

**First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)**  
 Six months ended September 30, 2010

## ONO PHARMACEUTICAL CO., LTD.

November 4, 2010

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2010.

This First - Second Quarter Flash Report 2011 (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			
	1st-2nd Quarter 6 months ended Sep 30 2010	1st-2nd Quarter 6 months ended Sep 30 2009	Annual 12 months ended Mar 31 2010	1st-2nd Quarter 6 months ended Sep 30 2010
Net sales	¥ 63,778	¥ 67,184	¥ 135,986	\$ 768,410
Net income	9,325	15,914	27,878	112,349
Total Net assets	398,411	405,759	406,109	4,800,133
Total assets	423,039	435,783	433,226	5,096,855
		Yen		US\$
Net income per common share	¥ 85.76	¥ 146.35	¥ 256.38	\$ 1.03

**First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)**  
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**Consolidated Financial Forecast for the Year  
Ending March 31,2011**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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	<b>Year ending March 31,2011</b>	
	<b>Millions of yen</b>	<b>Thousands of US\$</b>
<b>Net sales</b>	<b>¥ 129,000</b>	<b>\$ 1,554,217</b>
<b>Operating income</b>	<b>26,700</b>	<b>321,687</b>
<b>Ordinary income</b>	<b>28,700</b>	<b>345,783</b>
<b>Net income</b>	<b>18,500</b>	<b>222,892</b>
	<b>Yen</b>	<b>US\$</b>
<b>Net income per common share</b>	<b>170.14</b>	<b>2.05</b>

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(\*)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.

**First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)**  
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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 2010	1st-2nd Quarter September 30 2009	Annual March 31 2010	1st-2nd Quarter September 30 2010
<b>Current assets</b>				
Cash and bank deposits	¥ 16,084	¥ 12,581	¥ 15,387	\$ 193,783
Notes and accounts receivable	30,290	33,908	31,625	364,940
Marketable securities	116,113	111,115	97,830	1,398,952
Inventories	14,163	13,413	14,626	170,639
Others	15,819	14,418	22,386	190,590
Allowance for doubtful receivables	(11)	(8)	(13)	(133)
<b>Total current assets</b>	<b>192,458</b>	<b>185,427</b>	<b>181,841</b>	<b>2,318,771</b>
<b>Property, plant and equipment</b>				
Land	22,554	22,539	22,539	271,735
Buildings and structures	22,916	23,527	23,631	276,096
Machinery, equipment and others	3,257	2,749	3,202	39,241
Construction in progress	390	1,675	638	4,699
<b>Net property, plant and equipment</b>	<b>49,117</b>	<b>50,490</b>	<b>50,010</b>	<b>591,771</b>
<b>Investments and other assets</b>				
Investment securities	166,872	190,062	190,628	2,010,506
Intangible assets	909	1,048	866	10,952
Others	13,683	8,756	9,881	164,855
<b>Total investments and other assets</b>	<b>181,464</b>	<b>199,866</b>	<b>201,375</b>	<b>2,186,313</b>
<b>Total assets</b>	<b>¥ 423,039</b>	<b>¥ 435,783</b>	<b>¥ 433,226</b>	<b>\$ 5,096,855</b>

(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 2010	1st-2nd Quarter September 30 2009	Annual March 31 2010	1st-2nd Quarter September 30 2010
<b>Current liabilities</b>				
Current portion of long-term debt	¥ 2	¥ 2	¥ 2	\$ 24
Notes and accounts payable	3,778	6,248	2,345	45,518
Income tax payable	5,061	8,071	8,421	60,976
Others	12,200	12,477	12,674	146,988
<b>Total current liabilities</b>	<b>21,041</b>	<b>26,798</b>	<b>23,442</b>	<b>253,506</b>
<b>Long-term liabilities</b>				
Long-term debt, less current portion	13	15	14	157
Liabilities for retirement benefits	441	142	599	5,313
Asset retirement obligations	51	—	—	614
Others	3,082	3,069	3,062	37,133
<b>Total long-term liabilities</b>	<b>3,587</b>	<b>3,226</b>	<b>3,675</b>	<b>43,217</b>
<b>Equity</b>				
Common stock	17,358	17,358	17,358	209,133
Capital surplus	17,080	17,080	17,080	205,783
Retained earnings	430,425	428,693	430,871	5,185,843
Treasury stock-at cost	(63,446)	(63,432)	(63,440)	(764,410)
<b>Total equity</b>	<b>401,417</b>	<b>399,699</b>	<b>401,869</b>	<b>4,836,349</b>
<b>Other comprehensive income</b>				
Unrealized gain on securities (*)	2,417	11,554	9,707	29,120
Land revaluation surplus	(8,938)	(8,923)	(8,923)	(107,687)
Foreign currency translation adjustments	(216)	(136)	(174)	(2,602)
<b>Total other comprehensive income</b>	<b>(6,737)</b>	<b>2,495</b>	<b>610</b>	<b>(81,169)</b>
<b>Minority interests</b>	<b>3,731</b>	<b>3,565</b>	<b>3,630</b>	<b>44,952</b>
<b>Total net assets</b>	<b>398,411</b>	<b>405,759</b>	<b>406,109</b>	<b>4,800,132</b>
<b>Total liabilities and total net assets</b>	<b>¥ 423,039</b>	<b>¥ 435,783</b>	<b>¥ 433,226</b>	<b>\$ 5,096,855</b>

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

## First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)

Six months ended September 30, 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\$
	1st-2nd Quarter 6 months ended Sep 30 2010	1st-2nd Quarter 6 months ended Sep 30 2009	Annual 12 months ended Mar 31 2010	1st-2nd Quarter 6 months ended Sep 30 2010
<b>Net sales</b>	¥ <b>63,778</b>	¥ 67,184	¥ 135,986	\$ <b>768,410</b>
<b>Cost of sales</b>	<b>11,182</b>	9,963	20,838	<b>134,723</b>
Gross profit	<b>52,596</b>	57,221	115,148	<b>633,687</b>
<b>Selling, general and administrative expenses</b>	<b>39,497</b>	34,838	75,307	<b>475,868</b>
Operating income	<b>13,099</b>	22,383	39,841	<b>157,819</b>
<b>Other income (expenses)</b>				
Interest and dividend income	<b>1,626</b>	1,642	2,964	<b>19,590</b>
Interest expenses	(0)	(0)	(1)	(0)
Other, net	<b>(121)</b>	289	339	<b>(1,457)</b>
	<b>1,505</b>	1,931	3,302	<b>18,133</b>
Income before income taxes and minority interests	<b>14,604</b>	24,314	43,143	<b>175,952</b>
<b>Income taxes</b>	<b>5,171</b>	8,265	15,055	<b>62,301</b>
Income before minority interests	<b>9,433</b>	16,049	28,088	<b>113,651</b>
<b>Minority interests</b>	<b>(108)</b>	(135)	(210)	<b>(1,302)</b>
<b>Net income</b>	¥ <b>9,325</b>	¥ 15,914	¥ 27,878	\$ <b>112,349</b>
<b>Per share of common stock</b>				
Basic net income	¥ <b>85.76</b>	¥ 146.35	¥ 256.38	\$ <b>1.03</b>
Cash dividends applicable to the period	¥ <b>90.00</b>	¥ 90.00	¥ 180.00	\$ <b>1.08</b>

## First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)

Six months ended September 30, 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\$
	Ist-2nd Quarter 6 months ended Sep 30 2010	Ist-2nd Quarter 6 months ended Sep 30 2009	Annual 12 months ended Mar 31 2010	Ist-2nd Quarter 6 months ended Sep 30 2010
<b>Operating activities:</b>				
Income before income taxes and minority interests	¥ 14,604	¥ 24,314	¥ 43,143	\$ 175,952
Adjustments for:				
Depreciation and amortization	1,470	1,388	3,012	17,711
(Decrease) increase in allowance for doubtful receivables	(2)	(1)	10	(24)
decrease in provision for retirement benefits, net	(159)	(2,100)	(1,647)	(1,916)
Contribution to retirement benefits trust	—	5,000	5,000	—
Interest and dividend income	(1,626)	(1,642)	(2,964)	(19,590)
Interest expenses	0	0	1	0
Gain on sales of investment securities	—	—	(85)	—
Decrease in notes and accounts receivable	1,334	5,572	7,856	16,072
(Increase) decrease in inventories	463	(3,355)	(4,567)	5,578
Increase (decrease) in trade notes and accounts payable	1,332	3,013	(600)	16,048
Others	4,621	(2,337)	(8,016)	55,675
Interest and dividend income received	1,749	1,784	3,244	21,072
Interest paid	(0)	(0)	(1)	(0)
Payments for contribution to retirement benefits trust	—	(5,000)	(5,000)	—
Income taxes paid	(8,594)	(9,361)	(18,084)	(103,542)
<b>Net cash (used in) provided by operating activities</b>	<b>15,192</b>	<b>17,275</b>	<b>21,302</b>	<b>183,036</b>
<b>Investing activities:</b>				
Payments for purchases of marketable securities	(12,804)	(21,689)	(33,379)	(154,265)
Proceeds from sales of marketable securities	22,300	52,100	86,120	268,675
Payments for purchases of property, plant and equipment	(530)	(1,298)	(3,211)	(6,386)
Payments for purchases of investment securities	(4,473)	(14,606)	(32,348)	(53,892)
Proceeds from sales of investment securities	9	5	174	108
Other payments	(143)	(360)	(480)	(1,722)
<b>Net cash generated from provided by (used in) investment</b>	<b>4,359</b>	<b>14,152</b>	<b>16,876</b>	<b>52,518</b>
<b>Financing activities:</b>				
Repayment of current portion of long-term debt	(1)	(1)	(2)	(12)
Payments for obtaining treasury stock	(6)	(6)	(13)	(72)
Cash dividends	(9,783)	(9,779)	(19,553)	(117,868)
<b>Net cash used in financing activities</b>	<b>(9,790)</b>	<b>(9,786)</b>	<b>(19,568)</b>	<b>(117,952)</b>
<b>Foreign currency translation adjustments</b>				
<b>on cash and cash equivalents</b>	<b>(41)</b>	<b>64</b>	<b>26</b>	<b>(494)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>9,720</b>	<b>21,705</b>	<b>18,636</b>	<b>117,108</b>
<b>Cash and cash equivalents, beginning</b>	<b>72,097</b>	<b>53,461</b>	<b>53,461</b>	<b>868,639</b>
<b>Cash and cash equivalents, ending</b>	<b>¥ 81,817</b>	<b>¥ 75,166</b>	<b>¥ 72,097</b>	<b>\$ 985,747</b>

**First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)**  
**Six months ended September 30, 2010**

## **Notes to Consolidated Financial Statements**

**Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries**

- Note 1 This First Quarter Flash Report 2011 (unaudited) is a summary information extracted from the financial statements announced by the Company on November 4, 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 First Quarter Flash Report 2011 (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 83 = US\$ 1, the approximate exchange rate prevailing on September 30, 2010.

## First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)

Six months ended September 30, 2010

### 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 2010			
		Results	Increase/Decrease		
<b>Opalmon</b>	Circulatory system agent	¥ 203	¥ ▲ 23	▲ 10.0%	
<b>Onon</b>	Agent for bronchial asthma and allergic rhinitis	92	▲ 30	▲ 24.7%	
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	69	▲ 16	▲ 18.3%	
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	56	▲ 10	▲ 15.3%	
<b>Onon dry syrup</b>	Agent for pediatric bronchial asthma	37	▲ 4	▲ 9.1%	
<b>Glactiv</b>	Agent for type II diabetes	34	—	—	
<b>Staybla</b>	Agent for overactive bladder (pollakiuria and urinary incontinence)	27	+6	30.6%	
<b>Elaspol</b>	Agent for acute lung injury associated with SIRS	24	▲ 2	▲ 9.1%	
<b>Emend</b>	Agent for Chemotherapy-induced nausea and vomiting	20	—	—	
<b>Onoact</b>	Agent for tachyarrhythmia during and post operation	17	+1	8.6%	
<b>Recalbon</b>	Agent for osteoporosis	9	+5	105.7%	

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

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



## First-Second Quarter (April 1 – September 30, 2010) Flash Report (unaudited)

Six months ended September 30, 2010

Ono Pharmaceutical Co., Ltd. and  
Consolidated Subsidiaries

### Supplemental Information

## Status of Development Pipeline

as of November 4, 2010

### Developments in Japan

#### *NDA filed (New Formulations):*

- **Staybla<sup>®</sup> OD Tablets (ONO-8025OD / KRP-197OD)**  
(co-development with Kyorin Pharmaceutical Co., Ltd.)  
Overactive bladder (pollakiuria and urinary incontinence)  
[M<sub>3</sub> muscarinic receptor blocker]

#### *NDA filed (New Chemical Entities)*

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

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

#### *NDA filed (Additional Indications):*

- **Prostandin<sup>®</sup> for Injection**  
Use in various vascular diagnostic testing for erectile dysfunction [alprostadil alfadex]
- **Glactiv<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 I)  
[ghrelin mimetic]
- **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-2745 / CNS 7056 (injection)**  
(in-licensed from PAION AG)  
Short-acting general anesthetic (Phase I)  
[GABAA receptor agonist]

- **ONO-3951 (tablet)**  
(in-licensed from Tioga Pharmaceuticals, Inc.)  
Irritable Bowel Syndrome (Phase I)  
[kappa-opioid receptor agonist]

#### *Ongoing clinical studies (Additional Indications):*

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

### 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]

**Note:** The trade name candidate for ONO-2540 has been changed from Rivastach<sup>®</sup> Tape to Rivastach<sup>®</sup> Patch.

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Ono Pharmaceutical Co., Ltd. and  
Consolidated Subsidiaries

Supplemental Information

## New Drugs in Development

as of November 4, 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<sup>®</sup> Patch (ONO-2540 / ENA713D)***  
***(transdermal formulation)***

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

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

**Overseas:** Marketed (Novartis AG)

***Proemend<sup>®</sup> (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<sup>®</sup> Capsule) and is made available in injectable form.

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

**Europe:** 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 I / 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 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 I / 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-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

### **<New formulations>**

#### ***Staybla® OD Tablets (ONO-8025OD / KRP-197OD)***

Staybla® OD Tablets is the line extension program of Staybla® Tablets, which is a muscarinic receptor antagonist approved in Japan for the treatment of overactive bladder (OAB). The orally disintegrating (OD) tablet of the drug 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 to offer an additional treatment option on administering the drug and therefore contribute to the improvement of patient compliance.

**Japan:** J-NDA filed / OAB (co-development with Kyorin Pharmaceutical Co., Ltd.)

### ***ONO-5920 / YM529 (tablet)***

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>**

#### ***Prostandin® for Injection***

**Japan:** J-NDA filed / Use in various vascular diagnostic testing for erectile dysfunction

#### ***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

#### ***Emend® Capsules (ONO-7436 / MK-0869)***

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