

# Profile

## Dedicated to Man's Fight against Disease and Pain

Ever since being founded in 1717, Ono Pharmaceutical has for more than 290 years dedicated itself to man's fight against disease and pain, contributing to a healthier, happier life for people everywhere.

We have utilized our long years of experience and know-how to develop innovative therapeutic drugs. And, because all our major products are developed in-house, we have been able to maintain consistent profitability and have built up a reputation for quality and innovation within the Japanese pharmaceutical industry. We are well known for achieving the world's first successful development of prostaglandin-based drugs in 1973, and for our later development of various enzyme inhibitors. Ono Pharmaceutical's commitment to research and development continues today in such new fields as neuroscience, intracellular signaling, and genomic-based drugs.

Dedicated to serving humanity, Ono Pharmaceutical continues the relentless search for highly safe and effective new therapeutic drugs to meet the new and unmet medical needs of people throughout the world.

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Dedicated to Mans Fight  
against Disease and Pain  
1968

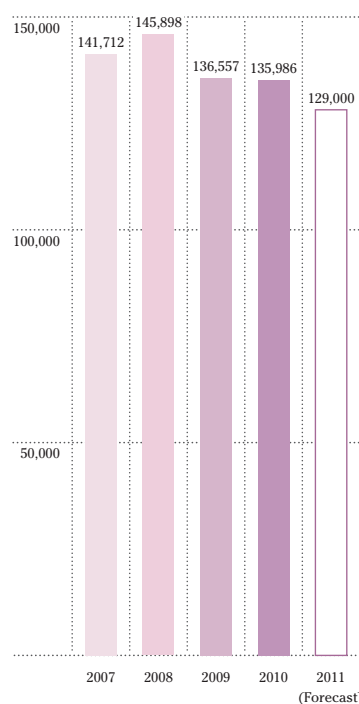
# Financial Highlights

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

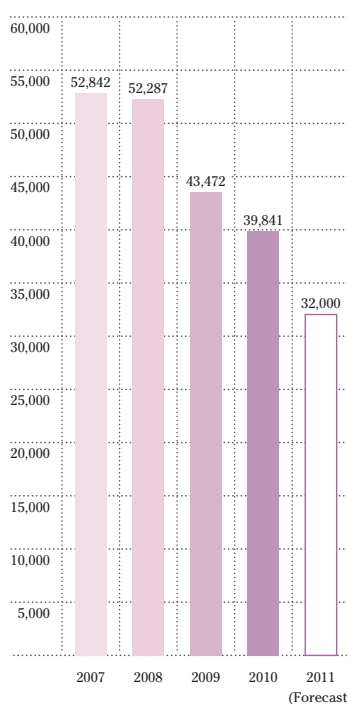
	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Net sales .....	¥ <b>135,986</b>	¥ 136,557	<b>\$1,462,215</b>
R&D expenditures .....	<b>39,717</b>	38,400	<b>427,065</b>
Operating income .....	<b>39,841</b>	43,472	<b>428,398</b>
Net income .....	<b>27,878</b>	23,767	<b>299,763</b>
Working capital .....	<b>158,399</b>	155,097	<b>1,703,214</b>
Property, plant and equipment .....	<b>50,010</b>	50,540	<b>537,742</b>
Total assets .....	<b>433,226</b>	421,280	<b>4,658,344</b>
Total equity .....	<b>406,109</b>	390,041	<b>4,366,763</b>
<b>Per share of common stock:</b>			
		Yen	U.S. dollars
Net income .....	¥ <b>256.38</b>	¥ 216.07	<b>\$ 2.76</b>
Cash dividends applicable to the year .....	<b>180.00</b>	180.00	<b>1.94</b>

(U.S. dollar amounts are translated at a rate of U.S.\$1 = ¥93. See Notes to consolidated financial statements.)

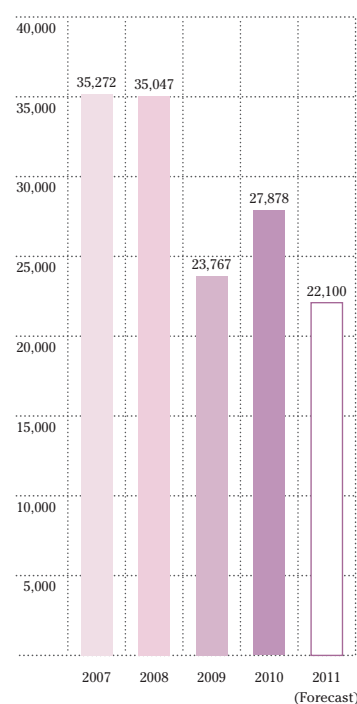
**Net Sales** (millions of yen)



**Operating Income** (millions of yen)



**Net Income** (millions of yen)



# Message from the Management



*Gyo Sagara*  
*President, Representative Director and CEO*

## **(1) Basic Management Philosophy**

The Ono Pharmaceutical Group is “Dedicated to Man’s Fight against Disease and Pain.” Under this management philosophy, we are committed to fulfilling unmet medical needs. We aim to develop innovative new drugs that deliver true benefit to patients, and we strive to serve as an R&D-oriented, international pharmaceutical company specializing in defined areas.

We are highly aware of our responsibility as a pharmaceutical company dealing in medicinal drugs upon which human lives depend, and we are working to further strengthen our level of compliance to ensure that all our actions not only fully comply with all legal regulations but also are based on higher ethical standards.

In new drug research, our drug discovery activities focus on areas where we can fully benefit from the technologies and know-how we have accumulated and continue to exploit our strengths as well as on areas such as biotechnology based medicines where we can make effective use of genes we possess as our genetic assets. We are in active pursuit of the discovery and development of drugs that meet the unmet medical needs at the frontline of healthcare.

Ono promotes drug discovery alliances with biopharmaceutical companies in the US and Europe - plus research collaborations with universities and research institutions.

Thus breakthrough drug discovery seeds and leading-edge technologies can be at our disposal to propel Ono’s drug discovery research.

As for drug development, our first priority is in gaining new drug approval in Europe and the US to respond to global therapeutic needs. Thus clinical development overseas is a key area of our endeavor.

Meanwhile, drug development in Japan focuses on obtaining early approval for compounds in late-stage development. We are also working on further speeding up the development of projects in their early development stage, filing by leveraging multinational clinical trials and global data for globally leading development programs. We are expanding our development pipeline by directing strong efforts into

licensing activities including acquiring commercialization rights to new drug candidates.

Because European and American pharmaceutical and biopharmaceutical companies are the target for our licensing activities, we inaugurated within Ono Pharma USA, Inc. (OPUS) Global Business Development & Licensing in July 2009, relocating the center for our activities from Japan to the United States. Led by Global Business Development & Licensing, we are driving our partnering activities further forward.

The marketing division is actively working to enhance the product value of our innovative drugs through presenting its scientific data mainly at workshops and lecture meetings and through the dissemination of high-quality information that is always backed by the latest medical knowledge, aimed at fulfilling the diversifying needs of healthcare professionals.

We envision that the NHI price revision and implementation of various healthcare cost containment policies may significantly and adversely affect our business. However, we will strive to attain stable growth by developing the markets of new products and by enhancing sales of existing products.

To ensure high product quality, the manufacturing division is dedicated to compliance with production methods

established in accordance with legislative and other regulations and to stringent quality assessment protocol. Through raw materials and inventory control and improved equipment and facility management, the division aims to deliver stable product supply to the market. Cost reduction through process improvement and streamlining of work practices are also areas where effort is directed. Compliance will remain a top priority for all, measured against high ethical standards. For the purpose of maintaining stable and high quality, improved productivity and reduced cost, all out effort will continue in improving and innovating the entire production practice.

## **(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 our business performance for each fiscal year.



Gyo Sagara  
President, Representative Director and CEO

# Aiming at Developing Original New Drugs for Patients Worldwide



Ono's research and development principle is to "Deliver our contributions to society by developing drugs that truly benefit patients". We put this into practice by tackling diseases that remain unconquered as yet and areas that are high in healthcare needs where patient satisfaction of treatment is still low.

Ono's discovery research aims to identify and develop original and breakthrough pharmaceutical products truly beneficial to patients worldwide through further progress of discovery research in bioactive lipids and enzyme inhibitors, fully exploiting the technologies and know-how accumulated through prostaglandin and enzyme inhibitor research. Ono also actively takes up new challenges, entering new areas of research utilizing know-how developed through neuroscience research and gene assets obtained through genome research. Across all these domains and areas, we are further strengthening our R&D capability by using cutting-edge drug discovery technologies acquired through alliances with biopharmaceutical companies and collaborations with academic institutions.

In clinical development, we are engaged in performing clinical studies in Japan, US and Europe, aiming to gain approval of new drugs to global standard. Faster clinical development by taking advantage of the results from multinational clinical trials and other international studies is of critical importance.

## With Outstanding Technology and Know-how, Producing Original New Drugs

Ono aims to develop drugs that truly benefit patients. We are focusing on the areas of bioactive lipids and enzyme inhibitors as domains where the technologies and know-how that we have nurtured can be fully exploited. We are also addressing areas of new challenge so as to pioneer new domains that would enable us to make new discoveries of world-class, original, breakthrough drugs.

Bioactive lipids and enzyme inhibitors are areas of Ono's strengths, where we can use the technologies and know-how accumulated through research into prostaglandins/leukotrienes and into enzyme inhibitors. We are engaged in drug discovery activities involving bioactive lipid signal mediators and protease/kinase inhibitors. In the areas of new challenge, we are utilizing know-how developed through neuroscience research and gene assets obtained through genome research in drug discovery efforts involving modulators of membrane transport system such as ion-channels and transporters as well as biotechnology based medicines. Across all these domains and areas, we are propelling our R&D by using the cutting-edge drug discovery technologies that biopharmaceutical companies and academic institutions possess.



*Tsukuba Research Institute (Ibaraki)*

## A Research Structure Converging Knowledge and Technology

The development of original new drugs is driven by the spirit of challenge and motivation of individual scientists and their ability to think along new paths. Ono sets out high but clear targets to enhance such motivation and creative thinking of its researchers. Our research organization is based on project teams where members converge and bring cutting-edge expertise from contrasting backgrounds. The interaction within the teams stimulates and mutually enhances research achievement. Drug discovery research is undertaken as a coordinated effort by three laboratories: the Tsukuba Research Institute, the Minase Research Institute and the Fukui Research Institute. State-of-the-art facilities for genomics and metabolomics technologies, X-ray crystallography, high-throughput synthesis and high-throughput screening are fully deployed in Ono's efficient and speedy discovery research effort. Through drug discovery alliances with biopharmaceuticals in Europe and the USA and through research collaborations with academic and research institutions, Ono is driving forward its search for new drugs, building on the technologies and know-how accumulated in the three research institutes while effectively injecting globally leading-edge drug discovery technologies.



Minase Research Institute (Osaka)



Fukui Research Institute (Fukui)

The Tsukuba Research Institute undertakes exploratory research for new compounds that can be “seeds” for new drugs, state-of-the-art genomics and metabolomic analysis, and pharmacokinetics of discovered compounds. The Minase Research Institute engages in medicinal chemistry research, research investigating the properties and efficacy of compounds and formulations research that can ensure quality assurance as a pharmaceutical product. The Fukui Research Institute works with safety of compounds as well as mass production and cost reduction for the clinical and commercial supply of drug substances.

## Developing Original and Innovative New Drugs, - in Japan, US and Europe

Patients suffering from disease are found in all corners of the globe. It is Ono's earnest desire to deliver to patients worldwide new drugs that fulfill the needs found at the frontline of healthcare. This has led to the introduction of many products throughout the world. Ono conducts clinical development in its three bases, Japan, US and Europe so as to achieve speedy confirmation of the efficacy and safety of original and innovative new drug candidates and to expedite new drug development that is globally viable.

## Global Clinical Development

Ono is actively pursuing clinical development harnessing the three bases in Japan, US and Europe in close coordination so that it can develop new drugs on a global level. Nerve centers for clinical development have been established within the overseas subsidiaries – Ono Pharma USA, Inc. (OPUS) and Ono Pharma UK Ltd. (OPUK). Both subsidiaries are strongly pursuing overseas clinical development of Ono's original and innovative new drug candidates. To ensure the speedy global development of new drugs, the clinical development framework is being strengthened by means such as the recruitment of more local staff.

## Forging Strategic Alliances with Biopharmaceuticals and Research Institutions Worldwide

Global Discovery Alliance Headquarters established within OPUS is actively pursuing drug discovery alliances with European and American biopharmaceutical companies and research collaborations with universities and other research institutions with the aim of identifying "seeds" for new breakthrough research and geared towards injecting state-

of-the-art technologies into in-house drug discovery activities.

In drug discovery alliances with biopharmaceutical companies, Ono is endeavoring to achieve its aim of discovering original and innovative new drug candidates by exploiting the state-of-the-art drug discovery technologies that these partners possess, in the domains of our strength such as bioactive lipids and enzyme inhibitors where Ono can use its accumulated technologies and know-how, and in the domains of new challenge such as modulator of membrane transport systems and biotechnology-based medicines where Ono can effectively use its accumulated know-how in neuroscience research and gene assets acquired through genome research. With respect to enzyme inhibitors, Ono is in drug discovery collaboration with Array BioPharma Inc. of the US and Ansaris, Inc. of the US, a division of Locus Pharmaceuticals, Inc for kinase inhibitors, and with Evotec AG of Germany for protease inhibitors. In the area of membrane transport systems, Ono is collaborating with Xention Limited of the UK and Evotec for drug discovery of ion-channel modulators. In March this year Ono commenced another drug discovery collaboration on bioactive lipid with BioSeek, LLC. of the US, a subsidiary of Asterand plc, utilizing BioSeek's drug screening and analysis systems. All these collaborations are ongoing in aid of drug discovery efforts for new drug candidates in the domains of inflammation, autoimmune disease, cancer, cardiovascular diseases and CNS disorders. Ono is also eagerly pursuing alliances with universities and research institutions undertaking pioneering research work. New discovery



targets and technologies are being explored through these alliances with the aim of identifying promising compounds that may lead to breakthrough drugs.

### Improving Development Pipeline through Strong In-Licensing Effort of New Drug Candidate Compounds

Because European and American drug companies and biopharmaceutical companies are the target for our licensing activities including in-licensing of new candidate compounds, Global Business Development & Licensing was established within OPUS in July, 2009, and the fulcrum of activity has thus been shifted from Japan to the US. Global activities will become more dynamic, with efforts stepped up in in-licensing new drug candidates not only in late development stages but also in early development stages such as pre-clinical or Phase I.

While licensing opportunities of new drug candidates with innovative mechanisms are scarcer globally now, Ono has been successful in in-licensing new drug candidates: in 2006 Ono acquired the license of a novel compound for cancer anorexia/cachexia from Sapphire Therapeutics, Inc. of the USA (now Helsinn Therapeutics (U.S.), Inc.), and in 2007 a short-acting general anesthetic from CeNes Ltd of the UK (now PAION AG, Germany), and a therapeutic agent for thrombocytopenia from Nissan Chemical Industries, Ltd.

Furthermore, in October 2008, Ono acquired from Progenics Pharmaceuticals, Inc. of the USA exclusive rights to develop and commercialize methylnaltrexone bromide in Japan, a drug for the treatment of intractable constipation induced by narcotic analgesic, and then in September 2009, from Tioga Pharmaceuticals, Inc. of the USA exclusive

rights to develop and commercialize asimadoline in Japan, South Korea and Taiwan, which is under development in the USA for the treatment of diarrhea predominant irritable bowel syndrome (D-IBS).

### New Drugs in Development (as of August 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> Tape** (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)

#### **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:** Phase III / Chemotherapy-induced nausea and vomiting

**Overseas:** NDA filed / 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-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-8539** (tablet)

ONO-8539 is a selective antagonist of EP1, one of the subtype receptors of prostaglandin E<sub>2</sub>, and overactive bladder is the first indication for its clinical development program. It is

expected that the drug can be given to those patients who have complications with glaucoma and with lower urinary tract obstruction including benign prostatic hypertrophy, for which the use of anticholinergics is limited due to their mechanism of actions.

**Japan:** Phase I / Overactive bladder

**Europe:** Phase II / Overactive bladder

**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-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 I / Opioid-induced constipation

**Overseas:** Marketed (Progenics Pharmaceuticals, Inc.)

**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).

**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)

ONO-5920 is a bisphosphonate for the treatment of osteoporosis. This is the line extension program of *Recalbon® Tablets*. The product offers once-monthly oral dosing.

**Japan:** Phase III / 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 alpha-glucosidase inhibitor for type II diabetes (co-development with Banyu Pharmaceutical Co., Ltd.)

Phase III / Combination therapy with insulin for type II diabetes (co-development with Banyu Pharmaceutical Co., Ltd.)

##### **Corebata® for Injection**

*Corebata®* is a candidate for the trade name of a low-dose formulation of *Onoact® Injection*.

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

##### **Emend® Capsules**

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

# Key Product Profiles

## **Glactiv® Tablets for the Treatment of Type II Diabetes**

*Glactiv®*, a dipeptidyl-peptidase (DPP) 4 inhibitor, is a new class of oral drug for type II diabetes. It regulates blood sugar levels in type II diabetes patients with the novel mechanism of action selectively inhibiting DPP-4, an enzyme which metabolites a gastrointestinal hormone, incretins. It thereby enhances the body's own insulin secretion ability in a glucose dependent manner and decreases glucagon release, signaling the liver to reduce its production of glucose.

**FY 2009 Sales: 1.5 billion yen (Launched December 2009)**



## **Recalbon® Tablets for the Treatment of Osteoporosis**

*Recalbon®*, a drug for the treatment of osteoporosis, is the first oral bisphosphonate discovered in Japan. It is one of the most potent bisphosphonates, rapidly preventing bone resorption at low doses, and is the first bisphosphonate that demonstrated significant effect in bone fracture prevention over placebo in Japanese osteoporosis patients.

**FY 2009 Sales: 900 million yen (Launched April 2009)**



## **Emend® Capsules for the Treatment of Chemotherapy-induced Nausea and Vomiting**

*Emend®* is the first selective neurokinin (NK) 1 receptor antagonist in the world. The drug is effective not only for the acute phase of chemotherapy-induced nausea and vomiting, but also for the delayed phase, for which there was no effective drug.

**FY 2009 Sales: 500 million yen (Launched December 2009)**



## **Staybla® Tablets for the Treatment of Overactive Bladder (OAB)**

*Staybla®* is a new anticholinergic, an antagonist selectively binding to M3 and M1 muscarinic receptors. By reducing the excessive contraction of the smooth cells of the bladder, it is effective in symptoms associated with OAB including frequent urination, urinary incontinence, and urgency of urination.

**FY 2009 Sales: 4.6 billion yen (Launched June 2007)**



### **Opalmon® Tablets for the Treatment of Peripheral Circulatory Disorder**

*Opalmon®* is an orally administered prostaglandin-E<sub>1</sub> derivative for the treatment of subjective symptoms and walking disability associated with acquired lumbar spinal canal stenosis and ischemic symptoms accompanying thromboangiitis obliterans. It improves symptoms caused by peripheral circulatory disorder such as numbness, pain or coldness of the hands or feet.

**FY 2009 Sales: 44.6 billion yen**



### **Onon® Dry Syrup for the Treatment of Bronchial Asthma**

*Onon® Dry Syrup* is a leukotriene receptor antagonist. Leukotriene is closely involved in the pathology of bronchial asthma (airway inflammation, contraction, and hypersensitivity). It is a dry syrup formulation, suitable for use with children.

**FY 2009 Sales: 9.1 billion yen**



### **Onon® Capsules for the Treatment of Bronchial Asthma and Allergic Rhinitis**

*Onon® Capsules* is a leukotriene receptor antagonist. Leukotriene is closely involved in the basic pathologies of bronchial asthma (airway inflammation, contraction, and hypersensitivity) and of allergic rhinitis. It relieves asthmatic symptoms, namely coughing, wheezing and breathlessness and rhinitis symptoms, namely sneezing, runny or blocked nose.

**FY 2009 Sales: 25.1 billion yen**



### **Kinedak® Tablets for the Treatment of Diabetic Peripheral Neuropathy**

*Kinedak®* is the first aldose reductase inhibitor marketed in Japan. By blocking aldose reductase which is activated under hyperglycemia, the drug reduces the production of sorbitol, which is involved in the development of neurological disorders associated with diabetes, and thereby alleviates accompanying symptoms such as numbness, pain and cramp in hands and feet and controls progress of the disease.

**FY 2009 Sales: 16.1 billion yen**



***Foipan® Tablets for the Treatment of Chronic Pancreatitis and Postoperative Reflux Esophagitis***

*Foipan® Tablets* inhibits pancreatic enzymes including trypsin which cause chronic pancreatitis and postoperative reflux esophagitis. It alleviates abdominal pain, nausea, tenderness and back pain due to the inflammation of the pancreas and relieves the symptoms and sensations after gastric operations, such as heartburn, backflow and cold or stinging feeling inside.

**FY 2009 Sales: 12.7 billion yen**



***Onoact® for Injection for the Treatment of Tachyarrhythmia during or after Operations***

*Onoact®* is a short-acting  $\beta_1$  blocker that selectively blocks  $\beta_1$  receptors mainly found in the heart, and thereby slows down the increase of heart rate that occurs during or after operations.

**FY 2009 Sales: 3.1 billion yen**



***Elaspol® for Injection for the Treatment of Acute Lung Injury Associated with Systemic Inflammatory Response Syndrome***

*Elaspol®* is the world's first selective inhibitor of the neutrophil elastase. No medication is yet available for the direct treatment of lung injury. This is a therapeutic drug for acute lung injury associated with systematic inflammatory response syndrome arising from the body's reaction to invasive operation or infection.

**FY 2009 Sales: 5.2 billion yen**



# Corporate Governance

## Corporate Value Enhanced by Highly Transparent Management and Strict Upholding of Corporate Ethics

To enhance corporate value, Ono believes that our important management tasks lie not only in achieving strict compliance with laws and regulations, but also in improving transparency in corporate management and in strengthening the functioning of management control.

To this end, the organizational framework of Ono's management includes the (Board of) Auditors. Bolstering corporate governance is a priority, focusing on functional reinforcement of the Board of Directors and the Board of Auditors.

The Board of Directors meets at least once a month aiming at expediting decision-making by boosting corporate dynamic action. For that purpose we endeavor to ensure that the Board is comprised of the appropriate number of directors. In the process of decision-making by the Board, comments and advice from legal and other external experts are obtained as necessary so that appropriate consensus can be formed.

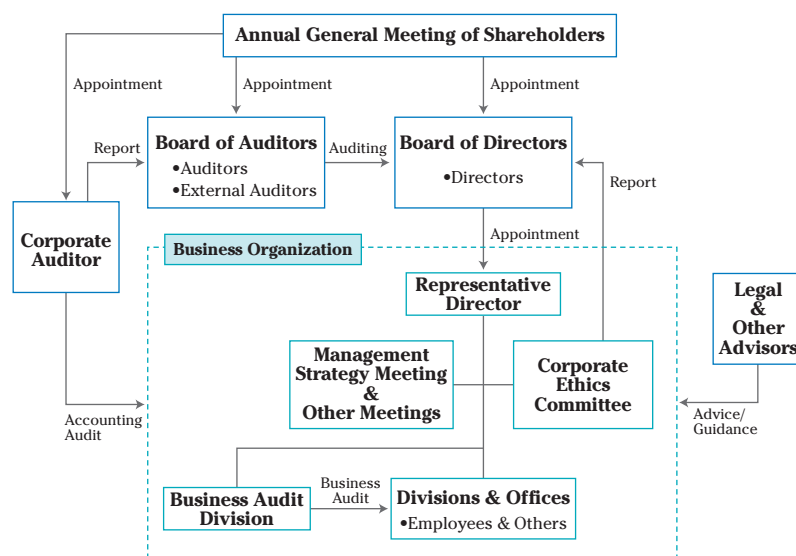
The Board of Auditors fulfils its role through its members attending the Board of Directors meeting and other key meetings, receiving reports from directors, and auditing the execution of duties by directors via interviews. As to external auditors, a lawyer and a certified public accountant are on the Board, providing audit from objective and expert perspectives.

Important operational management matters are discussed in meetings at different levels according to the significance and content of the business agenda, including the Management Strategy Meeting attended by the President and heads of headquarters,

plus meetings organized by directors and heads of headquarters. Here again, appropriate operational management should take place, using mutual monitoring, in decision-making, and referral to the Board of Directors being made through careful deliberation.

With regard to our system of internal control, the Board of Directors meeting held on May 9, 2006 resolved that "a system for ensuring appropriateness of the company's operations" should be in place. To this end, such a system was created and is constantly under review, so as to strengthen and improve operational compliance as well as overall internal control. Furthermore, we adopt a firm stance against any antisocial force or organization that may threaten social order or security.

## Corporate Governance Structure



# Environment Management

## Protecting the Environment

As awareness of environmental problems grows throughout the world, protection of the environment and limited natural resources has become not only the clear responsibility but also a social mission of every company doing business. As part of our company-wide efforts to make environmental protection a top priority, Ono established an Environmental Management Office in July 1998 and formulated an Environmental Self-regulating Action Plan, which delineates Ono's course of action in environmental protection. Certification of compliance with ISO 14001 environmental management standards has been obtained for both the Fujiyama Plant (November 2002) and the Joto Plant (February 2004). We remain committed to maintaining our environmental management system and engaging in environmental protection throughout our operations.

## Medium- to Long-Term Vision on Environmental Protection

Because we do not conduct any synthesis of pharmaceutical substances at Ono, our

discharge volumes of CO<sub>2</sub>, wastes and chemical substances have remained lower than the industry average and are within ranges that do not cause concerns to society. We have never experienced any environment-related accidents or litigations, and have never received any complaints concerning noise, malodor or vibration. However, the Kyoto Protocol requires reduction by 2010 of the total volume of CO<sub>2</sub>, waste and chemical substances down to below 1990 levels: the volumes discharged at Ono are higher than the 1990 levels. This is attributable to the company's growth resulting in the doubling of sales and tripling of R&D investment compared to those in 1990. Despite our continued efforts to reduce environmental impact during the period, increase of environmental impact associated with company growth has exceeded the volume that has been reduced. We recognize that future reduction of the environmental impact measured by total volume will continue to be an agenda for Ono to tackle. We will continue our efforts to consider all aspects of environmental action and achieve the targets in volume reduction before 2010.



### Environmental Guidelines

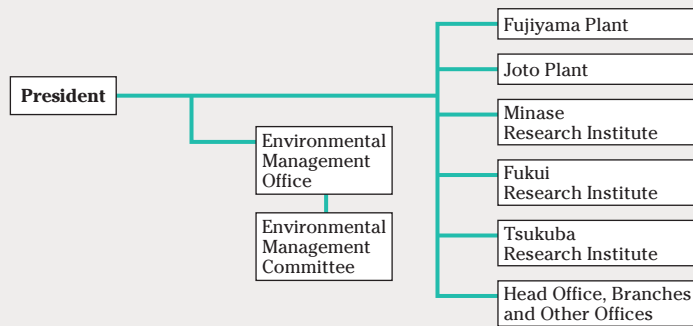
We recognize that our company has a social responsibility regarding the environment, and we will work to protect and preserve the global environment in all of our business operations.

- In addition to fully complying with all environment-related laws and regulations, we will establish targets and action plans in a continuous effort to protect and preserve the environment and natural resources.
- In all of our business operations we will implement environment-focused measures such as saving resource and energy, recycling, reducing waste and preventing pollution.
- We will endeavor to produce eco-friendly products and will cooperate with society.
- With the participation of every employee, we will strive to further understand environmental issues and to promote environment-related activities.

### Environmental Management Organization

The Environmental Management Office is responsible for all environment-related issues at Ono. Meanwhile, the Environmental Management Committee consisting of members from sections across the company gages the current situation and promotes environmental management.

In addition, facilities that have greater environmental impact such as a research institute or a manufacturing plant has a subcommittee at each site working on environmental issues.



### Environmental Self-regulating Action Plan

In compliance with the Environmental Guidelines, we have set specific action plans and targets in 6 areas and strive to achieve these targets.

Objectives	Targets
Measures to save energy and to counter global warming	Energy consumption in terms of CO2 emission in 2010 will be reduced to a level lower than that in 1990.
Control of chemical substances	Discharge and displacement of first class PRTR chemicals is around 10 tons or less. However, we will not only strengthen compliance with laws and regulations but also tackle as much discharge reduction as possible.
Waste reduction measures	By 2010 final disposal of wastes will be reduced to 20% of the volume disposed in 1990.
Measures against air and water pollution	Emission standards will be thoroughly complied with and our efforts will continue so as to prevent any environmental accident or complaint from local communities.
Environmental accounting	Environmental accounting has been disclosed in accordance with the guidelines of the Ministry of the Environment.
Community relations	In local communities, we participate in cleanup activities. We endeavor to prevent any workplace accidents involving employee injury.



# Financial Section

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## Financial Review

The following is a summary of the consolidated business results for this fiscal year ended March 31, 2010.

### Area of Business

Ono Pharmaceutical Co., Ltd. and its subsidiaries are engaged primarily in pharmaceutical-related businesses.

(See Notes 2 and 18 of the Notes to Consolidated Financial Statements.)

### Results for Fiscal Year Ended March 31, 2010

The Japanese economy during the fiscal year ended March 31, 2010 showed some signs of recovery in the wake of the US economy picking up in the second half of the year and demand rising in the emerging economies. However, fear of deteriorating employment prospects and dampened personal spending persisted strongly, resulting in the economic climate remaining tough. Against this backdrop, the environment surrounding the Japanese pharmaceutical industry in this fiscal year remained very challenging as with last year, due to the further pressures of various medical cost-containment measures by the government and intensified competition both in Japan and abroad.

The Ono Pharmaceutical Group attempted to improve operating efficiency throughout, focusing on the development of unique and innovative new drugs by strengthening R&D capabilities and on enhancing product value by energetically promoting dissemination of scientific information relating to our main strategic products. However, the withholding of orders in anticipation of NHI drug price cuts in April 2010 and greater promotion of generic product use affected performance negatively more than expected.

A summary of the business results for the consolidated fiscal year ended March 2010 is given below.

	Millions of yen	Thousands of U.S. dollars
Net sales	¥ 135,986	\$ 1,462,215
Operating income	39,841	428,398
Net income	27,878	299,763

## Sales

Looking at the performance of some key individual products, *Opalmon*<sup>®</sup> Tablets for peripheral circulation improving agent, saw further increase in new prescription in its area of the treatment of lumbar spinal canal stenosis. *Staybla*<sup>®</sup> Tablets for the treatment of overactive bladder also saw increase in sales, thanks to successful market development.

*Recalbon*<sup>®</sup> Tablets, the osteoporosis drug, was launched in April 2009, followed in December by *Glactiv*<sup>®</sup> Tablets for the treatment of Type II diabetes and *Emend*<sup>®</sup> Capsules for the treatment of chemotherapy-induced nausea and vomiting. These three new drugs pushed up sales.

Affected by intensifying competition from competitor products and generic products, *Onon*<sup>®</sup> Capsules, for the treatment of bronchial asthma and allergic rhinitis, *Onon*<sup>®</sup> Dry Syrup for the treatment of bronchial asthma, mainly used by pediatric patients, together with *Kinedak*<sup>®</sup> Tablets for the treatment of diabetic peripheral neuropathy suffered a fall in sales, bringing down overall sales to ¥135,986 million (US\$1,462,215 thousand), down ¥571 million year on year (US\$6,140 thousand) or a drop of 0.4%.

## Operating Income

Sales for the fiscal year ended March 31, 2010 totaled ¥135,986 million (US\$1,462,215 thousand), which was a year-on-year decrease of ¥571 million (US\$6,140 thousand) or 0.4%. Cost of sales fell to ¥20,838 million (US\$224,064 thousand), a year-on-year decrease of ¥481 million (US\$5,172 thousand), down by 2.3%. Selling, general and administrative expenses were ¥75,307 million (US\$809,753 thousand), a year-on-year increase of ¥3,541 million (US\$38,075 thousand) or

4.9%. Overall, these resulted in a decline of the operating income to ¥39,841 million (US\$428,398 thousand), a year-on-year decrease of ¥3,631 million (US\$39,043 thousand), down by 8.4%.

Among, SG&A expenses, R&D expenses rose to ¥39,712 million (US\$427,011 thousand), an increase of ¥1,329 million (US\$14,290 thousand), up by 3.5% over the previous fiscal year, reflecting the strong R&D efforts we are maintaining. Other SG&A expenses also increased because of marketing costs rising due to new product launches, up to ¥35,595 million (US\$382,741 thousand), a rise of ¥2,212 million (US\$23,785 thousand) or 6.6% over the previous fiscal year.

(See Note 10 of the Notes to Consolidated Financial Statements.)

## Net Income

Other income and expenses include: ¥2,964 million (US\$31,871 thousand) in interests and dividends income and ¥346 million (US\$3,720 thousand) of gain on reversal of R&D expenses for prior periods. This resulted in other income and expenses maintaining a gain, at ¥3,302 million (US\$35,505 thousand). For reference, other income and expenses for the previous fiscal year were posted at a loss of ¥3,201 million (US\$34,419 thousand).

As a result net income for this fiscal year rose ¥4,111 million (US\$44,204 thousand) or 17.3% up year on year to be ¥27,878 million (US\$299,763 thousand).

(See Notes 9 and 13 of the Notes to Consolidated Financial Statements.)

## R&D Policies

The Ono Pharmaceutical Group is “Dedicated to Man’s Fight against Disease and Pain.” Under this management philosophy, we are committed in our endeavor to become an R&D-oriented, international pharmaceutical company specializing in defined areas, and to develop innovative and world-class new drugs. In new drug research, we continue to focus the technologies and know-how we have nurtured into areas where our strengths can be fully exploited, namely in bioactive lipids and enzyme inhibitors. We have also designated modulators of membrane transport system and biotechnology based medicines

as new areas of challenge where our know-how from neuroscience research and our assets in genomic research can be effectively deployed, and we stand committed to the discovery of globally viable original breakthrough drugs. To fulfill the unmet needs at the frontline of healthcare, we are directing our efforts into discovering new drug candidate compounds that add high value to drugs that are already available. In pursuit of even more powerful drug discovery capability, we are forging drug discovery alliance with European and US biopharmaceutical companies and research collaborations with academic and other research institutions. With respect to enzyme inhibitors, we have drug discovery partnerships with Ansaris, Inc. (business division of Locus Pharmaceuticals, Inc. of the US) and Evotec AG of Germany and research is proceeding successfully. With respect to modulators of membrane transport system, in addition to the partnership we already have with Xention Ltd. of the UK, we newly signed a drug discovery partnership agreement with Evotec AG of Germany in October 2009. In March 2010, another drug discovery partnership was signed with BioSeek, Inc. of the US in the bioactive lipid domain. In these partnerships we are pursuing the discovery of new compounds in the areas of inflammation, immunological disorders, cancers, CNS disorders and pain. In our search for discovery research targets that offer promise of new drug discovery in future, we are actively seeking alliances with research institutions engaged in cutting-edge technologies. On the development side, our first priority is in gaining marketing approval of a world-class new drug, with strong input into overseas-driven clinical development. ONO-5334 for the treatment of osteoporosis and ONO-8539 for overactive bladder are undergoing Phase II trials in Europe. We have commenced multinational Phase II clinical study with ONO-4641 for multiple sclerosis in Japan, USA, and Europe. Phase I trials with ONO-7746 for thrombocytopenia, in-licensed from Nissan Chemical Industries Ltd., started in the USA. ONO-4538 for cancer under joint development with Bristol-Myers Squibb is now in Phase I trials in the USA.

Meanwhile in Japan, *Emend*<sup>®</sup> *Capsules* for the treatment of chemotherapy-induced nausea and vomiting and *Glactiv*<sup>®</sup> *Tablets* for the treatment of Type II diabetes were launched in December 2009. Work is underway to follow suit with marketing of new products. Marketing approval has been filed for *Staybla*<sup>®</sup> orally-disintegrating (OD) *Tablets* for the treatment of overactive bladder (additional formulation) and *Rivastach*<sup>®</sup> *Tape* for the treatment of Alzheimer's Disease. An all-out effort is being made to obtain approval at the earliest date for pipeline developments that are in Phase III such as additional indications for *Glactiv*<sup>®</sup> *Tablets* and *Onoact*<sup>®</sup> *for Injection*, and once monthly oral formulation of ONO-5920 for osteoporosis treatment and ONO-7847 for the treatment of chemotherapy-induced nausea and vomiting (injection version of *Emend*<sup>®</sup> *Capsules*). Ono intends to expedite the development of drugs in the early stages of development by utilizing the results from the multinational clinical trials and other international studies conducted ahead of Japan. In licensing activities, Ono established the Global Business Development & Licensing within the American subsidiary Ono Pharma USA, Inc. in July 2009 to further expand the development pipeline. In pursuit of this, achievements have been made such as acquisition of exclusive development and marketing rights of asimadoline in Japan, South Korea and Taiwan from Tioga Pharmaceuticals of the USA in September 2009. The drug is now under development in the USA for the treatment of diarrhea-predominant irritable bowel syndrome (D-IBS). Ono will push in-licensing activities on all three fronts, Japan, USA and Europe, with priority on in-licensing new candidate compounds in late development stages while keeping an eye on promising compounds in early development stages (pre-clinical and Phase I). The total expenditure on R&D was ¥39,717 million (US\$427,065 thousand).

## Consolidated Cash Flow

In the consolidated financial year ended March 31, 2010, the balance of cash and cash equivalents increased to a total of ¥72,097 million (US\$775,237 thousand) despite outgoings such as dividend payments, thanks to the positive balances of cash flow from operating activities of ¥21,301 million (US\$229,043 thousand) and from investing activities of ¥16,877 million (US\$181,474 thousand), which resulted in a year-on-year increase of ¥18,636 million (US\$200,388 thousand) or 34.9% up from ¥53,461 million (US\$574,849 thousand) of the previous fiscal year.

### •Cash Flow from Operating Activities

Cash flow from operating activities for this fiscal year showed a decrease of ¥3,224 million (US\$34,667 thousand) in income from the previous fiscal year, resulting in a positive cash flow balance of ¥21,301 million (US\$229,043 thousand). This is due to downward factors such as our corporate tax obligations being ¥18,084 million (US\$194,452 thousand) for this fiscal year while being ¥20,890 million (US\$224,624 thousand) for the previous fiscal year and inventory increase being ¥4,567 million (US\$49,108 thousand) while being ¥88 million (US\$946 thousand) for the previous fiscal year on the one hand but upward factors chiefly comprising pre-tax net profits of ¥43,143 million (US\$463,903 thousand) in this year while being ¥40,271 million (US\$433,022 thousand) in the previous fiscal year on the other hand.

### •Cash Flow from Investing Activities

Cash flow from investing activities for this fiscal year ended in a decrease from the previous fiscal year of ¥13,850 million (US\$148,925 thousand) in income, leaving a positive balance of ¥16,877 million (US\$181,474 thousand). The reasons for this are that although there was expenditure on the purchase of marketable and investment securities, there was also income from their disposal and redemption, creating an income balance of ¥20,567 million (US\$221,151 thousand), compared to the income of ¥32,544 million (US\$349,935 thousand) in the previous fiscal year and that spending for the acquisition of tangible fixed assets amounted to ¥3,211 million (US\$34,527 thousand), compared to ¥1,509 million (US\$16,226 thousand) of the previous fiscal year.

### •Cash Flow from Financing Activities

The cash flow from financing activities for this fiscal year showed a decrease of ¥29,450 million (US\$316,667 thousand) in payment over the previous fiscal year, leaving a negative balance of ¥19,568 million (US\$210,409 thousand). Dividend payments accounted for ¥19,549 million (US\$210,204 thousand), compared to the previous fiscal year's ¥22,449 million (US\$241,387 thousand).

## Investment in Plant and Equipment

Plant and equipment investment during this fiscal year totaled ¥2,443 million (US\$26,269 thousand), including investment into the enhancement and maintenance of manufacturing facilities amounting to ¥1,724 million (US\$18,538 thousand) and into maintenance of research facilities amounting to ¥375 million (US\$4,032 thousand).

## Outlook for the Coming Year

It is expected that Japanese government policies for containing healthcare costs, which have risen steadily over the years, will affect our operations more strongly during the coming year. At the same time, competition in the increasingly globalized pharmaceutical market continues to intensify, with the result that our business environment is likely to become even more challenging. The Ono Pharmaceutical Group is facing this challenge with stronger commitment to the research and development of world-class and innovative new pharmaceutical products, building an even more solid business base by actively forging alliances with research institutions and by enhancing the speed and efficiency of marketing and other business activities throughout the company to reap the rewards of improved business performance.

## Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

ASSETS	Millions of yen		Thousands of U.S. dollars (Note 1)
	2010	2009	2010
<b>Current assets:</b>			
Cash and cash equivalents (Notes 2.b & 3) .....	¥ 72,097	¥ 53,461	\$ 775,237
Time deposits .....	950	750	10,215
Marketable securities (Notes 3 & 4) .....	40,170	62,800	431,935
Notes and accounts receivable:			
Trade notes and accounts (Note 3) .....	31,625	39,480	340,054
Other .....	7,443	81	80,032
Allowance for doubtful receivables .....	(13)	(9)	(140)
Inventories (Note 5) .....	14,626	10,059	157,269
Deferred tax assets (Note 9) .....	13,753	13,061	147,882
Prepaid expenses and other current assets .....	1,190	874	12,795
<b>Total current assets</b> .....	<b>181,841</b>	<b>180,557</b>	<b>1,955,279</b>
<b>Property, plant and equipment:</b>			
Land.....	22,539	22,539	242,355
Buildings and structures .....	64,685	63,748	695,538
Machinery, equipment and others .....	25,740	24,796	276,774
Construction in progress .....	638	746	6,860
<b>Total</b> .....	<b>113,602</b>	<b>111,829</b>	<b>1,221,527</b>
Accumulated depreciation .....	(63,592)	(61,289)	(683,785)
<b>Net property, plant and equipment</b> .....	<b>50,010</b>	<b>50,540</b>	<b>537,742</b>
<b>Investments and other assets:</b>			
Investment securities (Notes 3 & 4) .....	189,867	177,627	2,041,581
Investments in affiliated companies .....	761	707	8,183
Long-term loans to employees .....	17	18	183
Intangible assets .....	866	1,033	9,312
Deferred tax assets (Note 9) .....	3,980	5,147	42,796
Other assets .....	5,884	5,651	63,268
<b>Total investments and other assets</b> .....	<b>201,375</b>	<b>190,183</b>	<b>2,165,323</b>
<b>Total</b> .....	<b>¥ 433,226</b>	<b>¥ 421,280</b>	<b>\$ 4,658,344</b>

See accompanying notes to consolidated financial statements.

LIABILITIES AND EQUITY	Millions of yen		Thousands of U.S. dollars (Note 1)
	2010	2009	2010
<b>Current liabilities:</b>			
Current portion of long-term debt (Note 6) .....	¥ 2	¥ 2	\$ 22
Notes and accounts payable:			
Trade notes and accounts payable .....	2,336	2,919	25,118
Construction .....	8	487	86
Affiliated companies .....	–	17	–
Income taxes payable (Notes 3 & 9) .....	8,421	9,130	90,548
Accrued expenses .....	11,422	11,562	122,817
Other current liabilities .....	1,253	1,343	13,474
<b>Total current liabilities</b> .....	<b>23,442</b>	<b>25,460</b>	<b>252,065</b>
<b>Long-term liabilities:</b>			
Long-term debt, less current portion (Note 6) .....	14	16	151
Long-term accounts payable .....	84	553	903
Liability for retirement benefits (Note 7) .....	599	2,240	6,441
Deferred tax liabilities (Note 9) .....	2,967	2,961	31,903
Other non-current liabilities .....	11	9	118
<b>Total long-term liabilities</b> .....	<b>3,675</b>	<b>5,779</b>	<b>39,516</b>
<b>Commitments and contingent liabilities</b> (Notes 11 & 15)			
<b>Equity</b> (Notes 8 & 17):			
Common stock,			
authorized, 300,000,000 shares; issued, 120,847,500			
shares in 2010 and 2009 .....	17,358	17,358	186,645
Capital surplus .....	17,080	17,080	183,656
Retained earnings .....	430,870	422,565	4,633,011
Unrealized gain on available-for-sale securities .....	9,707	2,171	104,376
Land revaluation difference (Note 14) .....	(8,923)	(8,923)	(95,946)
Foreign currency translation adjustments .....	(174)	(204)	(1,871)
Treasury stock-at cost			
12,113,089 shares in 2010 and 12,109,665 shares in 2009 .....	(63,439)	(63,425)	(682,140)
<b>Total</b> .....	<b>402,479</b>	<b>386,622</b>	<b>4,327,731</b>
Minority interests .....	3,630	3,419	39,032
<b>Total equity</b> .....	<b>406,109</b>	<b>390,041</b>	<b>4,366,763</b>
<b>Total</b> .....	<b>¥ 433,226</b>	<b>¥ 421,280</b>	<b>\$ 4,658,344</b>

## Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2010	2009	2010
<b>Net sales</b> .....	<b>¥ 135,986</b>	¥ 136,557	<b>\$ 1,462,215</b>
<b>Cost of sales</b> (Note 10) .....	<b>20,838</b>	21,319	<b>224,064</b>
Gross profit .....	<b>115,148</b>	115,238	<b>1,238,151</b>
<b>Selling, general and administrative expenses</b> (Note 10) .....	<b>75,307</b>	71,766	<b>809,753</b>
Operating income .....	<b>39,841</b>	43,472	<b>428,398</b>
<b>Other income (expenses)</b>			
Interest and dividend income .....	<b>2,964</b>	3,319	<b>31,871</b>
Interest expense .....	<b>(1)</b>	(1)	<b>(11)</b>
Loss on devaluation of investment securities .....	<b>-</b>	(7,808)	<b>-</b>
Other-net (Note 13) .....	<b>339</b>	1,289	<b>3,645</b>
Other income (expenses)-net .....	<b>3,302</b>	(3,201)	<b>35,505</b>
<b>Income before income taxes and minority interests</b> .....	<b>43,143</b>	40,271	<b>463,903</b>
<b>Income taxes</b> (Note 9):			
Current .....	<b>17,393</b>	16,217	<b>187,021</b>
Deferred .....	<b>(2,338)</b>	52	<b>(25,140)</b>
Total income taxes .....	<b>15,055</b>	16,269	<b>161,881</b>
Income before minority interests .....	<b>28,088</b>	24,002	<b>302,022</b>
<b>Minority interests in income</b> .....	<b>(210)</b>	(235)	<b>(2,259)</b>
<b>Net income</b> .....	<b>¥ 27,878</b>	¥ 23,767	<b>\$ 299,763</b>
<b>Per share of common stock</b> (Notes 2.o & 16):			
Basic net income .....	<b>¥ 256.38</b>	¥ 216.07	<b>\$ 2.76</b>
Cash dividends applicable to the year .....	<b>180.00</b>	180.00	<b>1.94</b>

See accompanying notes to consolidated financial statements.

## Consolidated Statements of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

	Thousands				Millions of yen						
	Outstanding number of shares of common stock	Common stock	Capital surplus	Retained earnings	Unrealized gain on available-for-sale securities	Land revaluation difference	Foreign currency translation adjustments	Treasury stock	Total	Minority interests	Total equity
BALANCE, APRIL 1, 2008 .....	113,373	¥17,358	¥17,080	¥421,279	¥17,112	¥(8,919)	¥(21)	¥(36,861)	¥427,028	¥3,235	¥430,263
Net income .....				23,767					23,767		23,767
Cash dividends, ¥202 per share .....				(22,485)					(22,485)		(22,485)
Purchase of treasury stock .....	(4,635)							(26,564)	(26,564)		(26,564)
Reversal of revaluation reserve for land .....				4					4		4
Net change in the year .....					(14,941)	(4)	(183)		(15,128)	184	(14,944)
BALANCE, MARCH 31, 2009 .....	108,738	17,358	17,080	422,565	2,171	(8,923)	(204)	(63,425)	386,622	3,419	390,041
Net income .....				27,878					27,878		27,878
Cash dividends, ¥180 per share .....				(19,573)					(19,573)		(19,573)
Purchase of treasury stock .....	(4)							(14)	(14)		(14)
Net change in the year .....					7,536		30		7,566	211	7,777
BALANCE, MARCH 31, 2010 .....	108,734	¥17,358	¥17,080	¥430,870	¥9,707	¥(8,923)	¥(174)	¥(63,439)	¥402,479	¥3,630	¥406,109

	Thousands of U.S. dollars (Note 1)										
	Common stock	Capital surplus	Retained earnings	Unrealized gain on available-for-sale securities	Land revaluation difference	Foreign currency translation adjustments	Treasury stock	Total	Minority interests	Total equity	
BALANCE, APRIL 1, 2009 .....	\$186,645	\$183,656	\$4,543,710	\$23,344	\$(95,946)	\$(2,194)	\$(681,989)	\$4,157,226	\$36,763	\$4,193,989	
Net income .....			299,763					299,763		299,763	
Cash dividends, \$1.94 per share .....			(210,462)					(210,462)		(210,462)	
Purchase of treasury stock .....							(151)	(151)		(151)	
Net change in the year .....				81,032		323		81,355	2,269	83,624	
BALANCE, MARCH 31, 2010 .....	\$186,645	\$183,656	\$4,633,011	\$104,376	\$(95,946)	\$(1,871)	\$(682,140)	\$4,327,731	\$39,032	\$4,366,763	

See accompanying notes to consolidated financial statements.



# Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2010	2009	2010
<b>Operating activities:</b>			
Income before income taxes and minority interests .....	¥ 43,143	¥ 40,271	\$ 463,903
Adjustments for:			
Income taxes paid .....	(18,084)	(20,890)	(194,452)
Depreciation and amortization .....	3,012	3,005	32,387
Increase (decrease) in allowance for doubtful receivables .....	10	(1)	108
Decrease in liability for retirement benefits .....	(1,641)	(6,428)	(17,645)
Gain on sales of investment securities .....	(85)	(1,327)	(914)
Loss on devaluation of investment securities .....	-	7,808	-
Changes in assets and liabilities, net of effects			
Increase in interest and dividends receivable .....	280	241	3,011
Decrease in trade notes and accounts receivable .....	7,856	1,649	84,473
Increase in inventories .....	(4,567)	(88)	(49,108)
Increase (decrease) in trade notes and accounts payable .....	(600)	44	(6,452)
Others-net .....	(8,023)	241	(86,268)
<b>Net cash provided by operating activities .....</b>	<b>21,301</b>	<b>24,525</b>	<b>229,043</b>
<b>Investing activities:</b>			
Payments for purchases of marketable securities .....	(33,379)	(93,655)	(358,914)
Proceeds from sales of marketable securities .....	86,120	158,963	926,022
Payments for purchases of property, plant and equipment .....	(3,211)	(1,509)	(34,527)
Payments for purchases of investment securities .....	(32,348)	(34,969)	(347,828)
Proceeds from sales of investment securities .....	174	2,205	1,871
Others-net .....	(479)	(308)	(5,150)
<b>Net cash provided by investment activities .....</b>	<b>16,877</b>	<b>30,727</b>	<b>181,474</b>
<b>Financing activities:</b>			
Repayment of current portion of long-term debt .....	(2)	(1)	(22)
Payments for purchases of treasury stock .....	(13)	(26,563)	(140)
Cash dividends .....	(19,549)	(22,449)	(210,204)
Cash dividends to minority shareholders .....	(4)	(5)	(43)
<b>Net cash used in financing activities .....</b>	<b>(19,568)</b>	<b>(49,018)</b>	<b>(210,409)</b>
<b>Foreign currency translation adjustments</b>			
on cash and cash equivalents .....	26	(206)	280
<b>Net increase in cash and cash equivalents .....</b>	<b>18,636</b>	<b>6,028</b>	<b>200,388</b>
<b>Cash and cash equivalents, beginning of year .....</b>	<b>53,461</b>	<b>47,433</b>	<b>574,849</b>
<b>Cash and cash equivalents, end of year .....</b>	<b>¥ 72,097</b>	<b>¥ 53,461</b>	<b>\$ 775,237</b>

See accompanying notes to consolidated financial statements.

## ■ Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2010 and 2009

### Note 1

#### **Basis of Presenting Consolidated Financial Statements**

The accompanying consolidated financial statements of Ono Pharmaceutical Co., Ltd. (the “Company”) and its subsidiaries have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in conformity with accounting principles generally accepted in Japan (“Japanese GAAP”), which are different in certain respects as to application and disclosure requirements of International Financial Reporting Standards.

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2009 financial statements to conform to the classifications used in 2010.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which the Company is incorporated and principally operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥ 93 to \$1, the approximate rate of exchange at March 31, 2010. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

### Note 2

#### **Summary of Significant Accounting Policies**

##### ***a. Consolidation and investments in affiliates***

The consolidated financial statements include the accounts of the Company and its four subsidiaries, consisting of two companies in Japan and two foreign subsidiaries at March 31, 2010 (together, the “Group”). Under the control or influence concept, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Company has the ability to exercise significant influence are accounted for by the equity method. Investments in two affiliated companies are accounted for by the equity method.

All significant intercompany transactions and accounts and unrealized intercompany profits are eliminated in consolidation.

The difference between the cost and underlying net assets of investments in subsidiaries at the time of acquisition is charged to income because it is immaterial.

The Company’s two foreign subsidiaries are consolidated using a fiscal year ending December 31. Any material effects occurring during January 1 to March 31 periods are adjusted in the consolidated financial statements.

##### ***b. Cash Equivalents***

Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value.

Cash equivalents include time deposits, certificates of deposit, commercial paper and bond funds, all of which mature or become due within three months of the date of acquisition.

#### **c. Marketable and investment securities**

Marketable and investment securities are classified and accounted for, depending on management's intent, as follows:

i) held-to-maturity debt securities, which are expected to be held to maturity with the positive intent and ability to hold to maturity are reported at amortized cost and ii) available-for-sale securities, which are not classified as the aforementioned securities, are reported at fair value, with unrealized gains and losses, net of applicable taxes, reported in a separate component of shareholders' equity. Non-marketable available-for-sale securities are stated at cost determined by the moving-average method. For other than temporary declines in fair value, investment securities are reduced to net realizable value by a charge to income.

#### **d. Inventories**

Inventories are stated principally at the lower of cost, determined by the first-in, first-out method, or net selling value.

#### **e. Property, Plant and Equipment and Intangible assets**

Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is principally computed using the declining balance method at rates based on the estimated useful lives of the assets, which are principally as stated below.

Buildings and structures: 15 - 50 years

Machinery and equipment: 4 - 8 years

Those buildings, excluding structures, which were acquired on or after April 1, 1998, are depreciated using the straight-line method.

Maintenance and repairs including minor renewals and improvements are charged to income as incurred.

Intangible assets are amortized using the straight-line method.

#### **f. Long-lived assets**

The Group reviews its long-lived assets for impairment whenever events or changes in circumstance indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss would be recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.

#### **g. Retirement benefits and pension plans**

The employees whose service with the Company and its domestic subsidiaries is terminated are, under most circumstances, entitled to a combination of lump-sum severance indemnities and pension payments, determined by reference to current basic rate of pay, length of service and conditions under which the termination occurs. Certain subsidiaries provide a reserve for retirement allowances for directors, executive officers and corporate auditors in required amounts calculated based on bylaws. "Partial Amendments to Accounting Standard for Retirement Benefits (Part3)" (the Accounting Standards Board of Japan (the "ASBJ") Statement No. 19, issued on July 31, 2008) became effective from the fiscal year beginning on and after April 1, 2009. Accordingly, The Group has applied them from this fiscal year. This accounting method has no impact on the consolidated financial statements for the fiscal year ended March 31, 2010.

#### **h. Research and development costs**

Expenses and costs relating to research and development activities are charged to income as incurred.

***i. Leases***

In March 2007, the ASBJ issued ASBJ Statement No.13, "Accounting Standard for Lease Transactions", which revised the previous accounting standard for lease transactions issued in June 1993. The revised accounting standard for lease transactions is effective for fiscal years beginning on or after April 1, 2008, with early adoption permitted for fiscal years beginning on or after April 1, 2007. Under the previous accounting standard, finance leases that deem to transfer ownership of the leased property to the lessee were to be capitalized. However, other finance leases were permitted to be accounted for as operating lease transactions if certain "as if capitalized" information was disclosed in the note to the lessee's financial statements. The revised accounting standard requires that all finance lease transactions should be capitalized to recognize lease assets and lease obligations in the balance sheet. In addition, the revised accounting standard permits leases which existed at the transition date and do not transfer ownership of the leased property to the lessee to be accounted for as operating lease transactions. The Company applied the revised accounting standard effective April 1, 2008. In addition, the Company accounted for leases which existed at the transition date and do not transfer ownership of the leased property to the lessee as operating lease transactions. All other leases are accounted for as operating leases.

***j. Bonuses to directors and corporate auditors***

Bonuses to directors and corporate auditors are accrued at the year end to which such bonuses are attributable.

***k. Income taxes***

The provision for income taxes is computed based on the pretax income included in the consolidated statements of income.

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement basis and the tax basis of assets and liabilities. Deferred taxes are measured by applying currently enacted tax laws to the temporary differences.

***l. Foreign Currency Transactions***

All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the income statement to the extent that they are not hedged by forward exchange contracts.

***m. Foreign Currency Financial Statements***

The balance sheet accounts of the foreign subsidiaries are translated into Japanese yen at the current exchange rate as of the balance sheet date except for equity, which is translated at the historical rate. Differences arising from such translation are shown as "Foreign currency translation adjustments" in a separate component of equity. Revenue and expense accounts of foreign subsidiaries are translated into yen at the average exchange rate.

***n. Derivatives and Hedging Activities***

The Company uses derivative financial instruments to manage its exposures to fluctuations in foreign exchange. Foreign exchange forward contracts are utilized by the Company to reduce foreign currency exchange risks. The Company does not enter into derivatives for trading or speculative purposes.

If the derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions.

***o. Per share information***

Basic net income per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding for the period, retroactively adjusted for stock splits. Cash dividends per share presented in the accompanying consolidated statements of income are dividends applicable to the respective years including dividends to be paid after the end of the year.

#### ***p. New Accounting Pronouncements***

##### ***Business Combinations***

In December 2008, the ASBJ issued a revised accounting standard for business combinations, ASBJ Statement No.21, “Accounting Standard for Business Combinations”. Major accounting changes under the revised accounting standard are as follows;

- (1) The current accounting standard for business combinations allows companies to apply the pooling of interests method of accounting when certain specific criteria are met such that the business combination is essentially regarded as a uniting-of-interests. The revised standard requires to account for such business combinations by the purchase method and the pooling of interests method of accounting is no longer allowed.
- (2) The current accounting standard accounts for the research and development costs to be charged to income as incurred. Under the revised standard, an in-process research and development (IPR&D) costs acquired by the business combination are capitalized as an intangible asset.
- (3) The current accounting standard accounts for a bargain purchase gain (negative goodwill) to be systematically amortized within 20 years. Under the revised standard, the acquirer recognizes a bargain purchase gain in profit or loss on the acquisition date after reassessing whether it has correctly identified all of the assets acquired and all of the liabilities assumed with a review of such procedures used.

This standard is applicable to business combinations undertaken on or after April 1, 2010, with early adoption permitted for fiscal years beginning on or after April 1, 2009.

##### ***Unification of Accounting Policies Applied to Foreign Associated Companies for the Equity Method***

The current accounting standard requires to unify accounting policies within the consolidation group. However, the current guidance allows to apply the equity method for the financial statements of its foreign associated companies which have been prepared in accordance with generally accepted accounting principles in their respective jurisdictions without unification of accounting policies. In December 2008, the ASBJ issued ASBJ Statement No.16

(Revised 2008), “Revised Accounting Standard for Equity Method of Accounting for Investments”. The new standard requires adjustments to be made to conform the associate’s accounting policies for similar transactions and events under similar circumstances to those of the parent company when the associate’s financial statements are used in applying the equity method unless it is impracticable to determine adjustments. In addition, financial statements prepared by foreign associated companies in accordance with either International Financial Reporting Standards or the generally accepted accounting principles in the United States tentatively may be used in applying the equity method if the following items are adjusted so that net income is accounted for in accordance with Japanese GAAP unless they are not material: 1) amortization of goodwill; 2) scheduled amortization of actuarial gain or loss of pensions that has been directly recorded in the equity; 3) expensing capitalized development costs of R&D; 4) cancellation of the fair value model accounting for property, plant, and equipment and investment properties and incorporation of the cost model accounting; 5) recording the prior years’ effects of changes in accounting policies in the income statement where retrospective adjustments to the financial statements have been incorporated; and 6) exclusion of minority interests from net income, if contained. This standard is applicable to equity method of accounting for investments effective on or after April 1, 2010, with early adoption permitted for fiscal years beginning on or after April 1, 2009.

##### ***Asset Retirement Obligations***

In March 31, 2008, the ASBJ published a new accounting standard for asset retirement obligations, ASBJ Statement No.18 “Accounting Standard for Asset Retirement Obligations” and ASBJ Guidance No.21 “Guidance on Accounting Standard for Asset Retirement Obligations”. Under this accounting standard, an asset retirement obligation is defined as a legal obligation imposed either by law or contract that results from the acquisition, construction, development and the normal operation of a tangible fixed asset and is associated with the retirement of such tangible fixed asset. The asset retirement obligation is recognized as the sum of the discounted cash flows required

for the future asset retirement and is recorded in the period in which the obligation is incurred if a reasonable estimate can be made. If a reasonable estimate of the asset retirement obligation cannot be made in the period the asset retirement obligation is incurred, the liability should be recognized when a reasonable estimate of asset retirement obligation can be made. Upon initial recognition of a liability for an asset retirement obligation, an asset retirement cost is capitalized by increasing the carrying amount of the related fixed asset by the amount of the liability. The asset retirement cost is subsequently allocated to expense through depreciation over the remaining useful life of the asset. Over time, the liability is accreted to its present value each period. Any subsequent revisions to the timing or the amount of the original estimate of undiscounted cash flows are reflected as an increase or a decrease in the carrying amount of the liability and the capitalized amount of the related asset retirement cost. This standard is effective for fiscal years beginning on or after April 1, 2010, with early adoption permitted for fiscal years beginning on or before March 31, 2010.

### ***Segment Information Disclosures***

In March 2008, the ASBJ revised ASBJ Statement No. 17 “Accounting Standard for Segment Information Disclosures” and issued ASBJ Guidance No.20 “Guidance on Accounting Standard for Segment Information Disclosures”. Under the standard and guidance, an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and such information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments. This accounting standard and the guidance are applicable to segment information disclosures for the fiscal years beginning on or after April 1, 2010.

### ***Accounting Changes and Error Corrections***

In December 2009, the ASBJ issued ASBJ Statement No. 24 “Accounting Standard for Accounting Changes and Error Corrections” and ASBJ Guidance No. 24 “Guidance on Accounting Standard for Accounting Changes and Error Corrections”. Accounting treatments under this standard and guidance are as follows;

(1) Changes in Accounting Policies:

When a new accounting policy is applied with revision of accounting standards, a new policy is applied retrospectively unless the revised accounting standards include specific transitional provisions. When the revised accounting standards include specific transitional provisions, an entity shall comply with the specific transitional provisions.

(2) Changes in Presentations

When the presentation of financial statements is changed, prior period financial statements are reclassified in accordance with the new presentation.

(3) Changes in Accounting Estimates

A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods.

(4) Corrections of Prior Period Errors

When an error in prior period financial statements is discovered, those statements are restated. This accounting standard and the guidance are applicable to accounting changes and corrections of prior period errors which are made from the beginning of the fiscal year that begins on or after April 1, 2011.

### Note 3

#### Financial Instruments and related disclosures

In March 2008, the ASBJ revised ASBJ Statement No. 10 “Accounting Standard for Financial Instruments” and issued ASBJ Guidance No.19 “Guidance on Accounting Standard for Financial Instruments and Related Disclosures”. This accounting standard and the guidance are applicable to financial instruments and related disclosures at the end of the fiscal years ending on or after March 31, 2010 with early adoption permitted from the beginning of the fiscal years ending before March 31, 2010. The Group applied the revised accounting standard and the new guidance effective March 31, 2010.

##### (1) Group policy for financial instruments

The Group manages its funds through investment in bonds (mainly government bonds). Highly liquid financial instruments are preferred in order to meet short-term capital needs to conduct daily pharmaceutical business activities. Derivatives are used to manage the impact of financial risks of foreign exchange rate fluctuation for payables denominated in foreign currencies including those for overseas clinical trials, but not for speculative dealings.

##### (2) Financial instruments, its associated risks and the risk management

Receivables such as trade notes and trade accounts are exposed to customer credit risk. In order to reduce such risks, due dates and amounts outstanding are strictly managed for each client in accordance with the Group’s standards pertaining to the management of sales and also the credit standing of major clients has been monitored semiannually.

Marketable and investment securities are mainly held-to-maturity securities and equity instruments of business partners of the Group, and are exposed to the risk of market price fluctuations. Fair values of those investments is regularly monitored by the officers.

Derivatives are managed according to the Company’s regulations. In order to reduce credit risk, the counterparties to these derivatives are limited to major international financial institutions with high credit rating. Please see Note 12 for more detail about derivatives.

##### (3) Fair value of financial instruments

Carrying amount, fair value and net unrealized gain/loss of the financial instruments as of March 31, 2010 (balance sheet date for the current fiscal year) are shown in the table below. It does not include items for which the fair value is recognized to be infeasible to accurately determine (See note b).

March 31, 2010	Millions of yen		
	Carrying amount	Fair value	Unrealized gain/loss
Cash and cash equivalents .....	¥ 72,097	¥ 72,097	–
Trade notes and accounts receivable .....	31,625	31,625	–
Marketable and investment securities			
Held-to-maturity .....	138,127	139,859	¥ 1,732
Available-for-sale .....	90,830	90,830	–
Income taxes payable .....	8,421	8,421	–
Derivative transactions .....	–	–	–

March 31, 2010	Thousands of U.S. dollars		
	Carrying amount	Fair value	Unrealized gain/loss
Cash and cash equivalents .....	\$ 775,237	\$ 775,237	–
Trade notes and accounts receivable .....	340,054	340,054	–
Marketable and investment securities			
Held-to-maturity .....	1,485,237	1,503,860	\$ 18,623
Available-for-sale .....	976,667	976,667	–
Income taxes payable .....	90,548	90,548	–
Derivative transactions .....	–	–	–

(a) Calculation of the fair value of financial instruments, and matters pertaining to securities and derivative transactions

***Cash and cash equivalents***

The carrying values of cash and cash equivalents approximate fair value because of their short maturities.

***Marketable and investment securities***

The fair values of marketable and investment securities are measured at the quoted market price of the stock exchange for the equity instruments, and at the quoted price obtained from the financial institution or notice by Japan Securities Dealers Association for certain debt instruments. The information of the fair value for the marketable and investment securities by classification is included in Note 4.

***Trade notes and accounts receivable, income taxes payable***

The carrying values of trade notes and accounts receivable, and income taxes payable approximate fair value because of their short maturities.

***Derivatives***

The information of the fair value for derivatives is included in Note 12.

(b) Financial instruments whose fair value cannot be reliably determined

March 31, 2010	Carrying amount	
	Millions of yen	Thousands of U.S. dollars
Investments in equity instruments that do not have a quoted market price in an active market .....	¥ 1,080	\$ 11,612

The above financial instruments are not included in marketable and investment securities because they have no market price and their fair value cannot be reliably determined.



(4) Maturity analysis for financial assets and securities with contractual maturities

	Millions of Yen			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
<b>March 31, 2010</b>				
Cash and cash equivalents .....	¥ 72,097	-	-	-
Trade notes and accounts receivable .....	31,625	-	-	-
Marketable and investment securities				
Held-to-maturity .....	30,100	¥ 107,560	-	-
Available-for-sale .....	10,000	655	¥ 3,000	-
Total .....	¥ 143,822	¥ 108,215	¥ 3,000	-

	Thousands of U.S.Dollars			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
<b>March 31, 2010</b>				
Cash and cash equivalents .....	\$ 775,237	-	-	-
Trade notes and accounts receivable .....	340,054	-	-	-
Marketable and investment securities				
Held-to-maturity .....	323,656	\$ 1,156,559	-	-
Available-for-sale .....	107,526	7,043	\$ 32,258	-
Total .....	\$ 1,546,473	\$ 1,163,602	\$ 32,258	-

**Note 4****Marketable and investment securities**

Marketable and investment securities as of March 31, 2010 and 2009 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Current:			
Government and corporate bonds .....	¥ 40,170	¥ 62,800	\$ 431,935
Non-current:			
Marketable and other equity securities .....	76,089	65,146	818,161
Government and corporate bonds .....	111,608	110,757	1,200,086
Trust fund investments and other .....	2,170	1,724	23,334
Total .....	¥ 189,867	¥ 177,627	\$ 2,041,581

The costs and aggregate fair values of marketable and investment securities at March 31, 2010 and 2009 were as follows:

March 31, 2010	Millions of yen			Fair value
	Cost	Unrealized gains	Unrealized losses	
Securities classified as:				
Available-for-sale:				
Equity securities .....	¥ 60,512	¥ 15,700	¥ (946)	¥ 75,266
Debt securities .....	13,801	2	(151)	13,652
Trust fund investments and other .....	1,599	330	(17)	1,912
Held-to-maturity .....	138,127	1,753	(21)	139,859
March 31, 2009				
Securities classified as:				
Available-for-sale:				
Equity securities .....	¥ 59,389	¥ 7,109	¥ (2,226)	¥ 64,272
Debt securities .....	34,780	9	(212)	34,577
Trust fund investments and other .....	1,610	–	(132)	1,478
Held-to-maturity .....	138,980	1,317	(29)	140,268
March 31, 2010	Thousands of U.S. dollars			Fair value
	Cost	Unrealized gains	Unrealized losses	
Securities classified as:				
Available-for-sale:				
Equity securities .....	\$ 650,667	\$ 168,817	\$ (10,172)	\$ 809,312
Debt securities .....	148,398	22	(1,624)	146,796
Trust fund investments and other .....	17,194	3,548	(183)	20,559
Held-to-maturity .....	1,485,237	18,849	(226)	1,503,860

Available-for-sale securities and held-to-maturity securities whose fair value is not readily determinable as of March 31, 2009 was as follows. The similar information for 2010 is disclosed in Note 3.

	Carrying amount	
	Millions of yen	
	2009	
Available-for-sale:		
Equity securities.....	¥ 874	
Trust fund investments and other .....	246	
Total .....	¥ 1,120	

Proceeds from sales of available-for-sale securities for the year ended March 31, 2009 were ¥ 14,191 million. Gross realized gains on these sales, computed on the moving average cost basis, were ¥1,330 million for the year ended March 31, 2009.

The information of available-for-sale securities which were sold during the year ended March 31, 2010 was as follows:

March 31, 2010	Millions of yen		
	Proceeds	Realized gains	Realized loss
Available-for-sale:			
Equity securities.....	¥ 164	¥ 85	-
Debt securities.....	0	-	¥ 0
Total .....	¥ 164	¥ 85	¥ 0

March 31, 2010	Thousands of U.S. dollars		
	Proceeds	Realized gains	Realized loss
Available-for-sale:			
Equity securities.....	\$ 1,763	\$ 914	-
Debt securities.....	0	-	\$ 0
Total .....	\$ 1,763	\$ 914	\$ 0

## Note 5 Inventories

Inventories at March 31, 2010 and 2009 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Merchandise.....	¥ 275	¥ 320	\$ 2,957
Finished products.....	5,501	4,165	59,151
Semi-finished products .....	4,037	954	43,409
Work in process.....	1,386	1,195	14,903
Raw materials and supplies.....	3,427	3,425	36,849
Total.....	¥ 14,626	¥ 10,059	\$ 157,269

**Note 6****Long-term debt**

Long-term loans payable at March 31, 2010 and 2009 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Unsecured loans for employees <sup>(*)</sup> .....	¥ 16	¥ 18	\$ 173
Less current portion .....	(2)	(2)	(22)
Long-term debt, less current portion.....	¥ 14	¥ 16	\$ 151

<sup>(\*)</sup>At March 31, 2010 and 2009: Interest rates ranging from 3.25% to 3.40%, maturing serially to March, 2026

At March 31, 2010, the annual maturities of long-term debt were as follows:

Years ending March 31	Millions of yen	Thousands of U.S. dollars
2011 .....	¥ 2	\$ 22
2012 .....	2	22
2013 .....	1	10
2014 .....	2	22
2015 .....	1	10
2016 and thereafter .....	8	87
Total .....	¥ 16	\$ 173

**Note 7****Retirement benefits and pension**

The liability for retirement benefits at March 31, 2010 and 2009 consisted of the followings:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Projected benefit obligation .....	¥ 38,448	¥ 37,711	\$ 413,419
Fair value of plan assets (including a pension trust) .....	(39,207)	(32,294)	(421,580)
Unrecognized actuarial loss (gain) .....	1,270	(3,259)	13,656
Net liability for retirement benefits, employees .....	511	2,158	5,495
Liability for retirement benefits, officers .....	88	82	946
Liability for retirement benefits, total .....	¥ 599	¥ 2,240	\$ 6,441

In September and March 2009, the Company contributed ¥5,000 million (\$53,763 thousand) and ¥10,000 million by cash respectively, to the employee retirement benefit trust for the Company's contributory pension plans.

Net periodic benefit cost for the years ended March 31, 2010 and 2009 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Service cost .....	¥ 1,581	¥ 1,552	\$ 17,000
Interest cost .....	526	516	5,655
Expected return on plan assets .....	(569)	(505)	(6,118)
Recognized actuarial loss .....	3,289	3,070	35,366
Net periodic benefit cost .....	4,827	4,633	51,903
Others .....	225	213	2,420
Total .....	¥ 5,052	¥ 4,846	\$ 54,323

Actuarial assumptions used for the years ended March 31, 2010 and 2009 are set forth as follows:

- 1) Method of attribution of retirement benefits to the period: Straight-line method for the years of service
- 2) Discount rate: 1.4%
- 3) Expected rate of return on plan assets: 1.0% - 2.0%
- 4) Prior service cost is expensed in the year in which the cost is recognized.
- 5) Actuarial gain or loss is expensed in the year following the year in which the gain or loss is recognized.

## Note 8

### Equity

Since May 1, 2006, Japanese companies have been subject to the Companies Act of Japan (the "Companies Act"). The significant provisions in the Companies Act that affect financial and accounting matters are summarized below:

#### (a) Dividends

Under the Companies Act, companies can pay semiannual interim dividends once a year in addition to the year-end dividend upon resolution by the Board of Directors if the articles of incorporation of the company so stipulate.

The Companies Act provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than ¥3 million.

#### (b) Increases / decreases and transfer of common stock, reserve and surplus

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the total of aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reversed without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus and retained earnings can be transferred among the accounts under certain conditions upon resolution of the shareholders.

#### (c) Treasury stock and treasury stock acquisition rights

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the Board of Directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders which is determined by specific formula.

**Note 9****Income taxes**

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 40.6% for the years ended March 31, 2010 and 2009.

The tax effects of significant temporary differences, which resulted in deferred tax assets and liabilities at March 31, 2010 and 2009, were as follows:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Deferred tax assets:			
Current assets:			
Prepaid R&D expenditures .....	¥ 9,515	¥ 9,092	\$ 102,312
Accrued bonuses .....	1,591	1,560	17,108
Accrued enterprise taxes .....	767	799	8,247
Depreciation and amortization .....	838	721	9,011
Others .....	1,042	889	11,204
Non-current assets:			
Provision for retirement benefits .....	6,313	4,930	67,882
Loss on valuation of investment securities .....	4,226	4,319	45,441
Depreciation and amortization .....	822	796	8,839
Others .....	2,190	2,230	23,548
Less valuation allowance .....	(4,203)	(4,572)	(45,194)
Total .....	23,101	20,764	248,398
Deferred tax liabilities:			
Long-term liabilities:			
Unrealized gain on available-for-sale securities .....	(5,113)	(2,295)	(54,978)
Revaluation of land .....	(2,941)	(2,941)	(31,624)
Others .....	(281)	(281)	(3,021)
Total .....	(8,335)	(5,517)	(89,623)
Net deferred tax assets .....	¥ 14,766	¥ 15,247	\$ 158,775

For the year ended March 31, 2009, because the differences between the normal effective statutory tax rate and the actual effective tax rate were not material, the tax reconciliation is not disclosed.

A reconciliation between the statutory tax rate and the effective income tax rate reflected for the year ended March 31, 2010 was as follows:

	<b>2010</b>
Statutory tax rate .....	40.6%
Expenses not permanently deductible for income tax purposes, such as entertainment expenses...	5.2
Income not permanently taxable for income tax purposes, such as dividend income .....	(0.7)
Tax credit for experiment and research expenses.....	(9.1)
Valuation allowance .....	(0.9)
Other - net .....	(0.2)
Effective tax rate.....	<b>34.9%</b>

## Note 10

### R&D expenditures

Research and development expenditures for the years ended March 31, 2010 and 2009 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	<b>2010</b>	2009	<b>2010</b>
Selling, general and administrative expenses .....	<b>¥ 39,712</b>	¥ 38,383	<b>\$ 427,011</b>
Cost of sales .....	<b>5</b>	17	<b>54</b>
Total .....	<b>¥ 39,717</b>	¥ 38,400	<b>\$ 427,065</b>

## Note 11

### Leases

The Group leases certain equipment, computers, office space and other assets.

As discussed in Note 2-i, the Company accounts for leases which existed at the transition date and do not transfer ownership of the leased property to the lessee as operating lease transactions. Pro forma information of such leases existing at the transition date, such as acquisition cost, accumulated depreciation, obligations under finance leases, depreciation expense, interest expense, on a "as if capitalized" basis for the years ended March 31, 2010 and 2009 was as follows:

#### 1. Acquisition cost, accumulated depreciation and net leased property

	Millions of yen		Thousands of U.S. dollars
	<b>2010</b>	2009	<b>2010</b>
	Machinery, equipment and others	Machinery, equipment and others	Machinery, equipment and others
Acquisition cost .....	<b>¥ 4</b>	¥ 13	<b>\$ 43</b>
Accumulated depreciation .....	<b>3</b>	10	<b>32</b>
Net leased property .....	<b>¥ 1</b>	¥ 3	<b>\$ 11</b>

## 2. Obligations under finance leases

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Due within one year.....	¥ 1	¥ 2	\$ 11
Due after one year .....	0	1	0
Total .....	¥ 1	¥ 3	\$ 11

## 3. Actual lease payments, depreciation expense of leased property

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Depreciation expense.....	¥ 2	¥ 3	\$ 22
Actual lease payments .....	2	3	22

Depreciation expense for leased properties, which is not reflected in the accompanying consolidated statements of income, is computed using the straight-line method over the estimated useful lives of the leased properties.

The minimum rental commitments under noncancelable operating leases at March 31, 2010 were as follows:

(lessee)

	Millions of yen		Thousands of U.S. dollars
	2010		2010
Due within one year.....	¥ 87		\$ 935
Due after one year .....	263		2,828
Total .....	¥ 350		\$ 3,763

(lessor)

	Millions of yen		Thousands of U.S. dollars
	2010		2010
Due within one year.....	¥ 16		\$ 172
Due after one year .....	54		581
Total .....	¥ 70		\$ 753



## Note 12

### Derivatives

The Company enters into forward foreign exchange contracts to hedge against the risk of foreign exchange rate fluctuation for payables denominated in foreign currencies, but does not use derivative transactions for speculative purposes or for gaining quick profits from sales of financial instruments.

Because the counterparties to these derivatives are limited to major international financial institutions, the Company believes there is little credit risk in dealing with them.

The Company utilizes forward foreign exchange contracts within the normal transaction range established for these banks. These forward foreign exchange contracts are entered into by the Accounting Department and the results of settlement of the contracts are regularly monitored by the Board of Directors.

As noted in Note 3, the Group applied ASBJ Statement No. 10 "Accounting Standard for Financial Instruments" and ASBJ Guidance No.19 "Guidance on Accounting Standard for Financial Instruments and Related Disclosures". The accounting standard and the guidance are applicable to financial instruments and related disclosures at the end of the fiscal years ending on or after March 31, 2010; therefore, the required information is disclosed only for 2010.

The Company did not have any open derivatives positions as of March 31, 2010.

## Note 13

### Other income and expenses

'Other-net' of other income (expenses) for the years ended March 31, 2010 and 2009 in the consolidated statements of income consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Gain on sales of investment securities .....	¥ 85	¥ 1,327	\$ 914
Gain on refund of research and development expenses for prior periods...	346	-	3,720
Reversal of allowance for doubtful receivables .....	-	0	-
Others, net .....	(92)	(38)	(989)
Total .....	¥ 339	¥ 1,289	\$ 3,645

**Note 14****Land revaluation difference**

In accordance with the Act concerning Revaluation of Land, land used for businesses owned by the Company was revalued. The unrealized gain or loss, net of deferred tax, was excluded from earnings and reported as "Land revaluation difference" in changes in equity, and the relevant deferred tax was included as "Deferred tax liabilities" in liabilities.

Related information is shown as follows:

Date of revaluation: March 31, 2002

	Millions of yen	Thousands of U.S. dollars
Difference between book value of land after revaluation and fair value at March 31, 2010 .....	¥ (3,084)	\$ (33,161)

**Note 15****Commitments and contingent liabilities**

There were no material commitments and contingent liabilities at March 31, 2010 and 2009.

**Note 16****Net income per share**

Net income after giving effect to the diluted potential of common stock has not been presented since there are no such potential shares to be issued.

Information for the computation of net income per share ("EPS") is as follows:

	Millions of yen	Thousands of shares	Yen	Dollars
	Net income	Weighted average shares	EPS	
<b>For the year ended March 31, 2010:</b>				
Basic EPS				
Net income available to common shareholders.....	¥ 27,878	108,736	¥ 256.38	\$ 2.76
<b>For the year ended March 31, 2009:</b>				
Basic EPS				
Net income available to common shareholders.....	¥ 23,767	109,995	¥ 216.07	

## Note 17

### Subsequent event

#### Appropriation of Retained Earnings

The following appropriation of retained earnings at March 31, 2010 was approved at the Company's shareholders meeting held on June 29, 2010:

	Millions of yen	Thousands of U.S. dollars
Year-end cash dividends, ¥90 (\$0.97) per share .....	¥ 9,786	\$ 105,226

## Note 18

### Segment information

#### (1) Business segment information

Information relating to business segments is omitted, as the Group operated solely in the 'pharmaceutical related business' for the years ended March 31, 2010 and 2009.

#### (2) Geographic area information

Information relating to geographic area is omitted, as 'Japan' accounted for more than 90% of net sales and assets of the Group for the years ended March 31, 2010 and 2009.

#### (3) Overseas sales information

Overseas sales of the Group to unrelated entities, which consisted of export sales from Japan including license royalty revenue, classified by geographic area for the years ended March 31, 2010 and 2009 were as follows:

	Millions of yen		Percentage in total net sales		Thousands of U.S. dollars
	2010	2009	2010	2009	2010
Europe .....	¥ 523	¥ 480	0.4%	0.3%	\$ 5,624
Asia .....	2,673	2,416	1.9	1.8	28,742
Other .....	1,484	1,529	1.1	1.1	15,957
Total .....	¥ 4,680	¥ 4,425	3.4%	3.2%	\$ 50,323

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors of Ono Pharmaceutical Co., Ltd.:

We have audited the accompanying consolidated balance sheets of Ono Pharmaceutical Co., Ltd. and subsidiaries ("the Company") as of March 31, 2010 and 2009, and the related consolidated statements of income, changes in equity, and cash flows for the years then ended, all expressed in Japanese yen. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ono Pharmaceutical Co., Ltd. and subsidiaries as of March 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in Japan.

Our audits also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in conformity with the basis stated in Note 1. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

*Deloitte Touche Tohmatsu LLC*

June 29, 2010

# Corporate Information

## BOARD OF DIRECTORS AND STATUTORY AUDITORS (as of June 29, 2010)

### Directors

#### Gyo Sagara

President, Representative Director and CEO

#### Hiroshi Awata

Senior Managing Director, Director of Development Headquarters

#### Kinya Morimoto

Managing Director, Director of Corporate Communication

#### Kazuhito Kawabata, Ph.D

Managing Director, Director of Research Headquarters, and Director of Minase Research Institute

#### Shinji Fujiyoshi

Managing Director, Director of Marketing Headquarters

#### Isao Ono

Executive Director, Director of Environment Management

#### Fumio Takahashi

Executive Director, Deputy Director of Marketing Headquarters, and Head of Marketing Promotion

#### Daikichi Fukushima, Ph.D

Executive Director, Director of Global Research Strategy Planning, Director of Tsukuba Research Institute, and Director of Advanced Medicinal Research Laboratories

#### Hiroshi Ichikawa

Executive Director, Director of Marketing Strategy Planning

#### Naonobu Endo

Executive Director, Director of Production & Distribution Headquarters

#### Shozo Matsuoka, Ph.D

Executive Director (part time)  
Chairman and CEO, Ono Pharma USA, Inc., Director of Global Development Headquarters

### Statutory Auditors

Shigeo Shimada (full time)

Kei Sano (full time)

Narihito Maishi

Yasuo Araki



Head Office

## ONO PHARMACEUTICAL CO., LTD.

<b>Founded</b>	1717
<b>Date of Incorporation</b>	July 4, 1947
<b>Paid-in Capital</b>	¥17,358 million (March 31, 2010)
<b>Number of Shareholders</b>	13,862 (March 31, 2010)
<b>Number of Employees</b>	2,430 (March 31, 2010)

### Head Office :

8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8564, Japan  
Tel : +81-6-6263-5670 Fax : +81-6-6263-2950

### Registered Office :

1-5, Doshomachi 2-chome, Chuo-ku, Osaka, Japan

### Branches in Japan :

Sapporo, Sendai, Tokyo I, Tokyo II, Kitakanto, Koshinetsu, Yokohama, Nagoya, Kyoto, Osaka, Kobe, Takamatsu, Hiroshima, Fukuoka

### Seoul Branch :

#1205, Sankoo Building, 70 Sogong-Dong, Chung-Ku, Seoul, 100-070, Korea  
Tel : +82-2-928-8423 Fax : +82-2-925-2151

### Research Institutes :

Minase Research Institute, Osaka, Japan  
Fukui Research Institute, Fukui, Japan  
Tsukuba Research Institute, Ibaraki, Japan

### Manufacturing Plants :

Fujiyama Plant, Shizuoka, Japan  
Joto Plant, Osaka, Japan

### Subsidiaries & Affiliates

#### Ono Pharma USA, Inc.

2000 Lenox Drive, Lawrenceville, NJ 08648, USA  
Tel : +1-609-219-1010 Fax : +1-609-219-9229

#### Ono Pharma UK Ltd

11th Floor, Marble Arch Tower  
55 Bryanston Street, London W1H 7AA, England  
Tel : +44-20-7258-5300 Fax : +44-20-7723-5812

#### Oriental Pharmaceutical & Synthetic Chemical Co., Ltd.

#### Bee Brand Medico Dental Co., Ltd.

#### Namicos Corporation

#### Tokai Capsule Co., Ltd.

<http://www.ono.co.jp>

