

First-Second Quarter (April 1 – September 30, 2012) Flash Report (unaudited)
Six months ended September 30, 2012

ONO PHARMACEUTICAL CO., LTD.

November 5, 2012

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2012.

This First - Second Quarter Flash Report 2013 (unaudited) is summary information extracted from financial statements announced, and the financial statements contained herein are prepared for the 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.			Thousands of US\$
	Millions of yen		Annual	
	1st-2nd Quarter 6 months ended Sep 30 2012	1st-2nd Quarter 6 months ended Sep 30 2011	12 months ended Mar 31 2012	1st-2nd Quarter 6 months ended Sep 30 2012
Net sales	¥ 71,112	¥ 70,170	¥ 145,779	\$ 911,692
Net income	11,072	8,383	24,361	141,949
Total Net assets	401,207	394,564	400,968	5,143,680
Total assets	430,038	424,556	436,414	5,513,308
		Yen		US\$
Net income per common share	¥ 104.44	¥ 79.07	¥ 229.78	\$ 1.34

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	\$ 1,874,359
Operating income	32,700	419,231
Ordinary income	34,100	437,179
Net income	23,000	294,872
	Yen	US\$
Net income per common share	216.94	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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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\$
	1st-2nd Quarter September 30 2012	1st-2nd Quarter September 30 2011	Annual March 31 2012	1st-2nd Quarter September 30 2012
Current assets				
Cash and bank deposits	¥ 16,474	¥ 20,647	¥ 20,960	\$ 211,205
Notes and accounts receivable	35,200	35,502	37,853	451,282
Marketable securities	112,957	111,260	104,814	1,448,167
Inventories	21,273	13,590	18,638	272,731
Others	19,213	16,249	19,977	246,320
Allowance for doubtful receivables	(6)	(5)	(6)	(77)
Total current assets	205,111	197,243	202,236	2,629,628
Property, plant and equipment				
Land	22,544	22,552	22,550	289,026
Buildings and structures	22,328	22,298	22,644	286,256
Machinery, equipment and others	2,492	2,832	2,525	31,949
Construction in progress	658	423	262	8,436
Net property, plant and equipment	48,022	48,105	47,980	615,667
Investments and other assets				
Investment securities	160,338	161,801	168,691	2,055,615
Intangible assets	1,142	829	995	14,641
Others	15,425	16,578	16,512	197,757
Total investments and other assets	176,905	179,208	186,198	2,268,013
Total assets	430,038	¥ 424,556	¥ 436,414	\$ 5,513,308

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

LIABILITIES AND EQUITY	Millions of yen			Thousands of US\$
	1st-2nd Quarter September 30 2012	1st-2nd Quarter September 30 2011	Annual March 31 2012	1st-2nd Quarter September 30 2012
Current liabilities				
Current portion of long-term debt	¥ 102	¥ 2	¥ 2	\$ 1,308
Notes and accounts payable	4,142	4,077	5,767	53,103
Income tax payable	6,202	6,489	8,876	79,513
Others	14,095	15,441	16,397	180,704
Total current liabilities	24,541	26,009	31,042	314,628
Long-term liabilities				
Long-term debt, less current portion	185	12	11	2,372
Liabilities for retirement benefits	1,342	864	1,628	17,205
Asset retirement obligations	54	53	53	692
Others	2,709	3,054	2,712	34,731
Total long-term liabilities	4,290	3,983	4,404	55,000
Equity				
Common stock	17,358	17,358	17,358	222,538
Capital surplus	17,080	17,080	17,080	218,974
Retained earnings	427,318	419,351	425,787	5,478,436
Treasury stock-at cost	(59,210)	(59,200)	(59,204)	(759,102)
Total equity	402,546	394,589	401,021	5,160,846
Other comprehensive income				
Unrealized gain on securities (*)	4,485	5,145	5,725	57,500
Land revaluation surplus	(8,578)	(8,939)	(8,577)	(109,974)
Foreign currency translation adjustments	(408)	(264)	(277)	(5,231)
Total other comprehensive income	(4,501)	(4,058)	(3,129)	(57,705)
Minority interests	3,162	4,033	3,076	40,539
Total net assets	401,207	394,564	400,968	5,143,680
Total liabilities and total net assets	430,038	¥ 424,556	¥ 436,414	\$ 5,513,308

(*) 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\$
	1st-2nd Quarter 6 months ended Sep 30 2012	1st-2nd Quarter 6 months ended Sep 30 2011	Annual 12 months ended Mar 31 2012	1st-2nd Quarter 6 months ended Sep 30 2012
Net sales	¥ 71,112	¥ 70,170	¥ 145,779	\$ 911,692
Cost of sales	16,283	13,494	28,987	208,756
Gross profit	54,829	56,676	116,792	702,936
Selling, general and administrative expenses	37,323	38,997	78,888	478,500
Operating income	17,506	17,679	37,904	224,436
Other income (expenses)				
Interest and dividend income	1,448	1,550	2,800	18,564
Interest expenses	(0)	(0)	(1)	(0)
Other, net	(1,480)	(3,891)	(693)	(18,974)
	(32)	(2,341)	2,106	(410)
Income before income taxes and minority interests	17,474	15,338	40,010	224,026
Income taxes	6,307	6,782	15,376	80,859
Income before minority interests	11,167	8,556	24,634	143,167
Minority interests	(95)	(173)	(273)	(1,218)
Net income	11,072	¥ 8,383	¥ 24,361	\$ 141,949
Per share of common stock				
Basic net income	¥ 104.44	¥ 79.07	¥ 229.78	\$ 1.34
Cash dividends applicable to the period	¥ 90.00	¥ 90.00	¥ 180.00	\$ 1.15

First-Second Quarter (April 1 – September 30, 2012) Flash Report (unaudited)

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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\$
	1st-2nd Quarter 6 months ended Sep 30 2012	1st-2nd Quarter 6 months ended Sep 30 2011	Annual 12 months ended Mar 31 2012	1st-2nd Quarter 6 months ended Sep 30 2012
Net income before minority interests	¥ 11,167	¥ 8,556	¥ 24,634	\$ 143,167
Other comprehensive income				
Unrealized loss on available-for-sale securities	(1,243)	986	1,578	(15,936)
Land revaluation difference	—	—	361	—
Foreign currency translation adjustments	(131)	3	(10)	(1,680)
Share of other comprehensive income in associates	2	(1)	4	26
Total other comprehensive income	(1,372)	988	1,933	(17,590)
Comprehensive income	9,795	9,544	26,567	125,577
Total comprehensive income attributable to				
Owners of the parent	9,701	9,367	26,274	124,372
Minority interests	94	177	293	1,205

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Six months ended September 30, 2012

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\$
	1st-2nd Quarter 6 months ended Sep 30 2012	1st-2nd Quarter 6 months ended Sep 30 2011	Annual 12 months ended Mar 31 2012	1st-2nd Quarter 6 months ended Sep 30 2012
Operating activities:				
Income before income taxes and minority interests	¥ 17,474	¥ 15,338	¥ 40,010	\$ 224,026
Adjustments for:				
Depreciation and amortization	1,333	1,422	3,005	17,090
Decrease (increase) in allowance for doubtful receivables	0	(1)	(0)	0
Decrease (increase) in provision for retirement benefits, net	(296)	362	1,123	(3,795)
Decrease (increase) in prepaid pension costs	1,114	(805)	(1,983)	14,282
Interest and dividend income	(1,448)	(1,551)	(2,800)	(18,564)
Loss on sales of investment securities	—	35	491	—
Gain on sales of investment securities	(128)	—	—	(1,641)
Loss on valuation of investment securities	1,606	3,854	226	20,590
Interest expenses	1	0	1	9
Decrease (increase) in notes and accounts receivable	2,651	1,202	(1,147)	33,987
Increase in inventories	(2,636)	(542)	(5,589)	(33,795)
Increase (decrease) in trade notes and accounts payable	(1,677)	(1,413)	450	(21,500)
Others	(768)	1,831	(1,010)	(9,847)
Interest and dividend income received	1,546	1,647	2,962	19,821
Interest paid	(1)	(0)	(1)	(9)
Income taxes paid	(8,997)	(7,767)	(14,103)	(115,346)
Net cash (used in) provided by operating activities	9,774	13,612	21,635	125,308
Investing activities:				
Payments for purchases of marketable securities	(10,116)	(17,195)	(33,002)	(129,692)
Proceeds from sales of marketable securities	25,478	37,090	66,370	326,641
Payments for purchases of property, plant and equipment	(1,978)	(1,067)	(2,023)	(25,359)
Payments for purchases of investment securities	(8,668)	(12,846)	(30,882)	(111,128)
Proceeds from sales of investment securities	218	176	469	2,795
Other payments	(121)	(91)	(1,065)	(1,552)
Net cash generated from provided by investment activities	4,813	6,067	(133)	61,705
Financing activities:				
Repayment of current portion of long-term debt	(26)	(1)	(2)	(334)
Proceeds from long-term loans payable	300	—	—	3,846
Payments for obtaining treasury stock	(5)	(5)	(10)	(64)
Cash dividends	(9,526)	(9,523)	(19,057)	(122,128)
Cash dividends to minority shareholders	(4)	(5)	(4)	(51)
Net cash used in financing activities	(9,261)	(9,534)	(19,073)	(118,731)
Foreign currency translation adjustments				
on cash and cash equivalents	(89)	5	61	(1,141)
Net decrease in cash and cash equivalents	5,237	10,150	2,490	67,141
Cash and cash equivalents, beginning	85,067	82,577	82,577	1,090,603
Cash and cash equivalents, ending	¥ 90,304	¥ 92,727	¥ 85,067	\$ 1,157,744

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Note 1 This First-Second Quarter Flash Report 2013 (unaudited) is a summary information extracted from the financial statements announced by the Company on November 5, 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 First-Second Quarter Flash Report 2013 (unaudited) are prepared for the 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, which are to follow the basis of presentation in the above original announcement.

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 78 = US\$ 1, the approximate exchange rate prevailing on September 28, 2012.

First-Second Quarter (April 1 – September 30, 2012) Flash Report (unaudited)

Six months ended September 30, 2012

Sales of Major Products

Supplemental Data

For information purpose only

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

		1st-2nd Quarter 6 months ended Sep 30 2012			Year ending March 31,2013
		Results	Increase/Decrease		Forecast
Opalmon	Circulatory system agent	¥ 174	¥ ▲ 27	▲13.4%	¥ 335
Glactiv	Agent for type II diabetes	170	+42	32.9%	350
Onon	Agent for bronchial asthma and allergic rhinitis	71	▲ 17	▲19.0%	165
Kinedak	Agent for diabetic peripheral neuropathy	46	▲ 13	▲21.5%	90
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	46	▲ 7	▲12.5%	85
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	39	+8	24.6%	75
Recalbon	Agent for osteoporosis	33	+20	155.1%	80
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	33	+3	11.5%	70
Onon dry syrup	Agent for pediatric bronchial asthma	31	▲ 2	▲5.7%	75
Elaspol	Agent for acute lung injury associated with SIRS	19	▲ 2	▲10.0%	40
Onoact	Agent for tachyarrhythmia during and post operation	18	+1	6.8%	36
Rivastach	Agent for Alzheimer's disease	17	+13	308.3%	38

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

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Six months ended September 30, 2012

Supplemental Information

Status of Development Pipeline

as of November 5, 2012

Developments in Japan

NDA filed (New Formulations):

- **Orencia® SC (ONO-4164 SC / BMS-188667SC)**
(Co-development with Bristol-Myers Squibb Company)
Rheumatoid Arthritis [T-cell activation inhibitor]
- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431) *1**
(Co-development with Merck & Co., Inc.)
Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection) *2**
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-2745 / CNS 7056 (injection) *3**
(In-licensed from PAION AG)
Short acting general anesthetic (Phase II / III)
[GABA_A receptor modulator]
- **ONO-7165 / EMD531444 (injection)**
(Co-development with Merck KGaA)
Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 / Methylalntrexone bromide (injection)**
(In-licensed from Progenics Pharmaceuticals, Inc.)
Opioid-induced constipation (Phase II)
[Mu-opioid receptor antagonist]
- **ONO-7643 / RC-1291 (tablet)**
(In-licensed from Helsinn Therapeutics (U.S.), Inc.)
Cancer anorexia / cachexia (Phase II)
[Ghrelin mimetic]
- **ONO-4538 / BMS-936558 (injection)**
Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-3951 / Asimadoline (tablet)**
(In-licensed from Tioga Pharmaceuticals, Inc.)
Irritable bowel syndrome (Phase II)
[Kappa-opioid receptor agonist]
- **ONO-2745 / CNS 7056 (injection) *4**
(In-licensed from PAION AG)
ICU sedation (Phase II)
[GABA_A receptor modulator]
- **ONO-7057 / Carfilzomib (injection)**
(In-licensed from Onyx Pharmaceuticals, Inc.)
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- **ONO-5163 / AMG-416 (injection) *5**
(In-licensed from Amgen Inc.)
Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase I) [LT receptor antagonist]
- **ONO-7056 / Salirasib (tablet)**
(In-licensed from Kadmon Corporation LLC)
Solid tumor (Phase I) [Ras signal inhibitor]

- **ONO-7268 MX1 (injection)**
(In-licensed from OncoTherapy Science, Inc.)
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-1162 / Ivabradine (tablet) *6**
(In-licensed from Les Laboratoires Servier)
Chronic heart failure (Phase I) [If channel inhibitor]

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]
- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**
(In-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]
- **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-tunn el Syndrome (Phase II) [PGE1 analogue]

Ongoing clinical studies (Additional Dosing Regimen):

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

Ongoing clinical studies (New Formulations):

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

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection) *7**
(Out-licensed to Bristol-Myers Squibb Company)
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection) *8**
(Out-licensed to Bristol-Myers Squibb Company)
Non-small-cell lung cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4641 (tablet)**
(Out-licensed to Merck KGaA)
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet) *9**
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-8539 (tablet)**
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Hepatitis C (Phase I) [Fully human anti-PD-1 antibody]

- **ONO-7746 (capsule)**
(In-licensed from Nissan Chemical Industries, Ltd.)
Thrombocytopenia (Phase I) [TPO receptor agonist]
- **ONO-2952 (tablet)**
Irritable bowel syndrome (Phase I) [TSPO 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]
- **ONO-8055 (tablet) *10**
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]

Changes from First Quarter Flash Report for the Fiscal Year ending March 2013 announced on August 2, 2012

- *1: NDA of Glactiv[®] Tablets 12.5mg (ONO-5435 / MK-0431) for Type II diabetes with severe renal dysfunction was filed to the Ministry of Health, Labour and Welfare of Japan on (new formulations).
- *2: Phase III clinical study of ONO-4538, fully human anti-PD-1 antibody, for renal cell cancer was commenced in Japan.
- *3: Phase II / III clinical study of ONO-2745, GABA_A receptor modulator, for general anesthesia was commenced in Japan.
- *4: Phase II clinical study of ONO-2745, GABA_A receptor modulator, for ICU sedation was commenced in Japan..
- *5: Phase I / II clinical study of ONO-5163, calcium sensing receptor agonist, for secondary hyperparathyroidism was commenced in Japan.
- *6: Phase I clinical study of ONO-1162, If channel inhibitor, for chronic heart failure was commenced in Japan.
- *7: Phase III clinical study of ONO-4538, fully human anti-PD-1 antibody, for renal cell cancer was commenced overseas.
- *8: Phase III clinical study of ONO-4538, fully human anti-PD-1 antibody for non-small-cell lung cancer was commenced overseas.
- *9: Phase II clinical study of ONO-4053, PGD2 receptor antagonist, for allergic rhinitis was commenced overseas.
- *10: Phase I clinical study of ONO-8055, PG receptor (EP2 / EP3) agonist, was commenced overseas.

Supplemental Information

New Drugs in Development

as of November 5, 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 Orenzia® 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. Orenzia® IV is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed

Japan: J-NDA filed / 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) (In-licensed from Progenics Pharmaceuticals, Inc.)

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

Japan: Phase II / opioid-induced constipation

Overseas: Marketed (Salix Pharmaceuticals, Inc.)

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

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase II / cancer anorexia / cachexia

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

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

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

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

ONO-4538 / BMS-936558 (injection)

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.

Japan: Phase II / melanoma, Phase III / renal cell cancer (multi-national clinical trial in Japan, US and Europe)

US & Other Countries: Phase III / renal cell cancer (co-development in Japan, US and Europe by Bristol-Myers Squibb Company), Phase III / non-small lung cancer (Bristol-Myers Squibb Company)

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

ONO-7057 / Carfilzomib (injection)(In-licensed from Onyx Pharmaceuticals, Inc.)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for poor prognosis multiple myeloma.

Japan: Phase I / II / multiple myeloma

Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012)

Phase III in Europe/ multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-3951 / Asimadoline (tablet) (In-licensed from Tioga Pharmaceuticals, Inc.)

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 II / irritable bowel syndrome (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 / IBS

ONO-4053 (tablet)

ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Europe: Phase II / allergic rhinitis

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

ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor

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

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

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

Japan: Phase I / II / secondary hyperparathyroidism

US: Phase 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.

Europe: Phase I / B cell lymphoma

ONO-8539 (tablet)

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

Europe: Phase I / GERD

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

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

ONO-7268 is a peptide vaccine and is expected to have effects on cancers such as hepatocarcinoma.

Japan: Phase I / hepatocarcinoma

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

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase I / chronic heart failure

Overseas: Marketed / stable angina, chronic heart failure

Emend[®] Capsules (ONO-7436 / MK-0869) (In-licensed from Merck & Co., Inc.)

Japan: J-NDA approved / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

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

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

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.)

Rivastach[®] Patch (ONO-2540 / ENA713D)

Japan: Phase III / alzheimer' disease (administration change)

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.)