

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2011

ONO PHARMACEUTICAL CO., LTD.

May 11, 2011

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2011.

This Annual Flash Report 2011 (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\$	
	2011	2010	2011	
Net sales	¥ 135,255	¥ 135,986	\$ 1,629,578	
Net income	24,222	27,878	291,831	
Total Net assets	394,573	406,109	4,753,892	
Total assets	424,443	433,226	5,113,771	
		Yen		US\$
Net income per common share	¥ 223.88	¥ 256.38	\$ 2.70	

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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.

Further we are expanding our development pipeline by directing strong efforts into licensing activities including acquisition of commercialization rights to new drug candidate compounds.

As for drug development, we aim to gain marketing approval of new drugs globally. Thus clinical development overseas including Asian countries 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.

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 new product launches and enhancement of sales of existing products.

Stable supply of our products with reliable quality, which is a social mission of pharmaceutical companies, is our first priority to be pursued in manufacturing. With respect to the quality of our products, we are actively pursuing higher level of manufacturing and quality control practice within the range of the GMP standard, and have achieved world-class quality assurance. Meanwhile we strive to ensure the stable supply of our products by proper risk management in overall manufacturing activities from raw material procurement to shipment of final products.

(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 based on business performance.

The year-end dividend for Fiscal 2010 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2010 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 2010. Meanwhile we acquired 2.7 million shares of the company's own shares from the market for the purpose of improving capital efficiency and as a part of measures for returns to shareholders during the second half of Fiscal 2010. Further we cancelled 3 million company's own shares including a part of its previously held own shares in April 2011.

Gyo Sagara
President, Representative
Director and CEO

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Consolidated Financial Forecast for the Year Ending March 31,2012

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2012	
	Millions of yen	Thousands of US\$
Net sales	¥ 140,000	\$ 1,686,747
Operating income	35,700	430,120
Ordinary income	37,800	455,422
Net income	24,500	295,181
	Yen	US\$
Net income per common share	231.09	2.78

(*)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, 2011

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\$
	2011	2010	2011
Current assets			
Cash and bank deposits	¥ 22,446	¥ 15,387	\$ 270,434
Notes and accounts receivable	36,704	31,625	442,217
Marketable securities	103,524	97,830	1,247,277
Inventories	13,048	14,626	157,205
Deferred taxes	13,642	13,753	164,361
Others	2,015	8,633	24,277
Allowance for doubtful receivables	(9)	(13)	(108)
Total current assets	191,370	181,841	2,305,663
Property, plant and equipment			
Land	22,552	22,539	271,711
Buildings and structures	65,246	64,685	786,096
Machinery, equipment and others	25,722	25,740	309,904
Construction in progress	658	638	7,928
Accumulated depreciation	(65,562)	(63,592)	(789,904)
Net property, plant and equipment	48,616	50,010	585,735
Investments and other assets			
Investment securities	167,953	190,628	2,023,530
Deferred taxes	5,764	3,980	69,446
Intangible assets	955	866	11,506
Prepaid pension cost	3,791	—	45,675
Others	5,994	5,901	72,216
Total investments and other assets	184,457	201,375	2,222,373
Total assets	¥ 424,443	¥ 433,226	\$ 5,113,771

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2011	2010	2011
Current liabilities			
Current portion of long-term debt	¥ 2	¥ 2	\$ 24
Notes and accounts payable	5,325	2,344	64,157
Income taxes payable	7,422	8,421	89,422
Others	13,449	12,675	162,035
Total current liabilities	26,198	23,442	315,638
Long-term liabilities			
Long-term debt, less current portion	13	14	157
Long-term payable	84	84	1,012
Liability for retirement benefits	547	599	6,590
Deferred tax liabilities	2,933	2,967	35,337
Asset retirement obligations	52	—	627
Others	43	11	518
Total long-term liabilities	3,672	3,675	44,241
Equity			
Shareholders' equity			
Common stock	17,358	17,358	209,133
Capital surplus	17,080	17,080	205,783
Retained earnings	435,536	430,870	5,247,422
Treasury stock	(74,219)	(63,439)	(894,205)
Total shareholders' equity	395,755	401,869	4,768,133
Accumulated other comprehensive income			
Unrealized gain on securities (*)	4,163	9,707	50,157
Land revaluation surplus	(8,939)	(8,923)	(107,699)
Foreign currency translation adjustments	(266)	(174)	(3,205)
Total Accumulated other comprehensive income	(5,042)	610	(60,747)
Minority interests			
Total equity	394,573	406,109	4,753,892
Total liabilities and equity	¥ 424,443	¥ 433,226	\$ 5,113,771

(*) 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\$
	2011	2010	2011
Net sales	¥ 135,255	¥ 135,986	\$ 1,629,578
Cost of sales	24,759	20,838	298,301
Gross profit	110,496	115,148	1,331,277
Selling, general and administrative expenses	75,295	75,307	907,169
Operating income	35,201	39,841	424,108
Other income (expenses)			
Interest and dividend income	2,947	2,964	35,506
Interest expenses	(1)	(1)	(12)
Other, net	(1,247)	339	(15,024)
	1,699	3,302	20,470
Income before income taxes and minority interests	36,900	43,143	444,578
Income taxes			
Current	12,669	17,393	152,639
Deferred	(249)	(2,338)	(3,000)
	12,420	15,055	149,639
Income before minority interests	24,480	28,088	294,939
Minority interests	(258)	(210)	(3,108)
Net income	¥ 24,222	¥ 27,878	\$ 291,831
		Yen	US\$
Amounts per common share			
Net income	¥ 223.88	¥ 256.38	\$ 2.70
Cash dividends applicable to the period	¥ 180.00	¥ 180.00	\$ 2.17

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Fiscal Year ended March 31, 2011

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)	(16)	(92)	(5,652)	230	(5,422)
Total changes of items during the period	(5,544)	(16)	(92)	(5,652)	230	(11,536)
Balance at the end of current period	4,163	(8,939)	(266)	(5,042)	3,860	394,573

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Fiscal Year ended March 31, 2011

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31, 2011

(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	209,133	205,783	5,191,205	(764,325)	4,841,796
Changes of items during the period					
Cash dividends paid			(235,807)		(235,807)
Net income			291,831		291,831
Purchase of treasury stock				(129,880)	(129,880)
Reversal of revaluation reserve for land			193		193
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	56,217	(129,880)	(73,663)
Balance at the end of current period	209,133	205,783	5,247,422	(894,205)	4,768,133

	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	116,952	(107,506)	(2,097)	7,349	43,735	4,892,880
Changes of items during the period						
Cash dividends paid						(235,807)
Net income						291,831
Purchase of treasury stock						(129,880)
Reversal of revaluation reserve for land						193
Net changes of items other than shareholder's equity during the period	(66,795)	(193)	(1,108)	(68,096)	2,771	(65,325)
Total changes of items during the period	(66,795)	(193)	(1,108)	(68,096)	2,771	(138,988)
Balance at the end of current period	50,157	(107,699)	(3,205)	(60,747)	46,506	4,753,892

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Fiscal Year ended March 31, 2011

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

	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	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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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\$
	2011	2010	2011
Cash flows from operating activities:			
Income before income taxes and minority interests	¥ 36,900	¥ 43,143	\$ 444,578
Adjustments:			
Depreciation and amortization	3,052	3,012	36,771
Increase (decrease) in allowance for doubtful receivables	(4)	10	(48)
Decrease in provision for retirement benefits, net	(57)	(1,647)	(687)
Contribution to retirement benefits trust	—	5,000	—
Interest and dividend income	(2,947)	(2,964)	(35,506)
Interest expenses	1	1	12
Gain on sales of investment securities	—	(85)	—
Loss on valuation of investment securities	614	—	7,398
Decrease(increase) in notes and accounts receivable	(5,082)	7,856	(61,229)
Others	7,814	(13,184)	94,145
Interest and dividend income received	3,178	3,244	38,289
Interest paid	(1)	(1)	(12)
Payments for contribution to retirement benefits trust	—	(5,000)	—
Income taxes paid	(13,672)	(18,084)	(164,723)
Net cash provided by operating activities	29,796	21,301	358,988
Cash flows from investing activities:			
Payments for purchases of marketable securities	(35,548)	(33,379)	(428,289)
Proceeds from sales and redemption of marketable securities	63,550	86,120	765,663
Payments for purchases of property, plant and equipment	(1,294)	(3,211)	(15,590)
Payments for purchases of investment securities	(15,321)	(32,348)	(184,590)
Proceeds from sales and redemption of investment securities	14	174	169
Other payments	(286)	(479)	(3,447)
Net cash generated from (used in) investment activities	11,115	16,877	133,916
Cash flows from financing activities:			
Repayment of current portion of long-term debt	(2)	(2)	(24)
Payments for obtaining treasury stock	(10,779)	(13)	(129,867)
Cash dividends	(19,552)	(19,549)	(235,567)
Cash dividends to minority shareholders	(3)	(4)	(36)
Net cash used in financing activities	(30,336)	(19,568)	(365,494)
Foreign currency translation adjustments on cash and cash equivalents	(95)	26	(1,145)
Net increase in cash and cash equivalents	10,480	18,636	126,265
Cash and cash equivalents, beginning	72,097	53,461	868,639
Cash and cash equivalents, ending	¥ 82,577	¥ 72,097	\$ 994,904

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Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2011 (unaudited) is summary information extracted from the financial statements announced by the Company on May 11, 2011.
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 2011 (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 83 = US\$ 1, the approximate exchange rate prevailing on March 31, 2011.

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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.

		2011		
		Results	Increase/Decrease	
Opalmon	Circulatory system agent	¥ 401	¥ ▲45	▲10.1%
Onon	Agent for bronchial asthma and allergic rhinitis	215	▲36	▲14.3%
Kinedak	Agent for diabetic peripheral neuropathy	132	▲29	▲18.0%
Glactiv	Agent for type II diabetes	111	+96	—
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	110	▲17	▲13.7%
Onon dry syrup	Agent for pediatric bronchial asthma	85	▲6	▲6.2%
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	58	+13	28.1%
Elaspol	Agent for acute lung injury associated with SIRS	50	▲3	▲6.1%
Emend	Agent for Chemotherapy-induced nausea and vomiting	47	+42	—
Onoact	Agent for tachyarrhythmia during and post operation	36	+4	13.0%
Recalbon	Agent for osteoporosis	20	+10	—

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 percentage are therefore not available.

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Supplemental Information

Status of Development Pipeline

as of May 11, 2011

Developments in Japan

NDA approved (Additional Indications):

- **Prostandin[®] for Injection**
Use in diagnostic testing for erectile dysfunction [alprostadil alfadex]

NDA approved (New Chemical Entities)

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

NDA filed (New Chemical Entities):

- **Proemend[®] for Injection (ONO-7847 / MK-0517) (in-licensed from Merck & Co., Inc.)**
Chemotherapy-induced nausea and vomiting [NK1 receptor antagonist]

NDA filed (Additional Indications):

- **Glactiv[®] Tablets (ONO-5435 / MK-0431) (co-development with MSD K.K.)**
Type II diabetes: combination therapy with an alpha-glucosidase inhibitor or an insulin product [DPP-4 inhibitor]

- **Corebeta[®] for Injection (ONO-1101)**
Improvement of image quality of coronary arteries for coronary CT angiography [short-acting beta-1 blocker]

NDA filed (New Dosage Regimen):

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

Ongoing clinical studies (New Chemical Entities):

- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 (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)**
Short acting general anesthetic (Phase II) [GABA_A receptor modulator]
- **ONO-5334 (tablet)**
Osteoporosis (Phase I) [cathepsin K inhibitor]
- **ONO-4538 / BMS-936558 (MDX-1106) (injection)**
Cancer (Phase I) [fully human anti-PD-1 antibody]
- **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]

Ongoing clinical studies (Additional Indications):

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

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

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-5334 (tablet)**
Osteoporosis (Phase II) [cathepsin K inhibitor]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-4538 / BMS-936558 (MDX-1106) (injection) (co-development with Bristol-Myers Squibb Company)**
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]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase I) [LT receptor antagonist]
- **ONO-2952 (tablet)**
Irritable bowel syndrome (Phase I) [TSPO antagonist]
- **ONO-4053 (tablet)**
Allergic rhinitis (Phase I) [PGD2 receptor antagonist]

Changes from the Third Quarter Flash Report for the Fiscal Year ended March 2011 announced on February 2, 2011

- An NDA of Prostandin[®] for Injection for use in diagnostic testing for erectile dysfunction (additional indication) was approved by the Ministry of Health, Labour and Welfare of Japan on February 23, 2011.
- An NDA of Rivastach[®] Patch (ONO-2540) for the treatment of Alzheimer's disease was approved by the Ministry of Health, Labour and Welfare of Japan on April 22, 2011.
- We commenced Phase II / III study of Onoact[®] for Injection (ONO-1101) for the treatment of tachyarrhythmia in patients with low cardiac function in Japan (additional indication). The product has been approved and marketed for emergency treatment of intra- and post-operative tachyarrhythmia.
- We commenced Phase II study of ONO-2745, a short acting general anesthetic in Japan.
- We commenced Phase I study of ONO-2952, a drug for irritable bowel syndrome outside of Japan.
- We commenced Phase I study of ONO-4053, a drug for allergic rhinitis outside of Japan.

Supplemental Information

New Drugs in Development

as of May 11, 2011

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:

Proemend[®] (ONO-7847 / MK-0517) ***(injection)***

ONO-7847 is a neurokinin (NK) 1 receptor antagonist being developed for the prevention of chemotherapy-induced nausea and vomiting. It is the prodrug of ONO-7436 / MK-0869 (Emend[®] Capsule) and is made available in injectable form.

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

Overseas: Approved / 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 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. 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.

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

ONO-3849 (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. The drug 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 II / Cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-5334 (tablet)

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

Japan: Phase I / Osteoporosis

Europe: Phase II / Osteoporosis

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 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 I / Cancer

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

ONO-2745 / CNS 7056 (injection)

The drug 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 anaesthesia 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 anaesthetic

US: Phase II (PAION AG)

ONO-3951 (tablet)

ONO-3951 or asimadoline is a highly selective kappa opioid receptor agonist, and is under clinical development for diarrhea predominant irritable bowel syndrome (D-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 are believed to play an important role in control of visceral pain and bowel motility.

Japan: Phase I / D-IBS

US: Phase III / D-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 I / 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 18kDr (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

New formulations

Recalbon[®] Tablets (ONO-5920 / YM529)

This is the line extension program of Recalbon[®] Tablets, which is a bisphosphonate for the treatment of osteoporosis and has already been approved and launched in Japan. This new formulation of the product offers once-monthly oral dosing.

Japan: J-NDA filed / Osteoporosis (co-development with Astellas Pharma Inc.)

Additional indications

Glactiv[®] Tablets (ONO-5435 / MK-0431)

Japan: J-NDA filed / Combination therapy with an alpha-glucosidase inhibitor or an insulin product for type II diabetes (co-development with MSD K.K.)

Corebata[®] for Injection (ONO-1101)

ONO-1101 has already been approved and marketed for the treatment of tachyarrhythmia during or after operations with the trade name of Onoact[®] for Injection. Because the dosage regimen for the new indication program (improvement of image quality of coronary arteries for coronary CT angiography) is much smaller than the already approved indication a low-dose formulation has been developed. Corebata[®] is a candidate for the trade name of this new formulation.

Japan: J-NDA filed / Improvement of image quality of coronary arteries for coronary CT angiography

Onoact[®] for Injection (ONO-1101)

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

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

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