Capsules (ONO-7436 / MK-0869)**
(In-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting in pediatric patients [NK1 receptor antagonist]

Ongoing clinical studies (New Chemical Entities):

- **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-2745 / CNS 7056 (injection)**
(In-licensed from PAION AG)
General anesthesia (Phase I)
[Short acting GABA_A receptor modulator]
- **ONO-4538 / BMS-936558 (injection)**
Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-7057 / Carfilzomib (injection)**
(In-licensed from Onyx Pharmaceuticals, Inc.)
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- **ONO-3951 / Asimadoline (tablet)**
(In-licensed from Tioga Pharmaceuticals, Inc.)
Irritable bowel syndrome (Phase I)
[Kappa-opioid receptor agonist]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase I) [LT receptor antagonist]
- **ONO-7056 / Salirasib (tablet)**
(In-licensed from Kadmon Pharmaceuticals, Inc.)
Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-5163 / KAI-4169 (injection)**
(In-licensed from Amgen Inc.)
Secondary hyperparathyroidism (Phase I) [Calcium sensing receptor agonist]

Ongoing clinical studies (Additional Indications):

- **Glactiv® Tablets (ONO-5435 / MK-0431)**
(Co-development with Merck & Co., Inc.)
Type II diabetes: Combination therapy with a rapid-acting insulin secretagogue (Phase III) [DPP-4 inhibitor]
- **Onoact® for Injection (ONO-1101)**
Tachyarrhythmia in low cardiac function (Phase II / III)
[Short acting beta-1 blocker]
- **Opalmon® Tablets (OP-1206)**
(Co-development with Dainippon Sumitomo Pharma Co., Ltd.)
Carpal-tunnel Syndrome (Phase II) [PGE1 analogue]

Ongoing clinical studies (New Formulations):

- **Glactiv® and metformin Combination Tablets (ONO-5435A / MK-0431A)**
(Co-development with Merck & Co., Inc.)
Type II diabetes (Phase III) / Combination product with Glactiv and biguanide

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

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-4641 (tablet)**
(Out-licensed to Merck KGaA)
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Renal Cell Cancer (Phase II)
Hepatitis C (Phase I)
[Fully human anti-PD-1 antibody]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-7746 (capsule)**
(In-licensed from Nissan Chemical Industries, Ltd.)
Thrombocytopenia (Phase I) [TPO receptor agonist]
- **ONO-2952 (tablet)**
Irritable bowel syndrome (Phase I) [TSPO antagonist]
- **ONO-4053 (tablet)**
Allergic rhinitis (Phase I) [PGD2 receptor antagonist]
- **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]

Changes from the Third Quarter Flash Report for the Fiscal Year ending March 2012 announced on February 2, 2012

- Phase I of ONO-5163 / KAI-4169, calcium sensing receptor agonist, was commenced in Japan..
- Development of ONO-5334 for the treatment of osteoporosis was discontinued comprehensively taking into consideration competitiveness as well as marketing conditions in osteoporosis area.
- Phase II of ONO-6950, LT receptor antagonist, was commenced outside Japan.
- Phase I of ONO-4059, Bruton's tyrosine kinase (Btk) inhibitor, was commenced outside Japan.

Supplemental Information

New Drugs in Development

as of May 9, 2012

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. Orencia[®] IV is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed

Japan: Phase III / rheumatoid arthritis (co-development with Bristol-Myers KK)

Overseas: Approved / rheumatoid arthritis (Bristol-Myers Squibb Company)

ONO-7165 / EMD531444 (injection)

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, US and Europe: Phase II / Multiple sclerosis (multi-national clinical trial)

ONO-3849 / Methylnaltrexone bromide (injection)

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 (Progenics Pharmaceuticals, Inc.)

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 (anabolic), 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)

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 for the induction and maintenance of general anesthesia and for 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 / General anesthesia

US: Phase II / Procedural sedation (PAION AG)

ONO-4538 / BMS-936558 (injection)

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer and infectious diseases. 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 II / Melanoma

US & Other Countries: Phase II / Renal Cell Cancer (co-development with Bristol-Myers Squibb Company)

US: Phase I / Hepatitis C (co-development with Bristol-Myers Squibb Company)

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 poor prognosis multiple myeloma.

Japan: Phase I / II / multiple myeloma

Overseas: Phase III / multiple myeloma (Onyx Pharmaceuticals, Inc.). In the US, NDA filed under Accelerated Drug Approval Program.

ONO-3951 / Asimadoline (tablet)

ONO-3951 is a highly selective kappa opioid receptor agonist, and is under clinical development for irritable bowel syndrome (IBS). It is expected to be a drug improving multiple abdominal symptoms such as pain. The kappa opioid receptor is one of the three opioid receptors (mu, kappa and delta), and is believed to play an important role in control of visceral pain and bowel motility.

Japan: Phase I / IBS

US: Phase III / IBS (Tioga Pharmaceuticals, 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-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-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 I / Irritable bowel syndrome

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 I / Allergic rhinitis

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 / pancreatic cancer

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

ONO-5163 / KAI-4169 (injection)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Japan: Phase I / secondary hyperparathyroidism

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

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..

US: Phase I / B cell lymphoma

Additional indications

Emend[®] Capsules (ONO-7436 / MK-0869)

Japan: J-NDA filed / Chemotherapy-induced nausea and vomiting in pediatric patients

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 Glactiv and biguanide for type II diabetes (co-development with MSD K.K.)

Onoact[®] for Injection (ONO-1101)

Japan: Phase II / III / Tachyarrhythmia in low cardiac function

Opalmon[®] Tablets (OP-1206)

Japan: Phase II / carpal canal syndrome (co-development with Dainippon Sumitomo Pharma Co., Ltd.)