

Semi-annual Flash Report (unaudited)

Six months ended September 30, 2006

ONO PHARMACEUTICAL CO., LTD.

November 9, 2006

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2006.

This Semi-annual Flash Report 2007 (unaudited) is 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.			Thousands of US\$
	Millions of yen			
	Semi-annual 6 months ended Sep 30 2006	Semi-annual 6 months ended Sep 30 2005	Annual 12 months ended Mar 31 2006	Semi-annual 6 months ended Sep 30 2006
Net sales	¥ 69,463	¥ 73,948	¥ 148,672	\$ 588,669
Net income	18,232	20,269	36,147	154,508
Total Net assets(*)	450,126	413,638	443,632	3,814,627
Total assets	501,959	466,884	504,447	4,253,890
		Yen		US\$
Net income per common share	¥ 155.26	¥ 172.60	¥ 307.32	\$ 1.32

(*)Total Net assets as of Semi-annual 6 months ended Sep 30 2005 and Annual 12 months ended Mar 31 2006 do not include minority interests. The shareholders'equity amounted to 447,462 million yen based on the former regulation.

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 meet the diverse medical needs of an aging society by creating innovative medicines for previously incurable diseases.

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.

The research division focuses its resources on the company’s four priority fields: prostaglandins, enzyme inhibitors, neuroscience, and intracellular signaling, where we can fully benefit from the technologies we have accumulated in the past, and on top of these four areas we now also employ genomic drug discovery. We hope to expeditiously commercialize innovative medicines that conform to global standards based on our expertise.

The Discovery Research Alliance, newly created in April last year, is pursuing drug discovery program relating to inhibitors of kinase, one of the intracellular enzyme with the bioventure companies that are our research partners. This newly established section continues to aggressively seek and promote alliances with bioventure companies and research organizations within and outside Japan in order to further strengthen discovery research capability by gaining access to cutting-edge technologies and discovery seeds.

In responding to the global trend toward the harmonization of pharmaceutical registration standards, the development division strives to develop new pharmaceuticals in Japan, the US and Europe.

At Ono, the focus had been on in-licensing compounds at later stages of development, but in future we will also direct effort into acquiring preclinical stage and Phase I compounds so that our development pipeline can be expanded further.

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 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. With regard to reserves, we allocate sufficient funds to meet the demand for research and development of new drugs in and outside Japan, as well as for alliances with bioventure companies and for in-licensing new products to expand our pipeline and balance development risk; this serves to maintain and enhance our profitability. We consider acquisition of our own company shares flexibly as the need arises for the purpose of improving capital efficiency and as a part of measures for returns to shareholders.

Interim dividend has been introduced starting from this financial term, and we will pay the interim dividend of Yen 40 per share for the current term.

(3) Ideas and policy concerning reduction in the minimum trading unit

Reduction of the minimum trading unit is an effective measure to enhance liquidity in the stock market and increase the number of individual investors. Therefore, effective August 1, 2003, the number of shares comprising one unit of investment has changed from 1,000 to 100.

*Toshiharu Korekane
President, Representative
Director and CEO*

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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\$
	Semi-annual September 30 2006	Semi-annual September 30 2005	Annual March 31 2006	Semi-annual September 30 2006
Current assets				
Cash and bank deposits	¥ 17,795	¥ 13,974	¥ 14,904	\$ 150,805
Notes and accounts receivable	39,607	42,440	43,396	335,653
Marketable securities	99,753	92,519	101,023	845,364
Inventories	9,703	8,848	9,346	82,229
Deferred taxes	12,199	13,466	13,432	103,381
Others	1,499	1,404	1,280	12,703
Allowance for doubtful receivables	(846)	(1,250)	(1,276)	(7,169)
Total current assets	179,710	171,401	182,105	1,522,966
Property, plant and equipment				
Land	22,546	22,546	22,546	191,068
Buildings and structures	62,318	61,975	62,050	528,119
Machinery and equipment	27,137	27,444	27,249	229,975
Construction in progress	26	1,213	238	220
Accumulated depreciation	(57,688)	(55,073)	(56,308)	(488,881)
Net property, plant and equipment	54,339	58,105	55,775	460,500
Investments and other assets				
Investment securities	258,548	227,933	257,268	2,191,085
Deferred taxes	2,460	2,457	2,459	20,847
Intangible assets	1,127	1,279	1,170	9,551
Others	5,775	5,709	5,670	48,941
Total investments and other assets	267,910	237,378	266,567	2,270,424
Total assets	¥ 501,959	¥ 466,884	¥ 504,447	\$ 4,253,890

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen			Thousands of US\$
	Semi-annual September 30 2006	Semi-annual September 30 2005	Annual March 31 2006	Semi-annual September 30 2006
Current liabilities				
Current portion of long-term debt	¥ 2	¥ 1	¥ 2	\$ 17
Notes and accounts payable	3,019	3,079	3,127	25,585
Income taxes	9,466	11,711	8,874	80,220
Others	11,570	12,065	13,870	98,051
Total current liabilities	24,057	26,856	25,873	203,873
Long-term liabilities				
Long-term debt, less current portion	19	23	20	161
Long-term payable	287	584	289	2,432
Accrued retirement benefits	11,188	14,276	13,413	94,814
Deferred taxes	16,281	9,156	18,745	137,975
Others	1	2	2	8
Total long-term liabilities	27,776	24,041	32,469	235,390
Minority interests	—	2,349	2,473	—
Shareholders' equity				
Common stock	—	17,358	17,358	—
Additional paid-in capital	—	17,002	17,002	—
Retained earnings	—	376,414	392,291	—
Revaluation surplus of land	—	(3,549)	(3,549)	—
Unrealized gain on securities (*)	—	28,709	42,825	—
Translation adjustments	—	(4)	17	—
Less, treasury stock	—	(22,292)	(22,312)	—
Total shareholders' equity	—	413,638	443,632	—
Total liabilities and shareholders' equity	¥ —	¥ 466,884	¥ 504,447	\$ —
Shareholders' equity				
Common stock	17,358	—	—	147,102
Additional paid-in capital	17,002	—	—	144,085
Retained earnings	401,076	—	—	3,398,949
Less, treasury stock	(22,334)	—	—	(189,271)
Total shareholders' equity	413,102	—	—	3,500,864
Other comprehensive income				
Revaluation surplus of land	(3,549)	—	—	(30,076)
Unrealized gain on securities (*)	37,898	—	—	321,169
Translation adjustments	11	—	—	93
Total other comprehensive income	34,360	—	—	291,186
Minority interests	2,664	—	—	22,576
Total net assets	450,126	—	—	3,814,627
Total liabilities and total net assets	¥ 501,959	¥ —	¥ —	\$ 4,253,890

(*) 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\$
	Semi-annual 6 months ended Sep 30 2006	Semi-annual 6 months ended Sep 30 2005	Annual 12 months ended Mar 31 2006	Semi-annual 6 months ended Sep 30 2006
Net sales	¥ 69,463	¥ 73,948	¥ 148,672	\$ 588,669
Cost of sales	10,364	10,845	21,815	87,831
Gross profit	59,099	63,103	126,857	500,839
Selling, general and administrative expenses	32,014	31,550	69,920	271,305
Operating income	27,085	31,553	56,937	229,534
Other income (expenses)				
Interest and dividend income	1,396	1,257	2,035	11,831
Interest expenses	(0)	(1)	(2)	(0)
Other, net	1,754	812	779	14,864
	3,150	2,068	2,812	26,695
Income before income taxes and minority interests	30,235	33,621	59,749	256,229
Income taxes				
Current	9,723	11,728	21,886	82,398
Deferred	2,115	1,455	1,428	17,924
	11,838	13,183	23,314	100,322
Income before minority interests	18,397	20,438	36,435	155,907
Minority interests	(165)	(169)	(288)	(1,398)
Net income	¥ 18,232	¥ 20,269	¥ 36,147	\$ 154,508
		Yen		US\$
Amounts per common share				
Net income	¥ 155.26	¥ 172.60	¥ 307.32	\$ 1.32
Cash dividends applicable to the period	¥ 40.00	¥ 0.00	¥ 80.00	\$ 0.34

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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\$
	Semi-annual 6 months ended Sep 30 2006	Semi-annual 6 months ended Sep 30 2005	Annual 12 months ended Mar 31 2006	Semi-annual 6 months ended Sep 30 2006
Cash flows from operating activities:				
Income before income taxes and minority interests	¥ 30,234	¥ 33,622	¥ 59,749	\$ 256,220
Adjustments:				
Depreciation and amortization	1,737	1,979	4,025	14,720
Decrease (increase) in allowance for doubtful receivables	(430)	224	250	(3,644)
Increase in provision for bonuses	9	244	383	76
Decrease in provision for retirement benefits, net	(2,095)	(1,627)	(2,521)	(17,754)
Interest and dividend income	(1,396)	(1,257)	(2,035)	(11,831)
Interest expenses	0	1	2	0
Gain on sales of investment securities	(10)	—	(62)	(85)
Increase in notes and accounts receivable	3,789	2,163	1,207	32,110
Others	(2,785)	(756)	1,377	(23,602)
Interest and dividend income received	1,715	1,593	2,750	14,534
Interest paid	(0)	(1)	(2)	(0)
Income taxes paid	(9,147)	(11,976)	(25,195)	(77,517)
Net cash provided by operating activities	21,621	24,209	39,928	183,229
Cash flows from investing activities:				
Payments for purchases of marketable securities	(35,762)	(29,999)	(67,973)	(303,068)
Proceeds from sales of marketable securities	55,360	43,900	81,215	469,153
Payments for purchases of property, plant and equipment	(519)	(708)	(1,175)	(4,398)
Payments for purchases of investment securities	(25,553)	(36,656)	(59,259)	(216,551)
Proceeds from sales of investment securities	874	1,809	3,094	7,407
Other payments	(536)	(184)	(66)	(4,542)
Net cash generated from (used in) investment activities	(6,136)	(21,838)	(44,164)	(52,000)
Cash flows from financing activities:				
Repayment of current portion of long-term debt	(1)	(3)	(5)	(8)
Repayment of long-term debt	—	(62)	(62)	—
Payments for obtaining treasury stock	(22)	(18)	(37)	(186)
Cash dividends	(9,373)	(7,616)	(7,621)	(79,432)
Cash dividends to minority shareholders	(4)	(4)	(4)	(34)
Net cash used in financing activities	(9,400)	(7,703)	(7,729)	(79,661)
Effect of exchange rate changes on cash and cash equivalents	(4)	10	32	(34)
Net decrease in cash and cash equivalents	6,081	(5,322)	(11,933)	51,534
Cash and cash equivalents, beginning	26,321	38,254	38,254	223,059
Cash and cash equivalents, ending	¥ 32,402	¥ 32,932	¥ 26,321	\$ 274,593

Semi-annual Flash Report (unaudited)

Six months ended September 30, 2006

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

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Semi-annual 6 months ended Sep 30 2006

(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					
Cash dividends paid (*)			(9,391)		(9,391)
Bonuses to directors and statutory auditors (*)			(56)		(56)
Net income			18,232		18,232
Purchase of treasury stock				(22)	(22)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	-	-	8,785	(22)	8,763
Balance at the end of previous period	17,358	17,002	401,076	(22,334)	413,102

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Revaluation surplus of land	Unrealized gain on available-for-sale securities	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	(3,549)	42,825	17	39,293	2,473	446,105
Changes of items during the period						
Cash dividends paid (*)						(9,391)
Bonuses to directors and statutory auditors (*)						(56)
Net income						18,232
Purchase of treasury stock						(22)
Net changes of items other than shareholder's equity during the period	-	(4,927)	(6)	(4,933)	191	(4,742)
Total changes of items during the period	-	(4,927)	(6)	(4,933)	191	4,021
Balance at the end of previous period	(3,549)	37,898	11	34,360	2,664	450,126

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

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Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Semi-annual 6 months ended Sep 30 2006

(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	147,102	144,085	3,324,500	(189,085)	3,426,602
Changes of items during the period					
Cash dividends paid (*)			(79,585)		(79,585)
Bonuses to directors and statutory auditors (*)			(475)		(475)
Net income			154,508		154,508
Purchase of treasury stock				(186)	(186)
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	-	-	74,449	(186)	74,263
Balance at the end of previous period	147,102	144,085	3,398,949	(189,271)	3,500,864

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Revaluation surplus of land	Unrealized gain on available-for-sale securities	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	(30,076)	362,924	144	332,992	20,958	3,780,551
Changes of items during the period						
Cash dividends paid (*)						(79,585)
Bonuses to directors and statutory auditors (*)						(475)
Net income						154,508
Purchase of treasury stock						(186)
Net changes of items other than shareholder's equity during the period	-	(41,754)	(51)	(41,805)	1,619	(40,186)
Total changes of items during the period	-	(41,754)	(51)	(41,805)	1,619	34,076
Balance at the end of previous period	(30,076)	321,169	93	291,186	22,576	3,814,627

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

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Consolidated Statements of Retained Earnings

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen	
	Semi-annual 6 months ended Sep 30 2005	Annual 12 months ended Mar 31 2006
Balance, beginning of period	¥ 364,239	¥ 364,239
Net income for the period	20,269	36,147
Cash dividends paid	(7,630)	(7,630)
Bonuses to directors and statutory auditors	(86)	(86)
Reversal of revaluation surplus of land	(136)	(136)
Decrease in exclusion of consolidated subsidiary	(243)	(243)
Balance, end of period	¥ 376,413	¥ 392,291

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Semi-annual Flash Report 2007 (unaudited) is summary information extracted from the financial statements announced by the Company on November 9, 2006. 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 Semi-annual Flash Report 2007 (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 down 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 118 = US\$ 1, the approximate exchange rate prevailing on September 30, 2006.

Semi-annual Flash Report (unaudited)

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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 off to the nearest hundred million yen.

		Hundred Millions of yen					
		Semi-annual 6 months ended Sep 30 2006		Semi-annual 6 months ended Sep 30 2005		Annual 12 months ended Mar 31 2006	
Opalmon	Circulatory system agent	¥	169	¥	159	¥	326
Onon	Agent for bronchial asthma and allergic rhinitis		122		128		265
Kinedak	Agent for diabetic peripheral neuropathy		88		113		212
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis		72		80		156
Onon dry syrup	Agent for pediatric bronchial asthma		48		39		94
Cataclot	Agent for (acute phase) cerebral thrombosis and cerebrovascular spasms		31		38		73
Prostandin	Circulatory system agent		31		36		71
Elaspol	Agent for acute lung injury associated with SIRS		26		26		55
FOY 500	Agent for DIC		22		27		52
Prostandin 500	Agent for perioperative hypotension		10		12		23
FOY	Agent for pancreatitis and DIC		8		10		19
Onoact	Agent for tachyarrhythmia during operation		2		2		4
Total		¥	634	¥	674	¥	1,358
Percentage to total net sales			91%		91%		91%

Status of Development Pipeline (as of November 9, 2006)

- Changes from the First Quarter Flash Report for the Fiscal Year ended March 2006 announced on August 4, 2006 -

(Japan)

- An additional indication of Onoact[®] 50 for Injection, “emergency treatment of post-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia), with monitoring of circulatory dynamics” was approved on October 20, 2006.
- Phase III study of Onon[®] Capsules for chronic sinusitis as an additional indication commenced in November.
- Ono and Novartis Pharma K.K. are jointly working on preparation for Phase III study of ONO-2540 / ENA713D, a drug for the treatment of Alzheimer’s disease.
- Ono had pursued approval of pediatric allergic rhinitis for Onon[®] Dry Syrup as an additional indication, but discontinued the development in August due to difficulty in evaluating subjective symptom of allergic rhinitis in pediatric patients.
- Ono had pursued development of Cereact[®] Capsules for Parkinson’s disease, but discontinued the development for the disease in August because it failed to demonstrate efficacy in Phase II studies.

Meanwhile the development for Alzheimer’s disease and amyotrophic lateral sclerosis (ALS) continues outside Japan.

- Phase II study of Elaspol[®] for Injection for acute respiratory failure associated with community-acquired pneumonia commenced in November.
- Ono signed the License Agreement with Sapphire Therapeutics, Inc. in October to acquire rights to RC-1291 for the treatment of cancer anorexia / cachexia. Ono plans to start Phase I studies during the first quarter of the fiscal year 2007.

(Outside of Japan)

- Merck & Co., Inc., our out-licensing partner for Arocyte[®] for Injection, will soon commence patient enrollment in new Phase II study of the drug for acute ischemic stroke in North America.
- New Phase II study of Cereact[®] Capsules for ALS commenced in Europe in September.
- Phase I study of ONO-4538 / MDX-1106, a fully human anti-PD-1 antibody, in cancer patients commenced in the US in October.

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Ono Pharmaceutical Co., Ltd. and
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Supplemental Information

Status of Development Pipeline

as of November 9, 2006

Developments in Japan

NDA filed:

New chemical entities:

- **Staybla® Tablets (ONO-8025 / KRP-197) (co-development with Kyorin Pharmaceutical Co., Ltd.)**
Overactive bladder (pollakiuria and urinary incontinence) [M₃ muscarinic receptor blocker]
- **Recalbon® Tablets (ONO-5920 / YM529) (co-development with Astellas Pharma Inc.)**
Osteoporosis [bone resorption inhibitor (bisphosphonate)]

Ongoing clinical studies:

New chemical entities:

- **ONO-5435 / MK-0431 (tablet) (co-development with Banyu Pharmaceutical Co., Ltd.)**
Type II diabetes (Phase III) [DPP-IV inhibitor]
- **Arocyte® for Injection (ONO-2506)**
Acute ischemic stroke (Phase II/III)
[neuroprotective effect (astrocyte modulator)]
- **ONO-2540 / ENA713D (transdermal patch) (co-development with Novartis Pharma K.K.)**
Alzheimer's disease (Phase II) [dual inhibitor of AChE and BuChE]
- **Emend® Capsules (ONO-7436 / MK-0869) (in-licensed from Merck & Co., Inc.)**
Chemotherapy-induced nausea and vomiting (Phase II) [NK₁ antagonist]
- **ONO-5129 (tablet)**
Type II diabetes (Phase II)
[dual agonist of PPAR α and PPAR γ]
- **ONO-2333Ms (tablet)**
Depression and anxiety disorder (Phase I)
[CRF receptor antagonist]

Additional indications:

- **Onon® Capsules**
Chronic sinusitis (Phase III) [LTC₄ and LTD₄ antagonist]
- **Opalmon® Tablets (co-development with Dainippon Sumitomo Pharma Co., Ltd.)**
Cervical Spondylosis (Phase II)
[increase of blood flow in nerve tissue]
- **Onoact® for Injection**
Improvement of multislice CT coronary imaging ability (Phase II) [short-acting β_1 blocker]
- **Elaspol® for Injection**
Acute respiratory failure associated with community-acquired pneumonia (Phase II)
[neutrophil elastase inhibitor]

Developments abroad

Ongoing clinical studies:

- **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)
Alzheimer's disease (Phase II)
[neuroprotective effect (astrocyte modulator)]
- **ONO-5129 (tablet)**
Type II diabetes (Phase II)
[dual agonist of PPAR α and PPAR γ]
- **ONO-2333Ms (tablet)**
Depression and anxiety disorder (Phase I)
[CRF receptor antagonist]
- **ONO-2231 (injection)**
Acute ischemic stroke (Phase I) [PARP inhibitor]
- **ONO-5334 (tablet)**
Osteoporosis (Phase I) [cathepsin K inhibitor]
- **ONO-4538 / MDX-1106 (injection) (co-development with Medarex, Inc.)**
Cancer (Phase I) [fully human anti-PD-1 antibody]

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Supplemental Information

New Drugs in Development

Development status as of November 9, 2006

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:

Staybla® Tablets (ONO-8025 / KRP-197)

Staybla®, an antagonist selectively binding to muscarinic receptors, is for the treatment of overactive bladder (pollakiuria and urinary incontinence). The drug remarkably reduces burdens on patient daily life, such as frequent urination, urinary incontinence, and urgency of urination. The drug is characterized by having the high efficacy, and by having less adverse effect, such as dry mouth, caused by existing drugs with similar modes of action.

Japan: NDA filed / Overactive bladder (pollakiuria and urinary incontinence) (co-development with Kyorin Pharmaceutical Co., Ltd.)

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.)

ONO-5435 / MK-0431 (tablet)

ONO-5435, 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: Phase III / Type II diabetes (co-development with Banyu Pharmaceutical Co., Ltd.)

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

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.)

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 II / Alzheimer's disease (co-development with Novartis Pharma K.K.)

Europe & US: NDA under preparation / Alzheimer's disease (Novartis AG)

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: Phase II / Chemotherapy-induced nausea and vomiting

Overseas: Marketed (Merck & Co., Inc.)

Cereact[®] Capsules (ONO-2506PO)

Abnormal activation of astrocyte has been blamed for neurodegenerative diseases such as Alzheimer's diseases and 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

North America: Phase II / Alzheimer's disease

ONO-5129 (tablet)

ONO-5129, a dual agonist of PPAR α and PPAR γ , intracellular nuclear receptors, has both the hypoglycemic effect exerted by PPAR γ action and the hypolipidemic effect exerted by PPAR α action. The drug is being developed primarily for the treatment of type II diabetes. Existing PPAR γ agonists increase insulin sensitivity, leading to accumulation of visceral lipid and weight increase, in addition to lowered blood glucose level. However, the dual agonists of PPAR α and PPAR γ do not contribute to triglyceride accumulation because of their hypolipidemic effect. Therefore, it is expected that ONO-5129 will be developed as an anti-type II diabetic drug with the advantages in low risks of fatty liver and weight increase.

Japan: Phase II / Type II diabetes

US: Phase II / Type II diabetes

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 I / Depression and anxiety disorder

ONO-2231 (injection)

ONO-2231, a poly ADP-ribose polymerase (PARP) inhibitor, is being developed for acute ischemic stroke. Since a poly ADP-ribose polymerase is an enzyme involved in cellular death, the drug is expected to be an effective drug for diseases such as acute ischemic stroke.

Europe: Phase I / Acute ischemic stroke

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.

Europe: Phase I / Osteoporosis

ONO-4538 / MDX-1106 (injection)

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer. 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 are recognized as foreign and eliminated.

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

<Additional Indications>

Onon[®] Capsules

Japan: Phase III / Chronic sinusitis

Opalmon[®] Tablets

Japan: Phase II / Cervical Spondylosis (co-development with Dainippon Sumitomo Pharma Co., Ltd.)

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