

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2008

ONO PHARMACEUTICAL CO., LTD.

May 14, 2008

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2008.

This Annual Flash Report 2008 (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\$	
	2008	2007	2008	
Net sales	¥ 145,898	¥ 141,712	\$ 1,458,980	
Net income	35,047	35,272	350,470	
Total Net assets	430,263	446,805	4,302,630	
Total assets	477,341	504,815	4,773,410	
		Yen		US\$
Net income per common share	¥ 306.80	¥ 302.73	\$ 3.07	

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Ono Pharmaceutical Co., Ltd.
and Consolidated Subsidiaries

MESSAGE FROM THE MANAGEMENT

(1) Basic management policy

The Ono Pharmaceutical Group, in keeping with its philosophy of “Dedicated to Man’s Fight against Disease and Pain,” has always striven to achieve its goal of serving as an R&D-oriented, international pharmaceutical company specializing in defined areas. In this endeavor, we have placed emphasis on R&D, aiming to fulfilling unmet medical needs through developing truly beneficial medicines for patients.

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.

From the aspect of the new drug research, we will strive to achieve commercialization of innovative new drugs on worldwide basis focusing on the company's four priority areas: prostaglandins, enzyme inhibitors, neuroscience, and intracellular signaling, where we can fully benefit from the technologies we have accumulated in the past, and employing genomic drug discovery on top of these four areas.

We have established Global Discovery Research Alliance Headquarters at Ono Pharma USA, Inc. ("OPUS") in order to further strengthen strategic alliances in discovery research. This newly formed section will advance our drug discovery research by proactively promoting discovery alliances with bio-pharmaceutical companies in U.S. and Europe having leading-edge technologies in the world and research collaborations with research institutions and universities aiming at seeking groundbreaking discovery seeds.

Furthermore, in addition to in-licensing of late stage compounds, we are directing our efforts into acquiring commercialization rights to new drug candidates in early development stage such as preclinical or Phase I stage, coordinating with OPUS and Ono Pharma UK Ltd in order to expand the development pipeline.

For the purpose of further strengthening global competitive position in new drug development, we newly established Global Development Headquarters at OPUS in May 2008. It takes overall management of clinical development in Japan, U.S. and Europe and promote performance of clinical studies more proactively than ever. We are working on further speeding up development in Japan by leveraging multi-national clinical trials and global data for globally leading development programs while continuing to direct efforts into obtaining early approval for compounds in late stage development in Japan for local development programs.

The marketing division is actively working to enhance the reputation of Ono's innovative pharmaceuticals through presenting its scientific data mainly at workshop and lecture meetings and through the dissemination of high-quality information that is always backed by the latest medical knowledge, in order that we fulfill 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 the competitiveness of existing products.

With top priority given to the pursuit of quality assurance of our products, the manufacturing division is further placing stronger emphasis on improving both its hardware and software, and establishing an efficient production management system.

(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 achievement. The company has set 100% for total payout ratio as its target on free cash flow basis, aggregating dividends and acquisition of its own shares during the three year period from Fiscal 2007 to Fiscal 2009. The company's annual dividend for Fiscal 2007 is projected to be JPY 202 per share (consisting of JPY 180 per share of common dividend and JPY 22 per share of extra dividend). The company has also acquired 2 million shares at the cost of JPY 12 billion during Fiscal 2007. Therefore the total payout ratio will be 100% for Fiscal 2007 as targeted. Meanwhile the annual dividend for the next fiscal term is projected to be JPY 180 per share.

*Toshiharu Korekane
President, Representative
Director and CEO*

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Consolidated Financial Forecast for the Year Ending March 31,2009

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2009	
	Millions of yen	Thousands of US\$
Net sales	¥ 143,000	\$ 1,430,000
Operating income	46,100	461,000
Ordinary income	49,100	491,000
Net income	32,100	321,000
	Yen	US\$
Net income per common share	283.14	2.83

(*)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, 2008

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\$
	2008	2007	2008
Current assets			
Cash and bank deposits	¥ 14,256	¥ 14,942	\$ 142,560
Notes and accounts receivable	41,107	42,073	411,070
Marketable securities	130,599	119,621	1,305,990
Inventories	9,972	9,300	99,720
Deferred taxes	14,775	12,928	147,750
Others	1,358	1,582	13,580
Allowance for doubtful receivables	(10)	(15)	(100)
Total current assets	212,057	200,431	2,120,570
Property, plant and equipment			
Land	22,546	22,546	225,460
Buildings and structures	63,005	62,460	630,050
Machinery, equipment and others	24,844	25,511	248,440
Construction in progress	296	38	2,960
Accumulated depreciation	(59,429)	(57,339)	(594,290)
Net property, plant and equipment	51,262	53,216	512,620
Investments and other assets			
Investment securities	207,517	244,771	2,075,170
Deferred taxes	48	42	480
Intangible assets	1,042	1,092	10,420
Others	5,415	5,263	54,150
Total investments and other assets	214,022	251,168	2,140,220
Total assets	¥ 477,341	¥ 504,815	\$ 4,773,410

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2008	2007	2008
Current liabilities			
Current portion of long-term debt	¥ 2	¥ 1	\$ 20
Notes and accounts payable	3,044	2,970	30,440
Income taxes payable	13,837	12,019	138,370
Others	12,527	12,869	125,270
Total current liabilities	29,410	27,859	294,100
Long-term liabilities			
Long-term debt, less current portion	17	19	170
Long-term payable	713	—	7,130
Liability for retirement benefits	8,668	9,148	86,680
Deferred tax liabilities	8,270	20,984	82,700
Total long-term liabilities	17,668	30,151	176,680
Equity			
Shareholders' equity			
Common stock	17,358	17,358	173,580
Capital surplus	17,080	17,002	170,800
Retained earnings	421,279	404,062	4,212,790
Treasury stock	(36,861)	(24,709)	(368,610)
Total shareholders' equity	418,856	413,713	4,188,560
Other comprehensive income			
Unrealized gain on securities (*)	17,112	39,161	171,120
Land revaluation surplus	(8,919)	(8,919)	(89,190)
Foreign currency translation adjustments	(22)	50	(220)
Total other comprehensive income	8,171	30,292	81,710
Minority interests	3,236	2,800	32,360
Total equity	430,263	446,805	4,302,630
Total liabilities and equity	¥ 477,341	¥ 504,815	\$ 4,773,410

(*) 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\$
	2008	2007	2008
Net sales	¥ 145,898	¥ 141,712	\$ 1,458,980
Cost of sales	20,861	21,085	208,610
Gross profit	125,037	120,627	1,250,370
Selling, general and administrative expenses	72,750	67,785	727,500
Operating income	52,287	52,842	522,870
Other income (expenses)			
Interest and dividend income	3,060	2,582	30,600
Interest expenses	(1)	(1)	(10)
Other, net	4,167	6,173	41,670
	7,226	8,754	72,260
Income before income taxes and minority interests	59,513	61,596	595,130
Income taxes			
Current	24,738	21,825	247,380
Deferred	(697)	4,187	(6,970)
	24,041	26,012	240,410
Income before minority interests	35,472	35,584	354,720
Minority interests	(425)	(312)	(4,250)
Net income	¥ 35,047	¥ 35,272	\$ 350,470
		Yen	US\$
Amounts per common share			
Net income	¥ 306.80	¥ 302.73	\$ 3.07
Cash dividends applicable to the period	¥ 202.00	¥ 100.00	\$ 2.02

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Fiscal Year ended March 31, 2008

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

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2008

(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	17,002	404,062	(24,709)	413,713
Changes of items during the period					
Cash dividends paid			(17,157)		(17,157)
Change of scope of equity method			(673)		(673)
Net income			35,047		35,047
Purchase of treasury stock				(12,167)	(12,167)
Disposal of treasury stock		78		15	93
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	78	17,217	(12,152)	5,143
Balance at the end of current period	17,358	17,080	421,279	(36,861)	418,856

	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	39,161	(8,919)	50	30,292	2,800	446,805
Changes of items during the period						
Cash dividends paid						(17,157)
Change of scope of equity method						(673)
Net income						35,047
Purchase of treasury stock						(12,167)
Disposal of treasury stock						93
Net changes of items other than shareholder's equity during the period	(22,049)	—	(72)	(22,121)	436	(21,685)
Total changes of items during the period	(22,049)	—	(72)	(22,121)	436	(16,542)
Balance at the end of current period	17,112	(8,919)	(22)	8,171	3,236	430,263

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Fiscal Year ended March 31, 2008

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2008

(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	173,580	170,020	4,040,620	(247,090)	4,137,130
Changes of items during the period					
Cash dividends paid			(171,570)		(171,570)
Change of scope of equity method			(6,730)		(6,730)
Net income			350,470		350,470
Purchase of treasury stock				(121,670)	(121,670)
Disposal of treasury stock		780		150	930
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	780	172,170	(121,520)	51,430
Balance at the end of current period	173,580	170,800	4,212,790	(368,610)	4,188,560

	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	391,610	(89,190)	500	302,920	28,000	4,468,050
Changes of items during the period						
Cash dividends paid						(171,570)
Change of scope of equity method						(6,730)
Net income						350,470
Purchase of treasury stock						(121,670)
Disposal of treasury stock						930
Net changes of items other than shareholder's equity during the period	(220,490)	—	(720)	(221,210)	4,360	(216,850)
Total changes of items during the period	(220,490)	—	(720)	(221,210)	4,360	(165,420)
Balance at the end of current period	171,120	(89,190)	(220)	81,710	32,360	4,302,630

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Fiscal Year ended March 31, 2008

Consolidated Statements of Changes in Net Asset

(Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2007

(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	17,002	392,291	(22,312)	404,339
Changes of items during the period					
Dividends from appropriation of surplus (*)			(9,391)		(9,391)
Dividends from retained earnings			(4,693)		(4,693)
Bonuses to directors and statutory auditors (*)			(56)		(56)
Net income			35,272		35,272
Purchase of treasury stock				(11,773)	(11,773)
Disposal of treasury stock		10		5	15
Cancellation of treasury stock		(10)	(9,361)	9,371	
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	11,771	(2,397)	9,374
Balance at the end of current period	17,358	17,002	404,062	(24,709)	413,713

	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	42,825	(3,549)	17	39,293	2,473	446,105
Changes of items during the period						
Cash dividends paid (*)						(9,391)
Dividends from retained earnings						(4,693)
Bonuses to directors and statutory auditors (*)						(56)
Net income						35,272
Purchase of treasury stock						(11,773)
Disposal of treasury stock						15
Cancellation of treasury stock						
Net changes of items other than shareholder's equity during the period	(3,664)	(5,370)	33	(9,001)	327	(8,674)
Total changes of items during the period	(3,664)	(5,370)	33	(9,001)	327	700
Balance at the end of current period	39,161	(8,919)	50	30,292	2,800	446,805

(*) Appropriation approved at the annual meeting of shareholders held in June 2006.

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Fiscal Year ended March 31, 2008

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\$	
	2008	2007	2008	
Cash flows from operating activities:				
Income before income taxes and minority interests	¥ 59,513	¥ 61,596	\$ 595,130	
Adjustments:				
Depreciation and amortization	3,384	3,521	33,840	
Decrease in allowance for doubtful receivables	(12)	(1,252)	(120)	
Increase (decrease) in provision for retirement benefits, net	186	(4,175)	1,860	
Interest and dividend income	(3,060)	(2,582)	(30,600)	
Interest expenses	1	1	10	
Gain on sales of investment securities	(5,393)	(2,794)	(53,930)	
Decrease in notes and accounts receivable	925	1,323	9,250	
Others	666	(1,450)	6,660	
Interest and dividend income received	3,302	3,153	33,020	
Interest paid	(1)	(1)	(10)	
Income taxes paid	(22,989)	(18,661)	(229,890)	
Net cash provided by operating activities	36,522	38,679	365,220	
Cash flows from investing activities:				
Payments for purchases of marketable securities	(109,282)	(109,843)	(1,092,820)	
Proceeds from sales of marketable securities	147,991	127,480	1,479,910	
Payments for purchases of property, plant and equipment	(1,592)	(1,131)	(15,920)	
Payments for purchases of investment securities	(42,441)	(28,035)	(424,410)	
Proceeds from sales of investment securities	13,308	5,079	133,080	
Other payments	(550)	(76)	(5,500)	
Net cash generated from (used in) investment activities	7,434	(6,526)	74,340	
Cash flows from financing activities:				
Repayment of current portion of long-term debt	(2)	(2)	(20)	
Payments for obtaining treasury stock	(12,165)	(11,771)	(121,650)	
Proceeds from sales of treasury stock	120	—	1,200	
Cash dividends	(17,119)	(14,062)	(171,190)	
Cash dividends to minority shareholders	(5)	(4)	(50)	
Net cash used in financing activities	(29,171)	(25,839)	(291,710)	
Foreign currency translation adjustments				
on cash and cash equivalents	(21)	34	(210)	
Net increase in cash and cash equivalents	14,764	6,348	147,640	
Cash and cash equivalents, beginning	32,669	26,321	326,690	
Cash and cash equivalents, ending	¥ 47,433	¥ 32,669	\$ 474,330	

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Fiscal Year ended March 31, 2008

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2008 (unaudited) is summary information extracted from the financial statements announced by the Company on May 14, 2008.
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 2008 (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 100 = US\$ 1, the approximate exchange rate prevailing on March 31, 2008.

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Sales of Major Products

Supplemental Data

For information purpose only

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

		Hundred Millions of yen	
		2008	2007
Opalmon	Circulatory system agent	¥ 373	¥ 338
Onon	Agent for bronchial asthma and allergic rhinitis	271	268
Kinedak	Agent for diabetic peripheral neuropathy	174	173
Onon dry syrup	Agent for pediatric bronchial asthma	110	114
Elaspol	Agent for acute lung injury associated with SIRS	54	53
Onoact	Agent for tachyarrhythmia during operation	19	9
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	5	—

Status of Development Pipeline (as of May 14, 2008)

- - Changes from the Third Quarter Flash Report for the Fiscal Year ended March 2008 announced on February 5, 2008 - -

(Japan)

- Phase I study of ONO-7847 / MK-0517, a drug for the treatment of chemotherapy-induced nausea and vomiting commenced in April this year. This is the compound modified, based on Emend[®] Capsules, to make it available in injectable form.
- Ono had pursued development of Opalmon[®] Tablets for Cervical Spondylosis as an additional indication program, but discontinued it in April this year because the compound failed to demonstrate the expected efficacy in the phase II studies.
- Ono had pursued development of Onon[®] Capsules for Chronic sinusitis as an additional indication program, but discontinued it in April this year because the compound failed to demonstrate the expected efficacy in the phase III studies.
- Phase I study of ONO-5920 / YM529, a drug for the treatment of Osteoporosis is ongoing. This is intermittently administered oral formulation of Recalbon[®] Tablets.

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Supplemental Information

Status of Development Pipeline

as of May 14, 2008

Developments in Japan

NDA filed (New chemical entities):

- **Recalbon® Tablets (ONO-5920 / YM529)**
(co-development with Astellas Pharma Inc.)
Osteoporosis [bone resorption inhibitor (bisphosphonate)]
- **Emend® Capsules (ONO-7436 / MK-0869)**
(in-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting
[NK1 antagonist]
- **Glactiv® Tablets (ONO-5435 / MK-0431)**
(co-development with Banyu Pharmaceutical Co., Ltd.)
Type II diabetes [DPP-IV inhibitor]

Ongoing clinical studies (New chemical entities):

- **ONO-2540 / ENA713D (transdermal patch)**
(co-development with Novartis Pharma K.K.)
Alzheimer's disease (Phase III)
[dual inhibitor of AChE and BuChE]
- **Arocyte® for Injection (ONO-2506)**
Acute ischemic stroke (Phase II / III)
[neuroprotective effect (astrocyte modulator)]
- **ONO-2333Ms (tablet)**
Depression and anxiety disorder (Phase I)
[CRF receptor antagonist]
- **ONO-7643 / RC-1291 (tablet)**
(in-licensed from Sapphire Therapeutics, 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 antagonist]
- **ONO-7847 / MK-0517 (injection)**
(in-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting (Phase I)
[NK1 antagonist]

Ongoing clinical studies (Additional indications):

- **Onoact® for Injection**
Improvement of multislice CT coronary imaging ability
(Phase II) [short-acting β1 blocker]
- **Elaspol® for Injection**
Acute respiratory failure associated with community-acquired
pneumonia (Phase II)
[neutrophil elastase inhibitor]

Ongoing clinical studies (New Dosage Regimen):

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

Developments abroad

Ongoing clinical studies (New chemical entities):

- **MK-0724 / ONO-2506 (injection)**
(out-licensed to Merck & Co., Inc.)
Acute ischemic stroke (Phase II)
[neuroprotective effect (astrocyte modulator)]
- **Cereact® Capsules (ONO-2506PO)**
Amyotrophic lateral sclerosis (ALS) (Phase II)
[neuroprotective effect (astrocyte modulator)]
- **ONO-2333Ms (tablet)**
Depression and anxiety disorder (Phase II)
[CRF receptor antagonist]
- **ONO-5334 (tablet)**
Osteoporosis (Phase II) [cathepsin K inhibitor]
- **ONO-4538 / MDX-1106 (injection)**
(co-development with Medarex, Inc.)
Cancer (Phase I)
Hepatitis C (Phase I)
[fully human anti-PD-1 antibody]
- **ONO-8539 (tablet)**
Overactive bladder (Phase I) [EP 1 antagonist]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase I) [S1P receptor agonist]

Supplemental Information

New Drugs in Development

Development status as of May 14, 2008

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:

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

Recalbon[®], a drug for the treatment of osteoporosis, is one of the most potent bisphosphonates, rapidly preventing bone resorption at low doses and increasing in bone mineral density. The drug is characterized by having the high efficacy, and by having less adverse reaction on the digestive tract.

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

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

Emend[®] is the first neurokinin (NK) 1 antagonist in the world. The drug is effective not only for acute phase of chemotherapy-induced nausea and vomiting, but also for delayed phase (24 hours or later after start of chemotherapy) of nausea and vomiting caused by chemotherapy for which there was no effective drug.

Japan: NDA filed / Chemotherapy-induced nausea and vomiting

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

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

Glactiv[®], a dipeptidyl-peptidase (DPP) IV inhibitor, is a new class of drug for type II diabetes and is expected to be useful for control of postprandial hyperglycemia with low risks of hypoglycemia and/or weight gain in type II diabetes patients.

Japan: NDA filed / Type II diabetes (co-development with Banyu Pharmaceutical Co., Ltd.)

Overseas: Marketed / Type II diabetes (Merck & Co., Inc.)

ONO-2540 / ENA713D (transdermal patch)

ONO-2540 or rivastigmine patch is a drug for the treatment of Alzheimer's disease with an inhibitory action on both acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE). The drug inhibits not only AChE which is known as an enzyme deeply

involved in Alzheimer's disease, but also BuChE which reportedly increases as the disease progresses. Therefore, the drug is expected to have an effect in patients who do not respond to existing drugs. The rivastigmine patch 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: Phase III / Alzheimer's disease (co-development with Novartis Pharma K.K.)

Europe & US: Marketed / Alzheimer's disease (Novartis AG)

Arocyte[®] for Injection (ONO-2506)

Arocyte[®] is a drug to prevent expansion of cerebral infarction by improving function of astrocyte, a kind of glial cells in the brain. In the late phase II study in Japan, safety and efficacy of Arocyte[®] in patients with acute ischemic stroke has been confirmed.

Japan: Phase II/III / Acute ischemic stroke

North America: Phase II / Acute ischemic stroke (Merck & Co., Inc.)

Cereact[®] Capsules (ONO-2506PO)

Abnormal activation of astrocyte has been blamed for neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS), one of the intractable diseases. Cereact[®] has a new mechanism of action to prevent the occurrence and progression of various neurodegenerative diseases by improving astrocyte function.

Europe: Phase II / ALS

ONO-2333Ms (tablet)

ONO-2333Ms, a corticotropin-releasing factor (CRF) receptor antagonist, is developed primarily for the treatment of depression and/or anxiety disorder. The drug is characterized by exhibiting more potent and more rapid action, compared with existing drugs. In addition, based on the mechanism of drug action, ONO-2333Ms is expected to exhibit a fewer adverse reactions, such as dry mouth, gastrointestinal

disorders, sexual dysfunction, and others than those with existing drugs.

Japan: Phase I / Depression and anxiety disorder

US: Phase II / Depression and anxiety disorder

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, muscle-building (anabolic) and gastrointestinal function modulating 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: Phase II / Cancer anorexia / Cachexia (Sapphire Therapeutics, 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-4538 / 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.

US: Phase I / Cancer and hepatitis C (co-development with Medarex, Inc.)

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 I / Overactive bladder

ONO-4641 (tablet)

ONO-4641, a sphingosine-1-phosphate (S1P) receptor agonist, is developed for the treatment of multiple sclerosis. The drug is a low molecular weight substance having pharmacological actions that keep lymphocytes in lymph nodes, reduce lymphocyte count in the blood, and as a result inhibit 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, one of the intractable diseases.

US: Phase I / Multiple sclerosis

ONO-7847 / MK-0517 (injection)

ONO-7847 is a neurokinin (NK) 1 antagonist, and is the compound modified, based on ONO-7436 (Emend[®] Capsules), to make it available in injectable form. The development for chemotherapy-induced nausea and vomiting has been pursued.

Japan: Phase I / Chemotherapy-induced nausea and vomiting

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

<New Dosage Regimen>

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 I / Osteoporosis (co-development with Astellas Pharma Inc.)

<Additional Indications>

Onoact[®] for Injection

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

Elaspol[®] for Injection

Japan: Phase II / Acute respiratory failure associated with community-acquired pneumonia