

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2010

ONO PHARMACEUTICAL CO., LTD.

May 13, 2010

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2010.

This Annual Flash Report 2010 (unaudited) is a 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\$		
	2010	2009	2010			
Net sales	¥ 135,986	¥ 136,557	\$ 1,462,215			
Net income	27,878	23,767	299,763			
Total Net assets	406,109	390,041	4,366,763			
Total assets	433,226	421,280	4,658,344			
		Yen			US\$	
Net income per common share	¥ 256.38	¥ 216.07	\$ 2.76			

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Ono Pharmaceutical Co., Ltd.
and Consolidated Subsidiaries

MESSAGE FROM THE MANAGEMENT

(1) 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. We aim to develop innovative new drugs that deliver true benefit to patients, and we strive to serve as an R&D-oriented, international pharmaceutical company specializing in defined areas.

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

In new drug research, our drug discovery activities focus on areas where we can fully benefit from the technologies and know-how we have accumulated and continue to exploit our strengths as well as on areas such as biotechnology based medicines where we can make effective use of genes we possess as our genetic assets. We are in active pursuit of the discovery and development of drugs that meet the unmet medical needs at the frontline of healthcare. We also actively promote drug discovery alliances with bio-pharmaceutical companies in the US and Europe - plus research collaborations with universities and research institutions. Thus breakthrough drug discovery seeds and leading-edge technologies can be at our disposal to propel Ono's drug discovery research.

As for drug development, our first priority is in gaining licensing approval in Europe and the US in order to pursue approval of new drugs meeting worldwide standard. Thus clinical development overseas is a key area of our endeavor.

Meanwhile, drug development in Japan focuses on obtaining early approval for compounds in late-stage development. We are also working on further speeding up the development speed of projects in their early development stage, filing by leveraging multinational clinical trials and global data for globally leading development programs.

We are expanding our development pipeline by directing strong efforts into licensing activities including acquisition of commercialization rights to new drug candidate compounds. Because European and American pharmaceutical and biopharmaceutical companies are mainly the target for our licensing activities, we inaugurated within Ono Pharma USA, Inc. (OPUS) Global Business Development & Licensing in July 2009, relocating the center for our activities from Japan to the United States.

The marketing division is actively working to further enhance product value of Ono's innovative pharmaceuticals through presenting its scientific data mainly at workshops and lecture meetings and through the dissemination of high-quality information that is always backed by the latest medical knowledge, aimed at fulfilling the diversifying needs of healthcare professionals.

We envision that the NHI price revision and implementation of various healthcare cost containment policies may significantly and adversely affect our business. However, we will strive to attain stable growth by launching new products and by enhancing sales of existing products.

For the purpose to ensure high quality of our products in the manufacturing, we aim to strictly adhere to the manufacturing process and quality evaluation established in accordance with laws and regulations, and pursue stable supply of our products to customers by enhancing the inventory management of raw materials and products and facility maintenance. We also actively promote cost reduction by improving the manufacturing process and work efficiency. We will continue to work hard to pursue compliance with laws and regulations with higher ethical standards and improvement of the overall manufacturing operations in order to maintain high and stable quality of our products, improve productivities and reduce manufacturing cost.

(2) 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 taking into account business performance in a relevant fiscal term.

The year-end dividend for Fiscal 2009 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2009 of JPY 180 per share including the interim dividend of JPY 90 per share. Meanwhile the annual dividend for the next fiscal term is projected to be JPY 180 per share.

*Gyo Sagara
President, Representative
Director and CEO*

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Consolidated Financial Forecast for the Year Ending March 31,2011

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2011	
	Millions of yen	Thousands of US\$
Net sales	¥ 129,000	\$ 1,387,097
Operating income	32,000	344,086
Ordinary income	34,000	365,591
Net income	22,100	237,634
	Yen	US\$
Net income per common share	203.25	2.19

(*)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, 2010

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\$
	2010	2009	2010
Current assets			
Cash and bank deposits	¥ 15,387	¥ 14,103	\$ 165,452
Notes and accounts receivable	31,625	39,480	340,054
Marketable securities	97,830	102,908	1,051,935
Inventories	14,626	10,059	157,269
Deferred taxes	13,753	13,061	147,882
Others	8,633	955	92,827
Allowance for doubtful receivables	(13)	(9)	(140)
Total current assets	181,841	180,557	1,955,279
Property, plant and equipment			
Land	22,539	22,539	242,355
Buildings and structures	64,685	63,748	695,538
Machinery, equipment and others	25,740	24,796	276,774
Construction in progress	638	746	6,860
Accumulated depreciation	(63,592)	(61,289)	(683,785)
Net property, plant and equipment	50,010	50,540	537,742
Investments and other assets			
Investment securities	190,628	178,334	2,049,763
Deferred taxes	3,980	5,147	42,796
Intangible assets	866	1,033	9,312
Others	5,901	5,669	63,452
Total investments and other assets	201,375	190,183	2,165,323
Total assets	¥ 433,226	¥ 421,280	\$ 4,658,344

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2010	2009	2010
Current liabilities			
Current portion of long-term debt	¥ 2	¥ 2	\$ 22
Notes and accounts payable	2,345	3,423	25,215
Income taxes payable	8,421	9,130	90,548
Others	12,674	12,905	136,280
Total current liabilities	23,442	25,460	252,065
Long-term liabilities			
Long-term debt, less current portion	14	16	151
Long-term payable	84	553	903
Liability for retirement benefits	599	2,240	6,441
Deferred tax liabilities	2,967	2,961	31,903
Others	11	9	118
Total long-term liabilities	3,675	5,779	39,516
Equity			
Shareholders' equity			
Common stock	17,358	17,358	186,645
Capital surplus	17,080	17,080	183,656
Retained earnings	430,871	422,565	4,633,022
Treasury stock	(63,440)	(63,425)	(682,151)
Total shareholders' equity	401,869	393,578	4,321,172
Other comprehensive income			
Unrealized gain on securities (*)	9,707	2,171	104,376
Land revaluation surplus	(8,923)	(8,923)	(95,946)
Foreign currency translation adjustments	(174)	(204)	(1,871)
Total other comprehensive income	610	(6,956)	6,559
Minority interests	3,630	3,419	39,032
Total equity	406,109	390,041	4,366,763
Total liabilities and equity	¥ 433,226	¥ 421,280	\$ 4,658,344

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

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Fiscal Year ended March 31, 2010

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\$
	2010	2009	2010
Net sales	¥ 135,986	¥ 136,557	\$ 1,462,215
Cost of sales	20,838	21,319	224,064
Gross profit	115,148	115,238	1,238,151
Selling, general and administrative expenses	75,307	71,766	809,753
Operating income	39,841	43,472	428,398
Other income (expenses)			
Interest and dividend income	2,964	3,319	31,871
Interest expenses	(1)	(1)	(11)
Other, net	339	(6,519)	3,645
	3,302	(3,201)	35,505
Income before income taxes and minority interests	43,143	40,271	463,903
Income taxes			
Current	17,393	16,217	187,022
Deferred	(2,338)	52	(25,140)
	15,055	16,269	161,882
Income before minority interests	28,088	24,002	302,021
Minority interests	(210)	(235)	(2,258)
Net income	¥ 27,878	¥ 23,767	\$ 299,763
		Yen	US\$
Amounts per common share			
Net income	¥ 256.38	¥ 216.07	\$ 2.76
Cash dividends applicable to the period	¥ 180.00	¥ 180.00	\$ 1.94

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Fiscal Year ended March 31, 2010

Consolidated Statements of Changes in Net Asset (Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2010

(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	422,565	(63,425)	393,578
Changes of items during the period					
Cash dividends paid			(19,573)		(19,573)
Net income			27,878		27,878
Purchase of treasury stock				(14)	(14)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	8,305	(14)	8,291
Balance at the end of current period	17,358	17,080	430,870	(63,439)	401,869

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	2,171	(8,923)	(204)	(6,956)	3,419	390,041
Changes of items during the period						
Cash dividends paid						(19,573)
Net income						27,878
Purchase of treasury stock						(14)
Net changes of items other than shareholder's equity during the period	7,536	—	30	7,566	211	7,777
Total changes of items during the period	7,536	—	30	7,566	211	16,068
Balance at the end of current period	9,707	(8,923)	(174)	610	3,630	406,109

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Fiscal Year ended March 31, 2010

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2010

(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	186,645	183,656	4,543,710	(681,989)	4,232,022
Changes of items during the period					
Cash dividends paid			(210,462)		(210,462)
Net income			299,763		299,763
Purchase of treasury stock				(151)	(151)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	89,301	(151)	89,150
Balance at the end of current period	186,645	183,656	4,633,011	(682,140)	4,321,172

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	23,344	(95,946)	(2,194)	(74,796)	36,763	4,193,989
Changes of items during the period						
Cash dividends paid						(210,462)
Net income						299,763
Purchase of treasury stock						(151)
Net changes of items other than shareholder's equity during the period	81,032	—	323	81,355	2,269	83,624
Total changes of items during the period	81,032	—	323	81,355	2,269	172,774
Balance at the end of current period	104,376	(95,946)	(1,871)	6,559	39,032	4,366,763

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Fiscal Year ended March 31, 2010

Consolidated Statements of Changes in Net Asset (Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2009

(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	421,279	(36,861)	418,856
Changes of items during the period					
Cash dividends paid			(22,485)		(22,485)
Net income			23,767		23,767
Purchase of treasury stock				(26,564)	(26,564)
Reversal of revaluation reserve for land			4		4
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	1,286	(26,564)	(25,278)
Balance at the end of current period	17,358	17,080	422,565	(63,425)	393,578

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	17,112	(8,919)	(21)	8,172	3,235	430,263
Changes of items during the period						
Cash dividends paid						(22,485)
Net income						23,767
Purchase of treasury stock						(26,564)
Reversal of revaluation reserve for land						4
Net changes of items other than shareholder's equity during the period	(14,941)	(4)	(183)	(15,128)	184	(14,944)
Total changes of items during the period	(14,941)	(4)	(183)	(15,128)	184	(40,222)
Balance at the end of current period	2,171	(8,923)	(204)	(6,956)	3,419	390,041

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Fiscal Year ended March 31, 2010

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\$
	2010	2009	2010
Cash flows from operating activities:			
Income before income taxes and minority interests	¥ 43,143	¥ 40,271	\$ 463,903
Adjustments:			
Depreciation and amortization	3,012	3,005	32,387
Decrease in allowance for doubtful receivables	10	(1)	108
Increase (decrease) in provision for retirement benefits, net	(1,647)	(6,436)	(17,710)
Contribution to retirement benefits trust	5,000	10,000	53,763
Interest and dividend income	(2,964)	(3,319)	(31,871)
Interest expenses	1	1	11
Gain on sales of investment securities	(85)	(1,327)	(914)
Loss on valuation of investment securities	—	7,808	—
Decrease in notes and accounts receivable	7,856	1,649	84,473
Others	(13,183)	204	(141,752)
Interest and dividend income received	3,244	3,560	34,882
Interest paid	(1)	(1)	(11)
Payments for contribution to retirement benefits trust	(5,000)	(10,000)	(53,763)
Income taxes paid	(18,084)	(20,890)	(194,452)
Net cash provided by operating activities	21,302	24,525	229,054
Cash flows from investing activities:			
Payments for purchases of marketable securities	(33,379)	(93,655)	(358,914)
Proceeds from sales and redemption of marketable securities	86,120	158,963	926,022
Payments for purchases of property, plant and equipment	(3,211)	(1,509)	(34,527)
Payments for purchases of investment securities	(32,348)	(34,969)	(347,828)
Proceeds from sales and redemption of investment securities	174	2,205	1,871
Other payments	(480)	(308)	(5,162)
Net cash generated from (used in) investment activities	16,876	30,727	181,462
Cash flows from financing activities:			
Repayment of current portion of long-term debt	(2)	(1)	(22)
Payments for obtaining treasury stock	(13)	(26,563)	(140)
Cash dividends	(19,549)	(22,449)	(210,204)
Cash dividends to minority shareholders	(4)	(5)	(43)
Net cash used in financing activities	(19,568)	(49,018)	(210,409)
Foreign currency translation adjustments			
on cash and cash equivalents	26	(206)	280
Net increase in cash and cash equivalents	18,636	6,028	200,387
Cash and cash equivalents, beginning	53,461	47,433	574,850
Cash and cash equivalents, ending	¥ 72,097	¥ 53,461	\$ 775,237

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Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2010 (unaudited) is summary information extracted from the financial statements announced by the Company on May 13, 2010.
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 2010 (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 93 = US\$ 1, the approximate exchange rate prevailing on March 31, 2010.

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Sales of Major Products

Supplemental Data

For information purpose only

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

		2009			
		Results	Increase/Decrease		
Opalmon	Circulatory system agent	¥ 446	¥ +27	6.4%	
Onon	Agent for bronchial asthma and allergic rhinitis	251	▲20	▲7.3%	
Kinedak	Agent for diabetic peripheral neuropathy	161	▲12	▲7.0%	
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	127	▲6	▲4.8%	
Onon dry syrup	Agent for pediatric bronchial asthma	91	▲7	▲6.7%	
Elaspol	Agent for acute lung injury associated with SIRS	52	▲3	▲5.3%	
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	46	+18	62.4%	
Onoact	Agent for tachyarrhythmia during and post operation	31	+1	3.4%	
Glactiv	Agent for type II diabetes	15	—	—	
Recalbon	Agent for osteoporosis	9	—	—	
Emend	Agent for Chemotherapy-induced nausea and vomiting	5	—	—	

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

Note: Glactiv, Recalbon and Emend were launched in Fiscal 2009, and year-on-year changes in value and percentage are therefore not available.

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Supplemental Information

Status of Development Pipeline

as of May 13, 2010

Developments in Japan

NDA filed (New Formulations):

- **Staybla® OD Tablets (ONO-8025OD / KRP-197OD) (co-development with Kyorin Pharmaceutical Co., Ltd.)**
Overactive bladder (pollakiuria and urinary incontinence)
[M₃ muscarinic receptor blocker]

NDA filed (New Chemical Entities)

- **Rivastach® Tape (ONO-2540 / ENA713D) (transdermal patch) (co-development with Novartis Pharma K.K.)**
Alzheimer's disease
[dual inhibitor of AChE and BuChE]

Ongoing clinical studies (New Chemical Entities):

- **ONO-7847 / MK-0517 (injection) (in-licensed from Merck & Co., Inc.)**
Chemotherapy-induced nausea and vomiting (Phase III)
[NK1 receptor antagonist]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-7643 / RC-1291 (tablet) (in-licensed from Helsinn Therapeutics (U.S.), Inc.)**
Cancer anorexia / cachexia (Phase I)
[ghrelin mimetic]
- **ONO-5334 (tablet)**
Osteoporosis (Phase I) [cathepsin K inhibitor]
- **ONO-8539 (tablet)**
Overactive bladder (Phase I) [EP 1 receptor antagonist]
- **ONO-4538 / BMS-936558 (MDX-1106) (injection)**
Cancer (Phase I)
[fully human anti-PD-1 antibody]
- **ONO-3849 (injection) (in-licensed from Progenics Pharmaceuticals, Inc.)**
Opioid-induced constipation (Phase I)
[mu-opioid receptor antagonist]
- **ONO-2745 / CNS 7056 (injection) (in-licensed from PAION AG)**
Short-acting general anesthetic (Phase I)
[GABA_A receptor agonist]

Ongoing clinical studies (Additional Indications):

- **Glactiv® Tablets (ONO-5435 / MK-0431) (co-development with Banyu Pharmaceutical Co., Ltd.)**
Type II diabetes: combination therapy [DPP-IV inhibitor]
 - with alpha-glucosidase inhibitor (Phase III)
 - with insulin (Phase III)
- **Onoact® for Injection**
Improvement of multislice CT coronary imaging ability (Phase III) [short-acting β₁ blocker]

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

Ongoing clinical studies (New Dosage Regimen):

- **ONO-5920 / YM529 (once-monthly oral tablet) (co-development with Astellas Pharma Inc.)**
Osteoporosis (Phase III)
[bone resorption inhibitor (bisphosphonate)]

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-5334 (tablet)**
Osteoporosis (Phase II) [cathepsin K inhibitor]
- **ONO-8539 (tablet)**
Overactive bladder (Phase II) [EP 1 receptor antagonist]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-4538 / BMS-936558 (MDX-1106) (injection) (co-development with Bristol-Myers Squibb)**
Cancer (Phase I)
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]

Changes from the Third Quarter Flash Report for the Fiscal Year ended March 2010 announced on February 4, 2010

- J-NDA of Rivastach® Tape (ONO-2540 / ENA713D) (transdermal patch) for the treatment of alzheimer's disease was submitted with the Ministry of Health, Labour and Welfare of Japan.
- We had performed exploratory phase II study of Elaspol® for Injection for the treatment of acute respiratory failure associated with community-acquired pneumonia in Japan, but decided to discontinue the development because it is difficult to narrow down the subjects eligible for efficacy evaluation.

Supplemental Information

New Drugs in Development

as of May 13, 2010

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 major drugs:

Rivastach[®] Tape (ONO-2540 / ENA713D) ***(transdermal patch)***

Rivastach[®] Tape or ONO-2540 is a drug for the treatment of Alzheimer's disease with an inhibitory action on both acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE). It is the first transdermal system developed for the disease and is expected to provide greater convenience, e.g. caregivers can easily confirm the administration of the drug.

Japan: NDA filed / Alzheimer's disease (co-development with Novartis Pharma K.K.)

Europe & US: Marketed (Novartis AG)

ONO-7847 / MK-0517 (injection)

ONO-7847 is a neurokinin (NK) 1 antagonist, and is the prodrug of ONO-7436 (Emend[®] Capsules) available in injectable form. The development for prevention of chemotherapy-induced nausea and vomiting has been pursued.

Japan: Phase III / Chemotherapy-induced nausea and vomiting

Overseas: NDA filed / Chemotherapy-induced nausea and vomiting (Merck & Co., Inc.)

ONO-4641 (tablet)

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, being developed for the treatment of multiple sclerosis. The drug is a low molecule compound that keeps lymphocytes in lymph nodes and reduces the lymphocyte count in the blood, as a result inhibiting the infiltration of lymphocytes into lesions. The compound 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. The ongoing Phase II is a multi-national study performed in Japan, North America and Europe.

Japan, North America and Europe: Phase II / Multiple sclerosis

ONO-7643 / RC-1291 (tablet)

ONO-7643 is a small molecule ghrelin mimetic and the development is underway in cancer anorexia / cachexia. The drug is a low molecular weight substance having similar pharmacological actions to

ghrelin, which is a circulating peptide hormone that has multiple physiological actions, including appetite stimulation and muscle-building (anabolic) effects. The compound is therefore expected to be a breakthrough drug that would improve patient quality of life (QOL) impaired by exhausted general conditions based on anorexia and loss of body fat and muscle mass associated with progression of cancer

Japan: Phase I / Cancer anorexia / cachexia
US, etc.: Phase II / Cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-5334 (tablet)

ONO-5334, a cathepsin K inhibitor, is being developed for osteoporosis with a novel mechanism of action. Unlike bisphosphonates, the drug only inhibits bone resorption without having impact on bone formation.

Japan: Phase I / Osteoporosis

Europe: Phase II / Osteoporosis

ONO-8539 (tablet)

ONO-8539 is a selective antagonist of EP1, one of subtype receptors of prostaglandin E2, and overactive bladder is the first indication for its clinical development program. It is expected that the drug can be given to the patients who are complicated with glaucoma for which use of anticholinergics is limited due to its mechanism of actions and with lower urinary obstruction including benign prostatic hypertrophy.

Japan: Phase I / Overactive bladder

Europe: Phase II / Overactive bladder

ONO-4538 / BMS-936558(MDX-1106) ***(injection)***

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer and other 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 I / Cancer

US: Phase I / Cancer and hepatitis C (co-development with Bristol-Myers Squibb)

ONO-3849 (injection)

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

Japan: Phase I / Opioid-induced constipation

Overseas: Marketed / Opioid-induced constipation (Progenics Pharmaceuticals, Inc.)

ONO-2745 / CNS 7056 (injection)

CNS-7056 is a new short-acting general anesthetic that acts on GABA_A receptors. The compound is under development as a sedative in the induction and maintenance of anaesthesia and under mechanical ventilation in the Intensive Care Unit (ICU). Sedative effect quickly disappears soon after the completion of the administration since the compound is continuously metabolized by an enzyme called esterase. It is therefore expected to be a safe anaesthetic due to possible excellence in its controllability and safety.

Japan: Phase I / General anesthetic

US: Phase II (Paion AG)

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. The compound will be developed as a new drug which may reduce the risk of bleeding in various diseases with thrombocytopenia and overcome risk of infection associated with platelet transfusion. Nissan Chemical is participated in co-development by process development and manufacturing of the drug substance.

US: Phase I / Thrombocytopenia

<New Dosage Regimen / New Formulation>

ONO-5920 / YM529 (tablet)

ONO-5920 is a drug for the treatment of osteoporosis, and is intermittently administered oral formulation of Recalbon[®] Tablets.

Japan: Phase III / Osteoporosis (co-development

with Astellas Pharma Inc.)

Staybla[®] OD Tablets (ONO-8025 / KRP-197)

Staybla[®] OD Tablets is orally-disintegrating tablets. It can be taken without water and is useful even in elderly patients, those with impaired swallowing function and those abstaining from water intake. It is expected that it can offer an additional treatment option on taking the drug and therefore improve patient compliance.

Japan: NDA Filed / Overactive bladder (co-development with Kyorin Pharmaceutical Co., LTD.)

<Additional Indications>

Emend[®] Capsules (MK-0869)

Japan: Phase III / Chemotherapy-induced nausea and vomiting in children

Glactiv[®] Tablets (MK-0431)

Japan: Phase III / Type II diabetes: combination therapy (co-development with Banyu Pharmaceutical Co., Ltd.)

- with an alpha-glucosidase inhibitor
- with an insulin

Onoact[®] for Injection

Japan: Phase III / Improvement of multislice CT coronary imaging ability