## to Mans Fight Viseose and Pain ate Report 2015

Year ended March 31, 2015



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

Our corporate philosophy is the foundation upon which we continue at ONO PHARMACEUTICAL to work positively toward the development of original new drugs for the true benefit of patients and to meet unmet medical needs.

#### Contents

Highlights	Financial Highlights	02
2014/4-2015/3	Annual Topics	04
Top Message		06
ONO's Mission		10
ONO's View		12
Key Product Profile	S	12 14 18 20
Status of Developm	nent Pipeline	18
CSR Management		20
	Corporate Governance	22
	Innovative Pharmaceutical Products	26
Initiatives by	Human Resources and Human Rights	34
Priority Area	The Environment	36
	Fair Operating Practices	40
	Society	34 36 40 42 44 46 48 49
	Financial Review	44
	Consolidated Statement of Financial Position	46
	Consolidated Statement of Income	48
Financial Section	Consolidated Statement of Comprehensive Income	49
	Consolidated Statement of Changes in Equity	50
	Consolidated Statement of Cash Flows	51
	Notes to Consolidated Financial Statements	52
Independent Audit	or's Report	113
ISO 26000 Compar	ison Table	114
Independent Practi	tioner's Assurance Report	115
Corporate	Management	116
Information	Corporate Profile	118

#### **Editorial Policy**

ONO PHARMACEUTICAL (ONO) publishes this report as a corporate report that, in addition to financial information, provides a broad range of non-financial information including corporate social responsibility (CSR) activity information.

This report contains financial results and other financial data, and non-financial information on corporate governance, and environmental and social awareness, serving as a communication tool to ensure that ONO's stakeholders can understand our current status and direction.

Coverage of this ReportScope of Coverage

This report covers the activities of ONO. Some pages also include the activities of the whole Group or group companies.

- Period of Coverage April 1, 2014 through March 31, 2015 (2014 fiscal year)
- Activities conducted in and after April 2015 are also covered in part.

#### Reference Guidelines

Sustainability Reporting Guidelines Version 3.1 by Global Reporting Initiative (GRI) ISO 26000

Environmental Reporting Guidelines 2012 by the Ministry of the Environment of Japan Environmental Accounting Guidelines 2005 by the Ministry of the Environment of Japan Publication Date

#### August 2015

Disclaimer Regarding Forward-Looking Statements This report includes forward-looking statements regarding the ONO Group's business. All the forward-looking statements are based on forecast analysis using the information available at the time of preparation of this report. Actual financial results may therefore differ from the current business outlook due to market and industry conditions, and risks and uncertainties associated with general economic conditions at home and abroad.

This report also includes information that provides details of pharmaceutical products, including compounds under development. Please note, however, that this information is not intended for advertising purposes or for giving medical advice.

## Highlights 2014/4-2015/3

#### **Financial Highlights**

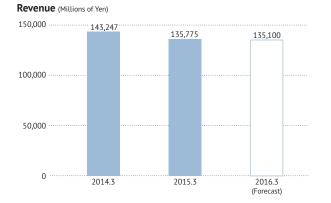
			Millions of Yen	Thousands of U.S. Dollars <sup>*1</sup>
	2013.3*2 (IFRS)	2014.3 <sup>*2</sup> (IFRS)	2015.3 (IFRS)	2015.3 (IFRS)
perating Results				
Revenue	¥142,806	¥143,247	¥135,775	¥1,131,459
Research and development costs	44,746	44,413	41,346	344,550
Operating profit	29,948	26,429	14,794	123,284
Profit for the year attributable to owners of the parent company	22,927	20,344	12,976	108,131
inancial Position				
Total assets	475,261	486,141	524,588	4,371,568
Total equity	442,276	451,724	475,213	3,960,111
Cash flows from operating activities	18,992	28,422	31,579	263,160
Cash flows from investing activities	4,365	6,926	(12,756)	(106,300
Cash flows from financing activities	(19,372)	(19,636)	(19,603)	(163,358
mount per share			Yen	U.S. Dollars <sup>*1</sup>
Basic earnings	216.26	191.90	122.40	1.02
Equity attributable to owners of the parent company	4,132.24	4,219.63	4,439.07	36.99
Cash dividends	180.00	180.00	180.00	1.50
inancial indicators				
Equity ratio (%)	92.2	92.0	89.7	
ROA (%)*3	7.1	6.1	3.6	
ROE (%)*4	5.3	4.6	2.8	
Payout ratio (%)	83.2	93.8	147.1	
Number of employees	2,807	2,858	2,913	

\*1 U.S. Dollar amounts are translated at a rate of US\$ 1 = ¥120. See Notes to consolidated financial statements.

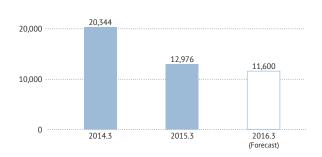
\*2 Due to partial changes in accounting policies, the financial figures of year ended March 31, 2013 and 2014 have been revised retroactively.

\*3 ROA = profit before tax / Total assets (average of beginning and end of fiscal year)

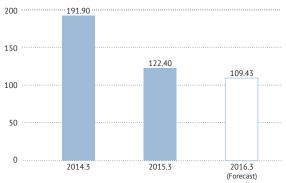
\*4 ROE = Profit for the year attributable to owners of the parent company / Equity attributable to owners of the parent company (average of beginning and end of fiscal year)



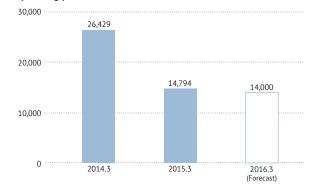
Profit for the year attributable to owners of the parent company (Millions of Yen) 30,000



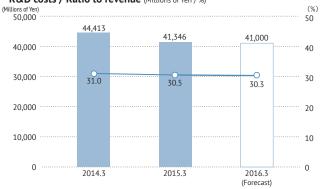
Basic earnings per share (Yen)

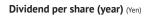


**Operating profit** (Millions of Yen)



R&D costs / Ratio to revenue (Millions of Yen / %)







## Highlights 2014/4-2015/3

#### **Annual Topics**

		Event	Brief overview					
	April	CSR Promotion Section established in Corporate Management Division	This office is intended to reinforce CSR activities					
		GLACTIV Tablets (oral type-2 diabetes drug) Partial change approved	This approval allows GLACTIV to be used in combination treatment with all oral medications for type-2 diabetes and insulin products					
	May	FORXIGA Tablets (oral type-2 diabetes drug) Launched	(Described in Key Product Profiles)					
		Visiting Lecture about Alzheimer's disease launched	This program is intended to give special lessons to high school and junior high school students to deepen understanding of dementia and consider possible community actions against this disease					
		Participation in the first tree-planting ceremony at Shiraito Nature Park	This is a contribution to the local community and an environmental protection activity in the area around the Fujiyama Plant					
		Total self-care support app released	A smartphone app designed for users to practice self-care to prevent or treat lifestyle diseases					
June	June	ONO donates dental goods to elementary schools, kindergartens and nursery schools in Shimamoto-cho, Osaka	This donation was made during Dental and Oral Healthcare Week as a contribution to the local communit in the area around the Minase Research Institute					
2014		OPDIVO Intravenous Infusion (anticancer drug) Approval obtained	World's first approval in Japan of OPDIVO for the treatment of unresectable melanoma					
2011		Oncology Research Laboratories established in the Discovery and Research Division	The new department integrates cancer drug developmen functions					
	July	ONO signs collaboration agreement to provide the University of Tokyo with a compound library	This provision is expected to accelerate open innovation through industry-academia alliances and the creation of seeds for drug development					
		ONO signs strategic collaboration agreement with Bristol-Myers Squibb company (BMS) regarding immuno-oncology therapies	Agreement for joint development and commercialization of OPDIVO and four immuno-oncology compounds in Japan, South Korea and Taiwan					
		ONO signs a development and commercialization collaboration agreement with Meiji Seika Pharma	ONO licenses out to Meiji Seika Pharma exclusive rights to develop and commercialize Limaprost alfadex (product name: OPALMON Tablets) in Thailand and Indonesia					
	August	ONO - ONCOLOGY. jp website launched	This website provides scientific information in oncology.					
		CMC - Production Division established	The new division integrates the CMC Research Center and the Production & Distribution Division to reinforce production functions					
	September	World's first launch of OPDIVO in Japan	For the treatment of unresectable melanoma (described in Key Product Profiles)					
		Participation in the Mt. Fuji cleanup event	Contribution to the local community and an environmental protection activity in the area around the Fujiyama Plant					

		Event	Brief overview					
		Participation in "Relay for Life Japan" 2014 in Ueno, Tokyo	Charity event aimed at supporting cancer patients and their families and making cancer controllable and survivable through community action against cancer					
	September	ONO joins the international industry-academia research organization GPCR Consortium	ONO joins up as a founding member of an organization aimed at promoting structural analysis of G-protein coupled receptors (GPCRs) through collaborations between the pharmaceutical industry and academia overseas					
	October	OPALMON Tablets (peripheral circulatory disorder drug) Partial change approved	Formulation change aimed at improving stability to humidity					
		ONO signs a development collaboration agreement with Kyowa Hakko Kirin and BMS regarding immuno- oncology therapies	Study for combination therapy with OPDIVO and Mogamulizumab for advanced solid tumor					
		ONO PHARMA TAIWAN CO., LTD. established	Fourth ONO overseas subsidiary following U.S.A., U.K. and South Korea					
	December	ONO signs a license agreement with Gilead Sciences	ONO licenses out to Gilead exclusive global rights to develop and commercialize ONO-4059 (BTK inhibitor) excluding Japan, South Korea, Taiwan, China and the ASEAN countries					
		OPDIVO: Approved in the U.S.A.	Approved for the first time overseas for the treatment of melanoma					
	Falsas	ONO awarded by Kansai Economic Federation	Development and commercialization of OPDIVO were highly evaluated					
	February	ONO signs a development collaboration agreement with Dako, an Agilent Technologies company	Intended for development of a PD-L1 companion diagnostic test for OPDIVO					
		OPDIVO: Approved in the U.S.A. for additional indication	Added indication for recurrent squamous non-small cell lung cancer					
2015		ONO signs a development and commercialization collaboration agreement with China Chemical & Pharmaceutical	ONO licenses out to China Chemical & Pharmaceutical the rights to develop and commercialize Limaprost alfadex (product name: OPALMON Tablets) in Taiwan.					
	March	ONO holds exhibition of art works by dementia people	An exhibition of art works created by people with dementia, of which images are posted on the website as part of ONO's CSR activities					
		ONO holds reconstruction assistance activities "Operation Slimmer and Healthier" start from Fukushima Prefecture	CSR activity to help children in quake-affected areas to stay healthy (Scheduled for Miyagi and Iwate Prefectures)					
		OPDIVO: Approved in South Korea	Approved in a third country for the treatment of melanoma					

## Top Message

Tackling a range of challenges for sustainable growth and realization of our corporate philosophy, and further raising our corporate social value



#### Business Environment and Risks Surrounding ONO PHARMACEUTICAL

The global economy remains on a gradual recovery path but also faces uncertainties, including economic slowdown and political instability in emerging countries.

The pharmaceutical industry is faced with a decrease in the success rate of drug discovery and an increase in R&D costs. In Japan, a country addressing the challenge of reducing social security costs with the population aging and the birthrate declining, the business environment is still severe for pharmaceutical companies with the introduction of new healthcare cost reduction measures, including the National Health Insurance drug price revision and generic use promotion measures. On the other hand, when seen from a global perspective, the pharmaceutical market is expected to continue growing on the back of populations aging in advanced economies and populations increasing in emerging economies.

Under these circumstances, with competition becoming tougher in the pharmaceutical industry, I believe that what ONO needs to continue growing is effort and speed aimed at developing breakthrough drugs.

#### **Our Social Value**

Since its establishment in 1717, ONO has resolutely pushed forward in the pharmaceutical industry up to the present day and has built a history that spans almost 300 years. Upholding the corporate philosophy "Dedicated to Man's Fight against Disease and Pain," we make united efforts to create innovative drugs that are globally competitive. We raise our social value by consistently pursuing the development and commercialization of pharmaceuticals that truly benefit patients.

We also always engage with the community seriously and with sincerity. Fully aware of our social responsibilities as a pharmaceutical company handling pharmaceuticals that support human life, we work to further strengthen compliance to ensure that we always act in accordance with high ethical values, as well as to achieve strict compliance with laws and regulations.

In addition, we have defined six priority areas for CSR activities, including corporate governance, in accordance with our corporate philosophy and Codes of Conduct, and contribute to sustainable social development through our business activities.

Sagara

Gyo Sagara President, Representative Director, and CEO

#### **Our Business Model**

Being a research-based pharmaceutical company specializing in prescription drugs, we have adopted a business model that pursues the in-licensing and development of promising new drug candidates from around the world, as well as the creation of innovative pharmaceuticals by ourselves, with focusing resources on the development of new drugs.

#### In-House Drug Discovery

In drug discoveries, we have pursued our "Compound-Orient" approach to development of innovative and novel drugs by identifying priority areas such as bioactive lipids and enzyme inhibitors, instead of targeting specific disease areas, by collecting a "library" of compounds that act on diverse targets, and by finding drugs that are effective against disease or support treatment from the library. On the other hand, we are also putting efforts into development of innovative drugs in a target area which is completely new to us (biopharmaceuticals). As an example, the anti-PD-1 antibody OPDIVO (nivolumab) was generated through genomics research. The area of cancer therapy and supportive treatment has now become one of our key strategic areas, and we are intensifying efforts in this area.

#### Open Innovation

We have long been driving drug discovery in various areas through the adoption of world-leading technologies and knowledge in various fields. In 1968, we became the world's first business enterprise to succeed in all chemical synthesis of prostaglandins (PGs), a class of bioactive lipid molecules, thereby have been developing many PG drugs. In 2014, we developed the world's first anti-human PD-1 monoclonal antibody OPDIVO. We will continue promoting the industry-academia open innovation strategy to accelerate collaboration with leading research institutions at home and abroad, with the aim of developing creative pharmaceuticals in areas with unmet medical needs and innovative drugs for cancer treatment.

#### Licensing Activities

We will vigorously pursue in-licensing of new drug candidates for stable expansion of our development pipeline for the future. The disease areas we concentrate on are cancers and related diseases, diabetes, and niche areas +  $\alpha$ . In these areas, we aim at in-licensing of new drug candidates that have high value in terms of corporate strategy and efficiency.

For global business of in-house developed new drug candidates except in Asia, we adopt a basic strategy of licensing out on a per-developed-compound basis to our overseas partners with outstanding development and commercialization capacity.



## Top Message

#### Management Challenges and Growth Strategy

Considering the circumstances surrounding us, we currently identify the following three areas as important management challenges: "expanding our development pipeline," "promotion of global business," and "strengthening corporate infrastructure." Under our growth strategy, we are tackling these challenges as below.

Expanding Our Development Pipeline	Being vital to realizing sustained growth, we must expand our development pipeline and deliver new products to the market in a continuous stream. To this end in drug discovery, we are working to accelerate the development of innovative and breakthrough drugs, promoting open innovation and using world- leading technologies and knowledge. We are also expanding the development pipeline by forging ahead with proactive licensing activities to introduce new drug candidates. For in-licensing, we select compounds with high value in terms of corporate strategy and efficiency, or attractive compounds for diseases with high therapeutic need, taking into consideration the development pipeline and existing products. We will also speed up the establishment of proof of concept for this expanded development pipeline to lift the pace of drug development.					
Promotion of Global Business	We are pursuing global expansion for early launch of our original compounds by out- licensing to overseas partners and by progressing clinical developments overseas to enable delivery of the new drugs we develop to the world. We are also reinforcing overseas business expansion in anticipation of our own overseas marketing of specialty products such as anticancer drugs. We have strengthened a direct marketing structure, setting up wholly owned subsidiaries in South Korea in 2013 and in Taiwan in 2014. At the same time, we are moving ahead to develop the personnel we anticipate for overseas business expansion.					
Strengthening Corporate Infrastructure	We are working to develop and bring dynamism to our human resources for enhanced global competitiveness. We are also pursuing speedy responses to all kinds of changing circumstances and to achieve our innovation goals, by enhancing diversification and strengthening internal and external collaborative ties, including creating a mechanism to promote opportunities for women to play active roles. In addition, we are driving CSR activities to a new level in accordance with our corporate philosophy and Codes of Conduct to strengthen our corporate infrastructure.					



Change in Number of Domestic Development Projects

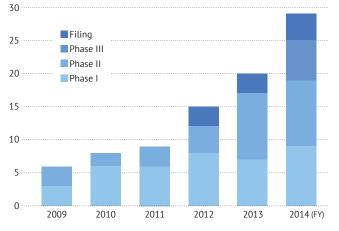
# Moving Out of Dependence on Long-Term Listed Products (%) 90 90 80 70 60 50 40 30

2012

2013

2014 (FY)

#### Change in Number of Overseas Development Projects



Long-term listed productsNew products

Patent-expired long-term listed products accounted for about 90% of sales in FY2009.

The ratio improved, down to the mid 40% range in FY2014, due to expanded sales of new products obtained through proactive licensing activities.

#### **To Our Stakeholders**

2010

20

10

0

2009

We are committed to continuing to make all-out efforts with energy and determination to deliver new drugs that meet the needs of frontline healthcare as soon as possible, for the sake of patients suffering from disease throughout the world. And we will continuously enhance our corporate value through business development to

2011

fulfill stakeholder expectations.

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.

We would appreciate your continued support.

## **ONO's** Mission

**Corporate Philosophy** 

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

ONO PHARMACEUTICAL's corporate philosophy is engraved on the stone monument at the Minase Research Institute, the hub of our drug discovery and research, in 1968. It was in 1717 when Ichibei Fushimiya set up his apothecary in Doshomachi, Osaka. Since then, ONO has dedicated itself to the business of developing and selling pharmaceutical products. Throughout this almost 300-year history, ONO has never stopped in its effort to fight against disease and pain. ONO will remain firm to our corporate philosophy, clearly engraved in stone and in mind, pursuing passion for the discovery of original and innovative drugs. ONO will rely on this commitment that has sustained us for nearly three centuries, combined with the technology and know-how we have against disease. Our continuous quest for the development of drugs will deliver true benefit to health of individuals and genuine contribution to the good of society.





#### **Our Vision**

#### Be passionate challengers

Our Vision is to strive with the utmost effort and strong determination to meet the challenge of combining our individual competencies to deliver new, innovative drugs to patients. We will continue being the most passionate champion in the fight against disease and pain, together with patients, their families, and healthcare providers.

#### **Our Values**

ONO aims to be a world-changing team

The greater the challenge, the more passionately ONO will rise to meet it

ONO acts with dignity and pride



We act with the pride of a person concerned with pharmaceuticals, aiming to uphold the hopes of people around the world.

## **ONO's View**

Unique drug development approach and high R&D capability

Business development with focus on prescription drugs and new drugs

> Active collaboration activities at home and abroad

Under its corporate philosophy "Dedicated to Man's Fight against Disease and Pain," ONO PHARMACEUTICAL has been making progress steadily towards building a pharmaceutical company that can compete on the global stage. Optimizing our strengths with an eye to the future, we are in active pursuit of becoming "Global Specialty Pharma," an R&D-oriented global pharmaceutical company specialized in particular areas.

Entering into oncology area on a full-scale basis Original anticancer drug, OPDIVO

- Approved and released in Japan for the treatment of melanoma
- Approved and released in the U.S.A. for the treatment of melanoma
  Approved in the U.S.A. for the treatment of squamous non-small cell lung cancer

• Approved in South Korea for the treatment of melanoma Signs a strategic collaboration agreement with Bristol-Myers Squibb Company regarding immuno-oncology therapies

Works to enhance overseas operations with an eye to our own marketing abroad

FY2013

FY2014

Establishes a local subsidiary in South Korea

#### FY2014

Establishes a local subsidiary in Taiwan

FY2007-

Stepping up licensing activities

A number of collaboration

agreements

Moving out of dependence on long-term listed products, and expanding sales of new products

FY2010

Percentage of long-term listed products About 90% in FY2010



FY2017 Celebrates the 300 years anniversary of foundation

#### FY2015-

Promotes oncology research and drug discovery based on Compound-Orient

Promotes global business

Maximizes the value of the anticancer drug, OPDIVO

Expands primary market sales and strengthens the oncology marketing system



FY2014

Mid 40% range in FY2014

## **Key Product Profiles**

#### **GLACTIV Tablets for the Treatment of Type 2 Diabetes**

GLACTIV, a dipeptidyl-peptidase (DPP) 4 inhibitor, is an oral drug for treatment of type 2 diabetes. It regulates blood sugar levels in type 2 diabetes patients with the mechanism of action selectively inhibiting DPP-4, an enzyme that metabolites a gastrointestinal hormone, incretin. 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 2014 Sales: 30.8 billion yen** 

#### **RECALBON Tablets for the Treatment of Osteoporosis**

RECALBON, a drug for the treatment of osteoporosis, is the first oral bisphosphonate discovered in Japan. It is one of the most potent bisphosphonates, rapidly preventing bone resorption, and is the first bisphosphonate that demonstrated significant effect in bone fracture prevention over placebo in Japanese osteoporosis patients. In addition to the Once-Daily 1mg formulation, the Once Per 4 Weeks 50mg formulation has been launched to improve convenience for patients by decreasing dosage frequency. **FY 2014 Sales: 10.3 billion yen** 

#### EMEND Capsules / PROEMEND for Intravenous Injection 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 for chemotherapy-induced nausea and vomiting. EMEND is available in two dosage forms: oral preparation (EMEND Capsules) and injection (PROEMEND for Intravenous Injection) for patients who have difficulty taking drugs orally.

FY 2014 Sales: 8.6 billion yen

#### **RIVASTACH** Patch for the Treatment of Alzheimer's Disease

RIVASTACH 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. **FY 2014 Sales: 6.8 billion yen** 









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

STAYBLA is a new anticholinergic, an antagonist selectively binding to M3 and M1 muscarinic receptors. It is available as standard tablets and as orally disintegrating (OD) tablets. By reducing the excessive contraction of the smooth muscle of the bladder, it is effective in symptoms associated with OAB including frequent urination, urinary incontinence, and urgency of urination. FY 2014 Sales: 5.3 billion yen

#### **ORENCIA** for Subcutaneous Injection for the Treatment of Rheumatoid Arthritis

ORENCIA is a subcutaneous injection for the treatment of rheumatoid arthritis. It inhibits secretion of cytokines by blocking the signal that activates T cells, resulting in the easing of joint inflammation.

It was launched in August 2013.

FY 2014 Sales: 4.1 billion ven

#### **OPDIVO Intravenous Infusion for the Treatment of Malignant Tumor**

OPDIVO is the world's first approved immune checkpoint inhibitor that targets PD-1 receptors. It provides antitumor benefits by blocking the PD-1-mediated interactions between cancer cells and T-cells (immune cells) and promoting the activation of T-cells, thereby enhancing the ability of the immune system to eliminate cancer cells. Japan: Launched in September 2014 - Unresectable melanoma

U.S.A.: Launched in January 2015 - Advanced, unresectable or metastatic melanoma Additional indication was approved in March 2015: Recurrent squamous non-small cell lung cancer

#### FY 2014 Sales: 2.5 billion yen

#### FORXIGA Tablets for the Treatment of Type 2 Diabetes

FORXIGA is a therapy that reduces blood sugar by excreting excess blood glucose via urine through the inhibition of SGLT2, a transporter that acts to regulate reabsorption of glucose in the kidney tubules. It is an oral drug for the treatment of type 2 diabetes and improves high blood sugar after meals and fasting blood sugar levels, independently of insulin. It was launched in May 2014. FY 2014 Sales: 1.5 billion yen









## **Key Product Profiles**

#### **OPALMON Tablets for the Treatment of Peripheral Circulatory Disorder**

OPALMON is an orally administered prostaglandin-E<sub>1</sub> derivative for the treatment of ischemic symptoms accompanying thromboangiitis obliterans and subjective symptoms and walking disability associated with acquired lumbar spinal canal stenosis. It improves symptoms caused by peripheral circulatory disorder such as numbness, pain or coldness of the hands or feet. The formulation that improves stability of the drug to humidity was launched in 2014. **FY 2014 Sales: 24.8 billion yen** 

#### r 201 i Sates. 2 no Bittion yen

#### ONON Capsules / ONON Dry Syrup for the Treatment of Bronchial Asthma and Allergic Rhinitis

Both ONON Capsules and ONON Dry Syrup are leukotriene receptor antagonist. Leukotriene is closely involved in the basic pathologies of bronchial asthma and of allergic rhinitis. The drug relieves asthma symptoms, namely coughing and breathlessness. ONON Dry Syrup is a formulation suitable for use with pediatric patients.

FY 2014 Sales: 10.2 billion yen / 5.8 billion yen

## FOIPAN Tablets for the Treatment of Chronic Pancreatitis and Postoperative Reflux Esophagitis

FOIPAN Tablets inhibits pancreatic enzymes which cause chronic pancreatitis and postoperative reflux esophagitis. It alleviates abdominal pain, nausea, abdominal distension 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 2014 Sales: 6.1 billion yen** 

#### KINEDAK Tablets for the Treatment of Diabetic Peripheral Neuropathy

KINEDAK is the first aldose reductase inhibitor marketed in Japan. By blocking aldose reductase, which is activated under hyperglycemia, the drug reduces the production of sorbitol intraneural, 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 2014 Sales: 4.8 billion yen







#### **ONOACT** for Intravenous Infusion for the Treatment of Intra-operative or Post-operative Tachyarrhythmia, or Tachyarrhythmia in Left Ventricular Dysfunction

ONOACT is a short-acting  $\beta_1$  blocker that selectively blocks  $\beta_1$  receptors mainly found in the heart. It is for emergency treatment of intra-operative or post-operative tachyarrhythmia (atrial fibrillation, atrial flutter, sinus tachycardia), and for treatment of tachyarrhythmia in left ventricular dysfunction (atrial fibrillation, atrial flutter). FY 2014 Sales: 4.7 billion yen

#### ELASPOL for Injection for the Treatment of Acute Lung Injury Associated with Systemic Inflammatory Response Syndrome

ELASPOL is the world's first selective inhibitor of the neutrophil elastase. No medication is yet available for the direct treatment of lung function. 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 2014 Sales: 2.7 billion yen

We have resolutely pushed forward in the pharmaceutical industry,

pursuing our original path in drug discovery using Compound-Orient to develop and deliver new drugs that meet the needs of frontline healthcare, for the sake of patients.







## Status of Development Pipeline

As of August 4, 2015

#### New Drugs in Development in Japan

New Drugs in Developmen	спізаран		De				
Product (Development Code)	Proposed Indication	Pharmacological Action, etc.	PI	elopm PII		age Filed	
RIVASTACH Patch	Alzheimer's disease	Dual inhibitor of AChE					Co-development with
(ONO-2540 / ENA713D)	(Additional dosing regimen)	and BuChE					Novartis Pharma
PROEMEND for i.v. infusion (ONO-7847 / MK-0517)	Chemotherapy-induced nausea and vomiting in pediatric patients	$NK_1$ receptor antagonist				$\rightarrow$	In-licensed from Merck (U.S.A.)
OPDIVO Intravenous Infusion	Non-small cell lung cancer	Human anti-human PD-1					Co-development with
/ BMS-936558		monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Renal cell cancer	Human anti-human PD-1 monoclonal antibody			$\rightarrow$		Co-development with Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Head and neck cancer	Human anti-human PD-1 monoclonal antibody			$\rightarrow$		Co-development with Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Gastric cancer	Human anti-human PD-1 monoclonal antibody			→		Co-development with Bristol-Myers Squibb
ORENCIA IV	Juvenile rheumatoid arthritis	T-cell activation inhibitor			→		Co-development with
(ONO-4164 / BMS-188667) ORENCIA IV	Lupus nephritis	T-cell activation inhibitor			->>		Bristol-Myers Squibb Co-development with
(ONO-4164 / BMS-188667)							Bristol-Myers Squibb In-licensed from Onyx
ONO-7057 / Carfilzomib	Multiple myeloma	Proteasome inhibitor					Pharmaceuticals
ONO-5163 / AMG-416	Secondary hyperparathyroidism	Calcium sensing receptor agonist					In-licensed from Amgen
ONOACT Intravenous Infusion 50mg / 150mg (ONO-1101)	Tachyarrhythmia in low cardiac function in pediatric patients	Short acting beta 1 blocker			->		In-house
ONOACT Intravenous Infusion 50mg / 150mg (ONO-1101)	Ventricular arrhythmia	Short acting beta 1 blocker			•		In-house
OPDIVO Intravenous Infusion / BMS-936558	Urothelial cancer	Human anti-human PD-1 monoclonal antibody		->			Co-development with Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Esophageal cancer	Human anti-human PD-1		->>			Co-development with
/ BMS-936558 OPDIVO Intravenous Infusion		monoclonal antibody Human anti-human PD-1					Bristol-Myers Squibb Co-development with
/ BMS-936558	Hodgkin's lymphoma	monoclonal antibody					Bristol-Myers Squibb
ONO-7643 / RC-1291	Cancer anorexia/cachexia	Ghrelin mimetic		→			In-licensed from Helsinn Healthcare
ONO-1162 / Ivabradine	Chronic heart failure	If channel inhibitor		→			In-licensed from Les Laboratoires Servier
ONO-6950	Bronchial asthma	LT receptor antagonist		->			In-house
ONO-5371 / Metyrosine	Pheochromocytoma	Tyrosine hydroxylase inhibitor		->			In-licensed from Valeant Pharmaceuticals North America
OPDIVO Intravenous Infusion / BMS-936558	Hepatocellular carcinoma	Human anti-human PD-1 monoclonal antibody					Co-development with Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Solid tumor (combination with Mogamulizumab)	Human anti-human PD-1 monoclonal antibody	-				Co-development with Bristol-Myers Squibb and Kyowa Hakko Kirin
ONO-7056/Salirasib	Solid tumor	Ras signal inhibitor					In-licensed from Kadmon
ONO-7268MX1	Hepatocellular carcinoma	Therapeutic cancer peptide vaccines					In-licensed from OncoTherapy Science
ONO-7268MX2	Hepatocellular carcinoma	Therapeutic cancer peptide vaccines	-				In-licensed from OncoTherapy Science
ONO-2160 / CD	Parkinson's disease	Levodopa pro-drug					In-house
ONO-2370 / Opicapone	Parkinson's disease	Long acting COMT inhibitor					In-licensed from Bial
ONO-4059	B cell lymphoma	Bruton's tyrosine kinase (Btk) inhibitor					In-house

Under our new drug research & development policy "Promoting oncology research and drug discovery based on Compound-Orient", ONO continues making efforts, driving expansion of the development pipeline through in-house drug discovery and licensing activities, tackling the diseases that remain unconquered as yet, and addressing areas that are high in healthcare needs where patient satisfaction of treatment is still low. No matter how difficult, ONO will never give up this endeavor but carry on taking up the challenge of discovering innovative pharmaceutical products, holding in our hearts the mission that ONO brings hopes to everyone in the world.

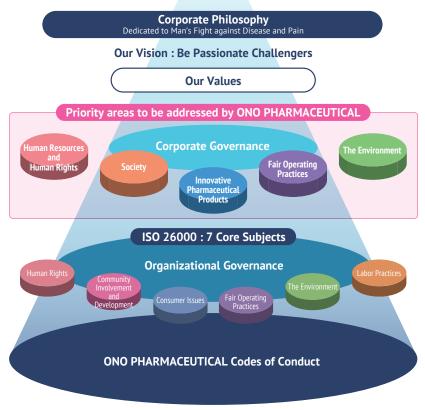
#### New Drugs in Development Overseas

Draduat			Dev	alanm	ont C	tago	
Product (Development Code)	Proposed Indication / Area	Pharmacological Action, etc.	PI	elopm PII	PIII	Filed	
<b>OPDIVO Intravenous Infusion</b>	Melanoma / Taiwan	Human anti-human PD-1					Co-development with
/ BMS-936558		monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Co-development with
/ BMS-936558	/ South Korea, Taiwan	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Non-small cell lung cancer	Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Head and neck cancer	Human anti-human PD-1					Co-development with
/ BMS-936558	/ South Korea, Taiwan	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Gastric cancer	Human anti-human PD-1					Co-development with
/ BMS-936558	/ South Korea, Taiwan	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	· · · · · ·	Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	0	monoclonal antibody					
	/ U.S.A. & Europe	Human anti-human PD-1			_		Bristol-Myers Squibb Out-licensed to
OPDIVO Intravenous Infusion	Diffuse large B cell lymphoma						
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody		-			Bristol-Myers Squibb
OPDIVO Intravenous Infusion	, , , , , , , , , , , , , , , , , , , ,	Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Urothelial cancer	Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion	Colon cancer	Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer) / U.S.A. & Europe	Human anti-human PD-1 monoclonal antibody		•			Out-licensed to Bristol-Myers Squibb
ONO-6950	Bronchial asthma / U.S.A.	LT receptor antagonist		→			In-house
ONO-2952	Irritable bowel syndrome / U.S.A.	TSPO antagonist		►			In-house
ONO-9054	Glaucoma, ocular hypertension / U.S.A.	PG receptor (FP / EP3) agonist		►			In-house
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion / BMS-936558	Hematologic cancer (T-cell lym- phoma, multiple myeloma, chronic leukemia, etc.) / U.S.A. & Europe	Human anti-human PD-1 monoclonal antibody	-				Out-licensed to Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
OPDIVO Intravenous Infusion		Human anti-human PD-1					Out-licensed to
/ BMS-936558	/ U.S.A. & Europe	monoclonal antibody					Bristol-Myers Squibb
		Bruton's tyrosine kinase (Btk)					Out-licensed to
ONO-4059	B cell lymphoma / U.S.A. & Europe	inhibitor					Gilead Sciences
ONO-8055	Underactive bladder / Europe	PG receptor (EP2 / EP3) agonist					In-house
ONO-1266	Portal hypertension / U.S.A.	S1P receptor antagonist					In-house
ONO-4232	Acute heart failure / U.S.A.	PG receptor (EP4) agonist	-				In-house
ONO-4474	Osteoarthritis / Europe	Tropomyosin receptor kinase (Trk) inhibitor	-				In-house

## **CSR** Management

## Identifying six priority areas based on our corporate philosophy and Codes of Conduct, and contributing to sustainable social development through business activities

Placing the ONO PHARMACEUTICAL Codes of Conduct at the foundation of our CSR management, we have cross-checked them against the 7 Core Subjects of ISO 26000, and identified Six Priority Areas for the CSR activities that would be expected of us. Based on our Corporate Governance, we have defined the other priority areas as Innovative Pharmaceutical Products, Human Resources and Human Rights, The Environment, Fair Operating Practices, and Society, and we are committed to demonstrating accountability to our stakeholders by disclosing information about our efforts in these areas.



\*ISO26000: The international standard on social responsibility for organizations, published by the ISO (International Organization for Standardization, based in Geneva) in November 2010

#### **ONO PHARMACEUTICAL Codes of Conduct**

- We will develop safe, high quality and effective drugs that help people have a healthy life, and provide society with them in addition to necessary information.
- We will act with respect for the human rights of all people in every aspect of our business activities.
- We will comply with the law in every field of our business activities and strive to maintain fair relationships with society.
- We will make efforts to conserve the global environment in every field of our business activities.
- 5. We will strive for highly transparent corporate management and proactively disclose business information.
- 6. We will seek harmony with society as a corporate citizen.



#### **CSR** Promotion Structure

To promote CSR activities, we have the CSR Committee in place, chaired by the Executive Director of Corporate Management Division. The Committee, which mainly consists of managers from various divisions, deliberates and makes decisions on important issues and subjects in the six priority areas for CSR activities.

The activities of the Committee are periodically reported to the management.



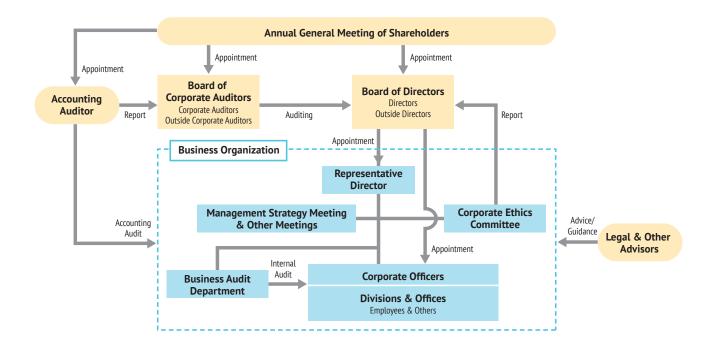


#### **Basic Concept**

To respond to the trust of all stakeholders and increase our corporate value, ONO PHARMACEUTICAL believes that our critical issues are not only the compliance of laws and regulations but also the enforcement of our management transparency and enhancement of our corporate governance.

#### **Corporate Governance Structure**

ONO has adopted the organizational framework with Corporate Auditor (or Board of Corporate Auditors) focusing on the enhancement of functions of the Board of Directors and the Board of Corporate Auditors, as a part of endeavors to bolster corporate governance.





#### Board of Directors

The Board of Directors consists of seven members including two outside directors. The Board of Directors aims to boost corporate dynamism, expedite the decision-making, and endeavors to ensure that the Board of Directors is comprised of the appropriate number of directors.

The term of office of each director is limited to one year to clarify his or her management responsibility and strengthen the management structure.

The Board of Directors holds a meeting every month in principle to deliberate and make decisions on important management issues.

#### Board of Auditors

The Board of Auditors consists of four members including two outside auditors.

The Board of Auditors holds a meeting every month in principle.

Working with the internal auditing department to enforce auditing efficiency, the Board of Corporate Auditors endeavors to improve its functions of the management oversight by enhancing the effectiveness of audits in cooperation with the accounting auditor.

#### Outside Directors / Outside Auditors

Since June 2013, we have invited two outside directors with expert knowledge and abundant experience, so as to maintain and improve the management soundness and operational preciseness for further enhancement of the corporate governance. They both are independent directors without potential conflicts of interest who have no special interests in ONO.

As to Outside Corporate Auditors, a lawyer and a certified public accountant are on the Board of Corporate Auditors, respectively conducting the audit with their experienced deep knowledge from objective and expert perspectives.

#### Operational Manegement Structure

With a Corporate Officer system in place, we seek to enhance operational management functions.

Important matters related to the operational management and executive decisions are discussed and made in various

meetings. The Management Strategy Meeting is attended by the President and Representative Director, the Directors and Corporate Officers, who take responsibility for each division, as well as the managers of those divisions. The Directors and Corporate Officers also variously preside over meetings according to the significance and details of the management issues at hand, to deliberate and make executive decisions on those issues. Through those activities, we strive to achieve appropriate operational management, taking supervisory functions into consideration such as employing checks and balances with Board members. ONO also includes attendance at the Management Strategy Meetings and inspection of the minutes within the scope of the Auditors' work. Important matters involving operational execution require the involvement of Directors who serve concurrently as Corporate Officers, to ensure continuous and stable business operations. Meanwhile, the Board of Corporate Auditors fulfills its role through its members attending the Board of Directors meeting and other key meetings, and reception of reports from Directors regarding the execution of duties by them and discussions thereof.

#### Internal Control System

With regard to the internal control system, the Board of Directors has resolved that "a system for ensuring appropriateness of the company's operations" should be in place. The internal control system has been established and its operational status is monitored. The system will be reviewed whenever it is necessary to strengthen and improve the operational compliance as well as overall internal control. Furthermore, we adopt a firm stance fighting against any antisocial forces or organizations that may threaten social order or security.

#### **Corporate Governance Code**

We are currently examining Japan's Corporate Governance Code (Final Proposal) released earlier this year, to take appropriate actions.

#### **Risk Management**

We work to identify potential major risks to prevent them from occurring, and have a structure in place to ensure that appropriate actions are taken in case of their occurrence.

#### Rules and Other Systems for Risk Management for Losses

- (1) Risks related to compliance, product quality and safety, safety and health, the environment, disasters, information security and other issues are managed by relevant division. Each division prepares and distributes risk management procedures in accordance with applicable internal rules, as well as provides its staff with appropriate training.
- (2) Risks deemed to have significant impact on management, and cross-organizational risks, are monitored and addressed at a meeting attended by the President and Representative Director, Directors and Corporate Officers in charge, as well

as the managers of relevant divisions. In case of unexpected risks, the President calls a meeting of the Emergency Response Committee to solve the problems promptly.

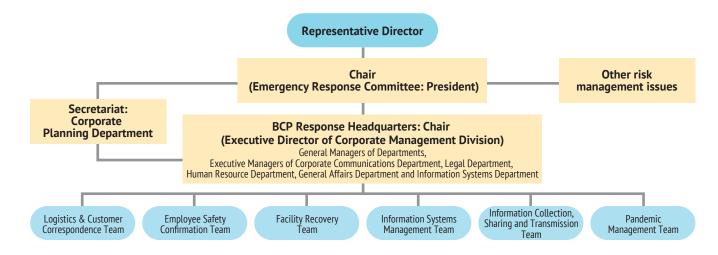
(3) Risks specific to each division are addressed by such division through preparation of handling procedures and other measures as necessary.

#### Systems to Ensure that the Company and its Corporate Group Composed of the Company's Subsidiaries are Operating in an Appropriate Manner

ONO provides sound advice and guidance to promote the compliance and risk management systems of the entire ONO's Group. As to the management of each group company, while respecting its autonomy, we periodically receive reports on their business operations and conducts preliminary consultations for important issues.

#### **Business Continuity Plan (BCP)**

In case of the occurrence of unexpected emergency such as a natural disaster or accident, we have a structure in place under the BCP Headquarters with the Executive Director of Corporate Management Division as chair to ensure that we can minimize its impact on mission-critical operations and continue business activities or to immediately recover and resume them if suspended. In case such emergency occurs, six teams have been established to perform specific tasks in accordance with the BCP: Logistics & Customer Correspondence Team, Employee Safety Confirmation Team, Facility Recovery Team, Information Systems Management Team, Information Collection, Sharing and Transmission Team, and Pandemic Management Team.





#### Information Disclosure

As specified in our Codes of Conduct, we strive for establishment of the transparent corporate management and recognize the importance of taking various opportunities to disclose information on our business activities in a timely and appropriate manner. We actively conduct investor relations (IR) activities based on the policy of pursuing accuracy, promptness, fairness, and impartiality.

We disclose financial results and other related information in a timely manner through TDnet, the timely disclosure network of the Tokyo Stock Exchange, and our website at the same time. Information that is not subject to the timely disclosure rules is also disclosed swiftly through our website and other means. For securities analysts and institutional investors, we actively

hold meetings and phone conferences, in addition to a financial result briefing or conference call on each quarterly statement. We also diligently participate in securities firmsponsored investor conferences and the like for individual investors to facilitate their deeper understanding of our business activities and management strategy. Our website contains IR Library, which provides useful current

and past data including flash report and development pipeline progress status, as well as Financial Highlights for the last five years. Also, we endeavor to convey our corporate information to a wider range of people in an easy-to-understand manner, by issuing business report for shareholders, and Annual Reports (titled "Corporate Report").

#### **Messages from Independent Executives**



Outside Director Yutaka Kato

I am an independent executive appointed as a Director of ONO PHARMACEUTICAL. Outside directors attend at Board of Directors meetings and get involved in management decision-making from a thirdparty perspective. Through such involvement, the directors play a role in strengthening the company's governance structure.

Outside directors may identify what the industry or the company takes for granted, as peculiar to the public at large. I believe that social perspectives need to be reflected on making management decisions on various issues to bring true competitive advantage to companies in which they are involved. In general, outside directors cannot participate in discussions if they have little knowledge about the industry and the company. ONO, however, makes sure to, upon appointment of outside directors, provide us with sufficient explanation with detailed information about modes of action of drugs on living organisms and clinical trials. This allows us to actively participate in discussions at the Meeting of Board of Directors. There is a culture in ONO where the idea takes root that "outsiders' views are valuable because they are outsider." This is one of ONO's strengths.



Outside Director Jun Kurihara

Amid continuously expanding and deepening globalization, ONO PHARMACEUTICAL is facing a business environment with further increasing uncertainties.

Under such circumstances, the company should actively and boldly create and evolve business models including drug discovery. At the same time, it should carry out its social responsibility as an innovative pharmaceutical company with global competitiveness. It is essential that ONO has foresight and deep consideration with global perspective to grow and expand, sticking to its corporate philosophy "Dedicated to Man's Fight against Disease and Pain," in a severely competitive global environment that is changing rapidly like a kaleidoscope.

As an outside director who is independently involved in the Board of Directors by exploiting their own professional experience, I would like to share my global network and long-term experience in decision making to contribute something, even if small, to ONO.

Innovative Pharmaceutical Products "Dedicated to Man's Fight against Disease and Pain" is our corporate philosophy as a pharmaceutical company dedicated to the development of new drugs, a philosophy to which all our divisions, all our people, dedicate themselves with passion and conviction in our research, licensing, development, manufacturing, and marketing, so that we can bring innovative drugs as soon as possible to patients throughout the world.

> Combining our distinctive drug discovery approach with cutting-edge technologies at home and abroad for development of innovative pharmaceutical products. **Research**

Expanding our development pipeline through in-licensing activities, and promoting global business through out-licensing activities. **Licensing**  Delivering new drugs that meet the needs of frontline healthcare as soon as possible.

#### Manufacturing

Manufacturing and stably supplying drugs with assured quality that can be used with peace of mind.

#### Marketing

Raising the true value of drugs through supply, collection and feedback of proper drug Information.



Research, Licensing, Development

#### **Our Mission in Research and Development**

Deliver our contribution to society by developing drugs that truly benefit patients

We are tackling the diseases that remain unconquered as yet, and addressing areas that are high in healthcare needs where patient satisfaction of treatment is still low. Our discovery research aims to identify and develop innovative and breakthrough pharmaceutical products.

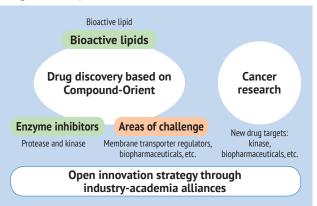
#### **Our Drug Development Policy**

In the course of research we have amassed a library of compounds that act on diverse targets, and have pursued our original path in drug discovery using the Compound-Orient approach that enables us to identify those compounds that are effective against disease or that support treatment. This is our distinctive approach that identifies priority areas of drug discovery targets such as bioactive lipids and enzyme inhibitors, instead of targeting specific diseases. We believe that maximizing the potential of the well-amassed library of compounds would raise the likelihood of success in the discovery of breakthrough drugs. In the meantime we have successfully developed the anti-PD-1 antibody OPDIVO (nivolumab) generated through genomics research, which is the world's first-in-class innovative anticancer drug in a target area completely new to us (biopharmaceuticals). The area of cancer therapy and supporting treatment has now become one of our key strategic areas, and we have newly organized a section called Oncology Research Laboratories. Leveraging cancer immunology technology and know-how accumulated through OPDIVO development, we vigorously work to produce novel drugs expanding our scope to cover new areas of potential drug targets and next-generation drugs including biopharmaceuticals. Our prostaglandin related products developed so far are the successful results of our open innovation alliance with universities and research institutions at home and abroad. OPDIVO is also a success of open innovation with Kyoto University. Even before this term came into common use, we have long been driving drug discovery through the adoption of world-leading technologies and knowledge.

We have also established Orientem Innovation<sup>®</sup>, a new form of research network in industry-academia alliance, which we believe provides researchers at academia with new framework to find pharmaceutical uses more rapidly than before using new compounds identified by us at an earlier stage of research. We have launched three Orientem Innovation<sup>®</sup> projects so far, including the research alliance with Tohoku University and The University of Tokyo for new bioactive lipids. We will continue to drive similar initiatives into the future, both in Japan and overseas. Other activities of open innovation alliance for drug discovery include an agreement to provide The University of Tokyo's Drug Discovery Initiative (former Open Innovation Center for Drug Discovery) with our original compound library and participation as a founding member of an organization, called GPCR Consortium, aimed at promoting structural analysis of G-protein coupled receptors (GPCRs) through collaboration between pharmaceutical companies and overseas academia.

Our drug discovery research efforts will be directed to promote discovery and development of innovative pharmaceuticals in areas with unmet medical needs and innovative anticancer drugs by maximizing the industry-academia open innovation strategy and accelerating collaboration with leading research institutions at home and abroad.

#### **Drug Discovery Research Domains**



## A Research Structure Combining Knowledge with Technologies

The development of innovative new drugs is driven by the spirit of challenge and motivation of individual scientists and their ability to think along new paths. We set out high but clear targets to enhance such motivation and creative thinking among its researchers. Our research organization is based on project teams where members converge from different fields, bringing cutting-edge expertise from contrasting backgrounds. The interaction within the teams stimulates and mutually enhances our research achievements. Drug discovery research coordinates the efforts of three laboratories: the Minase Research Institute, the Tsukuba Research Institute and the Fukui Research Institute. State-of-the-art facilities for genomics and metabolomics technologies, X-ray crystallography, high-throughput synthesis and highthroughput screening are fully deployed in our efficient and speedy discovery research efforts.



#### The Minase Research Institute

The Institute engages in medicinal chemistry research, research investigating the properties and efficacy of compounds, discovery research for cancer treatment, and formulations research to enable assurance of their quality and functions as pharmaceutical products.

#### The Fukui Research Institute

The Institute works with focus on compound safety assessment, and on mass production and cost reduction for the supply of active pharmaceutical ingredients.

#### The Tsukuba Research Institute

The Institute, in alliance with academic and research institutions, undertakes advanced medical research freely from established concepts, exploratory research for analysis of disease-causing substances and new compounds that can control these substances, as well as research to verify the pharmacokinetics of discovered compounds.



#### Vigorous Activities for Licensing Initiatives

We continue to forge ahead with licensing activities to introduce new drug candidates with the aim of introducing compounds attractive for diseases with high therapeutic need, and compounds that have high value in terms of corporate strategy and efficiency, while taking into consideration the development pipeline and existing products. Our aim is to expand the development pipeline to provide a continuous stream of new market launches. In 2014, we signed a strategic collaboration agreement with Bristol-Myers Squibb Company (BMS) regarding immuno-oncology therapies, and a development collaboration agreement with Kyowa Hakko Kirin and BMS regarding immuno-oncology therapies.

We are simultaneously directing efforts into out-licensing to overseas alliance companies so that patients around the world can use the new drugs we discover. In 2014, we signed a out-licensing and joint development agreement with Gilead Sciences (U.S.A.) regarding BTK inhibitor ONO-4059, and collaboration agreements with Meiji Seika Pharma and China Chemical & Pharmaceutical regarding development and commercialization of the oral prostaglandin E1 analogue Limaprost.

Continuously promoting vigorous licensing activities, we are making steady progress in expanding development pipeline and developing a road map for global business to deliver new drugs we develop.



\* Our partners (as of August 4, 2015)

#### Korea In-/out-licensing Dong-A Pharmaceutical

Taiwan

In-/out-licensing

Japan In-/out-licensing

Sumitomo Dainippon Pharma Kissei Pharmaceutical Astellas Pharma KYORIN Pharmaceutical OncoTherapy Science Meiji Seika Pharma **Development Collaboration** Kyowa Hakko Kirin

#### U.S.A.

In-/out-licensing

Merck Bristol-Myers Squibb Kadmon Onyx Pharmaceuticals Amgen Valeant Pharmaceuticals North America Gilead Sciences

Drug Discovery Alliances Array BioPharma Locus Pharmaceuticals BioSeek Receptos

#### Accelerated Clinical Development Framework

China Chemical & Pharmaceutical

We are committed to promoting clinical development with enthusiasm to deliver new drugs that meet the needs of frontline healthcare as soon as possible, for the sake of patients suffering from disease throughout the world.

We have established a Translational Medicine Center that brings together the functions necessary to bridge from the adequate assessment of efficacy, safety and quality of promising new drug candidates at the basic research and nonclinical stages, to clinical development in an effort to enable quicker decision making in development and shorten the period from commencement of drug development to establishment of efficacy and safety (POC). Clinical development plays a role in collecting data on drug efficacy and safety in humans to file with Ministry of Health, Labour and Welfare applications for marketing approval for prescription drugs. To obtain marketing approval as soon as possible, we are speeding up the clinical development process by advancing mutual use of results from multinational clinical trials and other overseas studies.

In the oncology area with unmet needs remaining high, we are enhancing our development framework through the establishment of the Oncology Clinical Development Planning Department in 2013 to further concentrate on this one of our strategic areas.

#### **Promotion of Global Business**

While our clinical development efforts are based in Japan, we have established nerve centers for clinical development within the overseas subsidiaries: ONO PHARMA USA, INC. (OPUS) and ONO PHARMA UK LTD. (OPUK). Both subsidiaries are pursuing overseas clinical development of our new drug candidates. We also strongly contribute to clinical development efforts in Asia.

We have commenced work to build an operations base in Asia enabling us to market some specialty products such as anticancer drugs overseas. We established ONO PHARMA KOREA CO., LTD., a wholly owned subsidiary of ONO in Seoul, South Korea in December 2013, and ONO PHARMA TAIWAN CO., LTD., in Taipei, Taiwan in 2014.

In South Korea, we obtained marketing approval for anticancer drug OPDIVO for melanoma in March 2015. After the launch of the drug, we will promote sales jointly under a strategic collaboration agreement with BMS. In Taiwan, we are also promoting drug development. In cooperation with medical professionals, we will continue to be committed to activities that help treatment of patients around the world.

## Manufacturing

#### **Quality Assurance Policy**

Pharmaceuticals are products concerned with life, they play a crucial role in maintaining health and in treating diseases. It is necessary to assure their quality to a high standard and to ensure their stable supply. Accordingly, we not only meet the legal requirements as a manufacturer and marketer, but also create our own quality manual to establish a drug quality system and work to develop and continuously improve quality pharmaceutical products from the viewpoints of patients, caretakers and healthcare professionals. In addition, we contribute to society through stable supply of pharmaceutical products that are assured to a high quality standard.



#### Efforts to Ensure Reliability

At ONO, all the divisions involved in manufacturing cooperate closely with each other and they consistently maintain a strong sense of responsibility and ethics as they perform evidence-based manufacturing operations and continuously make maximum efforts toward the stable supply of drugs of assured quality.

We also have a system in place to ensure reliability through preparation of drug risk management plans and operation of the drug quality system, so that patients and medical professionals can use our pharmaceutical products in a safe and reliable manner.

#### Production System Optimization

We continually review production systems and invest in suitable plant and equipment for further optimization of marketed products, while keeping in mind the timing of marketing, quantities and product features relevant to the production system structure for products destined for market launch.

#### Improvement of Quality Check System Reliability

We deliver only products that have been ascertained to have assured quality by monitoring safety and efficacy information and by checking manufacturing and testing records as well as visually inspecting all products.

#### Productivity Improvement

We strive to improve productivity, driving laborsaving initiatives such as automation of production processes, as well as careful examination of cost structures, from pharmaceutical substance to pharmaceutical production.

#### Human Resources Development

We strive to develop our human resources through specialist training for workers involved in production, passing skills from experienced technicians to young employees, in-house personnel exchange, and training in anticipation of globalization.

#### Risk Management

We have a risk management system in place to ensure stable drug supply. Our system is based on proper production facility management, ensuring proper product quantities, and avoiding the impacts of power outages by equipping production centers with emergency power provisions.

#### Maintenance of Product Recall System

We have a system in place to recall any products with efficacy, quality or safety problems, and to promptly provide medical professionals with information on them. We conduct periodical drills in preparation for recall to check that product recalls can be executed quickly even in unexpected circumstances.



## • Efforts toward the Proper Use of Pharmaceutical Products

We strive to prevent medication errors through various measures, including clear labeling on containers to avoid drug confusion by patients, their families and medical professionals, as well as printing the drug name and contents clearly on PTP sheets even after they are split up. We are also developing packaging of products on which necessary information can be marked to prevent patients from misusing them. Collecting and providing drug safety (side effects) information is a crucial role for pharmaceutical companies. The information is collected through reports from patients and medical professionals, reviews of academic papers, surveys conducted by pharmaceutical companies and other means. We assess the collected information and accordingly revise precautionary statements in the package inserts when necessary.

Examples of Measures to Prevent Malpractice



#### Production Centers with Established High Quality and Productivity

Our production centers in Shizuoka and Osaka are compliant with GMP (a set of standards relating to the manufacturing control and guality control of pharmaceuticals). The Fujiyama Plant, our key production center, constructed in Fujinomiya City, Shizuoka Prefecture in 1975, has continually improved and expanded its facilities, so that today the plant boasts computer-controlled manufacturing facilities. In 1999, a large-scale injection manufacturing plant was constructed within the grounds of the Fujiyama Plant, equipped with highperformance automation facilities. In 2009, a solid formulation manufacturing plant equipped with state-of-the-art manufacturing facilities was newly constructed. In May 2014 an injection line equipped with manufacturing facilities to handle highly active and antibody drugs was completed, including facilities that can handle new drugs through development phase. The injection manufacturing plant is equipped with high-performance facilities and world-class software that comply not only with Japanese but also European and U.S. GMP standards. Computers are used to give all the necessary operational commands in the manufacturing process, to check such operations, and to gather and record data. Industrial robots are used in all processes, from receiving pharmaceutical substances to the dispatch of finished products. The solid formulation manufacturing plant utilizes high-speed, high-performance machinery for thorough quality assurance.



Marketing

#### The Mission of MRs



Even if a drug is an excellent product, it is of no value unless it can be used correctly in medical treatment and be delivered to those who are suffering from disease. Moreover, drugs could determine life or death. It is of paramount importance that accurate information is supplied appropriately. Our Medical Representatives (MRs) shoulder this all-important role of communicating drug information. MRs visit medical professionals to provide information on proper drug usage, as well as to provide and collect information on drug efficacy and safety. The mission of MRs is to contribute to society by providing healthcare support in collaboration with medical professionals for the benefit of patient treatment, in accordance with high ethical standards.

#### Promotion of Efforts to Enhance True Value of Drugs

#### Information Sharing Framework Architecture

In addition to providing information, MRs uphold the importance of exchanging information with medical professionals to ascertain whether our drugs truly benefit each individual patient and their family throughout the course of the patient's treatment. ONO's information-sharing framework enables our MRs to share across the company the valuable information they gather from the frontline of healthcare. Our MR-support website carries a wide variety of information, notably the Product Q&A, a resource based on analysis of all information accumulated to date, as well as safety information, promotional materials, information on academic societies, conferences and research papers, and information on sponsored seminars. We also have a system in place that allows all the MRs to access useful information at all times from their tablet devices.

All the MRs are equipped with highly secure smartphones. The smartphones feature a sales force automation (SFA) system that makes the entire sales process more efficient, as well as functions for using the FAQ system.

Our structure promotes information sharing and enables them quick responses to healthcare providers' needs.

#### Relaying Up-to-date Drug Information to the Frontline of Healthcare

Medical technology undergoes daily advances and the same is true of pharmaceutical products. It is one of the roles of drug manufacturers to relay as quickly as possible up-to-date information about such drugs and to provide opportunities for information exchange. We actively provide information by organizing symposiums and seminars in conjunction with academic conferences held in Japan and through workshops and lectures in regional areas. We are also putting efforts into information technology-based measures, for example, live webinars and disease information dissemination from our ONO Medical Navi and ONO ONCOLOGY websites. In addition, we have been developing a framework that enables MRs to respond rapidly to the high-level needs of oncologists at universities and oncology institutes. In 2014, we appointed specialist MRs dedicated to oncology due to the launch of new products in this highly specialized field.



#### Enhancement of MR Training Programs

We are enhancing MR training programs as we increase the investment in our MRs, for the sake of their development. We provide training programs focusing on our products and related diseases and we also continuously provide training programs intended to familiarize MRs with the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice to build mutual relationships with researchers, medical professionals, and patient organizations. Training programs are delivered at Head Office and branches across the country to ensure that even amendments or supplementary articles are appropriately made known to all our MRs.

Moreover, MRs do on-site training at specialist institutions for dementia, diabetes, and cancer to enable them to identify



the needs of patients and their families for delivery of drugs that truly benefit patients.

In the field of dementia in particular, all our MRs have completed the Dementia Supporter Training Course — which aims to "get the facts straight on dementia, support people with dementia and their families, and carry on improving the amenity of everyday life for all members of society" — and work in a supporter capacity.

We enjoy the support and cooperation of medical institutions for these efforts.

Experience that cannot be gained only through normal MR activities is incorporated into marketing work that distinguishes ONO MRs from the rest, aiming to truly benefit patients and place importance on the views of patients and their families.





Human Resources and Human Rights Based on belief that "People make the company," we actively support the development of individual abilities and positive action taken without fear of failure. We promote efforts to improve safety and health conditions, and to create a working environment where the company and its employees can live in harmony and individual abilities blossom to their full extent.

We also value a society where human rights are fully respected and seek to establish a company with no discrimination due to race, nationality, ethnicity, gender, age, religion, belief or philosophy, academic background, disability or illness, and so on.



#### **Development of Human Resources**

#### Human Resources Sought by ONO

In a rapidly changing environment, we need human resources who:

- are innovation-minded and never give up trying until the end;
- can demonstrate their abilities in a team environment and can work collaboratively;
- have a strong sense of responsibility for, and are proud of, their own jobs;
- always take a positive approach and can learn and grow independently; and
- act in an ethical manner with common sense.

To help develop such human resources, we are committed to enhancing our education and training system, and cultivating employee-friendly workplaces.

#### Provision of Growth Opportunities

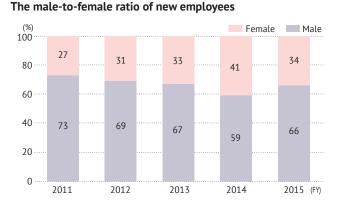
We organize a wide range of collective training programs for employees in each phase of career growth, including company-wide joint training for new employees from all divisions, departmental introductory training, annual training for young employees, and pre-management training. We also provide position-based training for managerial staff-namely division managers, assistant managers and section leaders-focusing on the management required for organizational growth.

In addition to these seniority- and position-based training programs, we organize training programs to develop employees who can work on the global stage, and send employees to overseas affiliates. As part of our commitment to promotion of diversity, we provide training for female employees. Furthermore, we have a system in place to assist employees in self-learning so as to develop a culture where they study and grow independently.



# **Diversity Promotion Initiatives**

At ONO, we make continuous efforts to promote diversity in our workplaces. We have been working on development of a structure to promote opportunities for women to play active roles and we have been increasing recruitment of women with the ratio of new female graduate recruits rising year by year. We have also been expanding mid-career employment to quickly obtain human resources with the skills and knowledge that are needed immediately. We have been actively recruiting persons with disabilities, who account for an employment rate of 2.12% as of March 31, 2015. This exceeds the legally stipulated rate (2.0%) set in 2013.





#### Employment rate of persons with disabilities

# Enhancing Cultivation of Employee-friendly Workplaces

We are committed to creating a pleasant working environment to ensure that employees can devote themselves to work with a sense of security.

#### Employment Programs

We offer employment programs that support employees at various stages of their lives, including childcare leave and shortened work hour programs for childcare, family and nursing care leave programs that exceed the legal requirements, and the non-regular re-employment scheme for retired employees. We also put continuous efforts into improving work-life balance, introducing measures to reduce overtime work, including the "No Overtime Day" program. In fact, we have been certified as a general business operator meeting the criteria based on the Law for Measures to Support the Development of the Next Generation in 2008, 2012 and 2014.

#### Safety and Health

For safety and health, we regularly hold safety and health committee meetings to continuously improve the working environment. In our plants and research institutes, safety and health inspectors report findings from inspection patrols to the committee and propose improvements, effectively familiarizing employees with health and safety procedures, and taking appropriate actions. All our establishments are inspected annually for fire and other disaster prevention measures, fire extinguishing and first aid equipment, safe handling of machinery, safety procedure implementation levels, transportation operations, as well as cleanliness and tidiness.

In Head Office and other workplaces in which a health committee needs to be established, health committee members from the labor and management have discussions on health and report the results of workplace environmental measurements.

#### Numbers of industrial accidents



# **Initiatives by Priority Area**

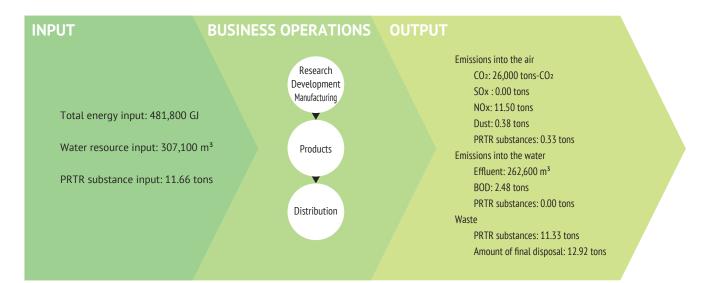
# **The Environment**

### **ONO PHARMACEUTICAL Environmental Guidelines**

- Aware of corporate social responsibility for the environment, 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, including natural resources and biodiversity.
- 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.

### **Overall Picture of Environmental Impact** (ONO's Involvement in the Environment Protection)

Annual inputs and outputs are grasped on a regular basis to use as reference data for our efforts to reduce environmental impact. (Scope: production and research sites/ FY2014)





## **Promotion of Environmental Management**

We recognize that ONO has social responsibility regarding the environment, and we are working to protect and preserve the global environment in all of our business operations.

We have formulated a voluntary environmental action plan in accordance with our Environmental Guidelines. Under the plan, we set and work to achieve specific action targets, and review the results (or progress) of the work toward the targets every year.

Our environmental management promotion structure consists of the Executive Director of Corporate Management Division, CSR Promotion Section, and the Environmental Management Committee. The Executive Director of Corporate Management Division supervises company-wide environment issues, and CSR Promotion section operates the Committee. Members of the Committee are chosen from relevant departments, and responsible for specific on-site monitoring and promoting environmental management. Each of the production and research sites with environmentally major impact has a subcommittee to work on environmental issues. Each production site makes continuous efforts to reduce environmental impact under an ISO 14000-compliant environmental management system in place.

# **Ongoing Environmental Protection Activities**

#### Energy Saving and Global Warming Prevention

Energy saving and global warming prevention are regarded as the most important environmental goals of ONO. All our places of business-plants, research institutes, and offices-take energy-saving and power-reducing measures appropriate to the nature of their operations. Efforts are made to reduce greenhouse gas emissions from our business activities with the aim of achieving our mid-term environmental target of more than 23% reduction in  $CO_2$  emissions (from the production and research sites) for FY2020 compared to FY2005.

In FY2014, CO<sub>2</sub> emissions from the production and research sites increased 5.7% compared to FY2005 due to the increase in emission factor for computing CO<sub>2</sub> emission from purchased electricity. On the other hand, FY2014 saw a 0.8% year-on-year decrease in CO<sub>2</sub> emissions from the production and research sites, some of which carried out fuel conversion. As a result, company-wide CO<sub>2</sub> emissions has remained unchanged.

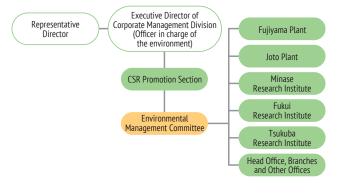
[Examples of Measures Taken]

Company-wide "Cool Biz" and "Warm Biz" campaigns, which recommend

The workers receive necessary training on environmental management concerning the operations that could have impact on the environment, to reduce environmental risks.

We also have a structure to minimize environmental impact arising from emergency disasters, by providing training and on-site education and formulating manuals to prepare for them.

#### **Environmental Management Promotion Structure**



to wear casual clothing during summer and winter seasons, are promoted to reduce energy burden.

The production and research sites take such measures as replacement of aging air conditioning equipment and cubicles with highest performance equipment, under their respective energy management regulations. As a specified business operator designated under the Law Concerning Rational Use of Energy, we report our energy consumption and energy saving plan every year to the Ministry of Economy, Trade and Industry and the Ministry of Health, Labour and Welfare. We will continue considering the adoption of more enhanced monitoring systems including factory energy management system (FEMS) and building energy management system (BEMS), and the introduction of new and renewable energies, to promote electricity demand leveling and reduce electricity consumption.

The Sales and Marketing Division encourages the staff to practice eco-driving, and has been gradually replacing its leased commercial vehicles with hybrid vehicles since FY2010. By the end of FY2013, hybrid vehicles replaced all conventional commercial vehicles except cold climate specification ones. The division is now considering replacement of more fuel-efficient hybrid vehicles.

# **Initiatives by Priority Area**

#### Energy-derived CO<sub>2</sub> Emissions



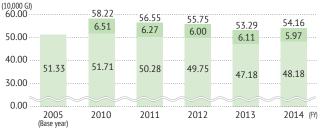
Production and research sites Head Office and other sites in Japan (including tenant locations) \* Sites where CO<sub>2</sub> emission data were collected: Fujiyama Plant, Joto Plant, Minase Research Institute, Fukui Research Institute, Tsukuba Research Institute, Head Office, branches, sales offices, and distribution centers.

 $CO_2$  emissions are calculated in accordance with the Act on the Rational Use of Energy.  $CO_2$  emissions = Purchased electricity x CO<sub>2</sub> emission factor (\*) +

Σ (Fuel consumption x Per unit calorific value x Carbon emission factor x 44 / 12)
 \* Actual emission factor of each electricity power supplier published by the Ministry of the Environment of Japan every year

The figure in the base year and the target value are those in the production and research sites.

#### Energy Consumption



Production and research sites Head Office and other sites in Japan (including tenant locations) \* Sites where energy consumption data were collected: Fujiyama Plant, Joto Plant, Minase Research Institute, Fukui Research Institute and Tsukuba Research Institute, Head Office, branches, sales offices, and distribution centers.

#### Waste Management

The production and research sites have achieved, and will be committed to continuing, "Zero Emissions\*". Also, we visit intermediate and final waste disposal contractors to confirm that our industrial waste is properly disposed of.

- Some hazardous substances and waste reagents are excluded from the "zero waste emission" activities because priority is given to disposal of them in a safe and reliable manner.
- This aims to reduce the proportion of waste landfilled below 1.0% through reuse of industrial waste generated from business activities.

#### Chemical Emission Reduction

We are committed to reducing chemical emissions to the lowest possible level not only in compliance with laws and regulations but also with awareness that they may have impact on human health and the ecosystem. We manage and report PRTR substances and polychlorinated biphenyl (PCB) in compliance with applicable laws and in an appropriate manner.

#### Independent Practitioner's Assurance

We have gotten the independent practitioner's assurance by the third organization to raise the credibility of our information disclosed in this report regarding energy-derived CO<sub>2</sub> emissions from our domestic business locations. Please refer to the "Independent Practitioner's Assurance Report" on page 115.

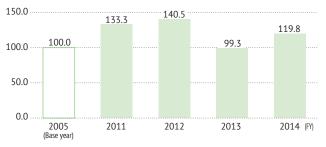
# Environmental Efficiency / Environmental Accounting

We have assessed environmental efficiency of our production and research sites to evaluate their environmental efforts in a quantitative form. In addition, we have disclosed environmental accounting data in reference to the Environmental Accounting Guidelines (2005 edition) issued by the Ministry of the Environment of Japan. We have disclosed an indicator that represents the efficiency of our environmental conservation activities in the reduction of environmental impact. To calculate the indicator, environmental impacts generated by our activities were categorized into the five categories of chemical substances, global warming, waste, water quality, and air quality. The level of the environmental impact in a representative environmental factor selected for each of these categories was divided by the sales for the fiscal year. The environmental efficiency indicator for FY2014 became worse in year-onyear comparison due to special factors (there was a period in which factories were out of operation in FY2013), and increased emissions of environmental factors into the atmosphere because regular power generators began operation at Fujiyama Plant. In comparing to FY2005, the indicator dropped by 19.8 percentage points. This is because of increased atmospheric NOx emissions from the start of the above mentioned power generator operation at Fujiyama Plant, and increased atmospheric PRTR substance emissions from increased research activities, in addition to decreased sales.

We will be committed to reducing environmental impact, and improve the environmental efficiency indictor.

#### Assessment of Environmental Efficiency

(Indicator with a score of 100 representing the level in 2005)





# **Environmental Cost and Effect in FY2014**

The environmental investment at our main production and research sites during FY2014 was aimed at global warming countermeasures and other environmental measures.

The environmental cost for FY2014 decreased from the previous year due to the investment plan revision.

Category	Environme	ental cost		Amount of investment in environmental equipment		
	FY2013 FY2014		FY2013	FY2014		
<ol> <li>Pollution prevention costs (prevention of air pollution, water pollution, soil pollution, groundwater pollution, hazardous chemicals, noise, vibration and offensive odor)</li> </ol>	91,264	53,037	10,276	2,149		
2: Global environment conservation costs (prevention of global warming and environmental conservation)	414,344	299,828	132,136	112,839		
3: Resource circulation costs (reduction of waste, proper treatment of waste and efficient use of resources)	117,105	95,814	28,000	0		
4: Administration activity costs (time and costs spent for relevant committees, ISO activities and environmental management)	6,985	8,526	-	_		
5: Research and development costs	72,659	116,208	-	-		
6: Social activity costs (promotion of cleanup and tree planting in the business sites and surrounding areas, etc.)	625	1,049	-	_		
Total	702,982	574,462	170,412	114,988		

#### **Environmental Conservation Effect**

Environmental performance indicator		Change in th environmer		Environmental impact		
		FY2013	FY2014	FY2013	FY2014	
	SOx emissions (tons)	-0.01	0.00	0.00	0.00	
	NOx emissions (tons)	-0.38	5.54	5.96	11.50	
Effect related to	Water use (10,000 m <sup>3</sup> )	-1.37	2.00	28.71	30.71	
	BOD load (tons)	0.25	-0.42	2.90	2.48	
business area costs	CO <sub>2</sub> emissions (10,000 tons-CO <sub>2</sub> )	-0.08	-0.02	2.62	2.60	
	Energy use (10,000 GJ)	-2.56	1.00	47.18	48.18	
	Total waste discharge (tons)	408.60	-322.44	1013.14	690.70	
	Amount of waste final landfilled (tons)	-9.96	-0.21	13.13	12.92	

#### Economic Effect Associated with Environmental Conservation Activities

Economic Effect Associated with Environmental Conservation Activities					
Details of effect	Tot	tal			
Detaits of effect	FY2013	FY2014			
1. Reduction in cost through energy saving activities	248,522	251			
2. Reduction in waste cost through recycling activities	23	0			
3. Profit on sales from waste recycling	90	108			
Annual total	248,635	359			

# Initiatives by Priority Area

Fair Operating Practices Being aware of responsibilities as a pharmaceutical company dealing in pharmaceuticals upon which human lives depend, ONO PHARMACEUTICAL has original Codes of Conduct in place to ensure that it takes actions in compliance with not only laws and regulations but also higher ethical standards. We thoroughly train all employees to ensure compliance and promote proper procurement activities in cooperation with suppliers.

## **ONO's Ethical System**

Our ethical system consists of ONO PHARMACEUTICAL Codes of Conduct, which serve as basic guidance for our corporate activities; the Compliance Program, which provides for standards of conduct for the activities; and the Codes of Practice, which are based on the industry standards on promotion and other activities. In putting the ethical system into practice, we repeatedly remind our employees of their duties to ensure transparency in transactions and prevent fraud and corruption, and act in consideration of social situations at home and abroad. Being keenly aware of corporate ethics as a pharmaceutical company, we will continue to further strengthen our level of compliance in line with our ethical system.

# **Compliance Promotion Initiatives**

#### Compliance Promotion System

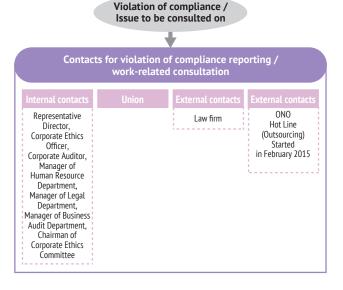
To promote compliance, we have appointed a Corporate Ethics Officer and set up a Corporate Ethics Committee under the officer to examine and deliberate compliance-related issues and to plan and promote relevant training programs.

We have internal and external contacts for compliance issues as well as a system to ensure that informants can also directly report to or consult with top management — that is, the Representative Director, the Corporate





Standards of conduct that govern the actions of all executives and employees on medical workers/institutions, researchers, patient groups and wholesalers





Ethics Officer, and the Corporate Auditors — to prevent the occurrence or recurrence of violation of compliance or to take necessary measures in the event of violation of compliance to minimize any loss or decrease in our credibility. External contacts include not only a law firm but also the 24-hour ONO Hot Line set up in February 2015, to enable employees to report or consult without hesitation.

#### Compliance Education System

We give the following training courses for employees to enhance their awareness of compliance:

We schedule a period for training (three months) every year during which all employees are required to join lectures given by the leaders of respective departments, and training courses using an e-learning system, to improve their familiarity with and understanding of compliance in general. In addition, in case of violation of compliance, we may give special company-wide training to prevent occurrence or recurrence of violation of compliance, depending on the nature of the case.

We periodically provide training for relevant departments on the internal standards established based on the laws and industry agreements. For example, in the Sales and Marketing Division, compliance promotion staff members visit each sales branch twice a year to provide MRs with compliance training focusing on dissemination of the internal standards especially for the pharmaceutical promotion code in our Codes of Practice.

#### Ethical Considerations

We take due consideration of ethics at every stage of research and development.

We have set up internal ethical rules for research using human-derived samples based on the basic guidelines issued by the Japanese government. Such research projects can be conducted only after the Ethics Committee assesses and determines so that the projects are ethically and scientifically valid.

For research using laboratory animals, we have an Institutional Animal Care and Use Committee in place. The committee reviews the protocols for such research in advance to determine whether they are prepared with due consideration of the 3Rs–replacement (to actively adopt alternative test methods), reduction (to use a smaller number of laboratory animals) and refinement (to relieve pain and distress) – to ensure appropriate conduct of animal experiments with respect for the lives of the animals and with

consideration for animal welfare. In addition, we conduct self-inspection and assessment of the status of ongoing animal experiments and obtain a third party certificate on these activities from the Center for Accreditation of Laboratory Animal Care and Use of the Japan Health Sciences Foundation. Clinical trials, which are essential for verifying the safety and efficacy of investigational compounds, must be performed with respect for the rights of trial subjects. Clinical trials are closely monitored for patients' safety and are stringently conducted under the high ethical standards. We are committed to evaluating the real merit of investigational compounds by steadily applying essential and complete testing procedures that comply with Japan's Pharmaceutical Affairs Law and other related legislation, as well as the global standards based on the spirit of the Declaration of Helsinki.

#### Fair and Transparent Business Activities

We conduct fair and transparent business activities.

We aim to contribute to healthcare all around the world and people's health through continuous R&D activities and stable supply of new drugs. To this end, we need to engage in collaborative activities (support for patient organizations) and cooperate with research and medical institutions to help patients overcome disease and pain. To enhance the fairness and transparency aspects of such collaboration and cooperation, it is important to ensure transparent relationships with our partners. We therefore disclose information on costs of our assistance to medical institutions and patient organizations in accordance with our transparency guideline developed in consideration with the JPMA's relevant guideline.

As for publicly funded research, we developed internal standard operating procedures for publicly funded joint research projects in March 2015, for appropriate operation and management in accordance with the Japanese government's guideline. Under these SOPs, we appropriately conduct publicly funded research projects.

We have established a basic policy for procurement activities in terms of fairness, sound economic reasonableness, and environmental protection. Our procurement staff members are required to act in accordance with this policy. The purchasing organization is clearly separated from other parts of the company and is subject to regular internal audit to ensure transparency. Starting in FY2015, we carry out surveys with the cooperation of our suppliers, assess their CSR activities under our procurement activity policy and ensure their thorough familiarity with proper procurement activities.

# Initiatives by Priority Area



ONO PHARMACEUTICAL provides information on its website that helps raise awareness of dementia and is useful for medical services and nursing care to support patients and their families. Its business facilities in various locations are actively involved in activities that contribute to local communities.

# Various Corporate Social Responsibility (CSR) Activities

#### Web-Based Information Dissemination

Our corporate website contains a section for patients and their families that provides information for the proper use of its key products. This section also explains common diseases, including diabetes, allergic rhinitis and hay fever, in an easy-to-understand manner with diagrams and illustrations. It introduces specific symptoms, therapeutic methods and things that patients should do in their daily life to support themselves and their families. We also have other web sources to disseminate information widely. We have launched a website specializing in dementia titled "Dementia Medical



Care with Smiles and Hearts", which provides comments and messages from a wide range of healthcare professionals involved in the treatment and care of people with dementia. We have also set up "ONO ONCOLOGY," a website to communicate information on diseases and treatments in oncology to a wide audience.

#### Initiatives for Medical Advancement

We are committed to contributing to medical advancement to meet unmet medical needs.

In 1988, ONO Medical Research Foundation was established with donations from ONO. The Foundation provides grants for research activities in the field of lipid metabolism disorders and also aims to promote research and treatment in that field through various projects and thereby contribute to the health and welfare of the public. The Foundation has provided research grants and scholarships every year for 27 years since its establishment. We also provide academic support through endowed courses at universities, including:

- Surgery and Multidisciplinary Treatment Chair, Kyushu University
- Advanced Therapy for Spine and Spinal Cord Disorders Endowed Chair III, Keio University
- Immunology and Genomic Medicine Chair, Kyoto University



#### Activities to Support the Health of People

We have conducted various activities to provide a wide range of support for the health of people including patients and their families.

After ONO received marketing approval for the anticancer drug OPDIVO for melanoma in July 2014, we offered a pre-NHI reimbursement drug access program based on ethical considerations until the product was listed on the NHI price list.

We also cooperated in holding disease seminars for citizens to raise disease awareness and provide correct disease information. In 2014, we participated for the first time in "Relay for Life," a charity event aimed at supporting cancer patients and their families and making cancer controllable and surmountable through community action against cancer.

In the field of dementia, all our MRs, who have completed the Dementia Supporters Training Program, consider what they can do on a daily basis to help people with dementia and their families live with a sense of security. We produce and release on our corporate website a series of short movies titled "Grandma's World" which are aimed at raising dementia awareness. We also present the "Communicate & Link" exhibition on the website, which





shows images of paintings, calligraphy and other art works created by people with dementia at medical institutions. This exhibition is aimed at spreading joy to them and their families and helping medical providers gain professional fulfillment. In 2015, we held a panel exhibition of such art works and a talk show with the selection committee members, including entertainer and artist Mr. Tsurutaro Kataoka.

In addition, we held the "Operation Slimmer and Healthier" in Aizu Misato-Machi, Fukushima Prefecture as a Great East Japan Earthquake reconstruction assistance activity, in cooperation with top athletes and specialists in lifestyle disease, to address childhood obesity, a social issue in the earthquake-affected areas. This project provides an opportunity for children and their parents to consider meals and lifestyle diseases through sports.

We will be committed to continuing to be involved in activities that help people keep healthy.

#### Engagement with Local Communities

In our role as a corporate citizen, we are committed to activities that contribute to local communities through our places of business, including cleanups and firefighting drills. In 2014, employees at Fujiyama Plant participated for the first time in the voluntary Mt. Fuji cleanup event.

We are also involved in activities to support people with disabilities. We offer workplace learning to educational institutions for people with disabilities. We hold sales events for bread baked at workshops that support the independence of persons with disabilities.

In addition, other CSR activities we carry out in line with the roles of a pharmaceutical company include giving special lessons to high school and junior high school students to deepen understanding of dementia, and holding Japan Red Cross Society blood drives at Head Office, research institutes, and plants.



# **Financial Section**

# **Financial Review**

The following is a summary of the consolidated business results for the fiscal year ended March 31, 2015.

## **Area of Business**

ONO PHARMACEUTICAL CO., LTD. and its subsidiaries are engaged in the pharmaceuticals business.

# **Results for Fiscal Year Ended March 31, 2015**

In the current consolidated fiscal year, the Japanese economy showed mixed signs of gradual recovery and stagnant trends. The export sector continued to benefit from the yen's depreciation due to quantitative easing by the Bank of Japan and economic stimulus measures by the government, while there was sluggish growth in personal consumption in the wake of rising prices due to the consumption tax increase and weak yen. The pharmaceutical industry was faced with a decreased success rate of drug discovery and increased R&D costs. In the domestic market, the strengthening of healthcare cost reduction measures continued through the introduction of new measures to promote the use of generics in addition to the National Health Insurance (NHI) drug price reduction in April last year. Thereby, the business conditions remained difficult for research-based pharmaceutical companies.

Under such circumstances, the Group reinforced its R&D structure under our corporate philosophy "Dedicated to Man's Fight against Disease and Pain" by combining its own original drug discovery knowhow with cuttingedge science and technologies acquired from around the world to create innovative drugs. In addition, the Group directed efforts into improving efficiencies across all corporate management areas, while seeking to enhance dissemination of scientific information for further product value improvement. The Group's business results for the current consolidated fiscal year are as follows:

	Millions of Yen	Thousands of U.S. Dollars
Revenue	¥ 135,775	\$ 1,131,459
Operating profit	14,794	123,284
Profit for the year (attributable to owners of the parent company)	12,976	108,131

#### Revenue

Revenue totaled ¥135,775 million (US\$1,131,459 thousand), a decrease of ¥7,472 million (US\$62,263 thousand), down 5.2% over the previous consolidated fiscal year.

- Revenue results were severe in the wake of the new generic use promotion measures in addition to the NHI drug price reduction in April last year.
- Sales of our key new products: GLACTIV Tablets for type-2 diabetes decreased 13.7% year-on-year to ¥30.8 billion (US\$256,445 thousand). RECALBON Tablets for osteoporosis decreased 7.4% year-on-year to ¥10.3 billion (US\$85,633 thousand). The combined sales of EMEND Capsules and PROEMEND for Intravenous Injection for chemotherapy-induced nausea and vomiting decreased 1.8% year-on-year to ¥8.6 billion (US\$71,633 thousand). RIVASTACH Patch for Alzheimer's disease increased 6.0% year-on-year to ¥6.8 billion (US\$56,465 thousand). ORENCIA for rheumatoid arthritis, launched in August 2013, increased 419.2% year-on-year to ¥4.1 billion (US\$34,482 thousand). Sales of FORXIGA Tablets for type-2 diabetes, launched in May 2014, reached ¥1.5 billion (US\$12,844 thousand) while OPDIVO Intravenous Infusion for malignant tumor, the world-first anti-human PD-1 monoclonal antibody launched in September, reached ¥2.5 billion (US\$21,087 thousand).
- Sales of the main long-term listed products: OPALMON Tablets for peripheral circulatory disorder decreased 23.6% year-on-year to ¥24.8 billion (US\$206,938 thousand). ONON Capsules for bronchial asthma and allergic rhinitis decreased 23.9% year-on-year to ¥10.2 billion (US\$85,363 thousand). FOIPAN Tablets for chronic pancreatitis and postoperative reflux esophagitis decreased 24.2% year-on-year to ¥6.1 billion (US\$50,596 thousand). KINEDAK Tablets for diabetic peripheral neuropathy decreased 35.5% year-on-year to ¥4.8 billion (US\$39,864 thousand).
- Revenue includes license income from licensing out the BTK inhibitor ONO-4059 in December 2014 to Gilead Sciences, Inc.

# **Profit and Loss**

Operating profit for the current consolidated fiscal year totaled ¥14,794 million (US\$123,284 thousand), a decrease of ¥11,635 million (US\$96,955 thousand), down 44.0% over the previous consolidated fiscal year.

- Cost of sales was up 7.3%, or ¥2,391 million (US\$19,922 thousand), from the previous consolidated fiscal year to ¥35,136 million (US\$292,802 thousand) because of reduced NHI drug prices and a change in sales composition.
- R&D costs were down 6.9%, or ¥3,067 million (US\$25,560 thousand), from the previous consolidated fiscal year to ¥41,346 million (US\$344,550 thousand). This is partly because although vigorous development investment was made to maximize the value of OPDIVO Intravenous Infusion, efforts were made to improve efficiency in the use of other investment expenses and impairment losses on intangible assets decreased.
- Selling, general, and administrative expenses were up 10.0%, or ¥3,845 million (US\$32,041 thousand), from the previous consolidated fiscal year to ¥42,222 million (US\$351,849 thousand) owing to significant operating expenses for FORXIGA Tablets and OPDIVO Intravenous Infusion launched in the current year, and increased pharmacovigilance costs.
- Other expenses were up 63.2%, or ¥1,025 million (US\$8,540 thousand), from the previous consolidated fiscal year to ¥2,645 million (US\$22,043 thousand) partly because the settlement payment from cancellation of inlicensing agreement was recorded.

Profit for the year (attributable to owners of the parent company) was down 36.2%, or ¥7,368 million (US\$61,400 thousand), from the previous consolidated fiscal year to ¥12,976 million (US\$108,131 thousand), with a decrease in profit before tax.

# **Consolidated Cash Flows**

The cash and cash equivalents balance at the end of the consolidated fiscal year was ¥104,222 million (US\$868,520 thousand), down 0.6%, or ¥675 million (US\$5,628 thousand) from the previous year's figure of ¥104,898 million (US\$874,148 thousand). The main factors were cash flows from operating activities ending in a positive balance of ¥31,579 million (US\$263,160 thousand) but cash flows from investing activities ended in a negative cash flow balance of ¥12,756 million (US\$106,300 thousand), and cash flows from financing activities ended in a negative cash flow balance of ¥19,603 million (US\$163,358 thousand) due to dividend payments.

#### Cash Flows from Operating Activities

Cash flows from operating activities for the current consolidated fiscal year ended in a positive cash flow balance of ¥31,579 million (US\$263,160 thousand), a year-on-year increase of ¥3,157 million. The main factors were profit before tax of ¥18,305 million (US\$152,541 thousand), a long-term unearned revenue increase of ¥6,724 million (US\$56,030 thousand), and depreciation and amortization of ¥6,100 million (US\$50,837 thousand).

#### Cash Flows from Investing Activities

Cash flows from investing activities for the current consolidated fiscal year ended in a negative balance of ¥12,756 million (US\$106,300 thousand) (The cash flows for the previous consolidated fiscal year ended in a positive balance of ¥6,926 million). The main factors were income of ¥18,719 million (US\$155,994 thousand) attributable to the margin between investment security purchases and sales/redemptions, but on the other hand, spending for tangible fixed asset and intangible asset purchases of ¥17,540 million (US\$146,168 thousand) and ¥13,578 million (US\$113,151 thousand), respectively.

#### Cash Flows from Financing Activities

Cash flows from financing activities for the current consolidated fiscal year ended in a negative balance of ¥19,603 million (US\$163,358 thousand), a year-on-year decrease in expenditure of ¥33 million. The main factor was the dividends paid to owners of the parent company of ¥19,060 million (US\$158,833 thousand).

# **Investment in Plant and Equipment**

Plant and equipment investment during the current consolidated fiscal year totaled ¥16,031 million (US\$133,590 thousand). This included investment in enhancement and maintenance of manufacturing facilities (¥2,804 million, or US\$23,368 thousand), research facilities (¥4,637 million, or US\$38,641 thousand), and business facilities (¥8,590 million, or US\$71,582 thousand).

# Consolidated Statement of Financial Position

	Notes	Million	Thousands of U.S. Dollars [Note 2(6)]	
Assets	Notes	March 31, 2014	March 31, 2015	March 31, 2015
Current assets:				
Cash and cash equivalents	7, 33	¥ 104,898	¥ 104,222	\$ 868,520
Trade and other receivables	8,33	42,240	41,960	349,670
Marketable securities	9, 20, 33	22,295	22,746	189,550
Other financial assets	10,33	905	820	6,837
Inventories	12	24,261	25,805	215,039
Other current assets	11	958	2,311	19,260
Total current assets		195,557	197,865	1,648,878
Non-current assets:				
Property, plant, and equipment	13	59,147	70,754	589,613
Intangible assets	14	22,690	33,913	282,610
Investment securities	9, 20, 33	188,360	212,162	1,768,017
Investments in associates		1,008	1,023	8,522
Other financial assets	10, 33	5,913	6,314	52,618
Deferred tax assets	16	10,003	45	374
Retirement benefit assets	23	905	_	_
Other non-current assets	11	2,559	2,512	20,935
Total non-current assets		290,585	326,723	2,722,690
Total assets		¥ 486,141	¥ 524,588	\$ 4,371,568

		Million	s of Yen	Thousands of U.S. Dollars [Note 2(6)] March 31, 2015	
Liabilities and Equity	Notes	March 31, 2014	March 31, 2015		
Current liabilities:					
Trade and other payables	17, 33	¥ 11,288	¥ 13,745	\$ 114,543	
Borrowings	18,21,33	508	287	2,390	
Other financial liabilities	19,33	846	2,585	21,544	
Income taxes payable		4,303	6,587	54,895	
Provisions	24	1,063	684	5,696	
Other current liabilities	22	10,264	11,109	92,576	
Total current liabilities		28,272	34,997	291,644	
Non-current liabilities:					
Borrowings	18,21,33	468	317	2,643	
Other financial liabilities	19,33	17	21	172	
Retirement benefit liabilities	23	3,945	5,426	45,213	
Provisions	24	87	89	745	
Deferred tax liabilities	16	1,002	1,156	9,632	
Long-term advances received		_	6,724	56,030	
Other non-current liabilities	22	626	645	5,379	
Total non-current liabilities		6,146	14,378	119,813	
Total liabilities		34,418	49,375	411,457	
Equity:					
Share capital	25	17,358	17,358	144,652	
Capital reserves	25	17,080	17,080	142,332	
Treasury shares	25	(59,274)	(59,308)	(494,235)	
Other components of equity	25	15,626	45,756	381,300	
Retained earnings	25	456,537	449,690	3,747,413	
Equity attributable to owners of the parent company		447,327	470,575	3,921,462	
Non-controlling interests		4,397	4,638	38,649	
Total equity		451,724	475,213	3,960,111	
Total liabilities and equity		¥ 486,141	¥ 524,588	\$ 4,371,568	

# **Consolidated Statement of Income**

		Million	s of Yen	Thousands of U.S. Dollars [Note 2(6)]	
	Notes	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Revenue	6	¥ 143,247	¥ 135,775	\$ 1,131,459	
Cost of sales		(32,746)	(35,136)	(292,802)	
Gross profit		110,501	100,639	838,657	
Selling, general, and administrative expenses	27	(38,377)	(42,222)	(351,849)	
Research and development costs		(44,413)	(41,346)	(344,550)	
Other income	29	338	368	3,069	
Other expenses	29	(1,620)	(2,645)	(22,043)	
Operating profit		26,429	14,794	123,284	
Finance income	30	3,107	3,565	29,707	
Finance costs	30	(76)	(67)	(557)	
Share of profit from investments in associates	15	4	13	107	
Profit before tax		29,464	18,305	152,541	
Income tax expense	16	(8,922)	(5,089)	(42,407)	
Profit for the year		20,541	13,216	110,134	
Profit for the year attributable to:					
Owners of the parent company		20,344	12,976	108,131	
Non-controlling interests		198	240	2,002	
Profit for the year		¥ 20,541	¥ 13,216	\$ 110,134	
		Y	en	U.S. Dollars [Note 2(6)]	
Earnings per share:					
Basic earnings per share	32	¥ 191.90	¥ 122.40	\$ 1.02	
Diluted earnings per share	32	_	_	_	

# Consolidated Statement of Comprehensive Income

		Million	s of Yen	Thousands of U.S. Dollars [Note 2(6)]	
	Notes	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Profit for the year		¥ 20,541	¥ 13,216	\$ 110,134	
Other comprehensive income:					
Items that will not be reclassified to profit or loss:					
Net gain on financial assets measured at fair value through other comprehensive income	31, 33	7,106	29,529	246,079	
Remeasurement of defined benefit plans	31	596	(640)	(5,330)	
Share of net gain on financial assets measured at fair value through other comprehensive income of investments in associates	15,31	3	4	35	
Total of items that will not be reclassified to profit or loss		7,706	28,894	240,783	
Items that may be reclassified subsequently to profit or loss:					
Exchange differences on translation of foreign operations	31	323	505	4,210	
Net fair value gain (loss) on cash flow hedges	31	6	(6)	(53)	
Total of items that may be reclassified subsequently to profit or loss		330	499	4,157	
Total other comprehensive income		8,036	29,393	244,941	
Total comprehensive income for the year		28,577	42,609	355,074	
Comprehensive income for the year attributable to:					
Owners of the parent company		28,367	42,364	353,036	
Non-controlling interests		210	245	2,038	
Total comprehensive income for the year		¥ 28,577	¥ 42,609	\$ 355,074	

# Consolidated Statement of Changes in Equity

					Millions	of Yen			
			Equity attri	butable to own	ers of the parent	t company			
	Notes	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non- controlling interests	Total equity
Balance at April 1, 2013		¥ 17,358	¥ 17,080	¥ (59,231)	¥ 8,198	¥ 454,681	¥ 438,086	¥ 4,190	¥ 442,276
Profit for the year						20,344	20,344	198	20,541
Other comprehensive income	31				8,023		8,023	12	8,036
Total comprehensive income for the year		-	-	-	8,023	20,344	28,367	210	28,577
Purchase of treasury shares	25			(43)			(43)		(43)
Cash dividends	26					(19,083)	(19,083)	(3)	(19,086)
Transfer from other components of equity to retained earnings	25				(595)	595	-		-
Total transactions with the owners		-	-	(43)	(595)	(18,487)	(19,126)	(3)	(19,129)
Balance at March 31, 2014		¥ 17,358	¥ 17,080	¥ (59,274)	¥ 15,626	¥ 456,537	¥ 447,327	¥ 4,397	¥ 451,724
Profit for the year						12,976	12,976	240	13,216
Other comprehensive income	31				29,389		29,389	4	29,393
Total comprehensive income for the year		-	_	_	29,389	12,976	42,364	245	42,609
Purchase of treasury shares	25			(34)			(34)		(34)
Cash dividends	26					(19,082)	(19,082)	(4)	(19,086)
Transfer from other components of equity to retained earnings	25				742	(742)	-		-
Total transactions with the owners		-	-	(34)	742	(19,823)	(19,116)	(4)	(19,119)
Balance at March 31, 2015		¥ 17,358	¥ 17,080	¥ (59,308)	¥ 45,756	¥ 449,690	¥ 470,575	¥ 4,638	¥ 475,213

				TI	nousands of U.S.	Dollars [Note 2(6	5)]		
				Equity attributable to owners of the parent company					
	Notes	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non- controlling interests	Total equity
Balance at March 31, 2014		\$ 144,652	\$ 142,332	\$ (493,954)	\$ 130,215	\$ 3,804,477	\$ 3,727,723	\$ 36,643	\$ 3,764,366
Profit for the year						108,131	108,131	2,002	110,134
Other comprehensive income	31				244,905		244,905	36	244,941
Total comprehensive income for the year		-	-	-	244,905	108,131	353,036	2,038	355,074
Purchase of treasury shares	25			(281)			(281)		(281)
Cash dividends	26					(159,016)	(159,016)	(32)	(159,048)
Transfer from other components of equity to retained earnings	25				6,180	(6,180)	-		-
Total transactions with the owners		_	_	(281)	6,180	(165,196)	(159,297)	(32)	(159,329)
Balance at March 31, 2015		\$ 144,652	\$ 142,332	\$ (494,235)	\$ 381,300	\$ 3,747,413	\$ 3,921,462	\$ 38,649	\$ 3,960,111

# **Consolidated Statement of Cash Flows**

		Million	s of Yen	Thousands of U.S. Dollars [Note 2(6)]	
	Notes	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Cash flows from operating activities					
Profit before tax		¥ 29,464	¥ 18,305	\$ 152,541	
Depreciation and amortization		5,109	6,100	50,837	
Impairment losses		2,016	560	4,668	
Interest and dividend income		(2,584)	(2,528)	(21,069)	
Interest expense		14	13	112	
Increase in inventories		(1,036)	(1,541)	(12,839)	
Decrease in trade and other receivables		1,156	282	2,353	
Increase in trade and other payables		990	3,999	33,329	
Increase in retirement benefit liabilities		515	526	4,387	
Decrease in retirement benefit assets		1,035	915	7,629	
Increase in long-term advances received		_	6,724	56,030	
Other		(93)	327	2,729	
Subtotal		36,585	33,685	280,707	
Interest received		667	450	3,747	
Dividends received		2,046	2,138	17,816	
Interest paid		(14)	(13)	(112)	
Income taxes paid		(10,862)	(4,680)	(38,997)	
Net cash provided by operating activities		28,422	31,579	263,160	
Cash flows from investing activities					
Purchases of property, plant, and equipment		(5,816)	(17,540)	(146,168)	
Proceeds from sales of property, plant, and equipment		(3,010)	(1,5.0)	9	
Purchases of intangible assets		(7,041)	(13,578)	(113,151)	
Purchases of investments		(31,353)	(13,677)	(30,640)	
Proceeds from sales and redemption of investments		51,526	22,396	186,634	
Other		(398)	(358)	(2,984)	
Net cash provided by (used in) investing activities		6,926	(12,756)	(106,300)	
Cash flows from financing activities					
Cash flows from financing activities		(10.077)	(10.060)	(1 5 0 0 7 7)	
Dividends paid to owners of the parent company		(19,073)	(19,060)	(158,833)	
Dividends paid to non-controlling interests		(3)	(4)	(34)	
Repayments of long-term borrowings		(515)	(487)	(4,057)	
Net decrease in short-term borrowings		(2)	(19)	(161)	
Purchases of treasury shares		(42)	(33)	(272)	
Net cash used in financing activities		(19,636)	(19,603)	(163,358)	
Net increase (decrease) in cash and cash equivalents		15,712	(780)	(6,498)	
Cash and cash equivalents at the beginning of the year		89,117	104,898	874,148	
Effects of exchange rate changes on cash and cash equivalents		69	104	869	
Cash and cash equivalents at the end of the year	7	¥ 104,898	¥ 104,222	\$ 868,520	

Year ended March 31, 2015

### Note 1

# **Reporting Entity**

ONO PHARMACEUTICAL CO., LTD. (the "Company") is a stock company incorporated in Japan. The addresses of its registered head office and principal business locations are disclosed on the Company's website (URL http://www.ono.co.jp/ eng/index.html).

The consolidated financial statements of the Company were

closed at its year-end of March 31, 2015, and comprise the Company, its subsidiaries, and equity interests in associates (collectively, the "Group"). The Group manufactures and sells medical and general pharmaceutical products. The business descriptions and principal activities of the Group are described in Note 6. Segment Information.

#### Note 2

#### **Basis of Preparation**

#### (1) Statements of Compliance with International Financial Reporting Standards

Pursuant to the provision of Article 93 of the Ordinance on Terminology, Forms and Preparation Methods of Consolidated Financial Statements, the Company qualifies as a "Specified Company" prescribed in Article 1-2 of the Ordinance, and the consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards ("IFRS").

#### (2) Basis of Measurement

Except for the financial instruments and others described in Note 3. Significant Accounting Policies, the consolidated financial statements are prepared on a historical cost basis.

#### (3) Functional Currency and Presentation Currency

The consolidated financial statements of the Group are presented in Japanese yen, which is the Company's functional currency. All financial information presented in Japanese yen has been rounded to the nearest million yen, except where otherwise indicated.

#### (4) Early Applying of New Accounting Standards

The Group has early applied IFRS 9 *Financial Instruments* (revised in October 2010).

#### (5) Changes in Accounting Policies

\$1. Applying of new accounting standards Accounting standards that the Group has applied from the current consolidated fiscal year are as follows:

	IFRS	Subject of new standard / amendment
IAS 32	Financial Instruments : Presentation	Offsetting financial assets and financial liabilities
IAS 36	Impairment of Assets	Recoverable amount disclosures for non-financial assets
IFRIC 21	Levies	Clarification of the accounting for levies

The accounting standards above have been applied in accordance with each transitional measure and the amounts for the previous fiscal year have been revised retrospectively.

The above adoption of the accounting standards did not have a significant impact on its consolidated financial statements. §2. Changes in method of measurement of inventories From the current consolidated fiscal year, the group has changed the main method of measurement of inventories from the first-in, first-out method to the weightedaverage method. The purpose of this change is to measure inventories and calculate profit and loss during the term in a rapid and appropriate manner with a new cost calculation system from the current consolidated fiscal year. Furthermore, the impact of this change has been negligible so it has not been applied retrospectively.

#### (6) U.S. Dollar Amounts

The accompanying consolidated financial statements are

stated in Japanese yen. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of ¥120 to \$1, the approximate rate of exchange at March 31, 2015. 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. Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements. As a result, the totals in yen and U.S. dollars do not necessarily agree with the sum of the individual amounts.

#### Note 3

## **Significant Accounting Policies**

The significant accounting policies have been applied consistently to all periods presented in the consolidated financial statements, unless otherwise stated.

#### (1) Basis of Consolidation

#### §1. Subsidiaries

A subsidiary refers to an entity that is controlled by the Group. Control is obtained when all of the following criteria are met:

- The Group has power over the investee;
- The Group has rights to variable returns from its involvement with the investee; and
- The Group has the ability to affect the amount of variable returns through its power over the investee
  The Group reassesses whether it controls an investee if facts and circumstances indicate that there are changes in any of the three elements of control listed above.
  Even if the Group does not have a majority of voting rights, the Group concludes that it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally.

Consolidation of a subsidiary begins on the date the Group obtains control over the subsidiary and continues through the date the Group loses control of the subsidiary. In cases where the accounting policies applied by a subsidiary are different from those applied by the Group, adjustments are made to the subsidiary's financial statements, if necessary. Changes in ownership interest in a subsidiary without a loss of control are accounted for as equity transactions. The carrying amounts of the controlling and non-controlling interests of the Group are adjusted to reflect the changes in their respective percentage interests in the subsidiary. If there is a difference between the amount by which the non-controlling interests are adjusted and the fair value of the consideration paid or received, the difference is recognized directly in equity as equity attributable to owners of the parent company.

All intercompany receivables, payables, and transactions of the Group and unrealized profit and loss from intercompany transactions are eliminated in preparing the consolidated financial statements.

The closing date of all subsidiaries is the same as that of the Company.

#### §2. Associates

An associate refers to an entity over which the Group does not have control but has significant influence over the financial and operating policies of the entity. Significant influence is the power to participate in the financial and operating policy decisions of the investee, but does not have control over those policies. Investments in associates are initially recognized at cost and accounted for by the equity method of accounting in the consolidated statement of financial position from the date when the Group obtains significant influence until the date the Group loses significant influence. In cases where the accounting policies applied by an associate are different from those applied by the Group, adjustments are made to the associate's financial statements, if necessary.

The closing date of all associates is the same as that of the Company.

#### §3. Business Combinations

Business combinations are accounted for by applying the acquisition method.

At the acquisition date, identifiable assets acquired and liabilities assumed, excluding certain items required under IFRS, are recognized at their fair values on the acquisition date.

Acquisition-related costs are recognized in profit or loss as incurred.

The acquiree's identifiable assets and liabilities are measured at their fair values at the acquisition date.

#### (2) Foreign Currencies

The consolidated financial statements of the Group are presented in Japanese yen, which is the Company's functional currency. Each entity of the Group applies its own functional currency and measures its transactions using its functional currency.

Foreign currency transactions are translated into the functional currency using spot exchange rates or approximate rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency using spot exchange rates as of the closing date. Exchange differences arising from such translations and settlements are recognized in profit or loss. However, exchange differences arising from financial assets measured through other comprehensive income and cash flow hedges are recognized in other comprehensive income.

Assets and liabilities of foreign operations are translated into the functional currency using spot exchange rates as of the closing date, while income and expenses are translated into the functional currency at the average exchange rate for the period. The resulting exchange differences are recognized in other comprehensive income. In cases where foreign operations are disposed of, the cumulative amount of translation differences related to the foreign operations is recognized as profit or loss in the period of disposition.

#### (3) Financial Instruments

§1. Financial Assets

(i) Initial Recognition and Measurement Financial assets are classified as either financial assets measured at fair value or financial assets measured at amortized cost. For financial assets measured at fair value, each equity instrument is designated as measured at fair value through profit or loss ("FVPL") or as measured at fair value through other comprehensive income ("FVOCI"), except for equity instruments held for trading purposes, which must be measured at FVPL. Such designations are applied consistently.

All regular way purchases or sales of financial assets are recognized or derecognized on a settlement date basis. Regular way purchases or sales refer to purchases or sales of financial assets that require delivery of assets within the time frame generally established by regulation or convention in the marketplace.

#### Financial Assets Measured at Amortized Cost

Financial assets are classified as financial assets measured at amortized cost if both of the following conditions are met.

 The asset is held within a business model whose objective is to hold assets in order to collect contractual cash flows; and • The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets measured at amortized cost are initially recognized at fair value, plus directly attributable transaction costs. After initial recognition, the carrying amounts of the financial assets measured at amortized cost are calculated using the effective interest method, less impairment loss when necessary.

#### Financial Assets Measured at FVPL

Financial assets (other than the financial assets measured at FVOCI) that do not meet the above conditions for the classification of financial assets measured at amortized cost are classified to financial assets measured at FVPL. Financial assets measured at FVPL are initially measured at fair value and transaction costs are recognized as expenses when they are incurred. Financial assets measured at FVPL are measured at fair value after initial recognition and any changes in fair value are recognized in profit or loss for the year.

#### Financial Assets Measured at FVOCI

Equity instruments designated to be measured at FVOCI are initially recognized at fair value, plus directly attributable transaction costs. After initial recognition, they are measured at fair value, and any changes in fair value are included in "Net gain on financial assets measured at FVOCI" in other components of equity. When financial assets measured at FVOCI are derecognized, the accumulated amounts of net gain (loss) on the financial assets are immediately transferred to retained earnings. However, dividends on financial assets measured at FVOCI are recognized in profit or loss for the year as finance income.

#### (ii) Derecognition of Financial Assets

The Group derecognizes a financial asset when the contractual right to receive cash flows from the asset expires or is transferred, or when it transfers substantially all the risks and rewards of ownership of the asset.

#### §2. Impairment of Financial Assets

Financial assets measured at amortized cost are assessed on the reporting date as to whether there is objective evidence that the asset may be impaired. Evidence of impairment includes financial difficulties, default or delinquency of the debtor, or an indication that the debtor may go bankrupt.

When there is objective evidence that a financial asset is impaired, an impairment loss is measured as the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted by the original effective interest rate.

#### §3. Financial Liabilities

(i) Initial Recognition and Subsequent Measurement The Group holds financial liabilities that are measured at amortized cost. Financial liabilities measured at amortized cost are initially measured at fair value minus directly attributable transaction costs. After initial recognition, the carrying amounts of financial liabilities measured at amortized cost are calculated using the effective interest method. Gains or losses arising from amortization by the effective interest method and derecognition are recognized as profit or loss in the consolidated statement of income.

(ii) Derecognition of Financial Liabilities Financial liabilities are derecognized when the Group's contractual obligations are discharged, canceled, or expired.

#### §4. Offsetting of Financial Instruments

Financial assets and financial liabilities are offset and the net amounts are presented in the consolidated statement of financial position when, and only when, the Group currently has a legally enforceable right to offset the recognized amounts and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

#### §5. Derivatives

The Group enters into forward foreign exchange contracts as derivatives to address the risk of foreign exchange

rate fluctuations. Forward foreign exchange contracts are initially measured at fair value when the contract is entered into and are subsequently remeasured at their fair value. Changes in fair value of foreign exchange contracts are recognized as profit or loss in the consolidated statement of income. However, gains and losses on hedging instruments relating to the effective portion of cash flow hedges are recognized as other comprehensive income in the consolidated statement of comprehensive income.

#### §6. Hedge Accounting

The Group designates forward foreign exchange contracts that are derivatives in respect of addressing the risk of foreign exchange rate fluctuation as hedging instruments for cash flow hedges. At the inception of the hedge relationship, the Group documents the relationship between hedging instruments and hedged items in accordance with the strategy for undertaking hedge transactions. In addition, at the inception of the hedge and during the life of the hedge, the Group documents whether the hedging instruments are highly effective in offsetting changes in cash flows of the underlying hedged items attributable to the hedged risk.

#### Cash flow hedge accounting is as follows:

The effective portion of changes in fair value of derivatives that are designated and qualify as cash flow hedges is recognized in other comprehensive income and accumulated in other components of equity. The ineffective portion of gains or losses on the hedging instruments is recognized immediately in profit or loss. Amounts recognized in other comprehensive income and accumulated in equity are reclassified to profit or loss in the periods when the hedged item affects profit or loss in the same line as the recognized hedged item. However, in cases where the hedged forecast transaction results in the recognition of a non-financial asset or liability, the gains and losses previously recognized in other comprehensive income and accumulated in equity are transferred from equity and included in the initial measurement of the cost of the non-financial asset or liability.

Hedge accounting is discontinued when the Group revokes the hedging relationship, when a hedging instrument expires or is sold, terminated or exercised, or no longer qualifies for hedge accounting. Any gain or loss recognized in other comprehensive income and accumulated in equity remains in equity and is reclassified to profit or loss when the forecast transaction is ultimately recognized in profit or loss. When a forecast transaction is no longer expected to occur, the gain or loss accumulated in equity is recognized immediately in profit or loss.

#### §7. Fair Value of Financial Instruments

The fair values of financial instruments traded on active financial markets as of each reporting date are based on quoted prices in the markets or dealer prices. The fair values of financial instruments for which no active markets exist are calculated by using appropriate valuation techniques.

#### (4) Cash and Cash Equivalents

Cash and cash equivalents are composed of cash on hand, bank deposits drawable at any time, and short-term investments with maturities of three months or less from acquisition date, which are readily convertible to cash and are subject to insignificant risk of changes in value.

#### (5) Inventories

Inventory costs include raw materials, direct labor, and other direct costs as well as relevant overhead expenses. Inventories are measured at the lower of cost or net realizable value. Cost is mainly determined using the weighted-average method. Net realizable value is determined based on the estimated selling price in the ordinary course of business, less estimated costs of completion and costs necessary to make the sale.

#### (6) Property, Plant, and Equipment (Except for Leased Assets)

The Group applies the cost model for subsequent measurement of property, plant, and equipment and records them at cost less any accumulated depreciation and accumulated impairment losses. The cost of property, plant, and equipment comprises costs directly attributable to the acquisition of the assets and initial estimations of asset retirement obligations. Depreciation of an item of property, plant, and equipment commences when the assets are available for their intended use.

Property, plant, and equipment, other than non-depreciable assets such as land, are depreciated by the straight-line method over their estimated useful lives. The estimated useful lives of major asset items are as follows:

Buildings and structures:	15-50 years
Machinery and vehicles:	4-15 years
Tools, furniture, and fixtures:	2-20 years

The estimated useful lives and depreciation method, etc., are reviewed at the end of each fiscal year and any changes are treated as changes in accounting estimates and applied prospectively.

#### (7) Impairment of Property, Plant, and Equipment

During each fiscal year, the Group determines whether there is any indication of impairment on each asset. If any indication of impairment exists, the recoverable amount of the asset or cash-generating unit to which the asset belongs is estimated.

The recoverable amount is computed at the higher of fair value less costs to sell or value in use of the asset or cashgenerating unit. If the carrying amount of an asset or cashgenerating unit exceeds its recoverable amount, the carrying amount of the asset or cash-generating unit is reduced to its recoverable amount and impairment loss is recognized. The value in use is computed by discounting the estimated future cash flows to their present value using a pretax discount rate that reflects the time value of money and the risks inherent to the asset, etc. For the calculation of an asset's fair value less costs to sell, an appropriate valuation model is used based on available fair value indices. An impairment loss recognized in prior years is assessed as to whether there is any indication that the impairment loss for an asset or cash generating unit may have decreased or may no longer exist. If any such indication exists, the recoverable amount of the asset or cash-generating unit is estimated. In cases where the recoverable amount exceeds

the carrying amount of the asset or cash-generating unit, impairment losses are reversed up to the lower of the estimated recoverable amount or the carrying amount, net of accumulated depreciation that would have been determined if no impairment losses had been recognized in prior years.

#### (8) Intangible Assets

§1. Intangible Assets Acquired Separately

The Group applies the cost model for measurement of intangible assets and states them at cost less any accumulated amortization and accumulated impairment losses. However, intangible assets with indefinite useful lives acquired separately are stated at cost less any accumulated impairment losses.

Amortization for intangible assets commences when the related assets are available for use. Except for intangible assets with indefinite useful lives or which are not yet available for use, each intangible asset is amortized by the straight-line method over its estimated useful life. The estimated useful lives of major intangible asset items are as follows:

Sales licenses:	8-15 years
Software:	3-8 years

The estimated useful lives used in calculating the amortization of sales licenses are determined by considering the effective period of the patents and others. The estimated useful lives and amortization method are reviewed at the end of each fiscal year, and any changes are treated as changes in accounting estimates and applied prospectively.

- §2. Internally Generated Intangible Assets (Research and Development Costs Internally Generated) Under IFRS, an intangible asset arising from development (or from the development phase of an internal project) shall be recognized as an asset if, and only if, all of the following have been demonstrated:
  - (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale;
  - (ii) the intention to complete the intangible asset and use or sell it;

(iii) the ability to use or sell the intangible asset;

- (iv) how the intangible asset will generate probable future economic benefits;
- (v) the availability of adequate technical, financial, and other resources to complete the development and to use or sell the intangible asset; and
- (vi) the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Due to the risks and uncertainties relating to the approval and development activity of pharmaceutical drugs, the Group determines that the recognition criteria for capitalization as intangible assets are considered not to have been met unless it obtains marketing approval from the relevant regulatory authorities.

Internally generated development expenses arising before marketing approval has been obtained are expensed under "Research and development costs" at the time incurred.

§3. Impairment of Intangible Assets

Intangible assets with indefinite useful lives or intangible assets not yet available for use are not subject to amortization and are tested for impairment individually or on a cash-generating unit basis, at the end of each fiscal year or whenever any indication of impairment exists. Impairment tests are performed by calculating the recoverable amount of each intangible asset and comparing the recoverable amount with its carrying amount. In cases where a recoverable amount of an individual asset cannot be estimated, the recoverable amount of the cash-generating unit to which the asset belongs is estimated.

The recoverable amount of an asset or a cash-generating unit is measured at the higher of its fair value less costs to sell or its value in use. The value in use is computed by discounting the estimated future cash flows to the present value.

The discount rate used reflects the time value of money and the risks inherent to the asset using unadjusted estimates of future cash flows.

#### (9) Leases

Leases are classified as finance leases when substantially all the risks and rewards of ownership are transferred to the Group. All other leases are classified as operating leases. In finance lease transactions, leased assets and lease obligations are carried at the lower of the fair value of the leased property and the present value of the minimum lease payments, each determined at the inception of the lease. Leased assets and lease obligations are presented as property, plant, and equipment and borrowings, respectively, in the consolidated statement of financial position. Leased assets are depreciated using the straight-line method over their estimated useful lives or lease terms whichever is shorter. Lease payments are apportioned between the finance costs and the repayments of the lease obligations based on the interest method, and finance costs are recognized as an expense in the consolidated statement of income. In operating lease transactions, lease payments are recognized as an expense over the lease terms in the consolidated statement of income. Contingent rents are recognized as an expense in the period when they are incurred. Determining whether an arrangement is, or contains, a lease is based on the substance of the arrangement in accordance with IFRIC Interpretation (IFRIC) 4 Determining Whether an Arrangement Contains a Lease.

#### (10) Employee Benefits

The Group participates in both defined benefit and defined contribution plans as employee retirement benefit plans.

#### §1. Defined Benefit Plans

For the Group's defined benefit plans, the cost of providing retirement benefits is measured by the projected unit credit method, with actuarial valuations being carried out at the end of each reporting period. Remeasurements, comprising actuarial gains and losses, the effect of any changes in the asset ceiling, and the return on plan assets (excluding net interest), are recognized through other comprehensive income in the period in which they are incurred and immediately reflected in the consolidated statement of financial position. Remeasurements recognized in other comprehensive income are immediately reclassified to retained earnings and will not be reclassified to profit or loss. Past service costs are recognized in profit or loss in the period in which revisions to the plans occurred. Net interest is calculated by applying the discount rate at the beginning of the reporting period to the net defined benefit liability or asset. Defined benefit expenses are classified into the following components:

- Service costs (current service costs, past service costs and others)
- Net interest expense or income
- Remeasurements

The retirement benefit assets or liabilities recognized in the consolidated statement of financial position represent the actual surplus or deficit in the Group's defined benefit plans. Any surplus resulting from this calculation is limited to the present value of available future economic benefits in the form of refunds from the plan or reductions in future contributions to the plan.

#### §2. Defined Contribution Plans

Expenses for defined contribution plans are recognized as an expense when they are paid.

#### (11) Provisions

The Group recognizes provisions when it has a present obligation (legal or constructive) as a result of a past event, it is probable that it will be required to settle the obligation, and a reliable estimate can be made.

Where time value of money is material, a provision is measured at the present value of estimated expenditures required to settle the obligation. The present value is computed using a pretax discount rate that reflects the time value of money and the risks inherent to the liabilities.

#### (12) Revenue

The Group measures revenue at the fair value of the consideration received or receivable, less discounts, rebates, and taxes such as consumption tax.

#### §1. Sale of Goods

The Group sells medical and general pharmaceutical products. Revenue from the sale of goods is recognized

when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods, the Group retains neither continuing involvement nor effective control over the goods, it is probable that the future economic benefits associated with the transaction will flow to the Group, and the economic benefits and the costs in respect of the transaction can be measured reliably.

#### §2. Royalty Income

The Group has license agreements with third parties permitting product manufacturing and use of technology. Income (up-front payments and milestone payments) attributable to the agreements is recognized as revenue when the performance obligations under the agreements are fulfilled. In case that the performance obligations under the agreements occur over the licensing period, the revenue is recognized over the period based on rational methods.

#### §3. Interest Income

Interest income is recognized using the effective interest method.

#### §4. Dividend Income

Dividend income is recognized when the shareholder's right to receive payment is established.

#### (13) Income Taxes

Income tax expense represents the sum of current tax expense and deferred tax expense.

Current tax expense is measured at the expected amount of a refund or payment of taxes from/to the taxation authorities. The Group's income taxes are calculated using tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period. Current tax expense is recognized as an expense, except for the taxes attributable to items recognized directly either in other comprehensive income or equity.

Deferred tax expense is calculated based on temporary differences between the carrying amounts of assets and liabilities for accounting purposes and their tax basis as of

the closing date. Deferred income tax assets are recognized to the extent that it is probable that taxable profits will be available against which the deductible temporary differences, and the carryforward of unused tax credits and tax losses can be utilized. Deferred tax liabilities are principally recognized for all taxable temporary differences.

Deferred tax assets or deferred tax liabilities are not recognized for the following temporary differences:

- Deductible temporary differences associated with investments in subsidiaries and associates where it is probable that the temporary differences will not reverse in the foreseeable future or it is not probable that taxable profits will be available against which the temporary differences can be used.
- Taxable temporary differences associated with investments in subsidiaries and associates where the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets and deferred tax liabilities are calculated

using tax rates that are estimated for the year in which these assets are realized or these liabilities are settled, based on tax rates that have been enacted or substantively enacted by the closing date.

#### (14) Treasury Shares

Treasury shares are recognized at cost and deducted from equity. Neither gain nor loss is recognized on the purchase, sales, or retirement of the treasury shares. Any difference between the carrying amount and proceeds on sales is treated as capital reserves.

#### (15) Earnings per Share

Basic earnings per share are calculated by dividing profit and loss for the year attributable to owners of the parent company by the weighted-average number of ordinary shares outstanding during the year, adjusted by the number of treasury shares for the period. Diluted earnings per share have not been calculated because no potentially dilutive shares of ordinary shares are outstanding.

#### Note 4

### Significant Accounting Estimates and Critical Judgment Involving Estimations

The Group's consolidated financial statements include management estimates and assumptions for measurements of income and expense, and assets and liabilities. These estimates and assumptions are based on management's best judgment along with historical experience and other various factors that are believed to be reasonable under the circumstances as of the closing date. However, there is a possibility that these estimates and assumptions may differ from actual results in the future due to their nature. The estimates and underlying assumptions are continually reevaluated by management. The effect of revisions to the accounting estimates and assumptions are recognized in the period of the revision and future periods.

The estimates and assumptions that have a significant

effect on the amounts recognized in the Group's consolidated financial statements are as follows:

• Impairment of property, plant, and equipment, and intangible assets

With regard to property, plant, and equipment and intangible assets, if there is any indication that the recoverable amount of an asset is less than its carrying amount, the Group performs an impairment test. Important factors that trigger the impairment test to be performed include significant changes adversely affecting the results of past or projected business performance, significant changes in the usage of acquired assets or changes in overall business strategy, and significant deterioration in industry or economic trends. The amount of impairment is determined based on the higher of the fair value less costs to sell or the value in use measured based on the valuation of risk-adjusted future cash flows discounted at an appropriate rate. Future cash flows are estimated based on business forecasts. There is a possibility that a future event may result in changes in assumptions used in such impairment tests and may affect future operating results of the Group.

- Recoverability of deferred tax assets
   Deferred tax assets are recognized on temporary
   differences between the carrying amounts of assets and
   liabilities for accounting purposes and the corresponding
   tax bases, using the effective tax rate applied to the
   temporary differences to the extent that it is probable
   that future taxable profits will be available against
   which they can be utilized to recover the deferred tax
   assets.
- Actuarial assumptions for retirement benefit accounting The Group has a number of retirement benefit plans, including defined benefit plans. The Group calculates the present value of the defined benefit obligations and related service costs based on actuarial assumptions. The actuarial assumptions require estimates and judgments on variables, such as discount rates and net interest, etc.

The Group obtains advice from external pension actuaries with respect to the appropriateness of the actuarial assumptions including the variables.

The actuarial assumptions are determined based on the best estimates and judgments made by management; however, there is a possibility that these assumptions may be affected by changes in uncertain future economic conditions. In cases where the assumptions need to be revised, the revision may have a material impact on amounts recognized in the consolidated financial statements.

#### Note 5

### Standards and Interpretations Issued but Not Yet Applied

The Group has not elected early application of the following new and revised standards and interpretations, except for IFRS 9 *Financial Instruments* (revised in October 2010), that have been issued but not come into effect. The major new standards, interpretations, and amendments issued as of the date of the approval for the consolidated financial statements that may affect the Group are as follows. The Group is currently evaluating the potential impact of applying these standards on its consolidated financial statements, which is currently not available.

	IFRS	Mandatory application (from the year beginning)	To be applied by the Group	Subject of new standard / amendment
IFRS 15	Revenue from Contracts with Customers	January 1, 2017	Not determined	Issuance of a single and comprehensive model for accounting treatment for revenue from contracts with customers
IFRS 9 (final ver.)	Financial Instruments	January 1, 2018	Not determined	Impairment of financial assets and revision of hedge accounting

#### Note 6

### Segment Information

#### (1) Reportable Segments

Based on the Group's corporate philosophy, "Dedicated to Man's Fight against Disease and Pain," in order to fulfill medical needs that have not yet been met, the Group is dedicated to developing innovative new pharmaceutical drugs for patients and focuses its operating resources on a single segment of the pharmaceutical business (research and development, purchasing, manufacturing, and sales). Accordingly, segment information is omitted herein.

#### (2) Details of Revenue

Details of revenue are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Revenue of goods and products			
Circulatory and respiratory drugs	¥ 61,889	¥ 50,105	\$ 417,541
Metabolic pharmaceutical drugs and vitamins	47,404	43,343	361,192
Digestive system drugs	16,722	14,733	122,772
Nervous system drugs	5,807	6,146	51,213
Urinary drugs	5,934	4,714	39,283
Cellular function activating drugs	-	2,294	19,117
Chemical therapy, hormone drugs, and others	837	805	6,708
Others	2,972	2,770	23,085
Subtotal	141,567	124,909	1,040,909
Royalty and other revenue	1,680	10,866	90,550
Total	¥ 143,247	¥ 135,775	\$ 1,131,459

Notes: 1. The disclosure regarding royalty and other revenue has been separately presented since the significance of the amount increased in the consolidated fiscal year ended March 31, 2015. Therefore, revenue of goods and products by geographic area is stated instead of revenue from external customers by geographic area. Accordingly, details of revenue for the fiscal year ended March 31, 2014, have been reclassified to conform to the presentation for the fiscal year ended March 31, 2015.

2. Details of revenue of goods and products by geographic area are as follows:

	Millior	Millions of Yen	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Revenue of goods and products			
Japan	¥ 139,613	¥ 123,028	\$ 1,025,233
Europe	364	378	3,148
Asia	1,589	1,503	12,528
Total	¥ 141,567	¥ 124,909	\$ 1,040,909

Note: Revenue of goods and products is presented on the basis of the place of destination for sales.

# (3) Major Customers

Details of revenue from major customers are as follows:

	Million	Millions of Yen	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Mediceo Corporation	¥ 33,699	¥ 30,951	\$ 257,924
Suzuken Co., Ltd.	25,600	22,536	187,804
Toho Pharmaceutical Co., Ltd.	19,335	16,794	139,952
Alfresa Corporation	17,247	13,884	115,702

# Note 7

# Cash and Cash Equivalents

Details of cash and cash equivalents are as follows:

	Millions	Millions of Yen	
	March 31, 2014	March 31, 2015	March 31, 2015
(Cash and cash equivalents)			
Cash and deposits	¥ 19,999	¥ 25,285	\$ 210,704
Short-term investments	84,899	78,938	657,816
Cash and cash equivalents in the consolidated statement of financial position	¥ 104,898	¥ 104,222	\$ 868,520
Cash and cash equivalents in the consolidated statement of cash flows	¥ 104,898	¥ 104,222	\$ 868,520

### Note 8

## **Trade and Other Receivables**

Details of trade and other receivables are as follows:

	Millions	Millions of Yen	
	March 31, 2014	March 31, 2015	March 31, 2015
Notes receivable	¥ 517	¥ 451	\$ 3,756
Trade accounts receivable	35,938	35,336	294,464
Other accounts receivable	5,791	6,180	51,498
Allowance for doubtful accounts	(6)	(6)	(47)
Net total	¥ 42,240	¥ 41,960	\$ 349,670

Notes: 1. Amounts shown in the consolidated statement of financial position are net of the allowance for doubtful accounts.

2. The credit risk management and fair value of "Trade and other receivables" are described in Note 33. Financial Instruments.

3. The Group discounts certain notes receivable resulting from export transactions to financial institutions before maturity. The Group incurs payment obligations to these financial institutions for these notes in the event of a default. These discounted notes continue to be presented in "Trade and other receivables." In addition, the carrying amounts of the discounted notes are presented as borrowings (current). The carrying amounts of the discounted notes are ¥45 million and ¥26 million (\$213 thousand) as of March 31, 2014 and 2015, respectively.

### Note 9

# Marketable Securities and Investment Securities

#### (1) Details

Details of marketable securities and investment securities are as follows:

	Classification —		Millions	of Yen	Thousands of U.S. Dollars
			March 31, 2014	March 31, 2015	March 31, 2015
Marketable	Financial assets measured at FVPL	Bonds	¥ —	¥ –	\$
securities	Financial assets measured at amortized cost	Bonds	22,295	22,746	189,550
	Total		¥ 22,295	¥ 22,746	\$ 189,550
	Financial assets measured at FVOCI	Stock	¥ 114,244	¥ 159,321	\$ 1,327,677
Investment	Financial assets measured	Bonds	_	_	-
securities	at FVPL	Other	897	1,040	8,670
	Financial assets measured at amortized cost	Bonds	73,219	51,801	431,671
	Total		¥ 188,360	¥ 212,162	\$ 1,768,017

Notes: 1. Stocks are designated as financial assets measured at FVOCI because they are held mainly to strengthen business relationships and for the purpose of improving long-term corporate value.

2. Bonds meeting the qualifying criteria to be measured at amortized cost are designated as financial assets measured at amortized cost, while other bonds are designated as financial assets measured at FVPL.

# (2) Major Holdings of Issues and Fair Value

Major holdings of issues and the fair value of the financial assets measured at FVOCI include the following:

March 31, 2014		March 31, 2015			
Description	Millions of Yen	Description	Millions of Yen	Thousands of U.S. Dollars	
NISSIN FOODS HOLDINGS CO., LTD.	¥ 11,453	SANTEN PHARMACEUTICAL CO., LTD.	¥ 16,286	\$ 135,720	
SANTEN PHARMACEUTICAL CO., LTD.	8,525	NISSIN FOODS HOLDINGS CO., LTD.	14,541	121,175	
DAIKIN INDUSTRIES, LTD.	7,025	DAIKIN INDUSTRIES, LTD.	9,776	81,466	
T&D Holdings, Inc.	7,000	T&D Holdings, Inc.	9,439	78,656	
DAIICHI SANKYO COMPANY, LIMITED	5,007	YAKULT HONSHA CO., LTD.	6,758	56,316	
Astellas Pharma Inc.	4,053	Astellas Pharma Inc.	6,515	54,294	
Nissan Chemical Industries, Ltd.	3,680	Nissan Chemical Industries, Ltd.	5,914	49,282	
Sumitomo Dainippon Pharma Co., Ltd.	3,523	DAIICHI SANKYO COMPANY, LIMITED	5,494	45,784	
YAKULT HONSHA CO., LTD.	3,421	MEIJI Holdings Co., Ltd.	4,435	36,955	
Kurita Water Industries Ltd.	3,247	Kurita Water Industries Ltd.	4,213	35,107	
OBAYASHI CORPORATION	2,263	KISSEI PHARMACEUTICAL CO., LTD.	3,174	26,446	
IGC CORPORATION	2,208	Sumitomo Dainippon Pharma Co., Ltd.	3,059	25,491	
KISSEI PHARMACEUTICAL CO., LTD.	2,167	OBAYASHI CORPORATION	3,033	25,272	
HISAMITSU PHARMACEUTICAL CO., INC.	2,091	KYORIN Holdings, Inc.	2,773	23,112	
NIPPON KAYAKU CO., LTD.	1,978	KIKKOMAN CORPORATION	2,735	22,795	
KYORIN Holdings, Inc.	1,902	Nippon Shinyaku Co., Ltd.	2,713	22,604	
Alfresa Holdings Corporation	1,596	NIPPON KAYAKU CO., LTD.	2,563	21,362	
SUZUKEN CO., LTD.	1,569	HISAMITSU PHARMACEUTICAL CO., INC.	2,210	18,418	
Otsuka Holdings Co., Ltd.	1,448	KOKUYO CO., LTD.	2,086	17,386	
MEIJI Holdings Co., Ltd.	1,405	SUMITOMO CHEMICAL COMPANY, LIMITED	1,774	14,786	
KOKUYO CO., LTD.	1,403	Otsuka Holdings Co., Ltd.	1,764	14,697	
KIKKOMAN CORPORATION	1,396	Mitsubishi Tanabe Pharma Corporation	1,745	14,538	
Mitsubishi Tanabe Pharma Corporation	1,221	FUJIFILM Holdings Corporation	1,705	14,205	
Mitsubishi Logistics Corporation	1,165	Alfresa Holdings Corporation	1,608	13,399	
OKAMURA CORPORATION	1,154	SUZUKEN CO., LTD.	1,583	13,196	
MEDIPAL HOLDINGS CORPORATION	1,145	Mitsubishi Logistics Corporation	1,521	12,672	
OSAKA GAS CO., LTD.	1,129	JGC CORPORATION	1,469	12,241	
FUJIFILM Holdings Corporation	1,105	OSAKA GAS CO., LTD.	1,452	12,098	
SUMITOMO CHEMICAL COMPANY, LIMITED	1,094	MIURA CO., LTD.	1,417	11,810	
MAEDA CORPORATION	1,032	MAEDA CORPORATION	1,384	11,532	

#### (3) Dividends Received

Dividends received from the financial assets measured at FVOCI are as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Stock held at year-end	¥ 1,903	¥ 2,129	\$ 17,740	
Stock disposed of during the year	_	_	_	
Total	¥ 1,903	¥ 2,129	\$ 17,740	

#### (4) Financial Assets Measured at FVOCI Disposed of During the Year

Fair value at the date of sale of financial assets measured at FVOCI that were disposed of during the year, and cumulative (pretax) gains or loss are as follows:

	Million	Millions of Yen	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Fair value at the date of sale	¥ –	¥ 10	\$ 86
Cumulative gains or losses	_	(158)	(1,320)

Notes: 1. The Group sold the investments as a result of a reconsideration of its business relationships.

2. The Group transferred cumulative gains or losses (net of tax) of ¥(102) million (\$(850) thousand) from other components of equity to retained earnings for the year ended March 31, 2015.

### Note 10

## **Other Financial Assets**

Details of other financial assets are as follows:

		Millions	Millions of Yen		
	Classification	March 31, 2014	March 31, 2015	March 31, 2015	
(Current assets)					
Time deposits	Financial assets measured at amortized cost	¥ 800	¥ 800	\$ 6,667	
Other	_	105	20	171	
	Total	¥ 905	¥ 820	\$ 6,837	
(Non-current assets)					
Insurance reserve fund	Financial assets measured at FVPL	¥ 5,913	¥ 6,314	\$ 52,618	
	Total	¥ 5,913	¥ 6,314	\$ 52,618	

#### Note 11

## **Other Assets**

Details of other current assets and other non-current assets are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	March 31, 2014	March 31, 2015	March 31, 2015
(Other current assets)			
Prepaid expenses	¥ 613	¥ 1,651	\$ 13,756
Advance payments	150	543	4,527
Other	195	117	977
Total	¥ 958	¥ 2,311	\$ 19,260
(Other non-current assets)			
Lease deposits	¥ 779	¥ 796	\$ 6,637
Long-term prepaid expenses	276	217	1,810
Other	1,503	1,498	12,487
Total	¥ 2,559	¥ 2,512	\$ 20,935

### **Note 12**

### Inventories

Details of inventories are as follows:

	Million	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
Merchandise and finished goods	¥ 14,878	¥ 14,367	\$ 119,728	
Work in process	5,966	7,527	62,722	
Raw materials and supplies	3,418	3,911	32,589	
Total	¥ 24,261	¥ 25,805	\$ 215,039	

Note: Inventories recognized as an expense for the years ended March 31, 2014 and 2015, amounted to ¥31,384 million and ¥32,717 million (\$272,643 thousand), respectively. In addition, the write-downs of inventories recognized as an expense for the years ended March 31, 2014 and 2015, were ¥227 million and ¥124 million (\$1,034 thousand), respectively.

The Group has introduced a new cost calculation system from the current consolidated fiscal year to measure inventories and calculate profit and loss during the term in a rapid and appropriate manner. The Group reviewed definitions of "finished goods," "semifinished goods," and "work in process", accordingly. As a result, the reclassification for the amount ¥3,560 million has been made from "Merchandise and finished goods" to "Work in process" for the previous fiscal year.

# Note 13

# Property, Plant, and Equipment

#### (1) Schedule of Movements

The movements in the cost, accumulated depreciation, and accumulated impairment losses and carrying amount of property, plant, and equipment are as follows:

#### Cost

			Million	is of Yen		
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total
Balance at April 1, 2013	¥ 19,172	¥ 67,438	¥ 19,046	¥ 23,110	¥ 1,438	¥ 130,203
Acquisition	862	835	436	475	5,240	7,848
Transfer	_	901	290	559	(1,750)	-
Sale or disposal	(3)	(225)	(525)	(620)	_	(1,373)
Exchange differences on translation of foreign operations	_	14	_	26	0	40
Other	_	_	_	_	(168)	(168)
Balance at March 31, 2014	¥ 20,031	¥ 68,962	¥ 19,247	¥ 23,550	¥ 4,760	¥ 136,550
Acquisition	264	938	290	1,123	14,289	16,904
Transfer	6,462	3,153	3,380	120	(13,114)	-
Sale or disposal	(2)	(1,157)	(931)	(1,107)	(3)	(3,199)
Exchange differences on translation of foreign operations	_	6	_	14	0	20
Other	_	_	-	_	(686)	(686)
Balance at March 31, 2015	¥ 26,755	¥ 71,902	¥ 21,985	¥ 23,701	¥ 5,246	¥ 149,589

	Thousands of U.S. Dollars					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total
Balance at March 31, 2014	\$ 166,922	\$ 574,687	\$ 160,391	\$ 196,253	\$ 39,663	\$ 1,137,916
Acquisition	2,200	7,819	2,413	9,359	119,074	140,865
Transfer	53,849	26,275	28,163	998	(109,285)	-
Sale or disposal	(17)	(9,644)	(7,756)	(9,221)	(22)	(26,660)
Exchange differences on translation of foreign operations	_	48	_	119	3	169
Other	-	-	_	-	(5,713)	(5,713)
Balance at March 31, 2015	\$ 222,954	\$ 599,185	\$ 183,211	\$ 197,508	\$ 43,721	\$ 1,246,579

	Millions of Yen					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total
Balance at April 1, 2013	¥ —	¥ (41,820)	¥ (15,176)	¥ (17,426)	¥ —	¥ (74,422)
Depreciation	_	(1,933)	(726)	(1,473)	_	(4,132)
Impairment losses	-	(114)	(3)	(18)	_	(134)
Sale or disposal	_	188	513	595	_	1,297
Exchange differences on translation of foreign operations	_	(1)	_	(10)	_	(11)
Other	-	-	_	-	_	-
Balance at March 31, 2014	¥ —	¥ (43,680)	¥ (15,391)	¥ (18,332)	¥ —	¥ (77,403)
Depreciation	-	(2,186)	(829)	(1,430)	_	(4,445)
Impairment losses	(29)	_	_	_	_	(29)
Sale or disposal	-	1,058	921	1,073	_	3,052
Exchange differences on translation of foreign operations	-	(1)	_	(9)	-	(11)
Other	_	_	_	_	_	_
Balance at March 31, 2015	¥ (29)	¥ (44,810)	¥ (15,299)	¥ (18,698)	¥ —	¥ (78,836)

Accumulated depreciation and accumulated impairment losses

	Thousands of U.S. Dollars					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total
Balance at March 31, 2014	\$	\$ (364,002)	\$ (128,257)	\$ (152,764)	\$ —	\$ (645,023)
Depreciation	_	(18,220)	(6,908)	(11,914)	_	(37,042)
Impairment losses	(243)	_	_	-	_	(243)
Sale or disposal	_	8,814	7,677	8,940	_	25,431
Exchange differences on translation of foreign operations	_	(12)	_	(76)	_	(88)
Other	_	_	_	-	_	_
Balance at March 31, 2015	\$ (243)	\$ (373,420)	\$ (127,488)	\$ (155,814)	\$ -	\$ (656,965)

Carrying amount

		Millions of Yen					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total	
Balance at April 1, 2013	¥ 19,172	¥ 25,618	¥ 3,871	¥ 5,684	¥ 1,438	¥ 55,781	
Balance at March 31, 2014	20,031	25,282	3,856	5,219	4,760	59,147	
Balance at March 31, 2015	26,725	27,092	6,687	5,003	5,246	70,754	

		Thousands of U.S. Dollars				
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Construction in progress	Total
Balance at March 31, 2015	\$ 222,712	\$ 225,765	\$ 55,722	\$ 41,694	\$ 43,721	\$ 589,613

Notes: 1. Depreciation of property, plant, and equipment is included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs" in the consolidated statement of income.

2. Commitments related to property, plant, and equipment purchases are described in Note 37. Commitments for Expenditure.

#### (2) Assets Held under Finance Leases

The carrying amounts of leased assets held under finance leases, which are included in items of property, plant, and equipment as of April 1, 2013, and March 31, 2014 and 2015, are as follows:

		Millions of Yen						
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Total				
Balance at April 1, 2013	¥ 41	¥ 626	¥ 1	¥ 667				
Balance at March 31, 2014	227	558	0	785				
Balance at March 31, 2015	211	320	-	531				

		Thousands of U.S. Dollars					
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Total			
Balance at March 31, 2015	\$ 1,759	\$ 2,665	\$ -	\$ 4,423			

#### (3) Impairment Losses

Property, plant, and equipment are grouped into the smallest cash-generating unit(s) generating largely by independent cash inflows.

The Group recorded impairment losses for property, plant, and equipment of ¥134 million and ¥29 million (\$243 thousand) for the years ended March 31, 2014 and 2015, respectively, which are included in "Other expenses" in the

consolidated statement of income.

Impairment losses recognized for the years ended March 31, 2014 and 2015, represent reductions in the carrying amounts of assets to be disposed of and idle assets not expected to be used in the future to their recoverable amounts. The recoverable amounts were measured at fair value less costs to sell. The recoverable amounts of assets to be disposed of were considered to be zero.

# Intangible Assets

## (1) Schedule of Movements

The movements in the cost, accumulated amortization, and accumulated impairment losses and carrying amount of intangible assets are as follows:

## Cost

		Millions of	Yen	
	Patents and licenses	Software	Other	Total
Balance at April 1, 2013	¥ 19,270	¥ 5,412	¥ 2,366	¥ 27,048
Acquisition	5,528	378	1,008	6,913
Transfer	_	434	(434)	_
Disposal	(1,917)	(19)	(146)	(2,082)
Exchange differences on translation of foreign operations	_	1	_	1
Other	_	_	(207)	(207)
Balance at March 31, 2014	¥ 22,881	¥ 6,205	¥ 2,587	¥ 31,674
Acquisition	12,851	622	498	13,971
Transfer	_	917	(917)	_
Disposal	(2,263)	(331)	(406)	(3,000)
Exchange differences on translation of foreign operations	_	1	_	1
Other	_	_	(323)	(323)
Balance at March 31, 2015	¥ 33,469	¥ 7,414	¥ 1,439	¥ 42,322

		Thousands of U.S. Dollars				
	Patents and licenses	Software	Other	Total		
Balance at March 31, 2014	\$ 190,675	\$ 51,712	\$ 21,562	\$ 263,949		
Acquisition	107,094	5,182	4,152	116,428		
Transfer	_	7,644	(7,644)	_		
Disposal	(18,862)	(2,762)	(3,379)	(25,003)		
Exchange differences on translation of foreign operations	_	8	_	8		
Other	_	_	(2,695)	(2,695)		
Balance at March 31, 2015	\$ 278,907	\$ 61,785	\$ 11,995	\$ 352,687		

Accumulated amortization and accumulated impairment losses

	Millions of Yen				
	Patents and licenses	Software	Other	Total	
Balance at April 1, 2013	¥ (3,982)	¥ (3,214)	¥ (983)	¥ (8,180)	
Amortization	(295)	(670)	(13)	(977)	
Disposal	1,917	14	123	2,054	
Impairment losses	(1,880)	_	_	(1,880)	
Exchange differences on translation of foreign operations	_	(1)	_	(1)	
Balance at March 31, 2014	¥ (4,240)	¥ (3,871)	¥ (874)	¥ (8,984)	
Amortization	(950)	(690)	(13)	(1,652)	
Disposal	2,263	283	287	2,834	
Impairment losses	(530)	_	_	(530)	
Exchange differences on translation of foreign operations	_	(1)	_	(1)	
Other	-	_	(75)	(75)	
Balance at March 31, 2015	¥ (3,457)	¥ (4,278)	¥ (674)	¥ (8,409)	

	Thousands of U.S. Dollars				
	Patents and licenses	Software	Other	Total	
Balance at March 31, 2014	\$ (35,336)	\$ (32,255)	\$ (7,279)	\$ (74,870)	
Amortization	(7,916)	(5,749)	(105)	(13,770)	
Disposal	18,862	2,359	2,395	23,615	
Impairment losses	(4,419)	_	-	(4,419)	
Exchange differences on translation of foreign operations	_	(5)	_	(5)	
Other	_	_	(629)	(629)	
Balance at March 31, 2015	\$ (28,808)	\$ (35,650)	\$ (5,619)	\$ (70,078)	

#### Carrying amount

		Millions of Yen				
	Patents and licenses	Software	Other	Total		
Balance at April 1, 2013	¥ 15,288	¥ 2,198	¥ 1,383	¥ 18,869		
Balance at March 31, 2014	18,641	2,335	1,714	22,690		
Balance at March 31, 2015	30,012	3,136	765	33,913		

		Thousands of U.S. Dollars				
	Patents and licenses	Software	Other	Total		
Balance at March 31, 2015	\$ 250,099	\$ 26,134	\$ 6,377	\$ 282,610		

Notes: 1. Amortization of intangible assets is included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs" in the consolidated statement of income.

2. Among the intangible assets above, intangible assets that are still not available for use amounted to ¥17,253 million and ¥19,898 million (\$165,816 thousand) as of March 31, 2014 and 2015, respectively. These mainly consist of separately acquired in-process research and development costs recorded in "Patents and licenses," which are still in research and development phases, and accordingly, they are not in a condition available for use until the phase where marketing approvals have been obtained from related authorities and they are finally made into products.

3. Commitments related to intangible asset purchases are described in Note 37. Commitments for Expenditure.

## (2) Individually Significant Intangible Assets

### §1. Details and Carrying Amounts

Details of significant intangible assets and their carrying amounts are as follows:

		Millions of Yen		Thousands of U.S. Dollars
Item Details		March 31, 2014	March 31, 2015	March 31, 2015
Patents and licenses	In-process research and development costs acquired separately	¥ 16,218	¥ 19,898	\$ 165,816
	Sales licenses	2,423	10,114	84,283

Note: Major items of in-process research and development costs acquired separately and sales licenses consisting of lump-sum payments for introductions to licensors and milestone payments are as follows:

	March 31, 2014	March 31, 2015
	ONO-7643/RC-1291	ONO-7643/RC-1291
In-process research and development costs acquired separately	ONO-7056/Salirasib	ONO-7056/Salirasib
	ONO-7057/Carfilzomib	ONO-7057/Carfilzomib
	ONO-5163/AMG-416	ONO-5163/AMG-416
	ONO-1162/Ivabradine	ONO-1162/Ivabradine
	ONO-2370/BIA9-1067	ONO-2370/BIA9-1067
	RECALBON	RECALBON
Calce licenses	STAYBLA	STAYBLA
Sales licenses	RIVASTACH	RIVASTACH
	FORXIGA	FORXIGA

#### §2. Remaining Amortization Period

The average remaining amortization periods of significant intangible assets are as follows:

ltem	Details	March 31, 2014	March 31, 2015
Patents and licenses	In-process research and development costs acquired separately	_	_
	Sales licenses (years)	9.3	12.5

Note: The average remaining amortization periods of in-process research and development costs acquired separately are not presented because they are not yet available for use.

### (3) Impairment Losses

Intangible assets are grouped into the smallest cashgenerating unit(s) generating largely independent cash inflows. In addition, patents and licenses are grouped separately by cash-generating units based on products and developed goods, which are the smallest group of units generating largely independent cash inflows.

Impairment losses on intangible assets are as follows:

		Million	Thousands of U.S. Dollars	
ltem	Details	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Patents and licenses	In-process research and development costs acquired separately	¥ 1,880	¥ 530	\$ 4,419

Notes: 1. Impairment losses on patents and licenses were attributable to reviews of recoverable amounts as a result of the suspension of new drug development, changes in development status, etc. The recoverable amount of an asset is calculated based on value in use. The Group's discount rate used in calculating value in use was 6.5% for the years ended March 31, 2014 and 2015, based on the pretax weighted-average cost of capital.

2. Impairment losses on patents and licenses recognized for the years ended March 31, 2014 and 2015, representing impairment losses on separately acquired in-process research and development costs were included in "Research and development costs" in the consolidated statement of income.

## Note 15

## **Investments in Associates**

Aggregate financial information of equity-method investees is summarized as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Net income from continuing operations attributable to the Group	¥ 4	¥ 13	\$ 107	
Other comprehensive income attributable to the Group	3	4	35	
Total comprehensive income attributable to the Group	¥ 7	¥ 17	\$ 142	

Note: There are no quoted stock prices available for associates.

# **Income Taxes**

## (1) Deferred Income Taxes

Details and movements of deferred tax assets and deferred tax liabilities by major sources are as follows:

For the year ended March 31, 2014

		Millio	ns of Yen	
	March 31, 2013	Recognized in profit or loss	Recognized in other comprehensive income	March 31, 2014
(Deferred tax assets)				
Accrued bonuses	¥ 1,642	¥ (59)	¥ –	¥ 1,583
Accrued enterprise tax	535	(123)	_	412
Expenses for research and development commissions and others	12,025	922	_	12,947
Property, plant, and equipment	4,070	1	_	4,071
Intangible assets	316	68	_	384
Retirement benefit liabilities	4,622	(199)	(330)	4,094
Other	1,955	68	0	2,024
Total	¥ 25,166	¥ 678	¥ (330)	¥ 25,514
(Deferred tax liabilities)				
Property, plant, and equipment	¥ (3,915)	¥ 236	¥ —	¥ (3,679)
Intangible assets	(367)	(325)	_	(691)
Investment securities	(8,186)	8	(3,930)	(12,108)
Other	(18)	(12)	(4)	(34)
Total	¥ (12,486)	¥ (93)	¥ (3,933)	¥ (16,513)

		Millio	ns of Yen	
	March 31, 2014	Recognized in profit or loss	Recognized in other comprehensive income	March 31, 2015
(Deferred tax assets)				
Accrued bonuses	¥ 1,583	¥ (133)	¥ —	¥ 1,450
Accrued enterprise tax	412	295	_	707
Expenses for research and development commissions and others	12,947	915	_	13,862
Property, plant, and equipment	4,071	(398)	_	3,673
Intangible assets	384	(85)	_	299
Retirement benefit liabilities	4,094	(569)	304	3,828
Long-term advances received	_	2,165	_	2,165
Other	2,024	731	4	2,758
Total	¥ 25,514	¥ 2,921	¥ 307	¥ 28,742
(Deferred tax liabilities)				
Property, plant, and equipment	¥ (3,679)	¥ 413	¥ —	¥ (3,267)
Intangible assets	(691)	(1,172)	_	(1,863)
Investment securities	(12,108)	(244)	(12,366)	(24,718)
Other	(34)	30	-	(5)
Total	¥ (16,513)	¥ (974)	¥ (12,366)	¥ (29,853)

## For the year ended March 31, 2015

	Thousands of U.S. Dollars				
	March 31, 2014	Recognized in profit or loss	Recognized in other comprehensive income	March 31, 2015	
(Deferred tax assets)					
Accrued bonuses	\$ 13,193	\$ (1,112)	\$	\$ 12,081	
Accrued enterprise tax	3,433	2,461	_	5,894	
Expenses for research and development commissions and others	107,890	7,627	_	115,517	
Property, plant, and equipment	33,924	(3,319)	_	30,605	
Intangible assets	3,199	(710)	_	2,489	
Retirement benefit liabilities	34,114	(4,742)	2,531	31,904	
Long-term advances received	-	18,042	_	18,042	
Other	16,864	6,090	29	22,984	
Total	\$ 212,617	\$ 24,338	\$ 2,561	\$ 239,515	
(Deferred tax liabilities)					
Property, plant, and equipment	\$ (30,661)	\$ 3,438	\$	\$ (27,223)	
Intangible assets	(5,761)	(9,765)	_	(15,526)	
Investment securities	(100,901)	(2,036)	(103,049)	(205,986)	
Other	(286)	248	_	(38)	
Total	\$ (137,609)	\$ (8,115)	\$ (103,049)	\$ (248,773)	

#### For the year ended March 31, 2015

Notes: 1. The differences between deferred tax expense and the amount recognized in profit or loss are exchange differences on translation of foreign operations and others.

2. The effective statutory tax rate used to calculate deferred tax assets and liabilities as of March 31, 2014, in Japan is 35.6%. The effective statutory tax rates used to calculate deferred tax assets and deferred tax liabilities as of March 31, 2015, in Japan are 33.0% for expected reversals up to March 31, 2016, and 32.2% for expected reversals on or after April 1, 2016.

3. Taxable temporary differences associated with investments in subsidiaries, for which deferred tax liabilities were not recognized, amounted to ¥1,323 million and ¥2,017 million (\$16,809 thousand) as of March 31, 2014 and 2015, respectively. This is because the Group is able to control the timing of the reversal of the temporary differences and it is certain the temporary differences will not reverse in the foreseeable future.

4. The amounts of tax credit carryforwards, which are not recognized as deferred tax assets, were ¥1,470 million and ¥1,743 million (\$14,528 thousand) as of March 31, 2014 and 2015, respectively.

#### (2) Income Tax Expense

Details of income tax expense are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Current tax expense	¥ 9,530	¥ 7,036	\$ 58,632
Deferred tax expense	(608)	(1,947)	(16,224)
Total	¥ 8,922	¥ 5,089	\$ 42,407

Notes: 1. The Group is subject to corporate tax, inhabitant tax, and enterprise tax in Japan, which in the aggregate resulted in an applicable tax rate for current tax expense of approximately 38.0% for the year ended March 31, 2014, and approximately 35.6% for the year ended March 31, 2015. Overseas subsidiaries use the income tax rates of the countries in which they are located.

2. The "Act on Partial Revision of the Income Tax Act, etc." (Act No. 9 of 2015) was promulgated on March 31, 2015. In line with this revision, the effective statutory tax rate used to calculate deferred tax assets and deferred tax liabilities for the year ended March 31, 2015, in Japan (limited to those to be eliminated on and after April 1, 2015), was changed from 35.6% in the previous fiscal year to 33.0% for those that are expected to be recovered or paid from April 1, 2015 to March 31, 2016, and to 32.2% for those that are expected to be recovered or paid on and after April 1, 2016. As a result, deferred tax liabilities (net of deferred tax assets) decreased by ¥648 million (\$5,404 thousand), while other components of equity increased by

¥2,553 million (\$21,277 thousand) and income tax expense for the current fiscal year increased by ¥1,905 million (\$15,873 thousand).3. Current tax expense includes benefits on temporary differences arising from previously unrecognized tax credits that were utilized to reduce income taxes.

As a result, income taxes decreased by ¥13 million for the year ended March 31, 2014. In addition, it is not applicable for the year ended March 31, 2015.

### (3) Reconciliation of applicable tax rates and average actual tax rates

Details of the differences between the applicable tax rates and average actual tax rates are as follows:

	For the year ended March 31, 2014	For the year ended March 31, 2015
Applicable tax rates	38.00 %	35.60 %
Permanent non-deductible items	2.18	1.77
Non-taxable dividends	(1.32)	(2.08)
Tax credit for research and other	(12.39)	(18.34)
Effect of change in tax rates	3.93	10.41
Other	(0.15)	0.44
Average actual tax rates	30.25 %	27.80 %

Note: The applicable tax rates used to reconcile the applicable tax rates and average actual tax rates are the Company's effective statutory income tax rates.

# **Trade and Other Payables**

Details of trade and other payables are as follows:

	Millions	Millions of Yen	
	March 31, 2014	March 31, 2015	March 31, 2015
Notes payable	¥ 764	¥ 366	\$ 3,049
Trade accounts payable	3,320	3,413	28,441
Other accounts payable	7,203	9,966	83,053
Total	¥ 11,288	¥ 13,745	\$ 114,543

# Note 18

# Borrowings

## (1) Details

Details of borrowings are as follows:

	Millions of Yen		Thousands of U.S. Dollars	
	March 31, 2014	March 31, 2015	March 31, 2015	
(Current liabilities)				
Short-term borrowings	¥ 45	¥ 26	\$ 213	
Current portion of long-term borrowings	101	26	216	
Short-term lease obligations	362	235	1,960	
Total	¥ 508	¥ 287	\$ 2,390	
(Non-current liabilities)				
Long-term borrowings	¥ 27	¥ 1	\$ 12	
Long-term lease obligations	441	316	2,631	
Total	¥ 468	¥ 317	\$ 2,643	

Notes: 1. Short-term borrowings are export documentary bills discounted with financial institutions before maturity.

2. Long-term borrowings, including the current portion, consist of unsecured loans from financial institutions with no financial covenants attached. The average interest rate of 1.96% for long-term borrowings is calculated based on the applicable outstanding balance at March 31, 2015.

## (2) Repayment Terms

The maturities of long-term borrowings are summarized as follows:

	Millions	Millions of Yen	
	March 31, 2014	March 31, 2015	March 31, 2015
More than 1 year to 2 years	¥ 113	¥ 50	\$ 414
More than 2 years to 3 years	154	81	677
More than 3 years to 4 years	15	15	126
More than 4 years to 5 years	15	16	131
More than 5 years	171	155	1,294
Total	¥ 468	¥ 317	\$ 2,643

# Note 19

# **Other Financial Liabilities**

Details of other financial liabilities are as follows:

	Millions	Millions of Yen	
	March 31, 2014	March 31, 2015	March 31, 2015
(Current liabilities)			
Dividends payable	¥ 90	¥ 88	\$ 733
Deposits received	756	2,497	20,811
Total	¥ 846	¥ 2,585	\$ 21,544
(Non-current liabilities)			
Other	¥ 17	¥ 21	\$ 172
Total	¥ 17	¥ 21	\$ 172

# Assets Pledged as Collateral

Assets pledged as collateral are as follows:

	Millions of Yen	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
Marketable securities	¥-	¥ 998	\$ 8,319	
Investment securities	¥ 1,990	¥ 997	\$ 8,307	
Total	¥ 1,990	¥ 1,995	\$ 16,626	

Note: The marketable securities and investment securities above were pledged as collateral for the deferred payment arrangements of customs duties and consumption taxes related to import transactions based on the Customs Act of Japan and Consumption Tax Act of Japan.

## Note 21

## Lease Transactions

#### (1) Finance Leases

Lessee

Details of future minimum lease payments under finance lease contracts and their present value are as follows:

	Millions	s of Yen	Thousands of U.S. Dollars	Million	s of Yen	Thousands of U.S. Dollars
	Mini	Minimum lease payments		Present valu	e of minimum lea	se payments
	March 31, 2014	March 31, 2015	March 31, 2015	March 31, 2014	March 31, 2015	March 31, 2015
1 year or less	¥ 374	¥ 245	\$ 2,038	¥ 362	¥ 235	\$ 1,960
More than 1 year to 5 years	301	190	1,581	270	160	1,337
More than 5 years	203	181	1,511	171	155	1,294
Total	¥ 878	¥ 616	\$ 5,130	¥ 803	¥ 551	\$ 4,590

Notes: 1. Lease transactions classified as finance leases of the Group are buildings and structures, machinery and vehicles, and tools, furniture, and fixtures, and these lease contracts do not include renewal options, purchase options, contingent rents, or escalation clauses, and there are no restrictions, such as additional borrowings and additional lease contract.

2. Future finance costs included in minimum lease payments were in the amounts of ¥75 million and ¥65 million (\$539 thousand) as of March 31, 2014 and 2015, respectively.

#### (2) Operating Leases

#### Lessee

### §1. Non-cancelable Operating Lease Contracts

Details of future minimum lease payments under non-cancelable operating lease contracts are as follows:

	Million	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
1 year or less	¥ 190	¥ 254	\$ 2,118	
More than 1 year to 5 years	463	486	4,049	
More than 5 years	114	50	417	
Total	¥ 767	¥ 790	\$ 6,584	

Note: The Group engages in office rental, etc., classified as operating leases under IAS 17. Certain lease contracts include renewal options. The lease contracts do not include contingent rents or escalation clauses, and there are no restrictions, such as additional borrowings and additional lease contracts, in the contracts.

### §2. Operating Lease Contracts Recognized as Expenses

Minimum lease payments based on operating lease contracts recognized as expenses are as follows:

	Million	Millions of Yen		
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Minimum lease payments	¥ 214	¥ 247	\$ 2,062	

#### Lessor

#### §1. Non-cancelable Operating Lease Contracts

Details of future minimum lease receipts based on non-cancelable operating lease contracts are as follows:

	Millions	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
1 year or less	¥ 2	¥ 2	\$ 14	
More than 1 year to 5 years	8	7	56	
More than 5 years	16	12	101	
Total	¥ 26	¥ 21	\$ 172	

Note: The Group engages in land rental, etc., classified as operating leases under IAS 17.

# **Other Liabilities**

Details of other current liabilities and other non-current liabilities are as follows:

	Millions	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
(Other current liabilities)				
Accrued consumption taxes	¥ 568	¥ 1,452	\$ 12,103	
Accrued salary and bonus	4,486	4,435	36,958	
Accrued compensated vacation	1,585	1,696	14,133	
Accrued expenses	3,621	1,974	16,447	
Other	3	1,552	12,935	
Total	¥ 10,264	¥ 11,109	\$ 92,576	
(Other non-current liabilities)				
Compensated long-service benefit obligations	¥ 495	¥ 514	\$ 4,281	
Other	131	132	1,098	
Total	¥ 626	¥ 645	\$ 5,379	

# Note 23

## **Retirement Benefits**

The Group has defined benefit corporate pension plans and lump-sum payment plans for its defined benefit schemes. Effective October 1, 2004, the Company introduced a new defined benefit corporate pension plan combining the defined benefit corporate pension plan (formerly additional pensions under employees' pension fund plan) and a taxqualified pension plan, and granted employees the option to select a defined contribution plan for certain lumpsum payment plans. In addition, the Company has set up a retirement benefit trust in order to supplement funding deficits in benefit obligations.

Further, two overseas subsidiaries have defined contribution plans, one overseas subsidiary has a lump-sum payment plan, and two domestic subsidiaries participate in employees' pension fund plans (multiemployer pension plans) in addition to lump-sum payment plans.

## (1) Defined Benefit Plans

## §1. Defined Benefit Plan Liabilities and Assets

Details of defined benefit plan liabilities and assets in the consolidated statement of financial position are as follows:

	Millions	of Yen	Thousands of U.S. Dollars
	March 31, 2014	March 31, 2015	March 31, 2015
(Contributory)			
Defined benefit obligations	¥ 43,389	¥ 46,132	\$ 384,434
Fair value of plan assets (including retirement benefit trust)	(40,798)	(41,251)	(343,762)
Subtotal	2,591	4,881	40,672
(Non-contributory)			
Defined benefit obligations	449	545	4,542
Subtotal	449	545	4,542
Net defined benefit liability (asset)	¥ 3,040	¥ 5,426	\$ 45,213
Retirement benefit liabilities stated in the consolidated statement of financial position	¥ 3,945	¥ 5,426	\$ 45,213
Retirement benefit assets stated in the consolidated statement of financial position	(905)	-	_

## §2. Obligations under Defined Benefit Plans

Movements in the defined benefit obligations are as follows:

	Million	Thousands of U.S. Dollars	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Opening balance of defined benefit obligations	¥ 43,318	¥ 43,838	\$ 365,320
Service cost	1,593	1,640	13,665
Interest cost	623	682	5,683
Remeasurements			
Actuarial losses (gains) due to changes in financial assumptions	(703)	1,508	12,567
Other	178	185	1,538
Benefits paid	(1,170)	(1,176)	(9,797)
Closing balance of defined benefit obligations	¥ 43,838	¥ 46,677	\$ 388,976

Notes: 1. The weighted-average payment years for the defined benefit obligations as of March 31, 2014 and 2015, were 17.3 years and 17.4 years, respectively.
 2. Remeasurements of defined benefit plans are the differences between the actuarial assumptions used for calculation of "Defined benefit liabilities" and actual experience, and the impact of changes in actuarial assumptions.

## §3. Plan Assets

Movements in the fair value of plan assets are as follows:

	Million	Millions of Yen		
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Opening balance of fair value of plan assets	¥ 40,901	¥ 40,798	\$ 339,984	
Interest income	597	647	5,391	
Remeasurement				
Return on plan assets	401	749	6,244	
Contributions from employers	_	167	1,396	
Benefits paid	(1,101)	(1,110)	(9,253)	
Closing balance of fair value of plan assets	¥ 40,798	¥ 41,251	\$ 343,762	

Note: The Group expected to make contributions of ¥156 million and ¥1,219 million (\$10,154 thousand) to the defined benefit corporate pension plans in the following year as of March 31, 2014 and 2015. For the year ended March 31, 2014, there were no contributions from employers to the defined corporate pension benefit plans as the contribution to the defined benefit corporate pension plans was reclassified from employee retirement benefit trusts.

The fair value of plan assets classified by nature of assets and risks is as follows:

	Millions of Yen						Tho	ousands of U.S. Dol	lars
		March 31, 2014			March 31, 2015		March 31, 2015		
	Assets with active market prices	Assets without active market prices	Total	Assets with active market prices	Assets without active market prices	Total	Assets with active market prices	Assets without active market prices	Total
(Equity instruments)									
Domestic equity instruments	¥ 1,399	¥ –	¥ 1,399	¥ 2,318	¥ –	¥ 2,318	\$ 19,313	\$ -	\$ 19,313
Overseas equity instruments	983	-	983	1,668	-	1,668	13,899	-	13,899
(Debt instruments)									
Domestic debt instruments	-	9,092	9,092	-	7,731	7,731	-	64,425	64,425
Overseas debt instruments	-	578	578	-	695	695	-	5,788	5,788
General accounts at life insurance companies	-	27,827	27,827	_	28,336	28,336	-	236,131	236,131
Other	-	919	919	-	505	505	-	4,206	4,206
Total	¥ 2,382	¥ 38,416	¥ 40,798	¥ 3,985	¥ 37,266	¥ 41,251	\$ 33,212	\$ 310,550	\$ 343,762

The Group's operating policy for plan assets is as follows: The Group's basic policy for plan asset management aims to secure necessary long-term returns within a tolerable risk level in order to ensure future payment of pension benefits stipulated in the terms of defined benefit corporate pension plans and lump-sum payments.

A target rate of return is set aiming to exceed the rate of return necessary for maintaining sound operations of the defined benefit corporate pension plans over the future, specifically higher than the expected rate of return for pension financing. In order to meet this return target, the asset portfolio is verified by both the Company and the investment management institutions to be in conformity with the basic policy, and, in addition, the composition of the asset portfolio is reviewed as necessary.

The basic policy is subject to change in accordance with changes in the Company's status and systems or operating environment surrounding the Company.

### §4. Profit and Loss on Defined Benefit Plans

Profit and loss on defined benefit plans for each fiscal year recognized in the consolidated statement of income are as follows:

	Million	Thousands of U.S. Dollars	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Service costs	¥ 1,593	¥ 1,640	\$ 13,665
Net interest	26	35	292
Expenses recognized in the consolidated statement of income	¥ 1,619	¥ 1,675	\$ 13,956

Note: Among the expenses above, net interest is included in "Finance income" and "Finance costs," and other expenses are included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs."

#### §5. Significant Assumptions Used for the Actuarial Valuations

The significant assumptions used for the purposes of the actuarial valuations are as follows:

	March 31, 2014	March 31, 2015
Discount rate (%)	1.6	1.4
Expected rate of salary increase (%)	3.4	3.4
Expected average remaining lives of current pensioners at age 60 at year-end (years)	24.9	25.0
Expected average remaining lives from age 60, of future pensioners at age 40 at year-end (years)	26.5	26.6

### §6. Sensitivity Analysis

The sensitivity analysis represents the effects of changes in significant actuarial assumptions on the present value of the defined benefit obligations. The effect of any changes in assumptions used for measuring defined benefit obligations as of March 31, 2014 and 2015, are as follows:

			Million	s of Yen		Thousands o	f U.S. Dollars
	Changes in principal assumptions			March 31, 2015		March 31, 2015	
	assumptions	Increase	Decrease	Increase	Decrease	Increase	Decrease
(Defined benefit obligations)							
Discount rate	0.5% increase/decrease	¥ (3,496)	¥ 3,984	¥ (3,825)	¥ 4,188	\$ (31,871)	\$ 34,901
Expected average remaining lives	1 year increase/decrease	643	(665)	640	(671)	5,334	(5,595)

Note: The analysis is based on the assumption that other factors remain constant.

### (2) Multiemployer Pension Plans

Two domestic consolidated subsidiaries have joined the employees' pension fund (multiemployer pension plans). The plans are integrated-type defined benefit plans, and therefore, the amount of pension assets corresponding to the contributions made by each company cannot be determined reasonably. Thus, the amount of the contribution is recognized as post-employment expenses in the same manner as defined contribution plans. The contributions for each fiscal year presented are as follows:

	Million	Millions of Yen		
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Contributions	¥ 43	¥ 43	\$ 359	

Notes: 1. At each year-end, the Group expected to make contributions of ¥45 million and ¥43 million (\$359 thousand) as of March 31, 2014 and 2015, respectively, for the following fiscal periods.

2. Funded status of pension plans

The aggregate funded status of plan assets for the entire plan is as follows:

	Millions	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
Plan assets	¥ 257,829	¥ 292,417	\$ 2,436,806	
Benefit obligations for purposes of pension financing calculations	354,525	366,867	3,057,225	
Net total	¥ (96,695)	¥ (74,450)	\$ (620,420)	

3. Share of Contributions

Share of contributions by the Group in the plan as a whole is as follows:

March 31, 2014	March 31, 2015
0.3475%	0.3496%

#### (3) Defined Contribution Plans

The Group recognized ¥2,222 million and ¥2,316 million

(\$19,297 thousand) as expenses for defined contribution plans for the years ended March 31, 2014 and 2015, respectively.

# Note 24

# Provisions

# (1) Details

Details of provisions are as follows:

	Millions	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
Provision for asset retirement obligations	¥ 55	¥ 59	\$ 495	
Provision for sales rebates	1,025	648	5,402	
Others	70	65	544	
Total	¥ 1,151	¥ 773	\$ 6,441	
Current liabilities	¥ 1,063	¥ 684	\$ 5,696	
Non-current liabilities	87	89	745	

### (2) Changes

Schedules of changes in provisions are as follows:

	Millions of Yen					
	Provision for asset retirement obligations	Provision for sales rebates	Others	Total		
Balance at April 1, 2013	¥ 54	¥ 822	¥ 44	¥ 920		
Added to provisions	_	1,025	38	1,063		
Interest cost on discounted provisions due to passage of time	1	_	_	1		
Settled	-	(822)	(12)	(834)		
Reversed	_	_	_	—		
Balance at March 31, 2014	55	1,025	70	1,151		
Added to provisions	-	648	35	684		
Interest cost on discounted provisions due to passage of time	4	_	_	4		
Settled	-	(1,025)	(40)	(1,065)		
Reversed	_	_	(0)	(0)		
Balance at March 31, 2015	¥ 59	¥ 648	¥65	¥ 773		

	Thousands of U.S. Dollars						
	Provision for asset retirement obligations	Provision for sales rebates	Others	Total			
Balance at March 31, 2014	\$ 461	\$ 8,542	\$ 587	\$ 9,590			
Added to provisions	-	5,402	294	5,696			
Interest cost on provisions due to passage of time	34	_	_	34			
Settled	-	(8,542)	(335)	(8,876)			
Reversed	-	_	(3)	(3)			
Balance at March 31, 2015	\$ 495	\$ 5,402	\$ 544	\$ 6,441			

Notes: 1. Provision for asset retirement obligations is recognized and measured based on estimated asbestos removal costs related to buildings, production facilities, and others in compliance with the "Ordinance on Prevention of Health Impairment due to Asbestos" and others. The expected timing of future outflows of economic benefits is more than one year from the end of each fiscal year.

2. Provision for sales rebates is recognized and measured based on the estimated future sales rebate payments to authorized distributors, determined by multiplying trade accounts receivable at year-end by a rebate rate based on historical experience to provide for such payments. The expected timing of future outflows of economic benefits is within one year from the end of each fiscal year.

3. Other provisions are recognized and measured based on the estimated disposal costs of PCB contaminated facilities. The expected timing of future outflows of economic benefits is more than one year from the end of each fiscal year.

In addition, a provision for sales returns is recognized and measured based on the historical experience for losses incurred by future returns of merchandise and finished goods. The expected timing of future outflows of economic benefits is within one year from the end of each fiscal year.

## Note 25

# Share Capital and Other Equity Items

## (1) Share Capital and Capital Reserves

Changes in the number of authorized shares and issued shares, share capital, and capital reserves are as follows:

	Number of	Number of	Millions	of Yen
	authorized shares (Shares)	issued shares (Shares)	Share capital	Capital reserves
Balance at April 1, 2013	300,000,000	117,847,500	¥ 17,358	¥ 17,080
Increase (decrease)	-	_	_	-
Balance at March 31, 2014	300,000,000	117,847,500	¥ 17,358	¥ 17,080
Increase (decrease)	-	_	_	-
Balance at March 31, 2015	300,000,000	117,847,500	¥ 17,358	¥ 17,080
	Number of	Number of	Thousands of	FU.S. Dollars
	authorized shares (Shares)	issued shares (Shares)	Share capital	Capital reserves
Balance at March 31, 2014	300,000,000	117,847,500	\$ 144,652	\$ 142,332
ncrease (decrease)	-	_	_	-
Balance at March 31, 2015	300,000,000	117,847,500	\$ 144,652	\$ 142,332

Note: All shares issued by the Company are fully paid-up ordinary shares with no par value.

## (2) Treasury Shares

Changes in the number and amount of treasury shares are as follows:

	Number of shares (Shares)	Amount (Millions of Yen)
Balance at April 1, 2013	11,831,010	¥ 59,231
Increase (decrease)	5,536	43
Balance at March 31, 2014	11,836,546	¥ 59,274
Increase (decrease)	3,196	34
Balance at March 31, 2015	11,839,742	¥ 59,308

	Number of shares (Shares)	Amount (Thousands of U.S. Dollars)
Balance at March 31, 2014	11,836,546	\$ 493,954
Increase (decrease)	3,196	281
Balance at March 31, 2015	11,839,742	\$ 494,235

Notes: 1. Increases in the number and amount of treasury shares are due to purchases of fractional unit shares.

2. Treasury shares held by associates as of March 31, 2014 and 2015, were ¥20 million and ¥21 million (\$179 thousand), respectively.

### (3) Other Components of Equity

Changes in Other Components of Equity are as follows:

			Millions of Yen		
	Exchange differences on translation of foreign operations	Net fair value gain (loss) on cash flow hedges	Net gain (loss) on financial assets measured at FVOCI	Remeasurement of defined benefit plans	Total
Balance at April 1, 2013	¥ 344	¥ —	¥ 7,854	¥ —	¥ 8,198
Increase (decrease)					
(Other comprehensive income)	323	6	7,097	596	8,023
Transfer to retained earnings	_	_	1	(596)	(595)
Other increase (decrease)	_	_	_	_	-
Balance at March 31, 2014	¥ 668	¥ 6	¥ 14,952	¥ —	¥ 15,626
Increase (decrease)					
(Other comprehensive income)	505	(6)	29,529	(640)	29,389
Transfer to retained earnings	_	_	102	640	742
Other increase (decrease)	-	_	_	_	-
Balance at March 31, 2015	¥ 1,173	¥ —	¥ 44,583	¥ —	¥ 45,756

		Thousands of U.S. Dollars						
	Exchange differences on translation of foreign operations	Net fair value gain (loss) on cash flow hedges	Net gain (loss) on financial assets measured at FVOCI	Remeasurement of defined benefit plans	Total			
Balance at March 31, 2014	\$ 5,563	\$ 53	\$ 124,599	\$	\$ 130,215			
Increase (decrease)								
(Other comprehensive income)	4,210	(53)	246,077	(5,330)	244,905			
Transfer to retained earnings	-	_	850	5,330	6,180			
Other increase (decrease)	_	_	_	_	_			
Balance at March 31, 2015	\$ 9,774	\$	\$ 371,527	\$	\$ 381,300			

Notes: 1. Exchange differences on translation of foreign operations are the difference arising from consolidating the financial statements of overseas subsidiaries, which were prepared in foreign currencies.

2. Net fair value gain (loss) on cash flow hedges is the portion determined to be effective of fair value change in derivative transactions, which are designated as cash flow hedges and meet their specific criteria.

3. Changes in fair value of financial assets measured through other comprehensive income are valuation differences in fair value of financial assets measured through other comprehensive income.

4. Remeasurement of defined benefit plans are recognized in "Other comprehensive income" when it is incurred, and immediately transferred from "Other components of equity" to "Retained earnings."

## Note 26

# Dividends

## (1) Dividends Paid

Dividends paid are as follows:

### For the year ended March 31, 2014

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Record date	Effective date
General shareholders' meeting held on June 26, 2013	Ordinary shares	¥ 9,541	¥ 90	March 31, 2013	June 27, 2013
Board of Directors' meeting held on November 5, 2013	Ordinary shares	¥ 9,541	¥ 90	September 30, 2013	December 2, 2013

## For the year ended March 31, 2015

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Total dividends (Thousands of U.S. Dollars)	Dividends per share (U.S. Dollars)	Record date	Effective date
General shareholders' meeting held on June 27, 2014	Ordinary shares	¥ 9,541	¥ 90	\$ 79,508	\$1	March 31, 2014	June 30, 2014
Board of Directors' meeting held on November 5, 2014	Ordinary shares	¥ 9,541	¥ 90	\$ 79,507	\$1	September 30, 2014	December 1, 2014

## (2) Dividends Whose Effective Date is in the Following Fiscal Year

Dividends whose cutoff date is in the current fiscal year and effective date is in the following fiscal year are as follows:

## For the year ended March 31, 2014

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Record date	Effective date
General shareholders' meeting held on June 27, 2014	Ordinary shares	¥ 9,541	¥ 90	March 31, 2014	June 30, 2014

## For the year ended March 31, 2015

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Total dividends (Thousands of U.S. Dollars)	Dividends per share (U.S. Dollars)	Record date	Effective date
General shareholders' meeting held on June 26, 2015	Ordinary shares	¥ 9,541	¥ 90	\$ 79,506	\$ 1	March 31, 2015	June 29, 2015

# Selling, General, and Administrative Expenses

Details of Selling, general, and administrative expenses are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Business planning expenses	¥ 4,816	¥ 5,318	\$ 44,317
Sales promotion expenses	964	1,095	9,125
Employee benefit expenses	18,076	19,324	161,032
Depreciation and amortization	1,481	1,398	11,649
Others	13,040	15,087	125,726
Total	¥ 38,377	¥ 42,222	\$ 351,849

## Note 28

# **Employee Benefit Expenses**

Details of the Group's employee benefit expenses are as follows:

	Million	is of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Salary and bonus	¥ 27,926	¥ 28,699	\$ 239,159
Retirement benefit expenses (Defined benefit plans)	1,593	1,640	13,665
Retirement benefit expenses (Multiemployer pension plans)	43	43	359
Retirement benefit expenses (Defined contribution plans)	2,222	2,316	19,297
Legal welfare expenses	1,424	1,687	14,061
Other welfare expenses	1,376	1,433	11,944
Other employee benefit expenses	1,999	2,082	17,347
Total	¥ 36,583	¥ 37,900	\$ 315,832

Notes: 1. Employee benefit expenses are included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs" in the consolidated statements of income.

2. The employee benefit expenses above include remuneration of key management personnel. Remuneration of key management personnel is described in Note 36. Related Parties.

# Note 29

# **Other Income and Other Expenses**

Details of other income and other expenses are as follows:

	Million	s of Yen	Thousands of U.S. Dollars	
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
(Other income)				
Rent	¥ 44	¥ 41	\$ 341	
Gain on sale of non-current assets	2	0	3	
Insurance proceeds	195	233	1,941	
Others	97	94	785	
Total	¥ 338	¥ 368	\$ 3,069	
(Other expenses)				
Impairment losses	¥ 134	¥ 30	\$ 249	
Loss on disposal of non-current assets	40	122	1,016	
Donations	1,204	1,334	11,115	
Settlement package	-	777	6,473	
Others	242	383	3,189	
Total	¥ 1,620	¥ 2,645	\$ 22,043	

Note: Settlement package is related to the Group's reaching agreement as to cancellation of the license contract.

# **Finance Income and Finance Costs**

Details of finance income and finance costs are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
(Finance income)			
Interest income			
Financial assets measured at amortized cost	¥ 483	¥ 342	\$ 2,848
Financial assets measured at FVPL	55	49	406
Dividend income			
Financial assets measured at FVPL	143	9	76
Financial assets measured at FVOCI	1,903	2,129	17,740
Gains and losses on marketable securities			
Financial assets measured at FVPL	_	144	1,198
Net interest on employee benefits	-	_	-
Exchange gains	164	765	6,377
Others	359	128	1,063
Total	¥ 3,107	¥ 3,565	\$ 29,707
(Finance costs)			
Interest expenses			
Financial liabilities measured at amortized cost	¥ 14	¥ 13	\$ 112
Gains and losses on marketable securities			
Financial assets measured at FVPL	35	_	-
Net interest on employee benefits	26	35	292
Others	1	18	154
Total	¥ 76	¥ 67	\$ 557

## Note 31

# **Other Comprehensive Income**

## (1) Other Comprehensive Income

Amounts incurred for the current year, reclassification adjustments to profit or loss, and tax effects (including non-controlling interests) for each item of "Other comprehensive income" are as follows:

For the year ended March 31, 2014

			Millions of Yen		
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
(Items that will not be reclassified to profit or loss)					
Net gain (loss) on financial assets measured at FVOCI	¥ 11,036	¥ —	¥ 11,036	¥ (3,930)	¥ 7,106
Remeasurement of defined benefit plans	926	_	926	(330)	596
Share of net gain (loss) on financial assets measured at FVOCI of associates	5	_	5	(2)	3
Total	11,967	_	11,967	(4,261)	7,706
(Items that may be reclassified to profit or loss)					
Exchange differences on translation of foreign operations	323	_	323	_	323
Net fair value gain (loss) on cash flow hedges (*Note)	231	(221)	10	(4)	6
Total	554	(221)	333	(4)	330
Total other comprehensive income	¥ 12,522	¥ (221)	¥ 12,301	¥ (4,265)	¥ 8,036

Note: The reclassification adjustment of net fair value gain (loss) on cash flow hedges includes ¥6 million, which was excluded from equity and added to the acquisition cost of the non-financial asset relating to the forecast transaction for the acquisition of the non-financial asset as a hedged item.

## For the year ended March 31, 2015

			Millions of Yen		
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
(Items that will not be reclassified to profit or loss)					
Net gain (loss) on financial assets measured at FVOCI	¥ 41,839	¥ —	¥ 41,839	¥ (12,310)	¥ 29,529
Remeasurement of defined benefit plans	(943)	_	(943)	304	(640)
Share of net gain (loss) on financial assets measured at FVOCI of associates	3	_	3	2	4
Total	40,898	_	40,898	(12,004)	28,894
(Items that may be reclassified to profit or loss)					
Exchange differences on translation of foreign operations	505	_	505	_	505
Net fair value gain (loss) on cash flow hedges (*Note)	(205)	195	(10)	4	(6)
Total	300	195	495	4	499
Total other comprehensive income	¥ 41,198	¥ 195	¥ 41,394	¥ (12,001)	¥ 29,393

	Thousands of U.S. Dollars				
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
(Items that will not be reclassified to profit or loss)					
Net gain (loss) on financial assets measured at FVOCI	\$ 348,658	\$	\$ 348,658	\$ (102,579)	\$ 246,079
Remeasurement of defined benefit plans	(7,861)	_	(7,861)	2,531	(5,330)
Share of net gain (loss) on financial assets measured at FVOCI of associates	21	_	21	14	35
Total	340,818	_	340,818	(100,035)	240,783
(Items that may be reclassified subsequently to profit or loss)					
Exchange differences on translation of foreign operations	4,210	_	4,210	_	4,210
Net fair value gain (loss) on cash flow hedges (*Note)	(1,710)	1,628	(82)	29	(53)
Total	2,500	1,628	4,128	29	4,157
Total other comprehensive income	\$ 343,318	\$ 1,628	\$ 344,946	\$ (100,005)	\$ 244,941

Note: The reclassification adjustment of net fair value gain (loss) on cash flow hedges includes ¥(7) million (\$(59) thousand), which was excluded from equity and excluded from the acquisition cost of the non-financial asset relating to the forecast transaction for the acquisition of the non-financial asset as a hedged item and ¥56 million (\$471 thousand), which was excluded from equity and added to the acquisition cost of the non-financial liability relating to the forecast transaction for the acquisition of the non-financial liability as a hedged item.

## (2) Other Comprehensive Income Attributable to Non-controlling Interests

Amounts incurred for the current year and tax effects for each item of other comprehensive income attributable to non-controlling interests are as follows:

## For the year ended March 31, 2014

	Millions of Yen				
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
Net gain (loss) on financial assets measured at FVOCI	¥ 19	¥ —	¥ 19	¥ (7)	¥ 12
Total other comprehensive income attributable to non-controlling interests	¥ 19	¥ —	¥ 19	¥ (7)	¥ 12

### For the year ended March 31, 2015

	Millions of Yen				
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
Net gain (loss) on financial assets measured at FVOCI	¥ (0)	¥ —	¥ (0)	¥ 4	¥ 4
Total other comprehensive income attributable to non-controlling interests	¥ (0)	¥ —	¥ (0)	¥ 4	¥ 4

	Thousands of U.S. Dollars				
	Amount incurred	Reclassification adjustments	Before tax effects	Tax effects	Net of tax amount
Net gain (loss) on financial assets measured at FVOCI	\$ (1)	\$	\$ (1)	\$ 37	\$ 36
Total other comprehensive income attributable to non-controlling interests	\$ (1)	\$	\$ (1)	\$ 37	\$ 36

# Earnings per Share

## (1) Basic Earnings per Share

Basic earnings per share are as follows:

	Ye	en	U.S. Dollars
	For the year ended March 31, 2014	,	
Basic earnings per share	¥ 191.90	¥ 122.40	\$ 1.02

## (2) Basis of Calculation of Basic Earnings per Share

The basis of calculation of basic earnings per share is as follows:

	Million	Millions of Yen		
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Profit for the year attributable to owners of the parent company	¥ 20,344	¥ 12,976	\$ 108,131	
Weighted-average number of ordinary shares outstanding (Thousands of shares)	106,014	106,009		

Diluted earnings per share are not presented because there were no potentially dilutive shares.

## Note 33

# **Financial Instruments**

### (1) Equity Management

The Group manages its equity in view of maintaining the confidence of investors, creditors, and the market, securing a firm capital base for continued future growth, and implementing strategic investments necessary to maximize corporate value while distributing consistent dividend payments.

The Group's capital management focuses on net debt where cash and cash equivalents are deducted from interestbearing debt, and equity (attributable to owners of the parent company and non-controlling interests). The Group considers methods of capital distribution to shareholders based on an evaluation of the medium-term strategic plan, including business performance, future research and development of new medicines, partnerships with bioventures, and additionally the introduction of new medicine candidate compounds to complement research and development risk. This evaluation will exert influence on decision-making regarding the level of dividend payments and the Group's market purchase of treasury shares.

The balance of the net debt and equity of the Group is as follows:

	Millions	Millions of Yen		
	March 31, 2014	March 31, 2015	March 31, 2015	
Interest-bearing debt	¥ 976	¥ 604	\$ 5,032	
Cash and cash equivalents	104,898	104,222	868,520	
Net debt	¥ (103,922)	¥ (103,619)	\$ (863,488)	
Total equity	451,724	475,213	3,960,111	

Note: Details of interest-bearing debt, cash and cash equivalents, and equity are described in Note 18. Borrowings, Note 7. Cash and Cash Equivalents, and Note 25. Share Capital and Other Equity Items, respectively.

#### (2) Financial Risk Management

The Group is constantly exposed in its operating activities to various financial risks, including credit risk, liquidity risk, market risks, and others (e.g., foreign exchange risk and price fluctuation risk). In order to avoid or mitigate these risks, the Group manages risks according to certain basic policies. The Group policy is not to enter into speculative derivative or equity transactions, but to operate funds primarily through debt instruments such as safe government bonds, etc., while also partially employing financial assets with guaranteed liquidity to meet short-term capital requirements. For derivative transactions, the Group enters into foreign exchange contracts to mitigate the foreign exchange risk associated with settling payments in foreign currencies. Such transactions are controlled by the Accounting Department of the Company.

#### (3) Credit Risk Management

The Group's trade receivables, such as notes receivable and trade accounts receivable, are exposed to the credit risk of its customers. In addition, like other pharmaceutical companies, the Group is exposed to concentrated credit risk from a small number of wholesale companies through which it sells its products. In cases where any of these wholesale companies face financial difficulties, there is a possibility it may have a severe and disadvantageous influence on the Group's financial performance.

In order to mitigate monetary damage caused by the default of such counterparties, the Group, in principle, determines credit limits and trade terms and conditions based on the credit management policy. In addition, in order to reduce doubtful collection, the Group manages due dates and balances by counterparty, and executes continuous credit evaluation by receiving semiannual credit updates for its main counterparties from third-party rating agencies. In the past, the Group has never recorded a significant bad debt loss on its trade receivables.

The Group is also exposed to issuer credit risk for bonds held to make use of surplus funds and shares held for political purposes. In addition, the Group is exposed to credit risk of the financial institutions that are the counterparties in derivatives transactions used to mitigate the foreign exchange risk associated with settling payments in foreign currencies. The Group operates funds primarily through safe debt instruments and executes transactions with highly rated financial institutions in order to prevent the emergence of credit risk in advance.

The carrying amounts of financial assets after impairment presented in the consolidated statement of financial position represent the Group's maximum exposure to financial asset credit risk.

#### (4) Liquidity Risk

The Group is exposed to the liquidity risk of not being able to fulfill its payment obligations at present or in the future due to an inability to source sufficient cash.

The Group, in particular the Accounting Department, maintains appropriate reserves and manages liquidity risk through monitoring of cash flow forecasts and results. Because the Group has sufficient cash and cash equivalents and quick assets and secures sound cash inflows from operating activities, this risk is low.

## Financial liabilities by maturity are as follows:

## March 31, 2014

	Millions of Yen				
	Carrying amount	Contractual cash flows	One year or less	More than one year	
Trade and other payables	¥ 11,288	¥ 11,288	¥ 11,288	¥ —	
Borrowings					
Short-term borrowings	45	45	45	_	
Current portion of long-term borrowings	101	101	101	_	
Long-term borrowings	27	27	_	27	
Short-term lease obligations	362	374	374	_	
Long-term lease obligations	441	504	_	504	
Other financial liabilities	863	863	846	17	

## March 31, 2015

	Millions of Yen				
	Carrying amount	Contractual cash flows	One year or less	More than one year	
Trade and other payables	¥ 13,745	¥ 13,745	¥ 13,745	¥ —	
Borrowings					
Short-term borrowings	26	26	26	_	
Current portion of long-term borrowings	26	26	26	_	
Long-term borrowings	1	1	-	1	
Short-term lease obligations	235	245	245	_	
Long-term lease obligations	316	371	_	371	
Other financial liabilities	2,606	2,606	2,585	21	

	Thousands of U.S. Dollars					
	Carrying amount	Contractual cash flows	One year or less	More than one year		
Trade and other payables	\$ 114,543	\$ 114,543	\$ 114,543	\$		
Borrowings						
Short-term borrowings	213	213	213	-		
Current portion of long-term borrowings	216	216	216	-		
Long-term borrowings	12	12	_	12		
Short-term lease obligations	1,960	2,038	2,038	_		
Long-term lease obligations	2,631	3,092	_	3,092		
Other financial liabilities	21,716	21,716	21,544	172		

### (5) Market Risk Management

§1. Foreign Exchange Risk

Foreign Exchange Risk Management
 The Group engages in research and development
 activities internationally, and, as the value of the yen
 falls, is exposed to the risk that yen-denominated
 expenses for overseas clinical trials will increase.
 This risk primarily arises from currencies such as

U.S. dollars, Euros, and British pounds. In order to mitigate this risk, the Group executes a risk hedge for a fixed portion of foreign currency-denominated transactions through forward foreign exchange contracts in accordance with the market risk management policy.

These forward foreign exchange contracts include maturities of one year or less.

# 2) Details of Forward Foreign Exchange Contracts by Currency

Details of forward foreign exchange contracts by currency are as follows:

	March 31	,2014	March 31	March 31, 2015	
	Contractual amount (In millions of foreign currencies)	Fair value (Millions of Yen)	Contractual amount (In millions of foreign currencies)	Fair value (Millions of Yen)	Fair value (Thousands of U.S. Dollars)
(Buy)					
U.S. Dollars	\$ 38	¥ 105	\$ 20	¥ 20	\$ 171
Cash flow hedge included in the above	18	10	_	_	_
Euro	€-	¥ —	€ –	¥ —	\$
Cash flow hedge included in the above	_	_	_	_	_
British Pounds	£ –	¥ —	£ –	¥ —	\$
Cash flow hedge included in the above	_	_	_	_	-

### 3) Foreign Exchange Sensitivity Analysis

At the end of the each fiscal year, the amount of impact on equity and profit or loss in the case of the yen depreciating by 10% against the U.S. dollar, Euro, and British pounds is as follows:

		Millions of		Thousands of U.S. Dollars			
	March	March 31, 2014		March 31, 2015		March 31, 2015	
	Equity	Profit or (loss)	Equity	Profit or (loss)	Equity	Profit or (loss)	
U.S. Dollars	¥ 453	¥ 691	¥ 315	¥ 969	\$ 2,627	\$ 8,073	
Euro	_	53	_	27	_	221	
British Pounds	69	33	85	63	705	521	

Note: The analysis is based on the assumption that other variable factors remain constant.

### §2. Price Fluctuation Risk Management

The Group is exposed to the risk of share price fluctuations that arise from equity instruments. These equity instruments are basically held for the purpose of business strategy and not for short-term trading purposes. In addition, the Group periodically reviews the fair value of the instruments, financial condition of issuers and the like, and in cases where the issuer is also a counterparty company, takes into account the relationship with that company and reconsiders the composition of holdings in the company as necessary. In the case that the share price of equity instruments held by the Group increases or decreases by 10% at year-end, accumulated other comprehensive income (net-of-tax) would increase or decrease respectively by ¥7,357 million and ¥10,802 million (\$90,016 thousand) as of March 31, 2014 and 2015, respectively, as a result of changes in fair value of the equity instruments designated as financial assets measured at FVOCI.

#### (6) Fair Value of Financial Instruments

\$1. Carrying Amount and Fair Value of Financial Assets and Financial LiabilitiesThe carrying amounts and fair value of financial assets and liabilities held by the Group by account are as follows:

		Thousands o	f U.S. Dollars			
	March 31, 2014		March 31, 2015		March 3	51,2015
	Carrying amounts	Fair value	Carrying amounts	Fair value	Carrying amounts	Fair value
(Financial assets)						
Financial assets measured at amortized cost						
Cash and cash equivalents	¥ 104,898	¥ 104,898	¥ 104,222	¥ 104,222	\$ 868,520	\$ 868,520
Trade and other receivables	42,240	42,240	41,960	41,960	349,670	349,670
Marketable securities and investment securities	95,515	95,833	74,547	74,852	621,222	623,769
Other financial assets	800	800	800	800	6,667	6,667
Financial assets measured at FVPL						
Marketable securities and investment securities	897	897	1,040	1,040	8,670	8,670
Other financial assets	6,018	6,018	6,335	6,335	52,789	52,789
Financial assets measured at FVOCI						
Investment securities	114,244	114,244	159,321	159,321	1,327,677	1,327,677
(Financial liabilities)						
Financial liabilities measured at amortized cost						
Trade and other payables	11,288	11,288	13,745	13,745	114,543	114,543
Borrowings	976	976	604	604	5,032	5,032
Other financial liabilities	863	863	2,606	2,606	21,716	21,716
Financial liabilities measured at FVPL						
Other financial liabilities	_	_	_	_	_	_

§2. Fair Value Measurements of Financial Assets and Financial Liabilities

The methods and assumptions used in measuring the fair values of financial assets and financial liabilities are as follows:

<u>Cash and cash equivalents, trade and other receivables,</u> <u>trade and other payables, and short-term borrowings</u> Since these items are settled in a short period of time, the fair values of these items are approximately equivalent to their carrying amounts.

Marketable securities and investment securities

The fair values of marketable securities and investment securities are measured using quoted market prices.

The fair values of unlisted shares are measured through rational methods such as the adjusted net assets method and others.

### Other financial assets

### Insurance reserve fund

The fair value of the insurance reserve fund is measured based on the surrender value because there are no significant contractual restrictions associated with a refund.

### Forward foreign exchange contracts

The fair values of forward foreign exchange contracts are measured based on quoted market prices for forward foreign exchange contracts under the same terms and conditions as of the closing date.

## Others

Since other items are settled in a short period of time, their fair values are approximately equivalent to their carrying amounts.

## <u>Borrowings</u>

The fair values of borrowings are based on discounted future cash flows using a current interest rate for liabilities under similar terms and conditions. The fair value of lease obligations is measured based on discounted cash flows using a current interest rate for lease agreements under the same terms and conditions.

### Other financial liabilities

Forward foreign exchange contracts

The fair values of forward foreign exchange contracts are measured based on quoted market prices for forward foreign exchange contracts under the same terms and conditions as of the closing date.

## Others

Since these items are settled in a short period of time, the fair values of these items are approximately equivalent to their carrying amounts.

## §3. Fair Value Hierarchy

IFRS 13 *Fair Value Measurement* requires an entity to classify the fair value of financial instruments into Level 1 through Level 3 of the fair value hierarchy based the observability of the inputs used in the fair value measurements of financial instruments. The fair value hierarchy is as follows:

- Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that are available at the measurement date.
- Level 2: Inputs are inputs other than quoted market prices included within Level 1 that are observable for assets or liabilities, either directly or indirectly.
- Level 3: Inputs are unobservable inputs for assets or liabilities.

1) Financial Assets and Financial Liabilities Measured at Fair Value

The fair values of financial assets and financial liabilities measured at fair value in the consolidated statement of financial position, grouped by fair value hierarchy are as follows:

	Millions of Yen March 31, 2014					
	Level 1 Level 2 Level 3		Level 3	Total		
(Financial assets)						
Financial assets measured at FVPL						
Marketable securities and investment securities	¥ 744	¥ —	¥ 152	¥ 897		
Other financial assets	_	105	5,913	6,018		
Financial assets measured at FVOCI						
Investment securities	112,913	_	1,331	114,244		
Total	¥ 113,657	¥ 105	¥ 7,396	¥ 121,158		
(Financial liabilities)						
Financial liabilities measured at FVPL						
Other financial liabilities	¥ —	¥ —	¥ —	¥ —		
Total	¥ –	¥ –	¥ –	¥ –		

	Millions of Yen						
	March 31, 2015						
	Level 1 Level 2 Level 3		Level 3	Total			
(Financial assets)							
Financial assets measured at FVPL							
Marketable securities and investment securities	¥ 893	¥ —	¥ 147	¥ 1,040			
Other financial assets	_	20	6,314	6,335			
Financial assets measured at FVOCI							
Investment securities	157,835	_	1,486	159,321			
Total	¥ 158,728	¥ 20	¥ 7,948	¥ 166,696			
(Financial liabilities)							
Financial liabilities measured at FVPL							
Other financial liabilities	¥ —	¥ —	¥ —	¥ —			
Total	¥ —	¥ –	¥ –	¥ –			

	Thousands of U.S. Dollars				
		March 31,	2015		
	Level 1	Level 2	Level 3	Total	
(Financial assets)					
Financial assets measured at FVPL					
Marketable securities and investment securities	\$ 7,444	\$	\$ 1,226	\$ 8,670	
Other financial assets	_	171	52,618	52,789	
Financial assets measured at FVOCI					
Investment securities	1,315,290	_	12,386	1,327,677	
Total	\$ 1,322,734	\$ 171	\$ 66,230	\$ 1,389,135	
(Financial liabilities)					
Financial liabilities measured at FVPL					
Other financial liabilities	\$	\$	\$	\$	
Total	\$	\$ -	\$ -	\$	

Note: For the years ended March 31, 2014 and 2015, the Group has not transferred any financial assets or liabilities between Levels 1, 2, and 3.

2) Financial Assets and Financial Liabilities Measured at Amortized Cost

The fair values of financial assets and financial liabilities measured at amortized cost in the consolidated statement of financial position, grouped by fair value hierarchy are as follows:

_		Millions of	Yen		
	March 31, 2014				
-	Level 1	Level 2	Level 3	Total	
(Financial assets)					
Financial assets measured at amortized cost					
Cash and cash equivalents	¥ 104,898	¥ —	¥ —	¥ 104,898	
Trade and other receivables	_	42,240	_	42,240	
Marketable securities and investment securities	_	95,833	_	95,833	
Other financial assets	800	-	_	800	
Total	¥ 105,698	¥ 138,073	¥ —	¥ 243,770	
(Financial liabilities)					
Financial liabilities measured at amortized cost					
Trade and other payable	¥ —	¥11,288	¥ —	¥ 11,288	
Borrowings	_	976	_	976	
Other financial liabilities	_	863	_	863	
Total	¥ –	¥ 13,127	¥ –	¥ 13,12	

# Notes to Consolidated Financial Statements

	Millions of Yen March 31, 2015				
_	Level 1	Level 2	Level 3	Total	
(Financial assets)					
Financial assets measured at amortized cost					
Cash and cash equivalents	¥ 104,222	¥ —	¥ —	¥ 104,222	
Trade and other receivables	_	41,960	_	41,960	
Marketable securities and investment securities	_	74,852	_	74,852	
Other financial assets	800	_	_	800	
Total	¥ 105,022	¥ 116,813	¥ —	¥ 221,835	
(Financial liabilities)					
Financial liabilities measured at amortized cost					
Trade and other payable	¥ —	¥ 13,745	¥ —	¥ 13,745	
Borrowings	_	604	_	604	
Other financial liabilities	_	2,606	_	2,606	
Total	¥ —	¥ 16,955	¥ –	¥ 16,955	

	Thousands of U.S. Dollars March 31, 2015				
_					
_	Level 1	Level 2	Level 3	Total	
(Financial assets)					
Financial assets measured at amortized cost					
Cash and cash equivalents	\$ 868,520	\$	\$ -	\$ 868,520	
Trade and other receivables	_	349,670	_	349,670	
Marketable securities and investment securities	_	623,769	_	623,769	
Other financial assets	6,667	_	_	6,667	
Total	\$ 875,187	\$ 973,439	\$ -	\$ 1,848,626	
(Financial liabilities)					
Financial liabilities measured at amortized cost					
Trade and other payable	\$	\$ 114,543	\$ -	\$ 114,543	
Borrowings	_	5,032	_	5,032	
Other financial liabilities	_	21,716	_	21,716	
Total	\$ -	\$ 141,291	\$	\$ 141,291	

Note: For the years ended March 31, 2014 and 2015, the Group has not transferred any financial assets or liabilities between Levels 1, 2, and 3.

3) Reconciliation of Financial Instruments Measured Using Level 3 Inputs on a Recurring Basis Movements of the financial assets measured using Level 3 inputs on a recurring basis from the beginning of the year to the end of the year are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Balance at beginning of the year	¥ 7,022	¥ 7,396	\$ 61,635
Total gains or losses	86	264	2,198
Profit or loss	19	98	818
Other comprehensive income	67	166	1,380
Purchase	330	373	3,111
Sale	_	(10)	(86)
Settlement	(41)	(75)	(627)
Balance at end of the year	¥ 7,396	¥ 7,948	\$ 66,230
Changes in unrealized gains or losses recognized in net profit or loss for assets held at the end of the year	¥ (66)	¥ 0	\$ 3

Notes: 1. Profit or loss included in gains and losses are related to financial assets measured at FVPL as of the closing date. These gains and losses are included in "Finance income" and "Finance costs."

2. Other comprehensive income included in gains and losses are related to financial assets measured at FVOCI as of the closing date. These gains and losses are included in "Net gain (loss) on financial assets measured at FVOCI."

3. There are no applicable financial liabilities measured using Level 3 on a recurring basis.

# Note 34

# **Non-cash Transactions**

Non-cash transactions (investments and financial transactions that do not involve the use of cash and cash equivalents) are as follows:

	Million	s of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015
Property, plant, and equipment acquired under finance leases	¥ 528	¥ 135	\$ 1,122
Total	¥ 528	¥ 135	\$ 1,122

# Notes to Consolidated Financial Statements

## Note 35

# **Subsidiaries**

Details of the Group's subsidiaries are as follows:

			Proportion of voting rig	ghts held by the Group
Name	Primary business	Location	March 31, 2014	March 31, 2015
	-		%	%
ONO PHARMA USA, INC.	Pharmaceutical business	New Jersey, United States of America	100.0	100.0
ONO PHARMA UK Ltd.	Pharmaceutical business	London, United Kingdom	100.0	100.0
ONO PHARMA KOREA CO., LTD.	Pharmaceutical business	Seoul, Korea	100.0	100.0
ONO PHARMA TAIWAN CO., LTD.	Pharmaceutical business	Taipei, Taiwan	_	100.0
Oriental Pharmaceutical & Synthetic Chemical Co., Ltd.	Pharmaceutical business	Chuo-ku, Osaka City	45.5	45.5
Bee Brand Medico Dental Co., Ltd.	Pharmaceutical business	Higashiyodogawa- ku, Osaka City	80.0 (40.0)	80.0 (40.0)

Notes: 1. The percentage of voting rights in parentheses represents the percentage held indirectly, which is inclusive of the proportion of voting rights held. 2. Commencing from this consolidated fiscal year, the Group has newly established ONO PHARMA TAIWAN CO., LTD. and included the company in the scope of

its consolidation.

3. The Group holds 50% or less of equity in Oriental Pharmaceutical and Synthetic Chemical Co., Ltd., but treats the company as a subsidiary because the Group substantially controls it.

# Note 36

# **Related Parties**

## (1) Transactions with Related Parties

Transactions and balances of receivables and payables between the Group and its associates are as follows:

				Millions of Yen				Thousands of U.S. Dollars	
Classification	Name of related	Nature of related		ear ended 31, 2014		ear ended 31, 2015	,	ear ended 31, 2015	
	party		Transaction amount	Outstanding balance	Transaction amount	Outstanding balance	Transaction amount	Outstanding balance	
Associate	Namicos Corporation	Purchase of medical glassware material	¥ 156	¥ 14	¥ 129	¥ 24	\$ 1,077	\$ 196	

Note: Transactions with associates stated above are made under general trade terms in the same manner as arm's-length transactions.

#### (2) Remuneration of Key Management Personnel

The remuneration of the Group's key management personnel is as follows:

	Millior	Millions of Yen		
	For the year ended March 31, 2014	For the year ended March 31, 2015	For the year ended March 31, 2015	
Remuneration	¥ 291	¥ 302	\$ 2,517	
Bonuses	39	40	329	
Total	¥ 330	¥ 342	\$ 2,846	

Notes: 1. Remuneration of key management personnel comprises the remuneration for 10 persons for the year ended March 31, 2014, and 9 persons for the year ended March 31, 2015, who are key management personnel having authority and responsibility for planning, supervising, and managing business activities of the Group.

2. Remuneration and other compensation for key management personnel consist of monthly remuneration and bonuses. The monthly remuneration is determined by resolutions of the board of directors' meetings, with consideration of factors such as the size of the Group's business, the nature of their duties and scope of responsibility of each management personnel, and consistency in treatment with respect to other employees, to the extent the monthly remuneration does not exceed the limits established under shareholders meeting resolutions. The bonuses are determined, separately from monthly remuneration, by shareholder meeting resolutions with consideration of factors such as their annual performance.

# Note 37

# **Commitments for Expenditure**

Payment commitments after the end of each fiscal year date are as follows:

	Millions	of Yen	Thousands of U.S. Dollars	
	March 31, 2014	March 31, 2015	March 31, 2015	
Property, plant, and equipment	¥ 2,787	¥ 9,135	\$ 76,127	
Intangible assets	_	_	_	
Total	¥ 2,787	¥ 9,135	\$ 76,127	

In addition to the above commitments, the Group has milestone payments relating to the success of development projects and achievement of specific sales targets. Milestone payments that the Group potentially pays within three years were ¥34,987 million and ¥29,632 million (\$246,937 thousand) as of March 31, 2014 and 2015, respectively. These milestone payments amounts are undiscounted and include all such potential payments assuming all projects currently in development are successful and specific sales targets are achievable.

# Note 38

# **Approval of Financial Statements**

The consolidated financial statements for the year ended March 31, 2015, were approved by Gyo Sagara, President and Representative Director, on June 26, 2015.

# Notes to Consolidated Financial Statements

### Note 39

# **Significant Subsequent Events**

(Revision of retirement benefit plan) The Company decided to revise its retirement benefit plan effective in the fiscal year ended March 31, 2016, for its stable business management. The main revision of this plan is the introduction of a points system along with the revision of a wage system. The effects of this revision are to decrease its pension benefit obligations by ¥6,297 million (\$52,473 thousand), and on the other hand, to decrease the amounts that can be recognized as asset due to the effects of the asset ceiling by ¥2,689 million (\$22,412 thousand). As a result, profit (net of tax) for the year ended March 31, 2016, is expected to increase by ¥4,269 million (\$35,577 thousand) and comprehensive income (net of tax) to increase by ¥2,446 million (\$20,382 thousand).

(Introduction of stock option program) In accordance with Article 361 of the Company Law, an assignment of subscription rights to shares for directors of the Company (excluding outside directors) was approved at the general meeting of stockholders held on June 26, 2015. The details of the stock option program is as follows.

Resolution date	June 26, 2015
Classification and number of grantees	Five directors of the Company ("Note)
Type of shares to be issued under the subscription rights to shares	Common stock
Number of shares	15,000 shares is the upper limit of the number of shares for directors of the Company, which shall be granted when the subscription rights to shares issued within one year from the date of the general meeting of stockholders for each business year may be exercised.
Amount to be paid at the time of exercise of the subscription rights to shares	Amount to be paid per share in exercising subscription rights to shares shall be ¥1, and total amount to be paid is calculated by multiplying one year by the number of shares to be issued.
Period during which the subscription rights to shares may be exercised	Such period shall be within 40 years from the day following the date of allotment of the share subscription rights, which is determined by the Company's board of directors.
Conditions for the exercise of the subscription rights to shares	A subscription right holder shall be allowed to exercise the subscription rights to shares from the day following the day he/she forfeits the director's position of the Company. Other conditions for the exercise of the subscription rights to shares shall be determined by the Board of Directors of the Company where the subscription of stock acquisition rights shall be resolved.
Matters relating to restriction on transfer of the subscription rights to shares	Approval of the Board of Directors of the Company via resolution thereat shall be required for the transfer of the subscription rights to shares.
Matters relating to substitute payment	-
Matters relating to the distribution of the subscription rights to shares following a reorganizat	ion —

Note: The same as the above-mentioned subscription rights to shares will be issued for the Company's executive.

# Independent Auditor's Report

# **Deloitte.**

Deloitte Touche Tohmatsu LLC Yodoyabashi Mitsui Building 4-1-1, Imabashi, Chuo-ku Osaka 541-0042 Japan

Tel: +81 (6) 4560 6000 Fax: +81 (6) 4560 6001 www.deloitte.com/jp

INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying consolidated statement of financial position of Ono Pharmaceutical Co., Ltd. and its subsidiaries as of March 31, 2015, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit 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 consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### 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 its consolidated subsidiaries as of March 31, 2015, and the consolidated results of their operations and their cash flows for the year then ended in conformity with International Financial Reporting Standards.

#### **Convenience** Translation

Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in accordance with the basis stated in Note 2 to the consolidated financial statements. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

Delotte Touche Tohmaten LLC

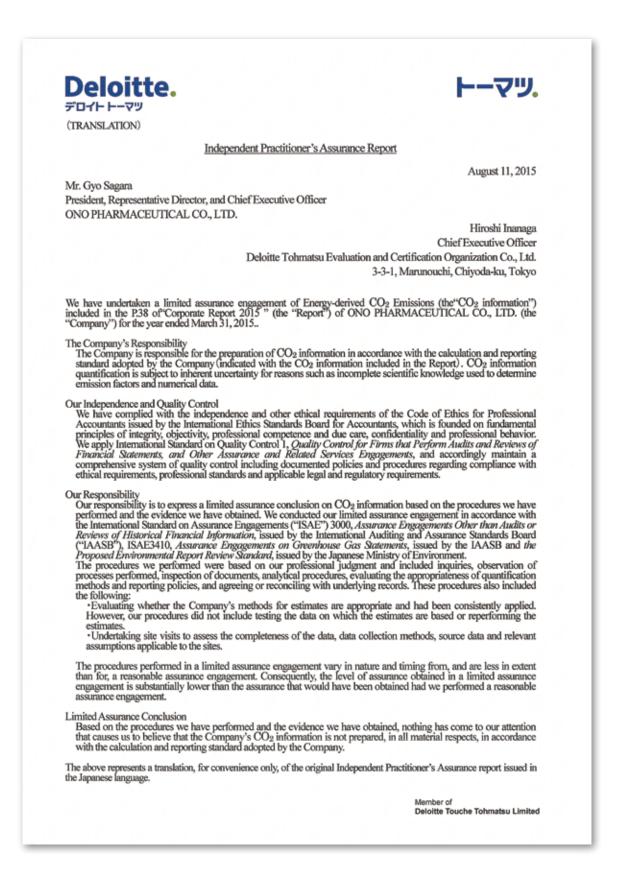
June 26, 2015

Member of Deloitte Touche Tohmatsu Limited

# ISO 26000 Comparison Table

	ISO26000	ONO PHA	ARMACEUTICAL Corporate Report 2015
Core subjects	Issues	Pages	Related items
Organizational Governance		P. 020 P. 022-023 P. 023 P. 024 P. 024	<ul> <li>CSR Management</li> <li>Corporate Governance Structure</li> <li>Internal Control System</li> <li>Risk Management</li> <li>Business Continuity Plan (BCP)</li> </ul>
	Due diligence		
	Human rights risk situations		
	Avoidance of complicity	P. 035	Diversity Promotion Initiatives
Lluman Diabta	Resolving grievances	P. 035	Enhancing Cultivation of Employee-
Human Rights	Discrimination and vulnerable groups		friendly Workplaces (Employment
	Civil and political rights		Programs, Safety and Health)
	Economic, social and cultural rights		
	Fundamental principles and rights at work		
	Employment and employment relationships		
	Conditions of work and social protection	P. 035	Diversity Promotion Initiatives
Labor Practices	Social dialog	P. 035	<ul> <li>Enhancing Cultivation of Employee- friendly Workplaces (Employment</li> </ul>
	Health and safety at work		Programs, Safety and Health)
	Human development and training in the workplace		
	Prevention of pollution	P. 037	Promotion of Environmental Management
	Sustainable resource use	P. 037-038	Ongoing Environmental Protection
The Environment	Climate change mitigation and adaptation	D 070	Activities
	Protection of the environment, biodiversity and restoration of natural habitats	P. 038	Environmental Efficiency / Environmental Accounting
	Anti-corruption		
Fair Operating	Responsible political involvement	5.040	
Practices	Fair competition	P. 040 P. 040-041	<ul><li>ONO's Ethical System</li><li>Compliance Promotion Initiatives</li></ul>
Plactices	Promoting social responsibility in the value chain		
	Respect for property rights		
	Fair marketing, factual and unbiased information and fair contractual practices		
	Protecting consumers' health and safety	P.014-017	Key Product Profiles
<b>C</b> 1	Sustainable consumption	P. 018-019	Status of Development Pipeline
Consumer Issues	Consumer service, support, and complaint and dispute resolution	P. 026-033	<ul> <li>Innovative Pharmaceutical Products (Research, Licensing, Development,</li> </ul>
	Consumer data protection and privacy		Manufacturing, and Marketing)
	Access to essential services		
	Education and awareness		
	Community involvement		
	Education and culture	P. 042-043	Various Corporate Social Responsibility
Community	Employment creation and skills development		Activities (Web-Based Information
Involvement and	Technology development and access		Dissemination, Initiatives for Medical Advancement, Activities to Support the
Development	Wealth and income creation		Health of People, Engagement with Local
	Health		Communities)
	Social investment		

# Independent Practitioner's Assurance Report



# **Corporate Information**

# Management (as of June 26, 2015)

#### Directors

President, Representative Director, and Chief Executive Officer	Gyo Sagara	
Member of the Board of Directors, Vice President Executive Officer/ Executive Director, Clinical Development	Hiroshi Awata	
Member of the Board of Directors, Senior Executive Officer/ Executive Director, Corporate Management	Kei Sano	
Member of the Board of Directors, Executive Officer/ Executive Director, Discovery and Research & Minase Research Institute	Kazuhito Kawat	pata, Ph.D
Member of the Board of Directors, Executive Officer/ Director, Corporate Research	Isao Ono	
Member of the Board of Directors, Outside Director	Yutaka Kato	Dean, Professor, Graduate School of Business, Doshisha University Outside Director, Bando Chemical Industries, Ltd.
Member of the Board of Directors, Outside Director	Jun Kurihara	Research Director, The Canon Institute for Global Studies Visiting Professor, School of Policy Studies, Kwansei Gakuin University

#### **Corporate Auditors**

Corporate Auditor (full time)	Katsuyoshi Nishimura	
Corporate Auditor (full time)	Shinji Fujiyoshi	
Outside Corporate Auditor	Narihito Maishi	Attorney-at-law Outside Corporate Auditor, SUMITOMO DENSETSU CO., LTD. Outside Corporate Auditor, OSAKA MONORAIL CO.,LTD.
Outside Corporate Auditor	Hiromi Sakka	CPA

## **Corporate Officers**

Corporate Officer/ Director, Medical Affairs	Shozo Matsuoka, Ph.D
Corporate Officer/ Senior Director, Metropolitan area Management & Metropolitan area First Branch	Hiroshi Ichikawa
Corporate Officer/ Executive Director, Corporate Development & Strategy	Toichi Takino, Ph.D
Corporate Officer/ Director, Kyusyu-Okinawa Branch	Katsuji Teranishi
Corporate Officer, Executive Director, Sales and Marketing	Noriyoshi Matsumoto
Corporate Officer, Executive Director, CMC Production & CMC Research	Takuya Seko

From Left: Yutaka Kato, Hiroshi Awata, Kazuhito Kawabata, Gyo Sagara, Isao Ono, Kei Sano, Jun Kurihara





From left: Narihito Maishi, Katsuyoshi Nishimura, Shinji Fujiyoshi, Hiromi Sakka

# **Corporate Information**

# Corporate Profile (as of March 31, 2015)

Company Name	ONO PHARMACEUTICAL CO., LTD.
Founded	1717
Date of Incorporation	July 4, 1947
Paid-in Capital	¥17,358 million
Number of Shareholders	10,711
Number of Employees	2,858 (consolidated)
	2,608 (unconsolidated)



EUROPE ONO PHARMA UK LT



Fukui Research Institute



Minase Research Institute



Joto Plant

Branch

Tsukuba Research Institute



Fujiyama Plant

JAPAN ONO PHARMACEUTICAL CO., LTD. Headquarters





TAIWAN ONO PHARMA TAIWAN CO., LTD.

#### 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

### **Tokyo Office**

2-5, Kanda Suda-cho, Chiyoda-ku, Tokyo 101-0041, Japan

#### Branches in Japan (as of April 1, 2015)

Hokkaido, Tohoku, Metropolitan area First, Metropolitan area Second, Kanto-Koushinetsu, Tokai, Kansai-Hokuriku, Chugoku-Shikoku, Kyusyu-Okinawa \* There are offices and sales branches in other major cities across the country.

### **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 ONO PHARMA UK LTD. MidCity Place, 71 High Holborn, London WC1V 6EA, UK Tel: +44-20-7421-4920 ONO PHARMA KOREA CO., LTD. The-K Twin Towers B-13F, 19 Junghak-dong, Jongno-gu, Seoul, 110-150, South Korea Tel: +82-2-928-8423 ONO PHARMA TAIWAN CO., LTD. Farglory Financial Center 7F-3, No. 1 Songgao Road, Xinyi District, Taipei City, Taiwan Tel: +886-2-8786-9750 Oriental Pharmaceutical & Synthetic Chemical Co., Ltd. Bee Brand Medico Dental Co., Ltd. Namicos Corporation Tokai Capsule Co., Ltd.

NORTH AMERICA ONO PHARMA USA, INC.

Corporate Website http://www.ono.co.jp/eng/index.html



