## **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. One 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, One 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.

#### **Contents**

Financial Highlights	1
Message from the Management	2
Aiming at Developing Original New Drugs to Global Standards	4
Key Product Profiles	10
Corporate Governance	13
Environment Management	14
Ono and the Community/Ono and Its Employees	16
Financial Section	17
Corporate Information	45

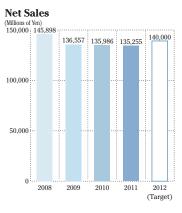


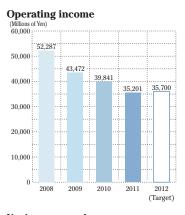
# Financial Highlights

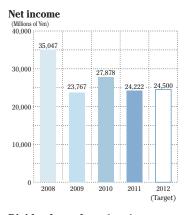
Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

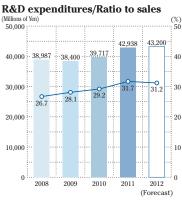
		Millions	of Yen		Thousand	s of U.S. Dollar
		2011		2010	4	2011
Net sales ····	¥	135,255	¥	135,986	\$1,6	29,578
R&D expenditures		42,938		39,717	5	17,325
Operating income		35,201		39,841	4	24,108
Net income ·····		24,222		27,878	2	291,831
Comprehensive income		18,820		35,659	2	226,747
Working capital		165,172		158,399	1,9	90,025
Property, plant and equipment		48,616		50,010	5	85,735
Total assets		424,443		433,226	5,1	13,771
Total equity		394,573		406,109	4,7	753,892
Per share of common stock:		Υe	en		U.S.	. Dollars
Net income ·····	¥	223.88	¥	256.38	\$	2.70
Cash dividends applicable to the year		180.00		180.00		2.17

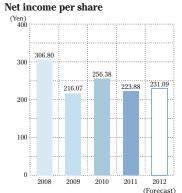
(U.S. Dollar amounts are translated at a rate of U.S.\$1 = \frac{4}{83}\$. See Notes to consolidated financial statements.)

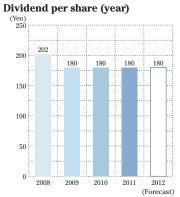












## **Message from the Management**



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 knowhow 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.

I 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 cuttingedge drug discovery technologies acquired through alliances with Japanese and foreign biopharmaceutical companies and through collaborations with academic and reserch 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 knowhow 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 from different departments, bringing 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, in alliance with academic and research insutitutions, undertakes analysis of disease-causing substances and exploratory research for new compounds that can control these substances, as well as 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 propel drug development in Asia, the newly established Asia Development Division is making strong contributions to Ono's global clinical development efforts embracing Asia.

## Forging Strategic Alliances with Biopharmaceuticals and Research Institutions Worldwide

Global Discovery Alliance Headquarters is actively pursuing drug discovery alliances with Japanese and foreign 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 knowhow, 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 knowhow in neuroscience research and gene assets acquired through genome research. Ono is in drug discovery collaboration with Array BioPharma Inc. of the US and Locus Pharmaceuticals, Inc. of the US, as well as Evotec AG of Germany, Xention Limited of the UK and BioSeek, LLC. of the US. 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. In the drug discovery alliance with Locus

researching into kinases, a new compound was discovered in February 2011 that is potentially effective against cancer and auto-immune disease.

Pre-clinical studies are currently underway at Opo In January

underway at Ono. In January 2011, Ono entered into a drug discovery alliance agreement with BioFocus of the UK, identifying new discovery targets for auto-

immune disease.

Ono is also eagerly pursuing research alliances with world-class leading-edge universities and research institutions. New discovery targets and technologies are being explored through these alliances



with the aim of identifying promising discovery targets and technologies 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. Thanks to this initiative to ensure dynamic global activities, Ono's development pipeline is thickening steadily in the context of the much-feared scarcity of new drug discovery successes. To illustrate, Ono was successful in 2006 in in-licensing a novel compound for cancer anorexia/cachexia (ONO-7643/RC-1291) from Sapphire Therapeutics, Inc. of the USA (now Helsinn Therapeutics (U.S.), Inc.), and in 2007 a short-active general anesthetic (ONO-2745/ CNS-7056) from CeNes Ltd of the UK (now PAION AG, Germany), and a therapeutic agent for thrombocytopenia (ONO-7746/NIP-022) from Nissan Chemical Industries, Ltd. Furthermore, in 2008, Ono in-licensed methylnaltrexone (ONO-3849), a drug for the treatment of intractable constipation induced by narcotic analgesic from Progenics Pharmaceuticals, Inc. of the US, and then in September 2009, in-licensed asimadoline (ONO-3951) which is under development in the USA for the treatment of diarrhea predominant irritable bowel syndrome (D-IBS) from Tioga Pharmaceuticals, Inc. of the US. In 2010, Ono in-licensed carfilzomib (ONO-

7057), a drug for the treatment of multiple myeloma, from Onyx Pharmaceuticals Inc. of the US, and salirasib (ONO-7056), a therapy drug for pancreatic cancer, from Concordia Pharmaceuticals Inc. of the US. In 2011, Ono in-licensed a liver cancer vaccine from OncoTherapy Science of Japan. Ono's active in-licensing drive will continue, strengthening the ever-expanding development pipeline.

## **New Drugs in Development** (As of September 2011)

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:

#### **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 autoimmune diseases such as multiple sclerosis, which is regarded as an intractable disease. Japan, US and Europe: Phase II / Multiple sclerosis (multi-national clinical trial)

## ONO-3849 / Methylnaltrexone bromide (injection)

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

Pharmaceuticals, Inc.)

#### **ONO-7643 / RC-1291** (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. The drug has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building (anabolic), and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer. Japan: Phase II / Cancer anorexia / cachexia US & Other Countries: Phase III / Cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

#### **ONO-2745 / CNS 7056** (injection)

ONO-2745 is an innovative short-acting general anaesthetic and sedative that is a GABAA receptor agonist, 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 II / General anaesthetic **US:** Phase II (PAION AG)

**ONO-7057 / Carfilzomib** (injection) ONO-7057 is a proteasome inhibitor under development for the treatment of multiple

myeloma, a cancer affecting the plasmocyte, which is a type of blood cell. The drug is expected to offer a new treatment option for this disease whose prognosis had been poor. **Japan:** Phase I / II / Multiple myeloma Overseas: Phase III (Onyx Pharmaceuticals, Inc.)

#### **ONO-5334** (tablet)

ONO-5334 is a cathepsin K inhibitor, a novel mechanism of action, and is being developed for osteoporosis. Unlike bisphosphonates, the drug only inhibits bone resorption without having any impact on bone formation.

**Japan:** Phase I / Osteoporosis **Europe:** Phase II / Osteoporosis

### ONO-4538 / BMS-936558 (MDX-1106) (injection)

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer and infections 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 / Malignant tumor US: Phase II / Renal cell carcinoma

(co-development with Bristol-Myers Squibb Company) **US:** Phase I / Hepatitis C (co-development

with Bristol-Myers Squibb Company)

## ONO-3951 / Asimadoline (tablet) ONO-3951 is a selective kappa opioid receptor agonist, and is under clinical

development for irritable bowel syndrome (IBS). By selectively targeting out of the three types of opioid receptors  $(\mu, \kappa, \delta)$ , the kappa receptor that is believed to be associated with pain and movement of the digestive tract, the drug relieves various abdominal symptoms including pain.

Japan: Phase I / IBS

US: Phase III / IBS (Tioga Pharmaceuticals,

#### **ONO-6950** (tablet)

ONO 6950 is a leukotriene receptor antagonist, under development for the treatment of bronchial asthma. By controlling inflammation of the airways, it is expected to relieve the symptoms of bronchial asthma patients.

Japan: Phase I / Bronchial asthma US: Phase I / Bronchial asthma

ONO-7746 (capsule) (In-licensed from Nissan Chemical Industries, LTD.) ONO-7746 is an orally active low molecule compound which may increase platelet count by activating a receptor of thrombopoietin, which is a hematopoietic factor to accelerate platelet production. It is therefore expected to be developed as a new drug which may reduce the risk of bleeding in various diseases with thrombocytopenia and overcome the risk of infection associated with platelet transfusion. Nissan Chemical Industries is participating in co-development by process development and manufacture of the drug substance.

#### **ONO-2952** (tablet)

**US:** Phase I / Thrombocytopenia

ONO-2952 is a TSPO (translocator protein) antagonist. TSPO is involved in the production of neurosteroids in the CNS. The drug is under development for the treatment of IBS. By blocking the mechanism whereby

stress triggers malfunction of brain-bowel interaction, it is expected to alleviate the range of IBS symptoms.

US: Phase I / IBS

#### **ONO-4053** (tablet)

ONO-4053 is a prostaglandine D2 receptor antagonist under development for the treatment of allergic rhinitis. Of the three main symptoms of allergic rhinitis, nasal congestion, sneezing and nasal discharge, it is especially expected to offer relief for congestion.

**Europe:** Phase I / Allergic rhinitis

Emend® Capsules (ONO-7436 / MK-0869) Japan: Phase III (additional indication in pediatric patients)/ Chemotherapy-induced nausea and vomiting

#### **Onoact**® for injection (ONO-1101)

Japan: Phase II / III / Tachyarrhythmia in cardiac hypofunction

#### **Opalmon**<sup>®</sup> **Tablets** (OP-1206)

Japan: Phase II / Carpal tunnel syndrome (co-development with Dainippon Sumitomo Pharma Co., Ltd.)

## **Key Product Profiles**

### Rivastach® Patch for the Treatment of Alzheimer's Disease

*Rivastach*<sup>®</sup> *Patch* is a transdermal patch for the treatment of Alzheimer's disease. It reduces the progression of deteriorating cognitive functions such as memory loss (forgetfulness) and disorientation (difficulty in recognizing time and place) by inhibiting acetylcholinesterase and thereby increasing the amount of acetylcholine in the brain and enhancing neurotransmission. (Launched July 2011)



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

Glactiv<sup>®</sup>, 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 2010 Sales: 11.1 billion yen (Launched December 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 2010 Sales: 4.7 billion ven (Launched December 2009)



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

Recalbon<sup>®</sup>, 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 2010 Sales: 2 billion yen (Launched April 2009)



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

Staybla<sup>®</sup> 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. In April 2011, orally disintegrating tablets (OD tablets) were launched as additional formulation.

#### FY 2010 Sales: 5.8 billion yen (Launched June 2007)



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

Opalmon® is an orally administered prostaglandin-E1 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 2010 Sales: 40.1 billion yen



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

Onon<sup>®</sup> 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 2010 Sales: 21.5 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 2010 Sales: 8.5 billion yen



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

*Kinedak*<sup>®</sup> 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 2010 Sales: 13.2 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 2010 Sales: 11 billion yen



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

*Elaspol*<sup>®</sup> 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 2010 Sales: 5 billion yen



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

*Onoact*<sup>®</sup> is a short-acting β<sub>1</sub> blocker that selectively blocks β1 receptors mainly found in the heart, and thereby slows down the increase of pulse rate that occurs during or after operations.

FY 2010 Sales: 3.6 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.

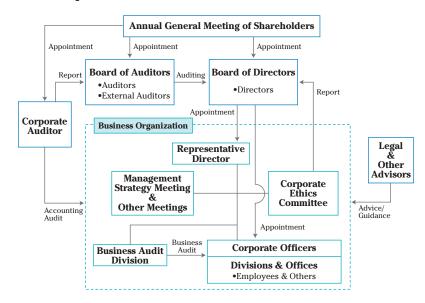
The Board of Directors aims to expedite decisionmaking by boosting corporate dynamic action. For that purpose we endeavor to ensure that the Board is comprised of the appropriate number of directors. Alongside the Corporate Executive system, the Board of Directors constitutes a system that allows management to respond speedily to changes in the business environment. External directors are not currently on the Board, as Ono believes that only executives who are thoroughly familiar with Ono's operations should serve on the Board.

Part of the commonly expected roles of external directors is fulfilled by comments and advice obtained from external auditors, legal experts consultants and other specialists.

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. Ever mindful of improving surveillance of corporate management, Ono ensures that audits conducted by auditors are made more efficient through coordination with the in-house audit division and more effective through coordination with accounting auditors.

Important operational management matters are discussed in meetings at different levels according to the significance and content of the business agenda. This includes the Management Strategy Meeting attended by the President and Representative Director, members of the Board of Directors and Corporate Executive Officers responsible for each division, and officers responsible for relevant divisions, plus meetings organized by members of the Board and the relevant Corporate Executive Officers, in aid of arriving at optimal executive decisions. Here again, appropriate operational management should take place, using mutual monitoring serving as an auditing vehicle. The Management Strategy Meeting is subject to audit, with auditors attending and inspecting the minutes. To make these processes operate more dynamically and rationally, only officers who are extremely knowledgeable about Ono's operations are appointed as members of the Board. 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, Ono believes that 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 Selfregulating 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 are low for a pharmaceutical company and are within ranges that do not cause concerns to society.

However, in the wider context, the Kyoto Protocol purports to reduce during the 2008-2012 period the total volume of six types of greenhouse gases to below 1990 levels: the total volume of CO2, waste and chemical substances 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. Ono will adopt various strategies in our continued effort so as to attain the new target for 2020 (numerical targets shown on the right).



#### **Environmental Guidelines**

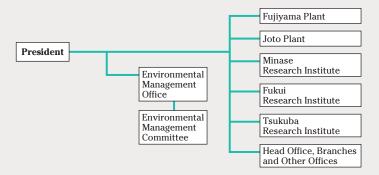
We recognize that our company has a social responsibility regarding the environment, and we will work to protect and preserve the global environment in all of our business operations.

- •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	The CO <sub>2</sub> emissions for 2020 shall be 23% less than that of the 2005 level.
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 2015 final disposal of wastes will be reduced to 40% of the volume disposed in 2010.
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.

# Ono and the Community/ Ono and Its Employees

## In Harmony with the Local Community

Ono takes active part in clean-up campaigns and firefighting activities in an effort to strengthen links and communication with the local community.

#### •Fujiyama Plant

Ono employees clean areas adjacent to the Fujiyama Plant just outside its perimeter. This is part of the ecofriendly activities conducted for the benefit of the local environment (external communication). Ono also participates in the firefighting skills competition organized by the Fire and Safety Association for better fire safety management and early-stage firefighting skills.

#### • Joto Plant

Employees at the Joto Plant take part in the Clean Campaign organized by the City of Osaka. Twice a year, they also clean around the perimeter of the plant, around the perimeter of the nearby primary school as well as the local park as part of the activities of the Higashinari Crime Prevention Association, to which the Plant belongs.

#### •Minase Research Institute

Ono is a member of the Rikyu-no-mizu Protection Society. This is an association that safeguards the pure spring here, which has been listed among the 100 best water springs in Japan. Twice a year, employees take part in major clean-up operations. In addition, to raise fire safety awareness of the local community, employees participate in the Shimamoto-cho Fire Prevention Festival held in November. On the second Sunday of January, Ono employees take part as voluntary firemen in fire drills of the Shimamoto-cho Fire Department's New Year event.

#### •Fukui Research Institute

Members of the Fukui Research Institute take part in the Fukui Environmental Clean-up Campaign and engage in cleaning activities including gathering litter found outside the perimeter of the Institute. They also participate in the annual firefighting skills competition as part of activities to raise fire prevention awareness and to improve firefighting skills. As a member of the

organizing committee of the Technoport Fukui Summer Festival sponsored by the Fukui Private Sector Council, the Institute engages in friendly activities with local residents.

#### •Tsukuba Research Institute

Members of the Tsukuba Research Institute regularly gather and dispose of litter discarded near the perimeter of the Institute.

## In Harmony with Employees

Ono's approach to employee relations is to ensure improvement of working conditions such as safety and hygiene and to provide a good welfare and benefits system.

Ono believes that "People make the company." Ono actively supports development of individual abilities and positive action taken without fear of failure, promoting a corporate climate where the company and its members can live in harmony and where individual abilities blossom to their full.

#### • Employment of Persons with Disabilities

Ono's employment rate of persons with disabilities as of March 31 2011 is 2.16%, which meets the legally designated ratio of 1.80%. One aims to continue in active recruitment.

### •Industrial Accidents and Workplace Health and **Safety Activities**

Ono regularly holds health and safety committee meetings particularly in plants and research institutes. The "health and safety patrol" reports on issues and proposes improvements. Ono endeavors to make members fully aware of health and safety procedures and issues arising.

The patrol checks on all establishments in a 12-month period including inspections of: fire and other disaster prevention, fire extinguishing and first aid equipment, safe handling of machinery, implementation of safety procedures, transfer operations, and cleaning and housekeeping.

## **Financial Section**

#### **Contents**

Financial Review	17
Consolidated Financial Data:	
Consolidated Balance Sheets	20
Consolidated Statements of Income	22
Consolidated Statement of Comprehensive Income	23
Consolidated Statements of Changes in Equity	24
Consolidated Statements of Cash Flows ·····	25
Notes to Consolidated Financial Statements	26

## Financial Review

The following is a summary of the consolidated business results for this fiscal year ended March 31, 2011.

#### Area of Business

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

(See Notes 2 and 19 of the Notes to Consolidated Financial Statements.)

#### Results for Fiscal Year Ended March 31, 2011

The Japanese economy during the fiscal year ended March 31, 2011 showed gentle recovery on the strength of the Government's economic stimulus package and the expansion of exports to newly emerging economies. Nevertheless, employment and personal income are still suffering hard and the economic outlook has been uncertain due to factors such as the dramatic rise in the value of the yen in autumn 2010 and the skyrocketing of crude oil prices triggered by instability in the Middle East and North Africa.

The Japanese pharmaceutical industry faced an extremely challenging environment. NHI drug prices were revised in April 2010 and drug prices fell. Generic products are being promoted further for greater diffusion for the purpose of medical cost containment. Against this backdrop, the Ono Pharmaceutical Group attempted to improve operating efficiency throughout, focusing on the development of unique and innovative new drugs and on enhancing product value by strengthening R&D capabilities and by energetically promoting dissemination of scientific information relating to our main strategic products. Despite our best efforts, the outcomes for the fiscal year were reduced revenue and reduced profits. A summary of the business results for the consolidated fiscal year ended March 31, 2011 is given below.

	Millions of yen	Thousands of U.S. dollars
Net sales	¥ 135,255	\$ 1,629,578
Operating income	35,201	424,108
Net income	24,222	291,831

#### Sales

Ono's products suffered drug price reduction at industry average level (mid-6%) as well as negative effects of generics diffusion and promotion policy. However, new products have been successfully nurtured and the drop in sales was contained at a very small level.

Looking at the performance of some key individual products, *Glactiv*<sup>®</sup> *Tablets* for the treatment of Type II diabetes launched in December 2009 has managed to acquire increased numbers of new prescriptions well beyond the original planned target, thanks to strong detailing and information activities. Sales totaled ¥11,113 million (US\$133,892 thousand), exceeding even the revised figure of ¥10,500 million (US\$126,506 thousand) which was an upward revision at the time of the business results announcement for the third quarter of FY 2011. Emend® Capsules for the treatment of chemotherapy-induced nausea and vomiting, which was launched at the same time, grew successfully in sales as the product won greater appraisal. Sales totaled ¥4,743 million (US\$57,145 thousand). Recalbon<sup>®</sup> Tablets, the osteoporosis drug, which was launched in April 2009 also has been increasing sales steadily to finish the year at ¥1,951 million (US\$23,506 thousand).

Meanwhile, Ono continued deploying strong efforts into opening up potential markets for our existing products including Opalmon® Tablets for peripheral circulation improvement, Onon® Capsules for bronchial asthma and allergic rhinitis, and *Kinedak*® *Tablets* for diabetic neuropathy. Regrettably, NHI price reduction and pressure from generics and competitors resulted in the poorer performance of some products. Opalmon® Tablets achieved sales of ¥40,093 million (US\$483,048 thousand), which was a drop of ¥4,486 million (US\$54,048 thousand), down 10.1% year on year. Onon<sup>®</sup> Capsules achieved sales of ¥21,535 million (US\$259,458 thousand), a fall of ¥3,598 million (US\$43,349 thousand), down 14.3% year on year. Kinedak® Tablets achieved sales of ¥13,196 million (US\$158,988 thousand), a fall of ¥2,896 million (US\$34,892 thousand), down 18.0% year on year.

### **Operating Income**

Operating income for the year ended March 2011 was ¥35,201 million (US\$424,108 thousand), a fall of ¥4,640 million (US\$55,904 thousand), down 11.6% year on year. The cost of sales increased by ¥3,921 million (US\$47,241 thousand), a rise of 18.8% year on year to ¥24,759 million (US\$298,301 thousand) mainly due to the increase in ratio to sales of new products (in-licensed products) that have a high sales-to-cost ratio, while selling, general and administrative (SG&A) costs remained at the same level year on year at ¥75,295 million (US\$907,169 thousand). Among SG&A expenses, R&D expenses rose to ¥42,938 million (US\$517,325 thousand), an increase of ¥3,226 million (US\$38,867 thousand), up by 8.1% over the previous fiscal year, due to the increase in licensing fees arising from the in-license of new drug candidate compounds. Other SG&A expenses decreased year on year by ¥3,238 million (US\$39,012 thousand) or 9.1% to total ¥32,357 million (US\$389,843 thousand). (See Note 10 of the Notes to Consolidated Financial Statements.)

#### Net Income

Other income and expenses include ¥2,947 million (US\$35,506 thousand) that was posted in interests and dividends income; however, ¥865 million (US\$10,422 thousand) of loss was posted in donations and ¥614 million (US\$7,398 thousand) in investment securities valuation loss. Thus the balance overall was posted at a loss of ¥1,247 million (US\$15,024 thousand). For reference, other income and expenses for the previous fiscal year were posted at a gain of ¥339 million (US\$4,084 thousand).

As a result, net income for this fiscal year fell ¥3,656 million (US\$44,048 thousand) or 13.1% down year on (See Notes 9 and 14 of the Notes to Consolidated Financial Statements.)

#### **Consolidated Cash Flow**

In the consolidated financial year ended March 31, 2011, the balance of cash and cash equivalents increased to a total of \pm 82,577 million (US\pm 994,904) thousand) despite outgoings such as dividend payments and acquisition of treasury stock: thanks to the positive balances of cash flow from operating activities of ¥29,796 million (US\$358,988 thousand) and from investing activities of ¥11,115 million (US\$133,916 thousand), which resulted in a year-on-year increase of ¥10,480 million (US\$126,265 thousand) or 14.5% up from ¥72,097 million (US\$868,639 thousand) at the end of the previous fiscal year.

### • Cash Flow from Operating Activities

Cash flow from operating activities for this fiscal year showed an increase of ¥8,495 million (US\$102,349 thousand) in income from the previous fiscal year, resulting in a positive cash flow balance of ¥29,796 million (US\$358,988 thousand). This is due to upward factors chiefly comprising pre-tax net profits of ¥36,900 million (US\$444,578 thousand) and depreciation cost of ¥3,052 million (US\$36,771 thousand) despite downward factors such as corporate tax obligations being ¥13,672 million (US\$164,723 thousand).

#### • Cash Flow from Investing Activities

Cash flow from investing activities for this fiscal year ended in a decrease from the previous fiscal year of ¥5,762 million (US\$69,422 thousand) in income, leaving a positive balance of ¥11,115 million (US\$133,916 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 ¥12,695 million (US\$152,953 thousand), and that spending for the acquisition of tangible fixed assets amounted to ¥1,294 million (US\$15,591 thousand).

#### • Cash Flow from Financing Activities

The cash flow from financing activities for this fiscal year showed an increase of ¥10,768 million (US\$129,735 thousand) in payment over the previous fiscal year, leaving a negative balance of ¥30,336

million (US\$365,494 thousand). The major payments were dividend payouts accounting for ¥19,552 million (US\$235,566 thousand) and acquisition of treasury stock accounting for ¥10,779 million (US\$129,868 thousand).

### **Investment in Plant and Equipment**

Plant and equipment investment during this fiscal year totaled ¥1,672 million (US\$20,145 thousand), including investment into the enhancement and maintenance of manufacturing facilities amounting to ¥710 million (US\$8,554 thousand) and into maintenance of research facilities amounting to ¥493 million (US\$5,940 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 progress further during the coming year. At the same time, competition in the increasingly globalized pharmaceutical market continues to intensify. The 2011 Tohoku Earthquake and Tsunami (Great East Japan Earthquake) which hit the country in March 2011 is affecting Japan in many ways. The Ono Pharmaceutical Group has suffered very little direct impact from the earthquake disaster but the future outlook is very uncertain.

Despite being placed in this seriously challenging business environment, the Group is resolved to propel strong action as described above in order to continue improving our business performance.

## **Consolidated Balance Sheets**

Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

	Millions	Thousands of U.S. Dollars (Note 1	
ASSETS	2011	2010	2011
Current assets:			
Cash and cash equivalents (Notes 2.b & 3)	¥ 82,577	¥ 72,097	\$ 994,904
Time deposits ·····	1,000	950	12,048
Marketable securities (Notes 3 & 4)	42,392	40,170	510,747
Notes and accounts receivable (Note 3):			
Trade ·····	36,704	31,625	442,217
Other	1,326	7,443	15,976
Allowance for doubtful receivables	(9)	(13)	(108)
Inventories (Note 5) ·····	13,048	14,626	157,205
Deferred tax assets (Note 9)	13,641	13,753	164,349
Prepaid expenses and other current assets	691	1,190	8,325
Total current assets	191,370	181,841	2,305,663
Property, plant and equipment:			
Land	22,552	22,539	271,711
Buildings and structures	65,246	64,685	786,096
Machinery, equipment and others	25,722	25,740	309,904
Construction in progress	658	638	7,928
Total ·····	114,178	113,602	1,375,639
Accumulated depreciation	(65,562)	(63,592)	(789,904)
Net property, plant and equipment	48,616	50,010	585,735
Investments and other assets:			
Investment securities (Notes 3 & 4)	167,129	189,867	2,013,602
Investments in affiliated companies (Note 3)	824	761	9,928
Long-term loans to employees	15	17	181
Intangible assets ·····	956	866	11,518
Deferred tax assets (Note 9)	5,764	3,980	69,446
Prepaid pension costs (Note 7)	3,790	_	45,663
Other assets	5,979	5,884	72,035
Total investments and other assets	184,457	201,375	2,222,373
Total	¥ 424,443	¥ 433,226	\$ 5,113,771

See accompanying notes to consolidated financial statements.

LIADILETICS AND CANTEV		of Yen	Thousands of U.S. Dollars (Not
LIABILITIES AND EQUITY	2011	2010	2011
Current liabilities:			
Current portion of long-term debt (Note 6)	¥ 2	¥ 2	<b>\$ 24</b>
Notes and accounts payable (Note 3):			
Trade ·····	5,270	2,336	63,494
Construction	36	8	434
Affiliated companies	19	_	229
Income taxes payable (Notes 3 & 9)	7,422	8,421	89,421
Accrued expenses	12,409	11,422	149,506
Other current liabilities	1,040	1,253	12,530
Total current liabilities	26,198	23,442	315,638
Long-term liabilities:			
Long-term debt, less current portion (Note 6)	12	14	145
Long-term accounts payable	84	84	1,012
Liability for retirement benefits (Note 7)	547	599	6,590
Deferred tax liabilities (Note 9)	2,933	2,967	35,337
Asset retirement obligations	<b>52</b>	_	627
Other non-current liabilities	44	11	530
Total long-term liabilities	3,672	3,675	44,241
Commitments and contingent liabilities (Notes 11 8 10)			
<b>Equity</b> (Notes 8, 18.1 & 18.3):			
Equity (Notes 8, 18.1 & 18.3): Common stock,			
Equity (Notes 8, 18.1 & 18.3):  Common stock,  authorized, 300,000,000 shares; issued, 120,847,500	17 358	17 358	209 133
Equity (Notes 8, 18.1 & 18.3):  Common stock,  authorized, 300,000,000 shares; issued, 120,847,500  shares in 2011 and 2010	17,358 17.080	17,358 17,080	209,133 205.783
Equity (Notes 8, 18.1 & 18.3):  Common stock,  authorized, 300,000,000 shares; issued, 120,847,500  shares in 2011 and 2010	17,080	17,080	205,783
Equity (Notes 8, 18.1 & 18.3):  Common stock,  authorized, 300,000,000 shares; issued, 120,847,500  shares in 2011 and 2010	•		•
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536	17,080 430,870	205,783 5,247,422
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080	17,080	205,783 5,247,422
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536 (74,219)	17,080 430,870 (63,439)	205,783 5,247,422 (894,205)
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536 (74,219) 4,163	17,080 430,870 (63,439) 9,707	205,783 5,247,422 (894,205) 50,157
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536 (74,219) 4,163 (8,938)	17,080 430,870 (63,439) 9,707 (8,923)	205,783 5,247,422 (894,205) 50,157 (107,687)
Equity (Notes 8, 18.1 & 18.3):  Common stock, authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536 (74,219) 4,163 (8,938) (267)	17,080 430,870 (63,439) 9,707 (8,923) (174)	205,783 5,247,422 (894,205) 50,157 (107,687) (3,217)
Equity (Notes 8, 18.1 & 18.3):  Common stock,     authorized, 300,000,000 shares; issued, 120,847,500     shares in 2011 and 2010	17,080 435,536 (74,219) 4,163 (8,938) (267) 390,713	17,080 430,870 (63,439) 9,707 (8,923) (174) 402,479	205,783 5,247,422 (894,205) 50,157 (107,687) (3,217) 4,707,386
authorized, 300,000,000 shares; issued, 120,847,500 shares in 2011 and 2010	17,080 435,536 (74,219) 4,163 (8,938) (267)	17,080 430,870 (63,439) 9,707 (8,923) (174)	205,783 5,247,422 (894,205) 50,157 (107,687) (3,217)

## **Consolidated Statements of Income**

Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

	Millions	Thousands of U.S. Dollars (Note		
	2011	2010	2011	
Net sales ····	¥ 135,255	¥ 135,986	\$ 1,629,578	
Cost of sales (Note 10)	24,759	20,838	298,301	
Gross profit	110,496	115,148	1,331,277	
Selling, general				
and administrative expenses (Note 10)	75,295	75,307	907,169	
Operating income	35,201	39,841	424,108	
Other income (expenses)				
Interest and dividend income	2,947	2,964	35,506	
Interest expense ·····	(1)	(1)	(12)	
Other–net (Note 14)	(1,247)	339	(15,024)	
Other income (expenses)-net	1,699	3,302	20,470	
Income before income taxes				
and minority interests	36,900	43,143	444,578	
Income taxes (Note 9):				
Current	12,669	17,393	152,638	
Deferred	(249)	(2,338)	(3,000)	
Total income taxes	12,420	15,055	149,638	
Net income before minority interests	24,480	28,088	294,940	
Minority interests in income	(258)	(210)	(3,109)	
Net income	¥ 24,222	¥ 27,878	\$ 291,831	
Per share of common stock (Notes 2.p & 17):	Yer	1	U.S. Dollars (Note 1)	
Basic net income	¥ 223.88	¥ 256.38	\$ 2.70	
Cash dividends applicable to the year	180.00	180.00	2.17	

See accompanying notes to consolidated financial statements.

## **■ Consolidated Statement of Comprehensive Income**

Ono Pharmaceutical Co., Ltd. and Subsidiaries Year ended March 31, 2011

	Millions of Yen	Thousands of U.S. Dollars (Note 1)
	2011	2011
Net income before minority interests	¥ 24,480	\$ 294,940
Other comprehensive income (Note 13)		
Unrealized loss on available-for-sale securities	(5,563)	(67,024)
Foreign currency translation adjustments	(93)	(1,121)
Share of other comprehensive income in associates ·······	(4)	(48)
Total other comprehensive income	(5,660)	(68,193)
Comprehensive income (Note 13)	18,820	226,747
Total comprehensive income attributable to (Note 13)		
Owners of the parent	18,585	223,916
Minority interests	235	2,831

See accompanying notes to consolidated financial statements.

## **■** Consolidated Statements of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

	Thousands					Millions	of Yen				
		Accumulated other comprehensive income									
	Outstanding number of shares of common stock	Common stock	Capital surplus	Retained earnings	Treasury stock	Unrealized gain on available- for-sale securities	Land revaluation difference	Foreign currency translation adjustments	Total	Minority interests	Total equity
BALANCE, APRIL 1, 2009	108,738	¥ 17,358	¥ 17,080	¥ 422,565	¥ (63,425)	¥ 2,171	¥ (8,923)	¥ (204)	¥ 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	(63,439)	9,707	(8,923)	(174)	402,479	3,630	406,109
Net income	(2,713)			24,222 (19,572)	(10,780)				24,222 (19,572) (10,780) 16		24,222 (19,572) (10,780)
Net change in the year ······				10		(5,544)	(15)	(93)	(5,652)	230	(5,422)
BALANCE, MARCH 31, 2011	106,021	¥ 17,358	¥ 17,080	¥ 435,536	¥ (74,219)	¥ 4,163	¥ (8,938)	¥ (267)	¥ 390,713	¥ 3,860	¥ 394,573

	Thousands of U.S. Dollars (Note 1)									
					Accumulated other comprehensive income					
	Common stock	Capital surplus	Retained earnings	Treasury stock	Unrealized gain on available- for-sale securities	Land revaluation difference	Foreign currency translation adjustments	Total	Minority interests	Total equity
BALANCE, APRIL 1, 2010	\$209,133	\$205,783	\$5,191,205	\$(764,325)	\$116,952	\$(107,507)	\$(2,096)	\$4,849,145	\$43,735	\$4,892,880
Net income ·····			291,831					291,831		291,831
Cash dividends, \$2.17 per share ······			(235,807)					(235,807)		(235,807)
Purchase of treasury stock·····				(129,880)				(129,880)		(129,880)
Reversal of land revalution difference ····			193					193		193
Net change in the year ·····					(66,795)	(180)	(1,121)	(68,096)	2,771	(65,325)
BALANCE, MARCH 31, 2011	\$209,133	\$205,783	\$5,247,422	\$(894,205)	\$50,157	\$(107,687)	\$(3,217)	\$4,707,386	\$46,506	\$4,753,892

See accompanying notes to consolidated financial statements.

## **Consolidated Statements of Cash Flows**

Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

_	Millions of	Yen	Thousands of U.S. Dollars (Note		
	2011	2010	2011		
Operating activities:					
Income before income taxes and minority interests	¥ 36,900	¥ 43,143	\$ 444,578		
Adjustments for:					
Income taxes paid	(13,672)	(18,084)	(164,723)		
Depreciation and amortization	3,052	3,012	36,771		
Increase (decrease) in allowance for doubtful receivables	(4)	10	(48)		
Decrease in liability for retirement benefits	(52)	(1,641)	(627)		
Increase in prepaid pension costs······	(3,790)	_	(45,663)		
Gain on sales of investment securities	_	(85)	_		
Loss on devaluation of investment securities	614	_	7,398		
Changes in assets and liabilities, net of effects					
Increase in interest and dividends receivable	232	280	2,795		
Decrease (increase) in notes and accounts receivable	(5,082)	7,856	(61,229)		
Decrease (increase) in inventories	1,580	(4,567)	19,036		
Increase (decrease) in notes and accounts payable	2,952	(600)	35,567		
Others-net	7,066	(8,023)	85,133		
Net cash provided by operating activities	29,796	21,301	358,988		
Investing activities:					
Payments for purchases of marketable securities	(35,548)	(33,379)	(428,289)		
Proceeds from sales and redemption of marketable securities ·······	63,550	86,120	765,663		
Payments for purchases of property, plant and equipment	(1,294)	(3,211)	(15,591)		
Payments for purchases of investment securities	(15,321)	(32,348)	(184,590)		
Proceeds from sales and redemption of investment securities	14	174	169		
Others-net ····	(286)	(479)	(3,446)		
Net cash provided by investment activities	11,115	16,877	133,916		
Financing activities:					
Repayment of current portion of long-term debt	(2)	(2)	(24)		
Payments for purchases of treasury stock ······	(10,779)	(13)	(129,868)		
Cash dividends ·····	(19,552)	(19,549)	(235,566)		
Cash dividends to minority shareholders	(3)	(4)	(36)		
Net cash used in financing activities	(30,336)	(19,568)	(365,494)		
Foreign currency translation adjustments					
on cash and cash equivalents	(95)	26	(1,145)		
Net increase in cash and cash equivalents	10,480	18,636	126,265		
Cash and cash equivalents, beginning of year	72,097	53,461	868,639		
Cash and cash equivalents, end of year	¥ 82,577	¥ 72,097	\$ 994,904		

See accompanying notes to consolidated financial statements.

## Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2011 and 2010

### 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.

Under Japanese GAAP, a consolidated statement of comprehensive income is required from the fiscal year ended March 31, 2011 and has been presented herein. Accordingly, accumulated other comprehensive income is presented in the consolidated balance sheet and the consolidated statement of changes in equity. Information with respect to other comprehensive income for the year ended March 31, 2010 is disclosed in Note 13. In addition, "net income before minority interests" is disclosed in the consolidated statement of income from the year ended March 31, 2011.

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 2010 financial statements to conform to the classifications used in 2011.

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 ¥83 to \$1, the approximate rate of exchange at March 31, 2011. 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, 2011 (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 the periods from January 1 to March 31 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 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) availablefor-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 straightline 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.

#### h. Asset Retirement Obligations

In March 2008, the Accounting Standards Board of Japan (the "ASBJ") published the 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 the 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 was effective for fiscal years beginning on or after April 1, 2010. The Group applied this accounting standard effective April 1, 2010. The effect of this change was not material.

#### i. Research and development costs

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

#### j. 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 was effective for fiscal years beginning on or after April 1, 2008.

Under the previous accounting standard, finance leases that were deemed to continue 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 notes 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 continue to be accounted for as operating lease transactions.

The Company applied the revised accounting standard effective April 1, 2008. In addition, the Company continues to account 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.

#### k. Bonuses to directors and corporate auditors

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

#### l. 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.

#### m. 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.

#### n. 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.

#### o. 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.

#### p. Per share information

Basic net income per share is computed by dividing net income available to common shareholders by the weightedaverage 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.

### q. New Accounting Pronouncements **Acounting 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 ended on or after 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 the credit standing of major clients is being 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 are 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, 2011 and 2010 are shown in the table below. Such amounts do not include items for which the fair value is recognized to be infeasible to accurately determine (See (b) below).

	Millions of Yen				
March 31, 2011	Carrying amount	Fair value	Unrealized gain/loss		
Cash and cash equivalents	¥ 82,577	¥ 82,577	_		
Notes and accounts receivable	38,021	38,021	_		
Marketable and investment securities					
Held-to-maturity	121,929	123,042	¥ 1,113		
Available-for-sale	86,570	86,570	-		
Notes and accounts payable	5,325	5,325	_		
Income taxes payable	7,422	7,422	-		
Derivative transactions	-	_	-		

March 31, 2010	Carrying amount	Fair value	Unrealized gain/loss
Cash and cash equivalents	¥ 72,097	¥ 72,097	_
Notes and accounts receivable	39,055	39,055	_
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, 2011	Carrying amount	Fair value	Unrealized gain/loss
Cash and cash equivalents	\$ 994,904	\$ 994,904	_
Notes and accounts receivable	458,085	458,085	_
Marketable and investment securities			
Held-to-maturity ·····	1,469,024	1,482,434	\$ 13,410
Available-for-sale	1,043,012	1,043,012	-
Notes and accounts payable	64,157	64,157	_
Income taxes payable	89,421	89,421	-
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 equity instruments, and at the quoted price obtained from financial institutions or notice by the Japan Securities Dealers Association for certain debt instruments. The information of the fair value for marketable and investment securities by classification is included in Note 4.

#### Notes and accounts receivable, notes and accounts payable and income taxes payable

The carrying values of notes and accounts receivable, notes and accounts payable 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) Carrying amount of financial instruments whose fair value cannot be reliably determined

Carryii	ng amount
Millions of Yen	Thousands of U.S. Dollars
¥ 824	\$ 9,928
1,022	12,313
¥ 761	
1,080	
	# 824  1,022  ¥ 761

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		
¥ 82,577	_	_	_		
38,021	_	_	_		
30,320	¥ 91,370	_	_		
12,050	550	¥ 3,000	_		
¥ 162,968	¥ 91,920	¥ 3,000	-		
	or less  ¥ 82,577 38,021  30,320 12,050	Due in one year or less       Due after one year through five years         ¥ 82,577       -         38,021       -         30,320       ¥ 91,370         12,050       550	Due in one year or less         Due after one year through five years         Due after five years through ten years           ¥ 82,577         -         -           38,021         -         -           30,320         ¥ 91,370         -           12,050         550         ¥ 3,000		

	Thousands of U.S.Dollars					
March 31, 2011	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years		
Cash and cash equivalents	\$ 994,904	_	_	_		
Notes and accounts receivable	458,085	_	_	_		
Marketable and investment securities						
Held-to-maturity	365,302	\$ 1,100,843	_	_		
Available-for-sale	145,180	6,627	\$ 36,145	_		
Total ·····	\$ 1,963,471	\$ 1,107,470	\$ 36,145	_		

Note 4 Marketable and investment securities

Marketable and investment securities as of March 31, 2011 and 2010 consisted of the following:

	Millions o	Millions of Yen	
	2011	2010	2011
Current:			
Government and corporate bonds	¥ 42,392	¥ 40,170	\$ 510,747
Non-current:			
Marketable and other equity securities	70,053	76,089	844,012
Government and corporate bonds······	95,134	111,608	1,146,192
Trust fund investments and other	1,942	2,170	23,398
Total	¥ 167,129	¥ 189,867	\$ 2,013,602

The costs and aggregate fair values of marketable and investment securities at March 31, 2011 and 2010 were as follows:

	Millions of Yen					
March 31, 2011	Cost	Unrealized gains	Unrealized losses	Fair value		
Securities classified as:						
Available-for-sale:						
Equity securities	¥ 61,261	¥ 10,955	¥ (2,986)	¥ 69,230		
Debt securities	15,806	0	(209)	15,597		
Trust fund investments and other	1,585	177	(19)	1,743		
Held-to-maturity ·····	121,929	1,147	(34)	123,042		
March 31, 2010						
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		
		Thousands	of U.S. Dollars			
March 31, 2011	Cost	Unrealized gains	Unrealized losses	Fair value		
Securities classified as:						
Available-for-sale:						
Equity securities	\$ 738,084	\$ 131,988	\$ (35,976)	\$ 834,096		
Debt securities	190,434	0	(2,518)	187,916		
Trust fund investments and other	19,096	2,133	(229)	21,000		
Held-to-maturity ······	1,469,024	13,819	(409)	1,482,434		

The information regarding available-for-sale securities and held-to-maturity securities whose fair value is not readily determinable as of March 31, 2011 and 2010, are disclosed in Note 3.

The information of available-for-sale securities which were sold during the years ended March 31, 2011 and 2010 was as follows:

March 31, 2011	Proceeds	Realized gains	Realized loss
Available-for-sale:			
Debt securities	¥ 2,000	¥ 0	_
Total ·····	¥ 2,000	¥ 0	_
March 31, 2010			
Available-for-sale:	¥ 164	¥ 85	
March 31, 2010  Available-for-sale:  Equity securities	¥ 164	¥ 85	- ¥ 0

	Thousands of U.S. Dollars			
March 31, 2011	Proceeds	Realized gains	Realized loss	
Available-for-sale:				
Debt securities····	\$ 24,096	\$ 0	_	
Total ·····	\$ 24,096	\$ 0	_	

For the year ended March 31, 2011, losses on write-downs of securities totaled ¥614 million (\$7,398 thousand) (Note 14). In evaluating security values, a security whose value has declined by more than 30% is considered to have experienced "significant deterioration." If a security has a strong chance of regaining its value, the security is not written down.

Note 5 **Inventories** Inventories at March 31, 2011 and 2010 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollar	
	2011	2010	2011	
Merchandise ·····	¥ 248	¥ 275	\$ 2,988	
Finished products	4,548	5,501	54,795	
Semi-finished products	3,064	4,037	36,916	
Work in process ·····	1,720	1,386	20,723	
Raw materials and supplies	3,468	3,427	41,783	
Total	¥ 13,048	¥ 14,626	\$ 157,205	

Note 6 Long-term debt Long-term loans payable at March 31, 2011 and 2010 consisted of the following:

	Millions of Yen				Thousands of U.S. Dollars	
	2011		2010		2011	
Unsecured loans for employees(*)	¥	14	¥	16	\$	169
Less current portion		<b>(2)</b>		(2)		(24)
Long-term debt, less current portion	¥	12	¥	14	\$	145

<sup>(\*)</sup>At March 31, 2011 and 2010: Interest rates ranging from 3.25% to 3.40%, maturing serially to March 2026

#### At March 31, 2011, the annual maturities of long-term debt were as follows:

Years ending March 31	Millions of Yen	Thousands of U.S. Dollars
2012	¥ 2	\$ 24
2013	1	12
2014	2	24
2015	1	12
2016	2	24
2017 and thereafter ·····	6	73
Total	¥ 14	\$ 169

## Note 7 Retirement benefits and pension

The liability for retirement benefits at March 31, 2011 and 2010 consisted of the following:

	Millions of	Yen	Thousands of U.S. Dollars
	2011	2010	2011
Projected benefit obligation	¥ 39,157	¥ 38,448	\$ 471,771
Fair value of plan assets (including a pension trust)	(41,909)	(39,207)	(504,928)
Unrecognized actuarial gain (loss)	(584)	1,270	(7,036)
Net liability for retirement benefits, employees	(3,336)	511	(40,193)
Prepaid pension costs	3,790	_	45,663
Liability for retirement benefits, officers	93	88	1,120
Liability for retirement benefits, total	¥ 547	¥ 599	\$ 6,590

In September 2009, the Company contributed ¥5,000 million by cash to the employee retirement benefit trust for the Company's contributory pension plans.

Net periodic benefit cost for the years ended March 31, 2011 and 2010 consisted of the following:

	Millions of	Yen	Thousands of U.S. Dollars
	2011	2010	2011
Service cost ·····	¥ 1,631	¥ 1,581	\$ 19,651
Interest cost ·····	538	526	6,482
Expected return on plan assets ·····	(633)	(569)	(7,627)
Recognized actuarial loss (gain)	(1,221)	3,289	(14,711)
Net periodic benefit cost	315	4,827	3,795
Others	40	225	482
Total	¥ 355	¥ 5,052	\$ 4,277

Actuarial assumptions used for the years ended March 31, 2011 and 2010 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 \(\frac{1}{2}\)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,  $resulted \ in \ a \ normal \ effective \ statutory \ tax \ rate \ of \ approximately \ 40.6\% \ for \ the \ years \ ended \ March \ 31, \ 2011 \ and \ 2010.$ The tax effects of significant temporary differences, which resulted in deferred tax assets and liabilities at March 31, 2011 and 2010, were as follows:

_	Millions of	Yen	Thousands of U.S. Dollars
	2011	2010	2011
Deferred tax assets:			
Current assets:			
Prepaid R&D expenditures ·····	¥ 9,478	¥ 9,515	\$ 114,193
Accrued bonuses	1,646	1,591	19,831
Accrued enterprise taxes ·····	715	767	8,614
Depreciation and amortization	671	838	8,084
Others	1,131	1,042	13,627
Non-current assets:			
Provision for retirement benefits	4,771	6,313	57,482
Loss on devaluation of investment securities	4,434	4,226	53,422
Prepaid R&D expenditures	3,752	1,798	45,205
Depreciation and amortization	716	822	8,626
Others	437	392	5,265
Less valuation allowance	(4,405)	(4,203)	(53,072)
Total	23,346	23,101	281,277
Deferred tax liabilities:			
Current liabilities:			
Others····	(0)	_	(0)
Long-term liabilities:			
Unrealized gain on available-for-sale securities	(3,654)	(5,113)	(44,024)
Revaluation of land ·····	(2,931)	(2,941)	(35,313)
Others	(289)	(281)	(3,482)
Total	(6,874)	(8,335)	(82,819)
Net deferred tax assets ·····	¥ 16,472	¥ 14,766	\$ 198,458

A reconciliation between the statutory tax rate and the effective income tax rates reflected for the years ended March 31, 2011 and 2010 was as follows:

	2011	2010
Statutory tax rate	40.6%	40.6%
Expenses not permanently deductible for income tax purposes, such as entertainment expenses	5.6	5.2
Income not permanently taxable for income tax purposes, such as dividend income	(0.9)	(0.7)
Tax credit for experiment and research expenses	(11.7)	(9.1)
Change in valuation allowance ·····	0.6	(0.9)
Other - net	(0.5)	(0.2)
Effective tax rates	33.7%	34.9%

Note 10 **R&D** expenditures Research and development expenditures for the years ended March 31, 2011 and 2010 consisted of the following:

	Millions of	Yen	Thousands of U.S. Dollars
	2011	2010	2011
Selling, general and administrative expenses	¥ 42,938	¥ 39,712	\$ 517,325
Cost of sales	_	5	_
Total ·····	¥ 42,938	¥ 39,717	\$ 517,325

## Note 11

#### Leases

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

As discussed in Note 2-j, 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, 2011 and 2010 was as follows:

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

	Millions	of Yen	Thousands of U.S. Dollars
_	2011	2010	2011
	Machinery, equipment and others	Machinery, equipment and others	Machinery, equipment and others
Acquisition cost ·····	¥ 4	¥ 4	\$ 48
Accumulated depreciation	4	3	48
Net leased property	¥ 0	¥ 1	\$ 0

#### 2. Obligations under finance leases

	Millions o	f Yen	Thousands of U.S. Dollars
	2011	2010	2011
Due within one year····	¥ 0	¥ 1	<b>\$ 0</b>
Due after one year ····	_	0	_
Total ·····	¥ 0	¥ 1	\$ 0

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

	Millions o	of Yen	Thousands of U.S. Dollars
	2011	2010	2011
Depreciation expense	¥ 1	¥ 2	\$ 12
Actual lease payments	1	2	12

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, 2011 were as follows: (lessee)

	Millions of Yen	Thousands of U.S. Dollars
	2011	2011
Due within one year	¥ 88	\$ 1,060
Due after one year ·····	517	6,229
Total ·····	¥ 605	\$ 7,289

#### (lessor)

	Millions of Yen	Thousands of U.S. Dollars
	2011	2011
Due within one year	¥ 16	\$ 193
Due after one year ····	38	458
Total ·····	¥ 54	\$ 651

#### Note 12

#### **Derivatives**

The Group 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 Group believes there is little credit risk in dealing with them.

The Group utilizes forward foreign exchange contracts within the normal transaction range established for these financial institutions. 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.

The Group did not have any open derivatives positions as of March 31, 2011 and 2010.

## Note 13 **Comprehensive income**

Total comprehensive income for the year ended March 31, 2010 was the following:

Total other comprehensive income .....

	Millions of Yen
	2010
Total comprehensive income attributable to:	
Owners of the parent	¥ 35,444
Minority interests ·····	215
Total comprehensive income	¥ 35,659
Other comprehensive income for the year ended March 31, 2010 consisted of the following:	
Other comprehensive income for the year ended March 31, 2010 consisted of the following:	Millions of Yen
Other comprehensive income for the year ended March 31, 2010 consisted of the following:	Millions of Yen 2010
Other comprehensive income for the year ended March 31, 2010 consisted of the following:  Other comprehensive income:  Unrealized gain on available-for-sale securities  Foreign currency translation adjustments	2010

¥ 7,571

Note 14 Other income and expenses

'Other-net' of other income (expenses) for the years ended March 31, 2011 and 2010 in the consolidated statements of income consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars	
	2011	2010	2011	
Gain on sales of investment securities	_	¥ 85	-	
Gain on refund of research and development expenses for prior periods	_	346	_	
Loss on adjustment for changes of accounting standard for asset				
retirement obligations	¥ (28)	_	\$ (337)	
Loss on devaluation of investment securities	(614)	_	(7,398)	
Contribution	(865)	(414)	(10,422)	
Others, net ····	260	322	3,133	
Total	¥ (1,247)	¥ 339	\$ (15,024)	

#### **Note 15**

#### 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, 2011 ·····	¥ (4,122)	\$ (49,663)

#### Note 16

#### **Commitments and contingent liabilities**

There were no material commitments and contingent liabilities at March 31, 2011 and 2010.

#### Note 17

#### 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	S
For the year ended March 31, 2011:				
Basic EPS				
Net income available to common shareholders	¥ 24,222	108,195	¥ 223.88	\$ 2.70
For the year ended March 31, 2010:				
Basic EPS				
Net income available to common shareholders	¥ 27,878	108,736	¥ 256.38	

#### **Note 18**

#### **Subsequent event**

1. Cancellation of treasury stock

The Company resolved to cancel shares of its own stock at the Board of Directors' meeting on April 6, 2011.

- (1) Reasons for the cancellation
  - As a part of measures for increasing returns to shareholders
- (2) Total number of shares to be cancelled 3,000,000 shares
- (3) The date of cancellation

April 13, 2011

#### 2. Revision of the retirement benefit plan

The Company revised the retirement benefit plan as of April 1, 2011, in order to stabilize operations. The revision primarily consisted of a change in benefit interest rates, applicable to "Accounting for Transfer between Retirement Benefit Plans (ASBJ Guidance No.1)."

As a result of this revision, the projected benefit obligation decreased by ¥3,697 million (\$44,542 thousand). As this reduction in projected benefit obligation corresponds to past service costs, the Company will treat the entire amount as an offset to retirement benefit expense in the consolidated fiscal year of incurrence.

#### 3. Appropriation of Retained Earnings

The following appropriation of retained earnings at March 31, 2011 was approved at the Company's shareholders meeting held on June 29, 2011:

	Millions of Yen	Thousands of U.S. Dollars
Year-end cash dividends, ¥90 (\$1.08) per share ······	¥ 9,542	\$ 114,964

#### Note 19

#### **Segment information**

#### For the year ended March 31, 2011

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.

Segment information is omitted as the Group operated solely in the 'pharmaceutical-related business'.

#### For the year ended March 31, 2010

#### (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.

#### (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.

#### (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 was as follows:

	Millions of Yen	Percentage in total net sales	
	2010	2010	
Europe ·····	¥ 523	0.4%	
Asia ·····	2,673	1.9	
Other	1,484	1.1	
Total ·····	¥ 4,680	3.4%	



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#### 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, 2011 and 2010, and the related consolidated statements of income for the years then ended, the consolidated statement of comprehensive income for the year ended March 31, 2011, and the related consolidated statements of 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, 2011 and 2010, 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.

Delvitte Touche Tohmaten LLC

June 29, 2011

## **Corporate Information**

## **BOARD OF DIRECTORS AND STATUTORY AUDITORS**

(as of June 29, 2011)

#### **Directors**

#### **Gyo Sagara**

President, Representative Director and Chief Executive Officer

#### Hiroshi Awata

Member of the Board of Directors Senior Executive Officer

Executive Director, Clinical Development

#### Kazuhito Kawabata, Ph.D

Member of the Board of Directors **Executive Officer** 

Executive Director, Discovery and Research

#### Shinji Fujiyoshi

Member of the Board of Directors **Executive Officer** 

## Executive Director, Sales and Marketing

Member of the Board of Directors **Executive Officer** Executive Director, Corporate Management

Member of the Board of Directors Corporate Officer Director, Environment Management

#### Fumio Takahashi

Member of the Board of Directors Corporate Officer Vice Executive Director, Sales and Marketing

#### Daikichi Fukushima, Ph.D

Member of the Board of Directors Corporate Officer

Director, Tsukuba Research Institute and Advanced Medicinal Research

#### **Statutory Auditors**

#### Shigeo Shimada

(full time)

Katsuyoshi Nishimura (full time)

Narihito Maishi

Yasuo Araki



#### ONO PHARMACEUTICAL CO., LTD.

Founded 1717

July 4, 1947 **Date of Incorporation** 

Paid-in Capital ¥17,358 million (March 31, 2011)

**Number of Shareholders** 15,716 (March 31, 2011) **Number of Employees** 2,418 (March 31, 2011)

#### **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.

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